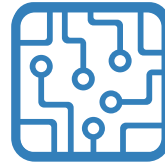


Next Generation Control Technology

Opti-Dry® Gen2

PC/PLC Freeze Dryer Control System

View



Synoptic



Status



Graph

Opti-Dry Gen2

rev 9/17/2024

MILLROCK
TECHNOLOGY

Opti-Dry Gen2 Freeze Drying Control System

Compare

NEW ADDED FEATURES	MILLROCK TECHNOLOGY	THE COMPETITION
Cycle Assist to Auto-Generate Freeze Drying Protocols	✓	✗
Auto-Generate Annealing and Super Cooling Steps	✓	✗
Batch Reporting with Interactive Graphing	✓	✗
Set Shelf Ramping Temperature by Time or Rate	✓	✗
Detailed Run Time Data for Customized PM	✓	✗
Customized System Testing by User Criteria	✓	✗
Flexible End of Primary Drying Trigger Points	✓	✗

Six Key Features

Opti-Dry Gen2 has been programmed with the deep knowledge of our scientists and engineering teams to ensure the most efficient and effective freeze drying cycle from the start.



Cycle Assist

Cycle Assist enables the operator to automatically generate freeze drying protocols, including annealing and supercooling steps.



Batch Reporting

Enables the user to produce detailed interactive graphs and tabular reports. Multi-dimensional reports and graphs are easily printed or exported to PDF or CSV formats.



Shelf Temperature Ramping by Rate or Time

Simply choose your shelf temperature ramping method, either by time or rate and Opti-Dry Gen2 does the rest.



Customized Preventative Maintenance Scheduling

Run-time data of critical components is constantly collected and available to both the operator and Millrock's service technicians for PM to reduce downtime.



Customized System Testing

Built-in system test to manufacturer's specifications or user specified criteria.



End of Primary Drying Trigger Points

End of primary drying trigger points by Pirani and Capacitance Manometer convergence or product temperature. User selectable EOPD trigger activation point ensuring minimum dry time.

Operational Overview of Opti-Dry Gen2

Freezing

The first major phase of the lyophilization process:

- The system ramps to a set shelf temperature at the set rate.
- Hold the shelves at that temperature for the set hold time, before proceeding to the next step.
- Once the end of the hold time for the last active Freezing step is reached the system will progress to **Extra Freeze**.

The screenshot displays the Opti-Dry Gen2 v. 2.5 control interface. At the top, it shows system status and setpoints: Shelf setpoint: 0.0, Vacuum setpoint: 0 mTorr, Shelf temperature: 25.5, Pirani: 760,330 mTorr, Condenser: 26.0, and Manometer: above range mTorr. The interface is divided into several sections: 'Freeze Drying' (with a 'Start' button), 'Options' (with 'Cycle Assist' and 'Proceed' buttons), 'Loading' (with 'Shelf: 20.0' and 'Proceed' button), 'Freezing' (a table with 10 steps for Shelf temperature, Ramping rate, and Hold time), 'Primary Drying' (a table with 16 steps for Shelf temperature, Ramping rate, Vacuum, and Hold time), 'Extra Freeze' (with Shelf temperature, Ramping rate, Hold time, and Primary vacuum), 'Extra Dry', 'Secondary Drying', 'Storage', 'Backfill', 'EOPD Triggers' (with 'Product average' and 'Pressure convergence' settings), and 'Alarm Settings' (with 'Condenser overload', 'Vacuum overload', and 'Power outage' settings).

SELECTABLE OPTIONS

- **Loading Step** - Precool the shelves to a set temperature while at atmospheric pressure.
- **Extra Freeze** - Option serves two purposes:
 - Final freezing step to further ensure complete product crystallization.
 - An alarm recovery step to attempt to protect the equipment and product in the event of an alarm response.
- **EZ Dry Cycle Assist Supercool** - Holds the shelves at the supercool temperature to allow the product to equilibrate before nucleation, increasing the homogeneity of the batch.
- **EZ Dry Cycle Assist Anneal** - Utilization allows time for the ice crystals to grow and rearrange to lower the product resistance in primary drying.

The screenshot shows the 'Loading' step interface. It features a 'Shelf: 20.0' input field and a green 'Proceed' button.

The screenshot shows the 'Extra Freeze' step interface. It features four input fields: 'Shelf temperature: -40.0 °C', 'Ramping rate: 0.00 °C/min', 'Hold time: 60 minutes', and 'Primary vacuum: 180 mTorr'.

Primary Drying

The shelves will ramp to the set shelf temperature at the set rate and will then hold at that temperature for the set hold time, before proceeding to the next step. During the entire ramping and holding duration of the step the system will also control the chamber pressure at the vacuum setpoint.

Primary Drying	Steps: 2 Cycle will skip to Secondary Dry once conditions are met															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Shelf temperature:	-40.0	-15.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Ramping rate:	0.50	0.50	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Vacuum:	150	150	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Hold time:	60	9,999	0	0	0	0	0	0	0	0	0	0	0	0	0	0

SELECTABLE OPTIONS

Extra Dry is an optional drying step following the primary drying phase.

- This step is used as a 'finishing sequence' to account for heterogeneity in drying rates across a batch, helping to ensure that the entire batch has been sublimated.
- The next step can be initiated manually or the activation of an **End of Primary Drying Trigger**.

Extra Dry	
Shelf temperature:	-15.0 °C
Ramping rate:	0.00 °C/min
Vacuum:	150 mTorr
Hold time:	60 minutes

Freeze Drying Mode – End of Primary Drying (EOPD) Triggers

EOPD Triggers enables the detection of end of sublimation during primary drying. These triggers are used to automatically end the Primary Drying phase once the 'end of sublimation' has been detected, reducing the total cycle time.

End of Primary Drying Triggers

- By Product Average Temperature
- By Pirani and Capacitance Manometer Pressure Differential

EOPD Triggers (?)	
Product average	
<input type="checkbox"/> Disabled	0.0 °C
Pressure convergence	
<input checked="" type="checkbox"/> Enabled	10 mTorr
Trigger step: 2	

The **Product Average Trigger** determines the end of primary drying based on the average product temperature of the enabled product probes. During primary drying, when the average of the enabled product thermocouples reaches the setpoint and remains equal to or greater than the setpoint for two continuous minutes, the system will automatically progress to Extra Dry or Secondary Dry depending on the Freeze Dry settings.

The **Pressure Convergence Trigger** determines the end of primary drying based on a comparison of the readings of the Pirani gauge and Capacitance Manometer. The Pirani vacuum gauge measures vacuum through a heated filament and reads higher than the capacitance manometer in the presence of water vapor. The Capacitance Manometer indicates the absolute vacuum and is not affected by water vapor in the system. The end of primary drying can therefore be detected when the reading from the Pirani gauge converges with the reading from the Capacitance Manometer, indicating an absence of water vapor in the chamber and the end of sublimation.

Secondary Drying

Secondary Drying is the final main phase in the lyophilization process:

- Bound water is driven off by desorption
- System ramps to set shelf temperature at set rate for set hold time
- Proceeds to storage

Storage is the final step in the lyophilization cycle:

- Ballistically controls the shelf temperature to set point
- Holds temperature until cycle is ended
- Controls chamber pressure to vacuum setpoint until end of cycle or backfill

Backfill and stoppering:

- Optional final steps before removing product
- Holds temperature until cycle is ended by the operator
- Controls chamber pressure to vacuum setpoint until end of cycle or backfill
- Release valve opens, backfill setpoint is reached and release valve closes

Secondary Drying	
Shelf temperature:	20.0 °C
Ramping rate:	0.50 °C/min
Vacuum:	75 mTorr
Hold time:	240 minutes

Storage	
Shelf temperature:	20.0 °C
Vacuum:	0 mTorr

Backfill	
Vacuum:	450,000 mTorr

EZ Dry Cycle Assist

Cycle Assist		
Product settings Critical temperature (Tc): -25.0 °C Total solids concentration: 5.0 %	Loading Loading enable <input checked="" type="checkbox"/> 20.0	Freezing options Supercool <input checked="" type="checkbox"/> -5.0 Anneal <input checked="" type="checkbox"/> -10.0
Product control setpoint: -27.0 °C Freezing shelf setpoint: -45.0 °C Primary dry shelf setpoint: -14.0 °C Primary dry vacuum setpoint: 150 mTorr		
<input type="button" value="Load"/>		

Intelligent, automatically generated protocols

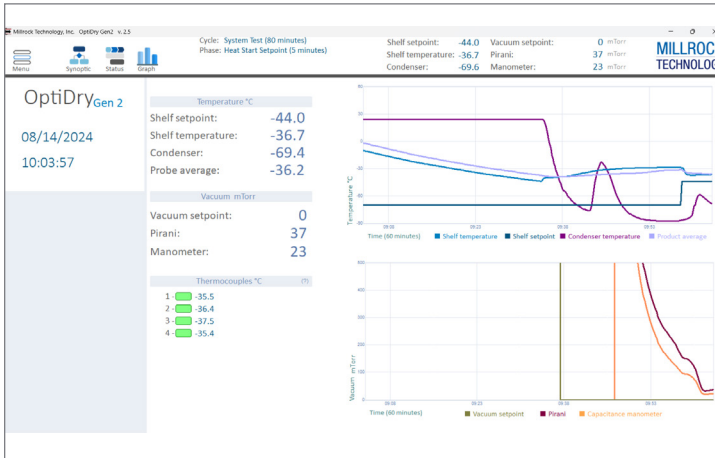
Enter the product critical temperature, % concentration, and freezing options and the software will automatically generate a recommended freeze-drying protocol.

- Product Control Temperature
- Freezing Shelf Temperature
- Primary Drying Shelf Temperature
- Primary Drying Chamber Pressure

EZ Dry Cycle Assist also enables the operator to add **Supercool** and **Annealing** steps automatically.

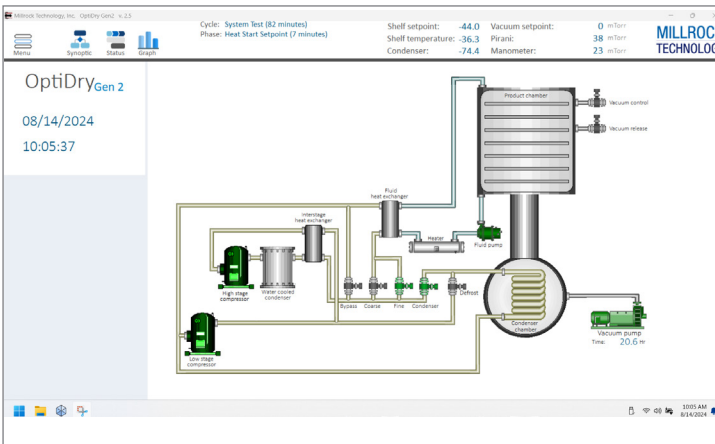
The **Supercool** option holds the shelves at the **Supercool** temperature for two hours before proceeding with freezing. This allows the product to equilibrate at a set temperature before nucleating, increasing the homogeneity of the batch. The **Anneal** option increases the shelf temperature to the selected temperature and hold for two hours after the initial freezing step, before then cooling back down to the freezing temperature. This allows time for the ice crystals to grow and rearrange to form larger pores and lower the product resistance in primary drying.

Sample Screens



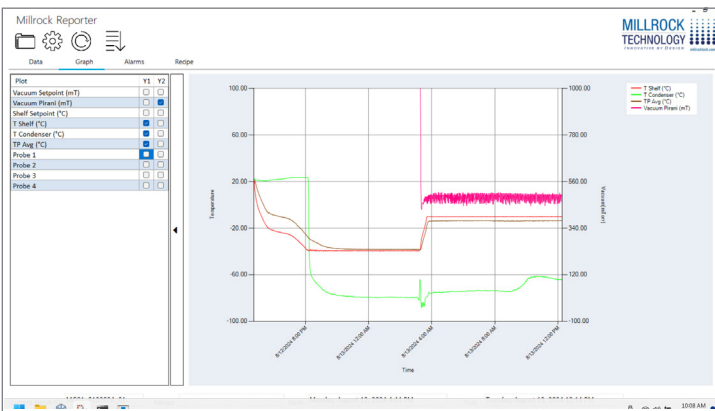
The Status Screen

- Displays all current live data
- System temperature
- Product temperature
- Pressure inputs



The Synoptic Screen

- Displays the status of all major freeze dryer components
- Shows active components in green
- Shows inactive components in grey



Millrock Reporter

- Produces a full batch report including:
 - Protocol/Recipe
 - Process Data
 - Graphical Data
 - Alarms
- All runs are stored for future access
- Easily produces tabular, graphical reports
- Maintains a library of all processing events
- Data can be exported to Excel

Millrock Reporter

All the process data is collected and stored in an unalterable file format. Data is collected and stored for all process parameters, both set points and read outs, in the freeze drying cycle. Millrock Reporter lets you pick and choose which parameters you want to see and will provide the information in either an alpha-numeric format or graph format. Want a different view, simply click another column entry, or drag and drop columns of data where you would like them to appear. The system also allows you to download and print out the recipe screen and to archive runs. Freeze dryer system alarm data collection is also included.

Millrock Reporter enables numerical and graph reporting as simple or as inclusive as you need and to change those requirements on the fly.

BATCH REPORTING

Robust Data Reportable

- Exports to CSV or PDF
- User easily selects sections to include
- Select content, preview, and print

Preventative Maintenance

Opti-Dry Gen2 provides you with the tools required to implement predictive maintenance.

- Runtime for all major components
- Remote access to Millrock service team
- Assists with diagnostics and maintenance

Time	Cycle Time (min)	Cycle	Phase	Step	Vacuum Setpoint (mT)	Vacuum Pressure (mT)	Shelf Setpoint (°C)	T Shelf (°C)	T Condenser (°C)
8/12/2024 4:44 PM	1	1	2	1	500000	612170	-65	16.22	22.39
8/12/2024 4:45 PM	1	1	3	1	500000	488430	-40	19.94	22.04
8/12/2024 4:46 PM	2	1	3	1	500000	488430	-40	20.32	21.99
8/12/2024 4:47 PM	3	1	3	1	500000	488430	-40	13.33	21.77
8/12/2024 4:48 PM	4	1	3	1	500000	488430	-40	11.11	21.57
8/12/2024 4:49 PM	5	1	3	1	500000	488430	-40	9.79	21.52
8/12/2024 4:50 PM	6	1	3	1	500000	488430	-40	8.16	21.52
8/12/2024 4:51 PM	7	1	3	1	500000	488430	-40	6.76	21.47
8/12/2024 4:52 PM	8	1	3	1	500000	488430	-40	5.31	21.39
8/12/2024 4:53 PM	9	1	3	1	500000	488430	-40	4.06	21.34
8/12/2024 4:54 PM	10	1	3	1	500000	488430	-40	2.97	21.32
8/12/2024 4:55 PM	11	1	3	1	500000	488430	-40	1.86	21.24
8/12/2024 4:56 PM	12	1	3	1	500000	488430	-40	0.9	21.17
8/12/2024 4:57 PM	13	1	3	1	500000	488430	-40	0.04	21.22
8/12/2024 4:58 PM	14	1	3	1	500000	488430	-40	-0.84	21.24
8/12/2024 4:59 PM	15	1	3	1	500000	488430	-40	-1.87	21.09
8/12/2024 5:00 PM	16	1	3	1	500000	488430	-40	-2.45	21.12
8/12/2024 5:01 PM	17	1	3	1	500000	488430	-40	-3.2	21.04
8/12/2024 5:02 PM	18	1	3	1	500000	488430	-40	-3.98	21.04
8/12/2024 5:03 PM	19	1	3	1	500000	483110	-40	-4.5	21.02
8/12/2024 5:04 PM	20	1	3	1	500000	483110	-40	-4.99	21.09
8/12/2024 5:05 PM	21	1	3	1	500000	483110	-40	-5.67	21.09

Step	Vacuum Setpoint (mT)	Vacuum Pressure (mT)	Shelf Setpoint (°C)	T Shelf (°C)	T Condenser (°C)
1	500000	612170	65	16.22	22.39
1	500000	488430	-40	19.94	22.04
1	500000	488430	-40	20.32	21.99
1	500000	488430	-40	13.33	21.77
1	500000	488430	-40	11.11	21.57
1	500000	488430	-40	9.79	21.52
1	500000	488430	-40	8.16	21.52
1	500000	488430	-40	6.76	21.47
1	500000	488430	-40	5.31	21.39
1	500000	488430	-40	4.06	21.34
1	500000	488430	-40	2.97	21.32
1	500000	488430	-40	1.86	21.24
1	500000	488430	-40	0.9	21.17
1	500000	488430	-40	0.04	21.22
1	500000	488430	-40	-0.84	21.24
1	500000	488430	-40	-1.87	21.09
1	500000	488430	-40	-2.45	21.12
1	500000	488430	-40	-3.2	21.04
1	500000	488430	-40	-3.98	21.04
1	500000	483110	-40	-4.5	21.02
1	500000	483110	-40	-4.99	21.09
1	500000	483110	-40	-5.67	21.09

Component	Runtime (hours)	On-Cycles	Reset	Last date reset
Compressor One	72.1	71	C	
Compressor Two	100.2	57	C	
Vacuum Pump	39.3	94	C	
Fluid Pump	12.8	55	C	
Heater	14.5	29,993	C	
Shelf Coarse	49.0	1,446	C	
Shelf Fine	57.7	3,309	C	
Condenser Valve	51.1	1,438	C	
Bypass Valve	5.2	207	C	
Defrost Valve	1.9	16	C	
Vacuum Control	0.4	890	C	
Vacuum Release	-1.4	27	C	
Alarm Output	5.4	58	C	

Summary

Opti-Dry Gen2 is designed to easily produce a freeze drying protocol in less time. It organizes the freeze drying process into a natural workflow of steps.

- Processes such as **Supercooling**, **Annealing**, **Extra Drying** and **EPDT** are accessible as one-click options making them easier to include for experienced operators and newcomers alike.
- The system's robustness for data collection, access and reporting allows users to visualize any aspect of the process including cycle comparison analysis.
- Machine component run times on all major parts such as compressors, pumps, heaters and valves are continuously recorded

OptiDry Gen2 features are derived from decades of experience to support the most complex freeze drying needs, as well as to support users with little experience and in need of baseline protocol development.

OptiDry Gen2 is available on the Millrock family of freeze dryers



STELLAR® FREEZE DRYER

Lab 3.75 ft2-6.25ft2



REVO® FREEZE DRYER

Lab R&D 2ft2-10ft2



MAGNUM® FREEZE DRYER

Pilot Scale 10ft2-20ft2



MAGNUM XL® FREEZE DRYER

Pilot Scale 20ft2-30ft2



EPIC FREEZE DRYER

Small Production 15ft2-30ft2

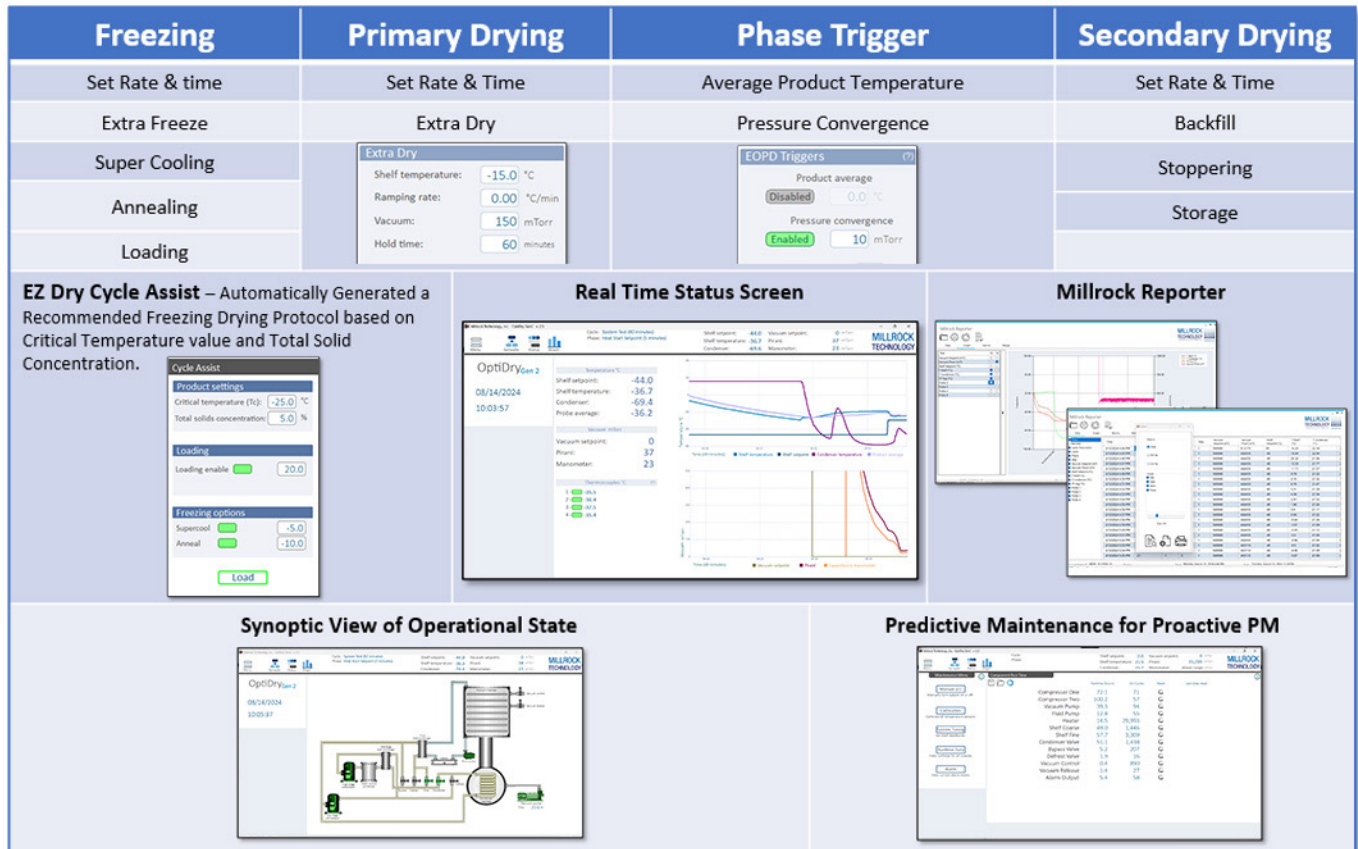


QUANTA FREEZE DRYER

Production Scale 8ft2-400ft2

Opti-Dry Gen2

Next Generation Freeze Drying Control Technology



Please give us a call at (845)339-5700 or reach out to our sales team sales@millrocktech.com
 Your Millrock Technology representative can walk you through the system online and answer any questions you and your team may have.

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Experience the Millrock Difference

When you purchase a Millrock product, you get more than a freeze dryer. You get a long-term partner delivering industry-changing innovations, high-performing products, and on-call expert support.

Contact us to learn more about how Millrock Technology can partner with your business to provide the highest-performance, advanced freeze drying services.

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