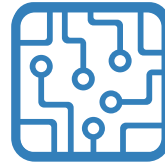


Next Generation Control Technology

Opti-Dry® Gen2

PC/PLC Freeze Dryer Control System

View



Synoptic



Status



Graph

Opti-Dry Gen2

rev 1/10/2023

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**.

Millrock Technology, Inc. OptiDry Gen2 V2.3

Menu View Synoptic Status Graph LyoPAT

Cycle: minutes: Phase: minutes:

Shelf setpoint: 30.0 Vacuum setpoint: 500 mTorr
Shelf temperature: 19.4 Pirani: 760,330 mTorr
Condenser: 19.8 Capacitance manometer: above range mTorr

MILLROCK TECHNOLOGY

Freeze Drying Recipe name: Product description: Recipe menu: + - [icon] [icon] [icon] X
Batch ID: Product name: Operator:

Options: Cycle Assist (?) Pressure Rise Test

Loading Optional: Shelf: 20.0 °C Proceed

Freeze 5 Total steps:

Step	1	2	3	4	5	6	7	8	9	10
Shelf temperature:	20.0	-5.0	-40.0	-10.0	-40.0	0.0	0.0	0.0	0.0	0.0
Ramping rate:	0.00	1.00	0.50	1.00	1.00	0.00	0.00	0.00	0.00	0.00
Hold time:	30	120	120	120	60	0	0	0	0	0

Extra Freeze: Shelf temperature: -45.0 °C Ramping rate: 0.00 °C/min Hold time: 60 minutes Primary vacuum: 225 mTorr

Primary Drying 2 Total steps: Cycle will skip to Secondary Dry once conditions are met

Step	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:	9,999	9,999	0	0	0	0	0	0	0	0	0	0	0	0	0	0

EOPD Triggers Optional (?) Product average: Disabled 0.0 °C Pressure convergence: Enabled 10 mTorr Trigger step: 2

Extra Dry (enabled with EOPD): Shelf temperature: -14.0 °C Ramping rate: 0.00 °C/min Vacuum: 150 mTorr Hold time: 60 minutes

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 Optional: Vacuum: 450,000 mTorr

Alarm Settings: Condenser overload: -40.0 °C Vacuum overload: 2,000 mTorr Power outage: 20 minutes Start

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.

Loading Phase Optional

Enabled

Shelf : 5 °C

Proceed

Extra Freeze

Shelf Temperature: 0.00 °C

Ramping rate: 0.00 °C/min

Hold Time: 0 minutes

Primary Vacuum: 0 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.



SELECTABLE OPTIONS

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

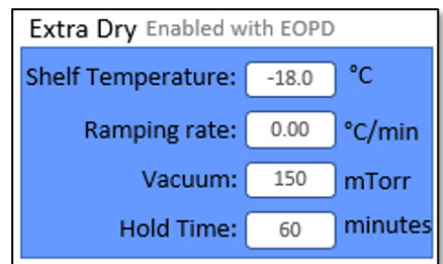
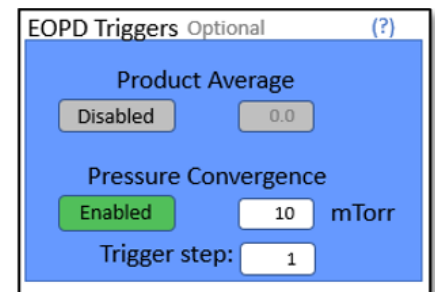
- This step is used as a 'finishing sequence' to account for heterogeneity in drying rates across a batch, helping to ensure that the entire batch has been sublimated.
- The next step can be initiated manually or the activation of an **End of Primary Drying Trigger**.

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



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

Secondary Drying	
Shelf Temperature:	10.0 °C
Ramping rate:	0.50 °C/min
Vacuum:	150 mTorr
Hold Time:	240 minutes

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

Storage	
Shelf Temperature:	0.0 °C
Pressure:	0 mTorr

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

Backfill Optional	
Pressure:	450,000 mTorr

EZ Dry Cycle Assist

Intelligent, automatically generated protocols

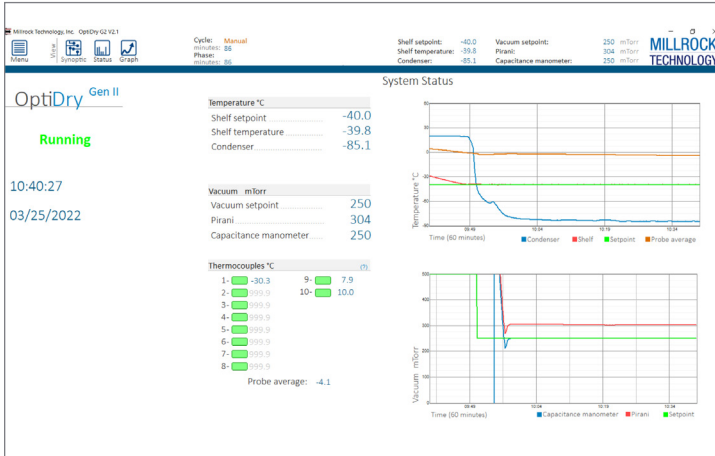
Enter the product critical temperature, % concentration, and freezing options and the software will automatically generate a recommended freeze-drying protocol.

- 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.

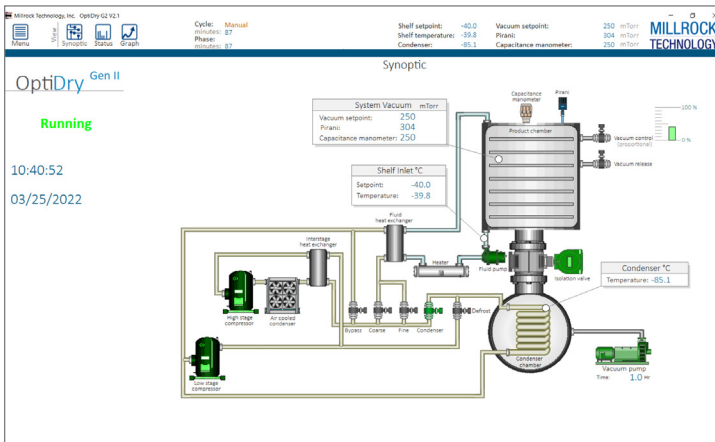
Cycle Assist X	
Product Settings	
Product Critical Temperature (Tc):	-32.0 °C
Product Total Solids Concentration:	5.0 %
Loading	
<input checked="" type="checkbox"/> Loading Enable	20.0
Freezing Options (?)	
<input checked="" type="checkbox"/> Supercool	-5.0
<input checked="" type="checkbox"/> Anneal	-10.0
Recommended Base Settings	
Product Control Temperature:	-34.0 °C
Freezing Shelf Temperature:	-47.0 °C
Primary Drying Shelf Temperature:	-21.0 °C
Primary Drying Chamber Pressure:	70 mTorr
<input type="button" value="Load Settings"/>	

Sample Screens



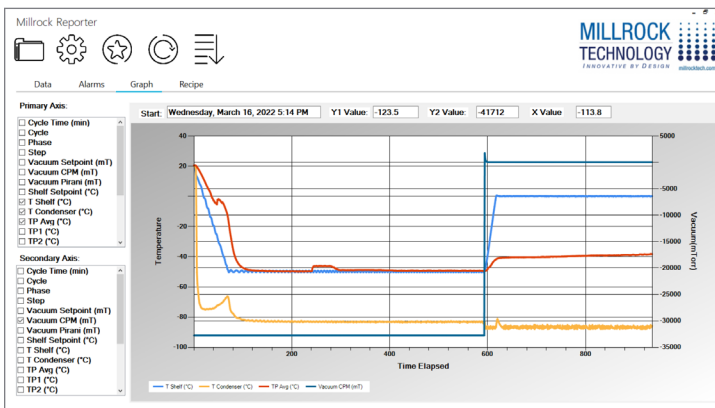
The Status Screen

- 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.

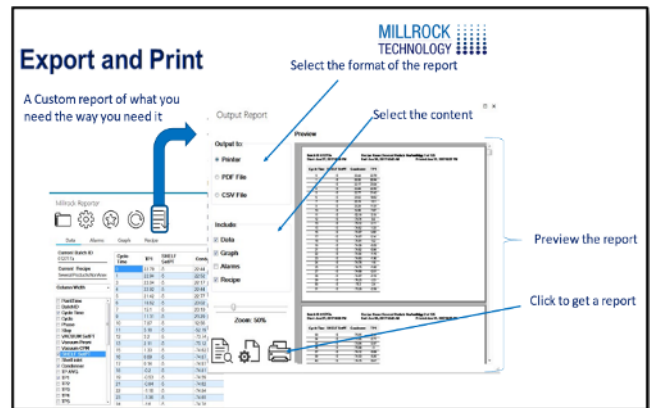
Cycle Time	Vacuum Setpoint	Vacuum CPM	Vacuum Pirani	Shelf Setpoint	T Shelf
0	500000	-32768	488430	-40	23.83877
1	500000	-32768	463110	-40	24.01349
2	500000	-32768	463110	-40	22.14152
3	500000	-32768	463110	-40	13.43064
4	500000	-32768	488430	-40	9.487024
5	500000	-32768	463110	-40	5.82123
6	500000	-32768	463110	-40	2.447674
7	500000	-32768	463110	-40	-0.3549728
8	500000	-32768	463110	-40	-2.975966
9	500000	-32768	463110	-40	-5.467208
10	500000	-32768	463110	-40	-7.505143
11	500000	-32768	463110	-40	-9.463574
12	500000	-32768	463110	-40	-11.30606
13	500000	-32768	438820	-40	-13.16088
14	500000	-32768	463110	-40	-14.76771
15	500000	-32768	438820	-40	-16.28705
16	500000	-32768	438820	-40	-17.69787
17	500000	-32768	438820	-40	-19.10868
18	500000	-32768	438820	-40	-20.38384
19	500000	-32768	438820	-40	-21.68613
20	500000	-32768	438820	-40	-22.74425
21	500000	-32768	438820	-40	-23.85662
22	500000	-32768	438820	-40	-24.77008
23	500000	-32768	438820	-40	-24.72067
24	500000	-32768	438820	-40	100.34

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

Component	Runtime (Hours)	On/Offs	Status	Last Date Reset
Compressor One	154.6	9	C	05/21/2021
Compressor Two	154.8	8	C	05/21/2021
Vacuum Pump	175.3	15	C	05/21/2021
Fluid Pump	153.1	5	C	05/21/2021
Heater	7,802,942.5	142,937	C	05/21/2021
Shelf Coarse	18,731.4	2,193	C	05/21/2021
Shelf Fine	688,977.1	15,150	C	05/21/2021
Condenser Valve	18,790.0	2,194	C	05/21/2021
Bypass Valve	3,379.5	302	C	05/21/2021
Defrost Valve	1.3	4	C	05/21/2021
Vacuum Release	269.2	15	C	05/21/2021
Isolation Valve	284.7	9	C	05/21/2021
Alarm Output	0.0	0	C	06/01/2021

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

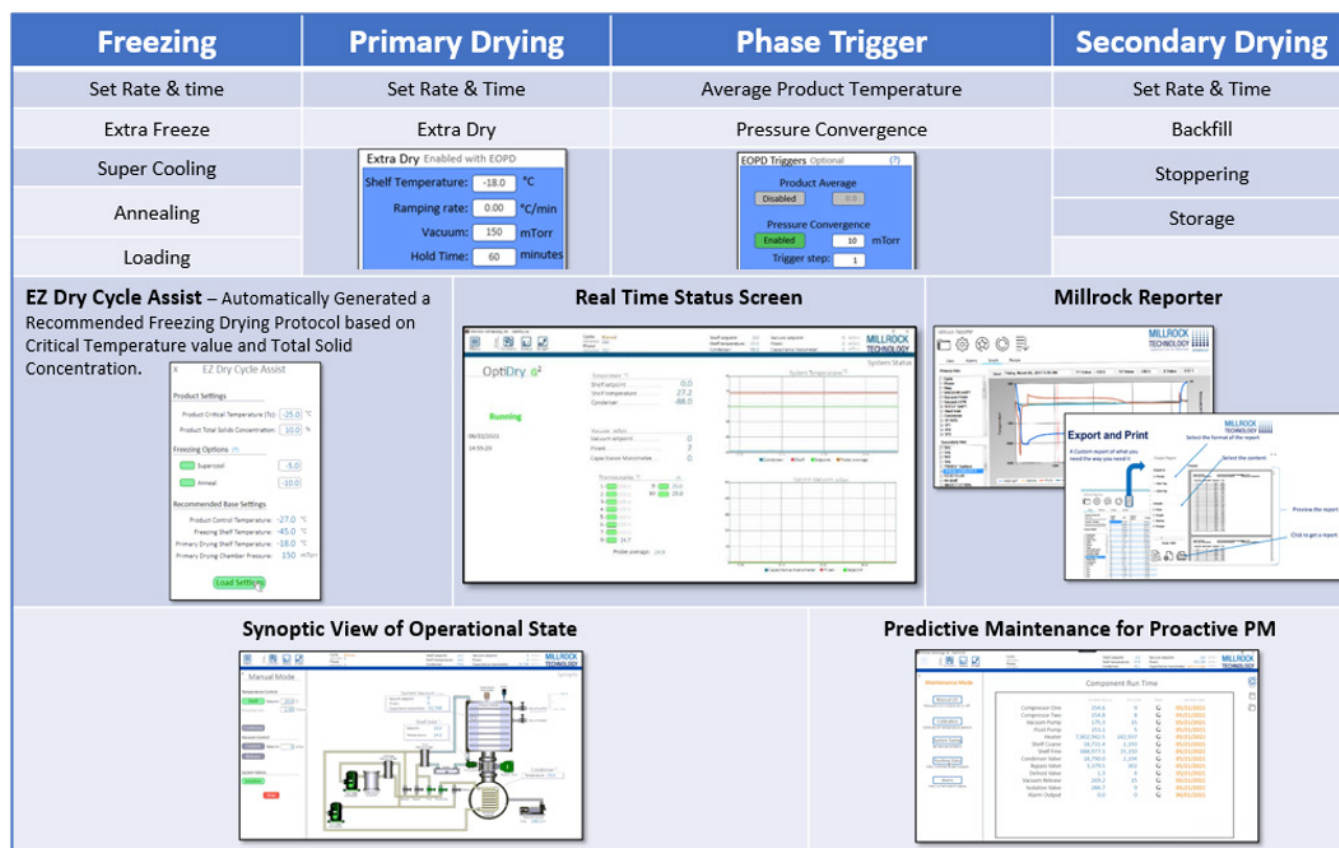


QUANTA FREEZE DRYER

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.

Copyright © 2022 Millrock Technology, Inc. All rights reserved.

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.

Sales: 845.339.5700 • sales@millrocktech.com | Service: 845.331.1279 • service@millrocktech.com

MILLROCK
TECHNOLOGY

Millrock Technology, Inc. • 39 Kieffer Lane • Kingston, NY 12401

Visit our website at <https://www.millrocktech.com>