

Freeze Dryer – Millrock Technology

INTRODUCTION

The Lumetics LINK™ software platform scans network locations for new measurement data files, copies data directly to a centralized database, and provides a powerful user interface for rapid multi-measurement multi-technique data aggregation, visualization, analysis, and reporting. LINK employs a client/server-based architecture where the LINK server hardware is provided by the end user and resides on the end user's network. The LINK client is a portable web-based application that may be placed on any computer with network connectivity to the LINK server. For successful import, the LINK webserver requires read access to the folders where user data resides.

The Millrock freeze dryers, specifically lyophilizers are custom designed and fit for GMP environments.

DETAILS

LINK requires a CSV export file for importing Millrock Lyophilization data.

The following Raw Data will be imported, in addition to all available instrument/analysis settings and parameters calculated by the instrument software for Elapsed Time & Time Stamp vs.

- Temperature
- Pressure
- Phase
- Cycle & Cycle Time
- ShelfSetPt
- Qshelf1, Qshelf2
- KvShelf1, KvShelf2
- KvSystem1, KvSystem2
- KvFinal1, KvFinal2
- PercentRM
- PercentFRZ1, PercentFRZ2
- PercentDried1, PercentDried2
- HeatFlux1, HeatFlux2
- HFSystem1, HFSystem2
- HFFinal1, HFFinal2
- MassFlowHr1, MassFlowHr2
- MassFlowHrFinal1, MassFlowHrFinal2
- Rp1, Rp2
- RpFinal1, RpFinal2
- DryFinal1, DryFinal2

Notes:

- Temperature inclusion/exclusion from 0-100°C is applied.
- Pressure data types data exclusion criteria for zero pressure. If a data set includes some zeros and some non-zeros, LINK will ignore the zero values and bringing in the rest of the pressure values.
- To overlay curves simultaneously, each curve will be imported into LINK as its own measurement (all sharing the same metadata). The dynamically created LINKdb field called "Measurement Type", will need to be added to the filter panel and a split applied. This will ensure that if the data is tied to a sample or cycle, the curves will not be averaged.

Import Method options can be defined and calculated each measurement during import if it is first created/defined and then requested within an Import Method. The following is the default Millrock-specific import method settings:

- Data Reduction Options: **Averaged Timepoints**
- Automated Metadata Extraction: **None**

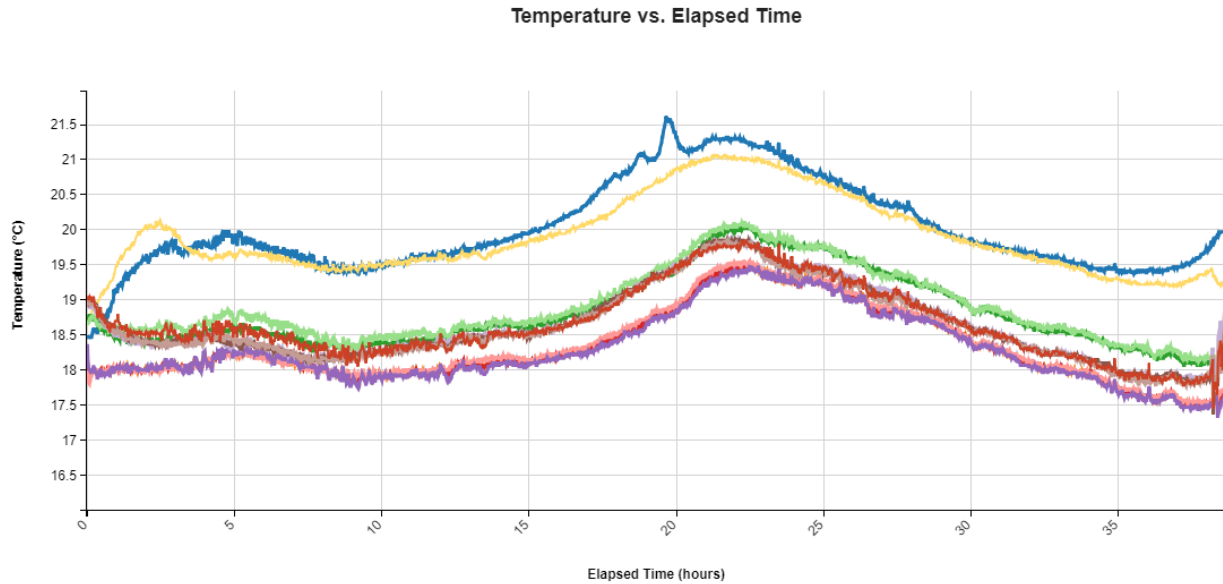
Data Reduction

To reduce the number of data points per curve and improve dashboard rendering times, LINK offers various options for reducing the data residing in the LINK database. Any options applied will in no way impact the original data files.

EXAMPLES

Included below are sample dashboards from Millrock measurement files:

1. Line Chart plotting raw data curves for Temperature vs. Elapsed Time



2. Tabular Summary examples:

Measurement Summary Table – Measurement Results

| LINK Record ID # | Instrument Name | Sample Name | Temperature (°C) (Elapsed Time (hours) >=1) - AVG | Pressure (mTorr) (Elapsed Time (hours) >=1) - AVG | Measurement Type Number - AVG | Measurement Type |
|------------------|-----------------|-------------|---|---|----------------------------------|------------------|
| 1 | Millrock | Sample A | 0.00 | 0 | 3 | Cycle |
| 2 | Millrock | Sample A | 0.00 | 0 | 4 | Phase |
| 3 | Millrock | Sample A | 0.00 | 1450500 | 6 | Vac setpt |
| 4 | Millrock | Sample A | 0.00 | 1462415460 | 8 | Vac pirani |
| 5 | Millrock | Sample A | 0.00 | 0 | 9 | Shelf setpt |
| 6 | Millrock | Sample A | 38526.99 | 0 | 10 | T shelf |
| 7 | Millrock | Sample A | 38770.78 | 0 | 11 | T cond |
| 8 | Millrock | Sample A | 35457.41 | 0 | 12 | Tp avg |

DASHBOARD DOWNLOAD

Included below is a link to downloadable dashboards for Millrock measurement files:

<http://lumetics.com/dashboards/Millrock/Millrock.zip>

CONTACT LUMETICS

For direct assistance, please contact Lumetics LINK™ Support:

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