

Lyophilization + Lumetics LINK™

INTRODUCTION

LINK is the software solution for automated analytical data import, analysis, and reporting. LINK scans network locations for new measurement files, extracts all useful data, and copies this data directly to a centralized database. The powerful analysis user-interface allows datasets to be aggregated, grouped, and visualized in the form of charts/tables/images. User-customizable analysis templates deliver rapid and error-free data visualization, with the ability to be replicated across many studies and shared within your organization.

All instrument settings and parameters calculated by the instrument software are copied to the LINK database, including full underlying raw data curves. Sample metadata may be easily assigned and incorporated within the analysis to integrate various product/process variables. LINK has been demonstrated to deliver time savings more than 90% and provide a highly affordable fully automated data management and analysis solution.

LINK currently supports LyoStar and Millrock for lyophilization systems.

LYOPHILIZATION DETAILS & APPLICATIONS

Freeze drying, also known as lyophilization or cryodesiccation, is a low temperature dehydration process that involves freezing the product, lowering pressure, then removing the ice by sublimation. The drying of materials in the frozen state, is a technique that is widely used in the laboratory as well as in industrial processes for the concentration, storage, and distribution of biological materials. LINK may be utilized to assist directly in the following Lyophilization application areas:

- Pharmaceutical diagnostics
- Drug development
- Particle breakdown
- Stability studies

INSTRUMENT SUPPORT DETAILS – LYOPHILIZATION

LyoStar from SP Scientific is designed to meet the needs of R&D professionals. Our freeze-drying equipment is used for applications ranging from process development for scale-up to product processing for stability studies to formulations work. LINK supports the application of multiple LyoStar modules to be imported for the LyoStar instrument. These modules and their mandatory files for import include:

- LyoStar (TDLAS) - LOG or TXT, Header Info, A1 = LyoFlux
- LyoStar (FLIR) - CSV named SensorData, No Header, A1 = Timestamp
- LyoStar (RGA Quantum) - XLSX, Header Info, A1 = Atonarp Analyzed
- LyoStar (RGA V2000P) - TXT, Header Info, A1 = "Spectra International Data File"

Millrock Lyophilizers from Millrock Technology is offers robust, technologically innovative advanced freeze dryer control for all freeze-drying processes/lyophilization process needs.

Link supports LyoStar and Millrock output data for instrument/analysis settings, parameters, calculations, and raw data curves for Elapsed Time & Time Stamp vs. multiple variables including temperature & pressure

VISUALIZATIONS – LINK ANALYSIS

LINK's dynamic analytical suite will aggregate data and provide visualization tools to suit your specific needs. Imported Lyophilization measurement data can be analyzed using the LINK platform's customizable charts, tables, calculations, images etc. User-customized analysis templates deliver rapid and error-free data visualization with the ability to be exported as a word report to share across your organization.



Fig 1. Line Chart visualizing Lyophilization measurement files plotting raw data Temp & Pressure profiles

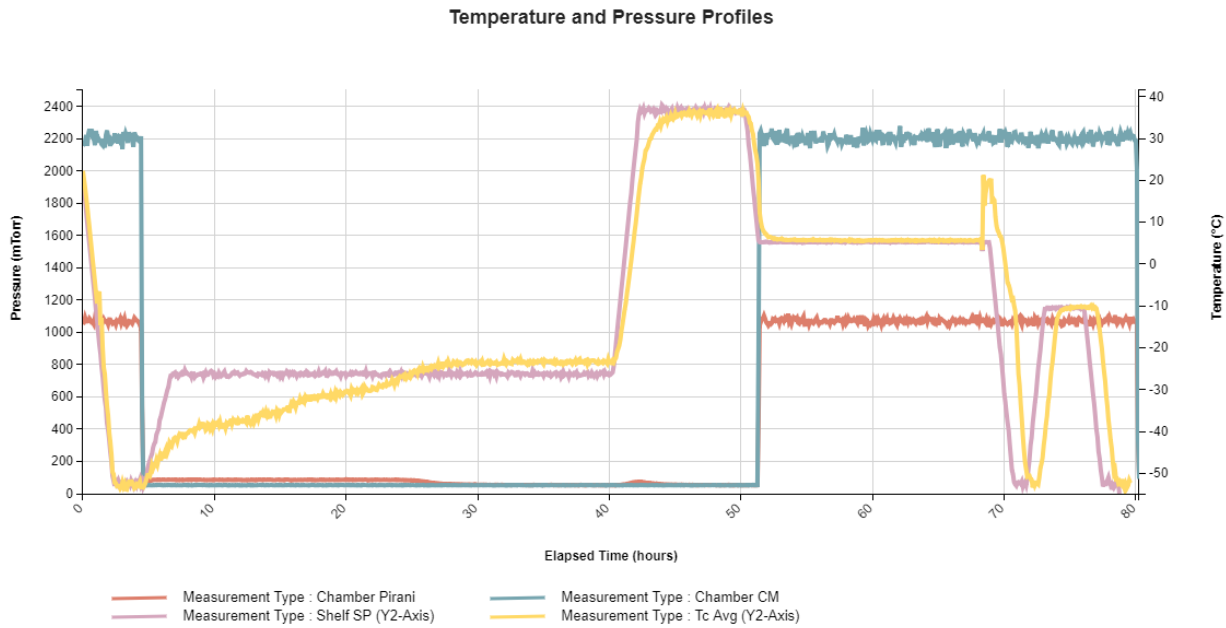


Fig 2. Line Chart visualizing Lyophilization measurement files plotting raw data curve profiles

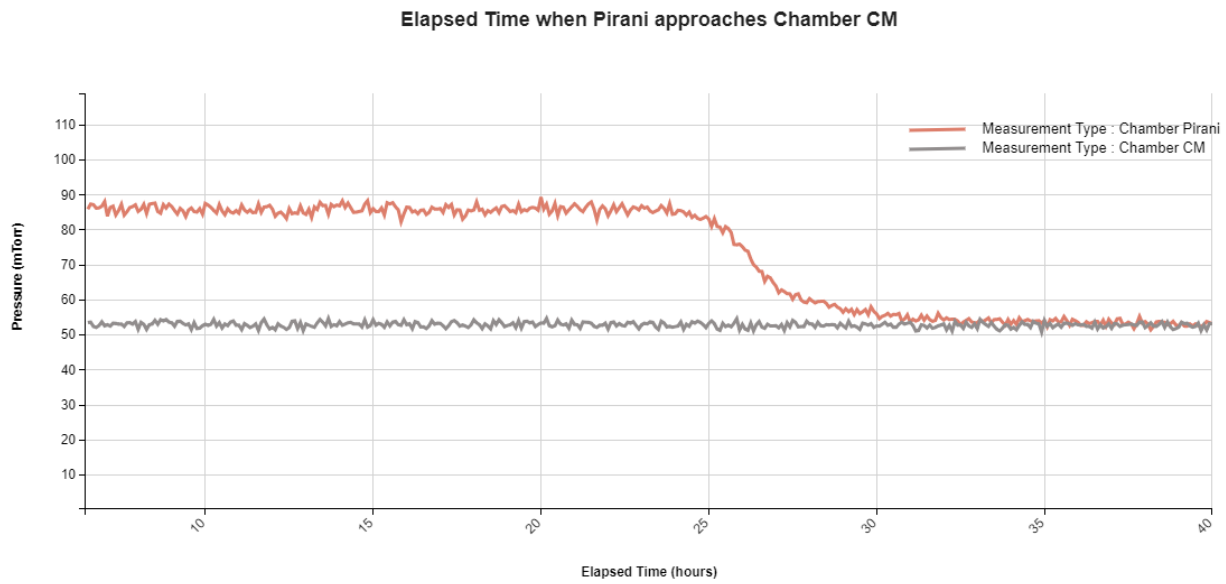


Fig 3. Line Chart visualizing Lyophilization measurement files plotting raw data curve profiles

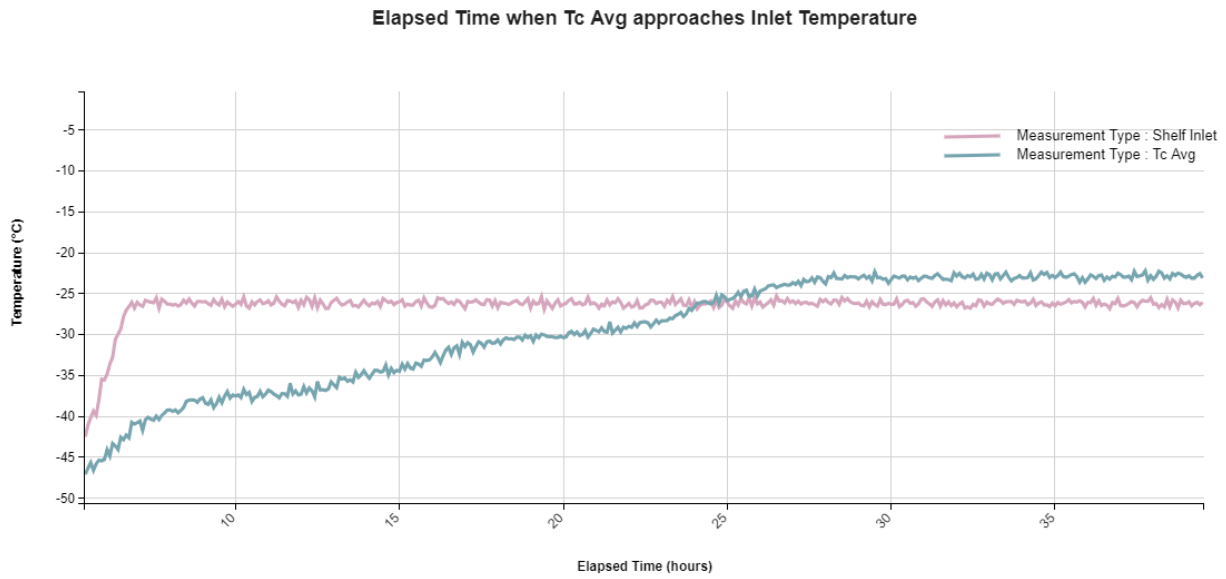


Fig 4. Line Chart visualizing Lyophilization measurement files plotting raw data Temperature probes

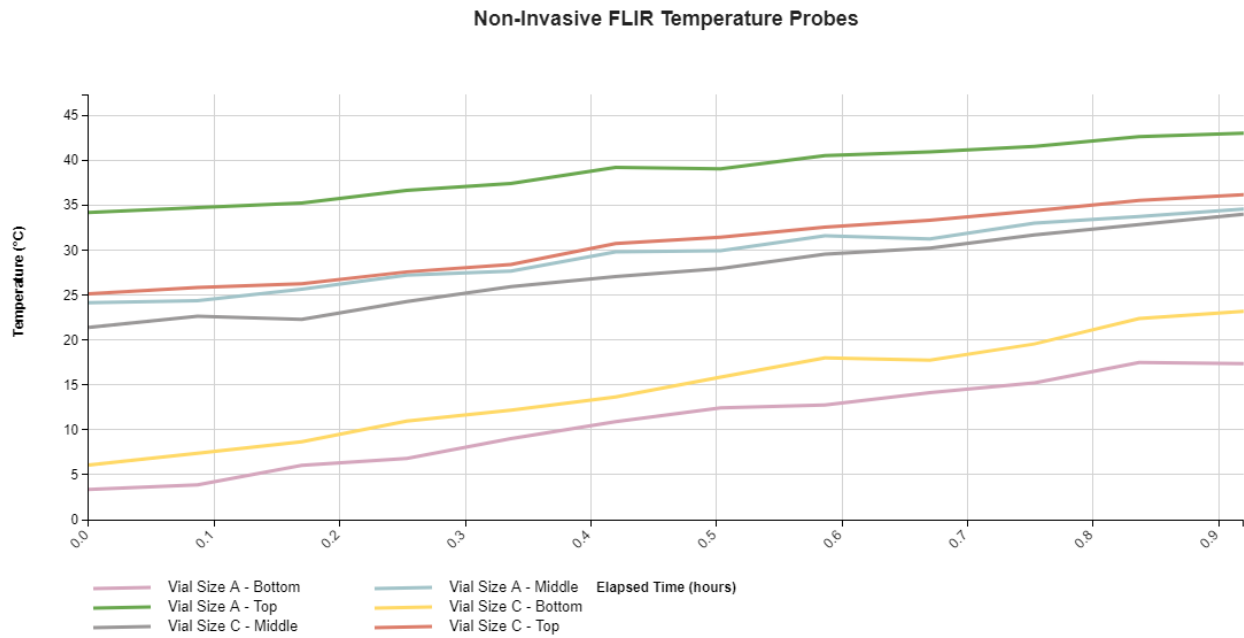


Fig 5. Tabular summaries

Measurement Summary Table – Measurement Results

LINK Record ID #	Sample Name	Measurement Type	Start Time	Analysis Date	Temperature (°C) (Elapsed Time (hours) >= .01) - AVG	Temperature (°C) (Elapsed Time (hours) >= 1) - AVG
13	Sample B	Tc Avg	02/22/19 08:00:00	0019-02-22 08:00:00	-13313.05	-13407.95
21	Sample C	Chamber CM	02/22/19 08:00:00	0019-02-22 08:00:00	0.00	0.00
22	Sample C	Chamber Pirani	02/22/19 08:00:00	0019-02-22 08:00:00	0.00	0.00
28	Sample C	Shelf SP	02/22/19 08:00:00	0019-02-22 08:00:00	-11858.88	-11910.72
29	Sample C	Tc Avg	02/22/19 08:00:00	0019-02-22 08:00:00	-12709.34	-12798.88

LINK Record ID #	Sample Name	Instrument Name	Measurement Type	Probe Approaches Inlet (C)
29	Sample C	LyoStar	Tc Avg	24.42
26	Sample C	LyoStar	Shelf Inlet	

DASHBOARD DOWNLOADS

These downloadable Analysis Dashboards are tailored to meet the most common needs of scientists using Lyophilization System applications. If assistance is required, please contact LINK experts to assist in dashboard modifications or development of new dashboards of interest.

- Lyophilization Dashboards: <http://lumetics.com/dashboards/Lyophilization/Lyophilization.zip>

CONTACT LUMETICS

For direct assistance, please contact Lumetics LINK™ Support:

E-mail: support@lumetics.com

Phone: 1.613.614.874

Website: <http://lumetics.com/>