

LyoStar™ 3 Safety Interlocks

Lyophilizers equipped with Praxair's ControLyo™ Nucleation On-Demand Technology.

This document defines the safety interlocks programmed into the PLC of LyoStar™ 3 lyophilizers equipped with Praxair's ControLyo™ Nucleation On-Demand Technology.

Door Interlock

The control system software will not permit pressurization or depressurization during a Freeze Dry Cycle, or manual Pressurization and Depressurization from the Semi-Auto tab, if the product-drying chamber door is not closed.

The PLC relies on feedback from the Door Closed Limit Switch before proceeding with any pressure-related actions. If this feedback is not detected by the PLC (e.g., the door is open) the Pressurization, Depressurization and Depressurization Bypass valves will not energize.

Note: The Pressurization, Depressurization and Depressurization Bypass valves are noted on the system electrical schematics as valves 1301, 1303 and 1307, respectively.

Isolation Valve

The control system software will not permit pressurization or depressurization during a Freeze Dry Cycle, or manual pressurization or depressurization from the Semi-Auto tab, if the lyophilizer's Isolation Valve is not closed.

The PLC relies on feedback from the Isolation Valve Close limit switch before proceeding with any pressure-related actions. If this feedback is not detected by the PLC (e.g., the Isolation Valve is not closed) the Pressurization, Depressurization and Depressurization Bypass valves will not energize.

Note: The Pressurization, Depressurization and Depressurization Bypass valves are noted on the system electrical schematics as valves 1301, 1303 and 1307, respectively.

Product-Drying Chamber Pressure

Pressurization

For added safety, whenever the PLC detects pressure within the product-drying chamber in excess of 1 psig, the Isolation Valve is not permitted to open.

Depressurization

During a Freeze-Dry cycle with Nucleation Control enabled, the pressure sensor and transmitter continues to monitor the pressure even after the depressurization steps are complete. If pressure in the product-drying chamber exceeds 0.5 psig after depressurization, the Depressurization Bypass opens to release pressure from the system.

Condenser Phase

Nucleation Control may be programmed during the Freezing/Thermal Treatment steps of a Freeze-Dry cycle. Once these steps are executed, the automatic cycle transitions to the Freeze, Hold (*i.e.*, extra freeze time), Condenser, and Evacuate phases. If the system advances to the Condenser phase and the pressure transmitter detects product-drying chamber pressure in excess of 0 psig, the Depressurization Bypass opens to release pressure from the system.

Additional Safety Interlocks

Pressurization Time Out Alarm

During a Freeze-Dry cycle with Nucleation Control enabled, the time it takes for the product-drying chamber to pressurize is monitored. If the time it takes to pressurize the system exceeds the Pressurization Timeout Alarm SP (setpoint) as programmed in the System Configuration settings, the cycle is interrupted and an alarm message is generated. Once the cycle is aborted by the user, pressure in the system is released.

Note: The configurable range of the Pressurization Time Out Alarm setpoint is 10 to 240 seconds.

System Leak Rate During Pressurization

System pressurization may be initiated during the Nucleation Control phase of a Freeze Dry Cycle, or manually from the Semi-Auto tab. As soon as the product-drying chamber pressure reaches the Final Nucleation Pressure setpoint as programmed in the System Configuration settings, the system begins calculating the leak rate. If at any time during the final pressurization, the leak rate exceeds a rate of .05 psi / second, the cycle is interrupted and an alarm message is generated. Once the cycle is aborted by the user, pressure in the system is released.

Note: The configurable range for the Final Nucleation Pressure setpoint is 1 to 3 psig.

Depressurization

System depressurization may be initiated during the Nucleation Control phase of a Freeze Dry Cycle, or manually from the Semi-Auto tab. When depressurization is initiated, the system terminates any active pressurization process. A 20-second warning delay will occur after a depressurization signal is received by the PLC. During this time, a buzzer will sound and an amber strobe will illuminate on the lyophilizer. Depressurization will be initiated approximately 3 seconds after this buzzer and strobe stop. The configurable range for the Final Nucleation Pressure setpoint is 1 to 3 psig