

IQ/OQ Protocol Installation Qualification/ Operation Qualification

**FreeZone[®] Stoppering Tray
Dryer & Bulk Tray Dryer
Freeze Dry Systems**

Labconco No: 1059501 Rev. -



For more information, please contact us:

[ExpotechUSA](#)
[10700 Rockley Road](#)
[Houston, Texas 77099](#)
[USA](#)

[281-496-0900 \[voice\]](#)

[281-496-0400 \[fax\]](#)

E-mail: sales@expotechusa.com

Website: www.ExpotechUSA.com

Purpose and Scope IQ and OQ

This Qualification Protocol is solely intended to be used with Labconco FreeZone Stopping Tray Dryer & Bulk Tray Dryer Freeze Dry Systems, which are new or relocated. Since an additional benchtop or console FreeZone Freeze Dry System is required to operate the Tray Dryer, it must be validated with its IQ/OQ Protocol, document, and # 1059500. This document is to be used to validate the following models:

Models:	FreeZone Stopping Tray Dryers			
	<table border="1"><tr><td>7948020</td><td>7948030</td><td>7948040</td></tr></table>	7948020	7948030	7948040
7948020	7948030	7948040		

Models:	FreeZone Bulk Tray Dryers				
	<table border="1"><tr><td>7806020</td><td>7806021</td></tr><tr><td>7806030</td><td>7806031</td></tr></table>	7806020	7806021	7806030	7806031
7806020	7806021				
7806030	7806031				

Check the model number on the equipment that needs to be validated to ensure the correct protocol is used. Protocol 1058901 is to be used to validate FreeZone Stopping Tray Dryers models 7948000, 7948001, 7948002 and FreeZone Bulk Tray Dryer 7806000, 7806001, 7806002, 7806003, 7806004, 7806005, 7806006 and 7806007.

This document is written to assist the end-user in validation of predetermined specifications. The protocol begins with planning the site for the piece of equipment and therefore is of value prior to receipt of delivery.

The use of this document does not replace the need for the User's Manuals, (Stopping Tray Dryer 7353900, Bulk Tray Dryer 7594900). Information within the User's Manual is required to complete this IQ/OQ Protocol. If the manual has been misplaced, copies can be obtained from the manufacturer or down-loaded from their website, www.labconco.com

Responsibilities

End-User – The ultimate user or otherwise appointed personnel in the lab is responsible to ensure the freeze dryer is installed and operating properly. This document can assist in that validation. This document cannot however anticipate every application or unique situation encountered with the installation and operation. It is therefore essential that users, lab managers and safety officers work together to broaden the scope of this document through careful forethought.

End-User Employer – The employer is responsible for supporting the validation through adequate resources and training. The organization shall also ensure the validation process has been fully carried out prior to applying the Tray Dryer. Records should be stored in a safe, easily retrievable location. The location of the equipment and required validation should be included in the company's quality system.

Manufacturer – Labconco Corporation, certified ISO-9001, is responsible to fully test each Tray Dryer prior to shipment. The manufacturer must retain these records. Labconco’s staff of Product Service Representatives and Product Specialists can assist with information on the purchase, delivery and installation. Labconco is not responsible for the actual installation or validation processes.

Performance Qualification

Once the Tray Dryer has been checked for proper installation and operation, its performance can be validated. Labconco cannot recommend specific procedures to do this. The performance validation should be designed to meet the specifications and accuracy required of the application.

In general, this requires establishing acceptance criteria, making several runs and testing the results with calibrated equipment and qualified personnel.

A. Installation Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	Site Planning			
1a	Freeze Dryer Base Unit	<p>These Tray Dryers are designed to operate with Labconco FreeZone Freeze Dry Systems of 6-Liter or greater capacity.</p> <p>Has a Labconco “Base Unit” been selected for use with the Tray Dryer?</p>	Y	N
		<p>Has the “Installation Qualification” for the base unit freeze dry system been successfully completed?</p> <p>Obtain and complete Labconco FreeZone Freeze Dryer IQ/OQ Protocol #1059500.</p>	Y	N
1b	Space Requirements	<p>Refer to the Appendix in the Bulk Tray Dryer User’s Manual or in the Stoppering Tray Dryer User’s Manual for dimensions of the model you have chosen. Has overhead and working space been provided for the equipment?</p> <p>(A minimum of 3-inches is required between the back of a Stoppering Tray Dryer or base unit and the wall for proper airflow through the refrigeration system.)</p>	Y	N
1c	Electrical Service	<p>Refer to the User’s Manual for electrical requirements. Are services available for the equipment to be connected to an electrical circuit of adequate size and the proper voltage?</p>	Y	N
		<p>230V models are shipped with a power cord with NEMA 6-20P plug. Does this match the available receptacle? Is a plug available to match the service outlet at the installation site?</p>	Y N/A	N
1d	Optional Features	<p>Drying Chambers and Manifolds for connecting flasks and ampules are not included with every Tray Dryer. Has a sample manifold been considered for this application?</p>	Y	N

		An Isolation Valve permits the vacuum in the Stoppering Tray Dryer to be separated from the vacuum in the freeze dryer base unit. Has an Isolation Valve been considered for this application? (Part Number 7761500)	Y	N
2	Prior to Operation			
2a	Damage Claims	<p>Have the delivered products been inspected for any signs of damage that may have occurred while in transit? Keep packaging materials until inspection is complete.</p> <p>WARNING: Do not attempt to pull a vacuum on a Tray Dryer with any damage to the clear door. Implosion and potential for injury can occur.</p> <p>If damaged, refer to the User’s Manual for information on shipping damage claims.</p>	Y	N
2b	Tray Dryer Installation	<p>Place the Tray Dryer on top of the freeze dryer base unit as shown in the User’s Manual.</p> <p>Caution: Tray Dryers are extremely heavy. Follow safe lifting guidelines.</p> <p>Has the Tray Dryer been attached to the base unit with the hardware included?</p>	Y	N
		<p>Has the vacuum port been connected using the rubber coupling and clamps provided?</p> <p>(The flat, round manifold gaskets should be removed before connecting the coupling to the vacuum port of the freeze dryer base unit.)</p>	Y	N
2c	Stoppering Tray Dryer only	<p>This (RS232) cable connects to the jack on the back of the Tray Dryer and to the jack on the rear of the freeze dryer. It is essential if the Tray Dryer is to control the vacuum pump in Automatic mode.</p>	Y	N
	Interconnect Cable #7353403	Has the Interconnect Cable been installed?	N/A	

Labconco FreeZone Tray Dryers IQ/OQ Protocol #1059501 Revision -

2d	Electrical Connection	Plug the Tray Dryer into a dedicated electrical outlet. Has the electrical service been verified to be adequate in size and voltage? (The ID plate on the rear of the freeze dryer has the electrical requirements.)	Y	N
	Electrical Grounding	Has the ground on the electrical service been verified?	Y	N

B. Operational Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	Freeze Dryer			
1a	Freeze Dryer Base Unit	Has the “Operational Qualification” for the freeze dryer base unit been successfully completed? Obtain and complete Labconco FreeZone Freeze Dryer IQ/OQ Protocol #1059500.	Y	N
1b	Stoppering Tray Dryer only Start Up	With the: Tray Dryer’s Power switch ON, Freeze dryer base unit cooled to -40°C or cooler, Stoppering control in the “lower” position, Vac Release control in the “close” position, Empty serum vials with loose stoppers on the four corners of each shelf, Temperature probes taped to the top-center of each shelf with aluminum tape, Door on the Tray Dryer latched & closed, Manual set point system temperature set at -40°C, Vacuum pump started, Room ambient temperature 75°F or cooler With the Stoppering Tray Dryer in the manual mode, press the Run/Stop button. Does the Tray Dryer’s refrigeration system start? (Allow it to continue to operate.) Record the time it started. _____	Y	N
1c	Stoppering Tray Dryer only	Did the Stoppering Tray Dryer system temperature reach -40°C, (+/-1 °C), within 2 hours of starting?	Y N/A	N
	Cooling of the Shelves	Do the Stoppering Tray Dryer shelf temperature probes, (P1, P2, P3) read -40°C, (+/-2°C), within 4 hours of starting?	Y N/A	N

1d	Vacuum Leaks	<p>Verify that the system is leak-free by continuously running the vacuum pump.</p> <p>The rate the freeze dryer without samples achieves a low level of vacuum, (less than 0.133 mBar), is dependent upon many factors: Internal volume & surface area of the unit. Cleanliness or cleaners used on interior. Condition & size of the vacuum pump. Period of time the parts have been exposed to environmental conditions.</p> <p>Based on the Tray Dryer's or freeze dryer's displayed vacuum level, the freeze dryer should reach its lowest level in less than 18 hours. If not, refer to Vacuum Troubleshooting Guide in the User's Manual.</p> <p>Does the system reach a displayed vacuum level of less than 0.050 mBar in 18 hours?</p>	Y	N
1e	Heating of the Shelves Stoppering Tray Dryer only	<p>Raise the set point of the shelves to 40°C and press "Enter" on the Stoppering Tray Dryer.</p> <p>Monitor the displayed temperature for the shelves. Does the temperature of the shelves reach 40°C, (+/-2°C) within 3 hours?</p>	Y N/A	N
	Bulk Tray Dryer only	<p>Raise the set point of the shelves to 40°C with the "Set Temp" buttons on the Bulk Tray Dryer).</p> <p>Monitor the displayed temperature for the shelves. Does the temperature of the shelves reach 40°C, (+/-2°C) within 15 minutes?</p>	Y N/A	N

1f	<p>Stopping Tray Dryer only</p> <p>Verify Interconnect Cable</p>	<p>To test the programmability functions and the Interconnect Cable operation, enter any parameters for a new program, for example: Segment 1: Ramp 1.5°C/min, Hold 24°C, Time 0.10 hr Segment 2: Ramp 1.5°C/min, Hold 18°C, Time 0.10 hr Segment 3: Ramp 1.5°C/min, Hold 28°C, Time 0.10 hr (Large temperature swings and long hold times will prolong the test.)</p> <p>Run the new program. Does the vacuum pump turn ON when segment 1 is completed?</p> <p>Continue with the program.</p>	<p align="center">Y N/A</p>	<p align="center">N</p>
1g	<p>Stopping Tray Dryer only</p> <p>Automatic Mode</p>	<p>Does the system's temperature rise and fall as programmed?</p>	<p align="center">Y N/A</p>	<p align="center">N</p>
1h	<p>Stopping Tray Dryer only</p> <p>Verify Displayed Temperature</p>	<p>The temperature indicated on the LCD display is measured where the heat transfer fluid enters the shelves. The value was calibrated at the factory by correlating its reading with that of a reference gauge attached to a thermocouple inside the rear of the machine. The T-type (red/blue) thermocouple can be accessed only by removal of the top cover of the Stopping Tray Dryer.</p> <p>CAUTION: Electrical Shock Hazard – Disconnect power to the unit prior to removal of any covers.</p> <p>Does the display correlate to the reference gauge/meter +/- 2°C?</p> <p>Ref. Instrument? _____</p> <p>If the temperature does not correlate, contact Labconco Product Service for calibration procedure.</p>	<p align="center">Y N/A</p>	<p align="center">N</p>

Labconco FreeZone Tray Dryers IQ/OQ Protocol #1059501 Revision -

1i	<p>Stoppering Tray Dryer only</p> <p>Stoppering Operation</p>	<p>Rotate the Stoppering knob to the “raise” position.</p> <p>Did the shelves slowly rise from the bottom and did each set of serum vials seal the stoppers?</p> <p>Rotate the Stoppering knob to the “lower” position.</p> <p>Did the shelves return to their lowest positions?</p> <p>(Occasionally, for the shelves to fully return, it is necessary to pull the drain plug of the freeze dryer base unit to remove all air from the Stoppering mechanism.)</p>	<p>Y</p> <p>N/A</p> <p>Y</p> <p>N/A</p>	<p>N</p> <p>N</p>
1j	Temperature Probes	<p>The shelf temperature probes can be verified simply by placing them into an ice bath. Agitate a crushed ice and water bath and place the temperature probes into it.</p> <p>Do the displayed temperatures read between 1°C and -1°C?</p> <p>If the temperature does not correlate, contact Labconco Product Service for calibration procedure.</p>	<p>Y</p> <p>N/A</p>	<p>N</p>

1k	Verify Displayed Vacuum	<p>The vacuum level indicated on the LCD display is measured in a tube on the upper-left side of the chamber. The value was calibrated at the factory by correlating its reading with that of a reference gauge. The calibration was performed at a very low level, approximately 0.010 mBar.</p> <p>NOTICE: Factory calibration was performed using a precision Active Piranni Gauge calibrated to a Capacitance Manometer standard. Despite the system's calibration and repeatability, the readings taken at such a low level of vacuum should only be considered as a verification of a leak-free system. Vacuum swings can be attributed to contamination of surfaces, which could take days to outgas. Adjustments are discouraged.</p> <p>Before any adjustments are made to the factory calibration of the vacuum measurement, answer positively to each of these questions:</p> <ol style="list-style-type: none"> 1) Is the vacuum standard being used to verify the freeze dryer accepted by the organization to be precise and has it been calibrated recently? 2) Is the level of accuracy we are attempting to reach pertinent to the freeze drying applications? <p>Does the vacuum display correlate to the reference gauge?</p> <p>Ref. Instrument? _____</p> <p>If vacuum is to be calibrated, contact Labconco Product Service for calibration procedure. It is normal for there to be a pressure differential with that of the freeze dryer base unit.</p>	Y N/A	N

2	Routine Maintenance	Below are helpful hints to be included in the organization's preventive maintenance plan.		
2a	Vacuum Grease	Vacuum grease should be applied to rubber components as required. In general, vacuum grease should be the first step in troubleshooting vacuum leaks. Thin layers of grease are adequate for all seals. Only use grease specially formulated for low vacuum service. Grease is not required on the door gasket. Use grease only on the inner and outer sealing surfaces of the rubber manifold valve body if the tray dryer is equipped with manifold valves. Is vacuum grease readily available and documented? Type of grease used? _____	Y	N
2b	Inspect for Wear & Damage	Has there been a procedure to periodically inspect the interior metal surfaces for corrosion due to acids?	Y	N
		Are there awareness and a maintenance procedure to check the clear acrylic door for chips, cracks, deep scratches or chemical attack? WARNING: This is a safety issue. Implosion can occur with damaged or corroded components!	Y	N
		Will all the rubber components be periodically inspected so that they are free from drying, cracks or deterioration?	Y	N
2c	Refrigeration System Cleaning	At least annually, will the refrigeration condenser be cleaned of dust that would restrict free airflow? (Include in the preventive maintenance schedule)	Y	N
2d	Stoppering Tray Dryer only	Annually check the fluid level of the Lexsol™ heat transfer fluid with the label applied to the side of the reservoir.	Y	N
	Heat Transfer Fluid	Has this been included in the preventive maintenance plan?	N/A	

Labconco FreeZone Tray Dryers IQ/OQ Protocol #1059501 Revision -

3	Personnel Training			
3a	User Training Related to Equipment	<p>Have personnel that will use the FreeZone Tray Dryers been adequately trained?</p> <p>Are personnel familiar with: All the buttons, knobs and displays on the control panel; The use of vacuum grease; Opening, closing and venting samples; Cleaning of the freeze dryer and neutralization of acids?</p>	Y	N
3b	User's Manual	Are the personnel who are to use or maintain the Tray Dryers able to locate the User's Manual for the machine?	Y	N

C. Summary

Labconco FreeZone Tray Dryers IQ/OQ Document 1059501 Revision -

Equipment Location _____

FreeZone Ser. No. _____ Model No. _____

User Protocol _____ Revision (or Date published) _____

Contact (print name): _____

Title: _____

Review the “Response” columns for answers of “NO.” Use the area below to describe the deficiency or unacceptable results. Those deficiencies are to be followed with an instruction for “Corrective Actions.” Once acceptable results are obtained, the deficiency is “accepted” by initialing the Corrective Action.

Step	Deficiency followed by Corrective Action	Initial

For more information, please contact us:

ExpotechUSA

10700 Rockley Road
Houston, Texas 77099
USA

281-496-0900 [voice]

281-496-0400 [fax]

E-mail: sales@expotechusa.com

Website: www.ExpotechUSA.com