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# **IQ/OQ Protocol**

## **Installation Qualification/ Operation Qualification**

### **FreeZone<sup>®</sup> Stoppering Tray Dryers & Bulk Tray Dryers**

(To be used with FreeZone Stoppering & Bulk Tray Dryers  
manufactured after July, 2017 - See model number chart inside)

## **Purpose and Scope IQ and OQ**

This Qualification Protocol is solely intended to be used with Labconco FreeZone Stoppering Tray Dryers & Bulk Tray Dryers, which are new or relocated. Since an additional Console FreeZone Freeze Dryer is required to operate the Tray Dryer, it must be validated with its IQ/OQ Protocol document # 1065800.

Design changes occurred in 2017 which impact which IQ/OQ protocol is to be used with your Tray Dryer. Check the model number on the equipment that needs to be validated to ensure the correct protocol is used. This document is to be used to validate the following models:

<b>Stoppering Tray Dryers</b>	<b>Bulk Tray Dryers</b>
794801*** Series	780601*** Series

\*\*\* represents the various combinations of the last three digits of the model number.

Protocol 1059501 is to be used to validate FreeZone Stoppering Tray Dryer models (7948020, 7948030, 7948040, 7948060 & 7948070) and FreeZone Bulk Tray Dryer models (7806020, 7806021, 7806030, 7806031, 7806040, 7806041, 7806060, 7806061, 7806070 & 7806071) manufactured between 2004 & 2017.

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, (Stoppering Tray Dryer 7343500 & Bulk Tray Dryer 7343400). 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](http://www.labconco.com)

## **Responsibilities**

**End-User** – The ultimate user or otherwise appointed personnel in the lab is responsible to ensure the Tray 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
<b>1</b>	<b>Site Planning</b>			
1a	Freeze Dryer Base Unit	These Tray Dryers are designed to operate with Labconco FreeZone Console Freeze Dryers		
		Has a Labconco Console Freeze Dryer been selected for use with the Tray Dryer?	Y	N
		Has the “Installation Qualification” for the Console Freeze Dryer been successfully completed?	Y	N
		Obtain and complete Labconco FreeZone Freeze Dryer IQ/OQ Protocol #1065800.		
1b	Space Requirements	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?  (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.)	Y	N
1c	Electrical Service	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?	Y	N
		115V Stoppering Tray Dryers are shipped with a NEMA 5-20 plug. 115V Bulk Tray Dryers are shipped with a NEMA 5-15 plug. 230V models are shipped with a region specific power cord. Does the power cord match the available receptacle at the installation site?	Y N/A	N
1d	Optional Features	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?	Y	N

		An Isolation Valve permits the vacuum in the Stoppering Tray Dryer to be separated from the vacuum in the Console freeze dryer. Has an Isolation Valve been considered for this application? (Part Number 7761500)	Y	N
<b>2</b>	<b>Prior to Operation</b>			
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><b>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.</b></p> <p>If damaged, refer to the User's Manual for information on shipping damage claims.</p>	Y	N
2b	Tray Dryer Installation	Place the Tray Dryer on top of the Console Freeze Dryer as shown in the User's Manual.		
		<p><b>Caution: Tray Dryers can weigh over 400 lbs. (181 Kg). Follow safe lifting guidelines.</b></p> <p>Has the Tray Dryer been attached to the Freeze Dryer 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 3" vacuum port of the Freeze Dryer.)</p>	Y	N
2c	Communication Cable (7364600)	<p>This communication cable connects to the jack on the back of the Tray Dryer labeled "OUTPUT TO FREEZE DRYER" and to the jack on the back of the Freeze Dryer labeled "DRYING ACCESSORY". This cable is essential for the Freeze Dryer to control the operation of the Tray Dryer.</p> <p>Has the Communication Cable been installed?</p>	Y N/A	N

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
<b>1</b>	<b>Freeze Dryer</b>			
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 #1065800.	Y	N
1b	<b>Stoppering Tray Dryer only</b>  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, Sample probes taped to the top-center of each shelf with aluminum tape, Door on the Tray Dryer latched & closed, Vacuum pump started, Room ambient temperature 75°F or cooler  Go to the “Drying Accessory” screen, press the “MANUAL” button, enter -40°C for Shelf Temp Set Point, and press the “Start” button. Does the Tray Dryer’s refrigeration system start? (Allow it to continue to operate.)  Record the time it started. _____	Y	N

1c	<b>Stoppering Tray Dryer only</b>	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 Sample probes, (Sample 1, 2 & 3) 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 that the freeze dryer (without samples) achieves a low level of vacuum, (less than 0.133 mbar), is dependent upon many factors:            Internal volume &amp; surface area of the unit.            Cleanliness or cleaners used on interior.            Condition &amp; 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 less than or equal to 0.040 mbar in 18 hours?</p>	Y	N
1e	Heating of the Shelves	Raise the Shelf Temp Set Point to 40°C and press "Apply" on the Stoppering Tray Dryer.		
	<b>Stoppering Tray Dryer</b>	<p>Monitor the "System Temp". Does the System Temp reach 40°C, (+/-1°C) within 1 hour?</p> <p>Monitor the shelf temperatures (displayed as Sample 1, 2, &amp; 3). Does the temperature of the shelves reach 40°C, (+/-2°C) within 3 hours?</p>	Y N/A  Y N/A	N   N

	<p>Heating of the Shelves</p> <p><b>Bulk Tray Dryer</b></p>	<p>Go to the “Drying Accessory” screen, press the “MANUAL” button, enter 40°C for Shelf Temp Set Point, and press the “Start” button.</p> <p>Monitor the displayed temperature for the shelves. Does the temperature of the shelves reach 40°C, (+/-3°C) within 15 minutes?</p>	<p>Y</p> <p>N/A</p>	<p>N</p>																																													
1f	<p><b>Program Operation</b></p>	<p>To test the programmability functions enter any parameters for a new program, for example:</p> <table><tr><th colspan="5">Stoppering Tray Dryer Program Table</th></tr><tr><th>Step</th><th>Ramp Rate (°C/min)</th><th>Shelf Temp. (°C)</th><th>Time (hh:mm)</th><th>Vacuum (mbar)</th></tr><tr><td>1</td><td>1.5</td><td>24</td><td>00:10</td><td>0.000</td></tr><tr><td>2</td><td>1.5</td><td>18</td><td>00:10</td><td>0.000</td></tr><tr><td>3</td><td>1.5</td><td>28</td><td>00:10</td><td>0.000</td></tr></table> <table><tr><th colspan="4">Bulk Tray Dryer Program Table</th></tr><tr><th>Step</th><th>Shelf Temp. (°C)</th><th>Time (hh:mm)</th><th>Vacuum (mbar)</th></tr><tr><td>1</td><td>24</td><td>00:10</td><td>0.000</td></tr><tr><td>2</td><td>18</td><td>00:10</td><td>0.000</td></tr><tr><td>3</td><td>28</td><td>00:10</td><td>0.000</td></tr></table> <p>(Large temperature swings and long hold times will prolong the test.)</p> <p>Run the new program. Does the System Temperature (Stoppering Tray Dryer) or Shelf Temperature (Bulk Tray Dryer) rise and fall as programmed?</p>	Stoppering Tray Dryer Program Table					Step	Ramp Rate (°C/min)	Shelf Temp. (°C)	Time (hh:mm)	Vacuum (mbar)	1	1.5	24	00:10	0.000	2	1.5	18	00:10	0.000	3	1.5	28	00:10	0.000	Bulk Tray Dryer Program Table				Step	Shelf Temp. (°C)	Time (hh:mm)	Vacuum (mbar)	1	24	00:10	0.000	2	18	00:10	0.000	3	28	00:10	0.000	<p>Y</p> <p>N/A</p>	<p>N</p>
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1g	<b>Stoppering Tray Dryer only</b>  Verify Displayed Temperature	<p>The system temperature is measured where the heat transfer fluid enters the shelves. If desired, the display value can be compared with a reference T-Type thermocouple wire that is embedded at the same sensor location. The T-type thermocouple (red/blue wires with brown outer sheathing) can be accessed only by removal of the back panel of the Stoppering Tray Dryer.</p> <p><b>CAUTION: Electrical Shock Hazard – Disconnect power to the unit prior to removal of any covers.</b></p> <p>Does the display correlate to the reference gauge/meter +/- 3°C?</p> <p>Ref. Instrument? _____</p> <p>If the temperature does not correlate, see Freeze Dryer User’s Manual or contact Labconco Product Service for calibration procedure.</p>	Y  N/A	N
1h	<b>Stoppering Tray Dryer only</b>  Stoppering Operation	<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 release the vacuum from the system by turning off the vacuum pump and turning the “Vac Release” valve to the Vent position.)</p>	Y  N/A  Y  N/A	N  N

1i	Sample Probes	<p>The Sample 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 in the bath.</p> <p>Do the displayed temperatures read between 1°C and -1°C?</p> <p>Sample probes that are out of range should be replaced.</p>	<p>Y</p> <p>N/A</p>	<p>N</p>
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1j	<p><b>Stoppering Tray Dryer only</b></p> <p>Verify Displayed Vacuum</p>	<p>The vacuum level indicated on the touch screen display is measured by a sensor 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 Pirani Gauge. 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"> <li>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?</li> <li>2) Is the level of accuracy we are attempting to reach pertinent to the freeze drying applications?</li> </ol> <p>Does the vacuum display correlate to the reference gauge?</p> <p>Ref. Instrument? _____</p> <p>If vacuum is to be calibrated, see the Freeze Dryer User's Manual or contact Labconco Product Service.</p> <p>Note: It is normal for there to be a differential between the vacuum sensor readings of the Freeze Dryer &amp; Stoppering Tray Dryer.</p>	<p>Y</p> <p>N/A</p>	<p>N</p>

<b>2</b>	<b>Routine Maintenance</b>	Below are helpful hints to be included in the organization's preventive maintenance plan.		
2a	Vacuum Grease	<p>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.</p> <p>Is vacuum grease readily available and documented?</p> <p>Type of grease used? _____</p>	Y	N
2b	Inspect for Wear & Damage	Is there a procedure to periodically inspect the interior metal surfaces for corrosion due to acids?	Y	N
		<p>Is there awareness and a maintenance procedure to check the clear acrylic door for chips, cracks, deep scratches or chemical attack?</p> <p>WARNING: This is a safety issue. Implosion can occur with damaged or corroded components!</p>	Y	N
		Will all the rubber components be periodically inspected so that they are free from drying, cracks or deterioration?	Y	N
2c	<b>Stoppering Tray Dryer only</b>  Refrigeration System Cleaning	<p>At least annually, will the refrigeration condenser be cleaned of dust that would restrict free airflow</p> <p>Has this been included in the preventive maintenance schedule?</p>	Y	N

2d	<b>Stoppering Tray Dryer only</b>	Annually check the fluid level of the Lexsol™ heat transfer fluid with the label applied to the side of the reservoir.	Y N/A	N
	Heat Transfer Fluid	Has this been included in the preventive maintenance plan?		
<b>3</b>	<b>Personnel Training</b>			
3a	User Training Related to Equipment	Have personnel that will use the FreeZone Tray Dryers been adequately trained?  Are personnel familiar with: All the switches, knob and indicator lights on the control panel; The use of vacuum grease; Opening, closing and venting samples; Cleaning of the Tray Dryer and neutralization of acids?	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?  Note: User's Manuals are stored in the Freeze Dryer's memory and can be accessed via the touch screen or can be downloaded at <a href="http://www.labconco.com">www.labconco.com</a>	Y	N

## C. Summary

**Labconco FreeZone Tray Dryers IQ/OQ Document 1065801 Revision B**

**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.**

<b>Step</b>	<b>Deficiency followed by Corrective Action</b>	<b>Initial</b>