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IQ/OQ Protocol
Installation Qualification/
Operation Qualification

FreeZone® Freeze Dryers

(To be used with FreeZone Freeze Dryers manufactured after July, 2017 - See model number chart inside)

Labconco No. – 1065800 Rev. E – ECO P282
Available at **labconco.com**

Purpose and Scope IQ and OQ

This Qualification Protocol is solely intended to be used with Labconco FreeZone Freeze Dryers, which are new or relocated. FreeZone Tray Dryers are covered in a separate document, #1065801.

Design changes occurred in 2017 which impact which IQ/OQ protocol is to be used with your Freeze Dryer. Check the model number listed on the serial number tag located on the rear of the equipment. Models using this protocol can be visually identified by the 5" color touch screen in the front control panel. This protocol is to be used to validate the following models:

Benchtop Freeze Dryers	Console Freeze Dryers
70020**** 2.5L -50C Series	70061**** 6L -50C Series
71020**** 2.5L -84C Series	71061**** 6L -84C Series
70040**** 4.5L -50C Series	70121**** 12L -50C Series
71040**** 4.5L -84C Series	71121**** 12L -84C Series
72040**** 4.5L -105C Series	70181**** 18L -50C Series
70080**** 8L -50C Series	

*** represents the various combinations of the last four digits of the model number.

Prior models manufactured between 2004 & 2017 have a two line display with yellow lettering and a black background. Use document #1059500 to perform the IQ/OQ on previous models.

It 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 FreeZone Freeze Dryer User's Manuals. 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 freeze 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 FreeZone Freeze 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 freeze 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	Space Requirements	Refer to Appendix B in User's Manual for dimensions of the model you have chosen. Has adequate floor or counter space been provided for placement of the equipment? (A minimum of 3-inches is required between the back of a freeze dryer and the wall and between the sides and the walls for proper airflow through the refrigeration system.)	Y	N
1b	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 models are shipped with a NEMA 5-20P power cord 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
1c	Vacuum Pump	Refer to the User's Manual. Have accommodations been made to provide a suitable vacuum pump? It must be capable of at least 98 Liters/min free-flow & 0.020 mbar ultimate vacuum, with an inlet fitting suitable for a ¾-inch ID vacuum hose and the same voltage rating as the freeze dryer. (An oil mist eliminator exhaust filter is recommended.) Pumps operating with 115V Freeze Dryers should have a NEMA 5-15P plug. Pumps operating with 230V Freeze Dryers should have a reverse IEC 320 plug.	Y	N

1d	Manifolds	Freeze drying chambers or manifolds are not included with the freeze dryer. Has a sample manifold or chamber been purchased for this application?	Y N/A	N
2	**Prior to Operation**			
2a	Damage Claims	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. WARNING: Do not attempt to pull a vacuum on a freeze dryer with any damage to the clear lids or stainless steel manifolds/chambers. Implosion and potential for injury can occur. If damaged, refer to the User's Manual for information on shipping damage claims.	Y	N
2b	PTFE Coated	If aggressive acids are to be used within this freeze dryer, PTFE coated collector chamber is recommended. Have the use of acids and potential for damage been considered?	Y N/A	N
2c	Handling Solvents	Has the Safety Officer or equivalent reviewed the safe handling and disposal of solvents trapped as well as used vacuum pump oil?	Y N/A	N
2d	Chamber or Manifold Installation	Place the desired drying chamber or manifold onto the 3-inch diameter port located on the top of the freeze dryer. Drying chambers are to be held in place with a stainless steel pin provided.	Y N/A	N
2e	Vacuum Pump Installation	Install the vacuum pump per the User's Manual. Is the pump attached to the vacuum port on the collector chamber with the vacuum tubing and clamps provided?	Y	N
	Vacuum Pump Electrical	Is the vacuum pump plugged into the vacuum pump receptacle at the back of the Freeze Dryer and the pump's power switch turned to the ON position?	Y	N
	Vacuum Ballast	The vacuum pump's ballast should remain closed. Is the pump's ballast closed?	Y	N

2f	Electrical Connection	Plug the freeze 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	Automatic Mode	With the freeze dryer system at ambient temperature, Press the button labeled "AUTO" on the Home Screen of the touch screen display. Does the refrigeration system start? Record the time it started. _____	Y	N
1b	Power to Vacuum Pump	For systems <u>without</u> the Purge Valve option, when the freeze dryer collector temperature reaches –40°C, the vacuum pump should start. When the display shows –40°C did the pump start? Or, for systems <u>with</u> the Purge Valve option, the vacuum pump should start 2 seconds after pressing the "AUTO" button. Did the pump start?	Y	N
1c	Purge Valve Option	If equipped with the Purge Valve option, the Purge Valve should remain closed until the collector temperature reaches –40°C. Does the system switch the purge valve at –40°C?	Y N/A	N

1d	Refrigeration Effectiveness	**For -50°C Freeze Dryer models** - Does the collector temperature reach –47°C in less than 40 minutes? (With the system under vacuum and 21°C ambient temperature.) **For -84°C Freeze Dryer models** - Does the collector temperature reach –81°C in less than 40 minutes? (With the system under vacuum and 21°C ambient temperature.) **For -105°C Freeze Dryer models** - Does the collector temperature reach –102°C in less than 40 minutes? (With the system under vacuum and 21°C ambient temperature.) NOTE: Freeze Dryers are tested to -50°C, -84°C or -105°C in the factory. Conditions may vary in the field resulting in warmer acceptance temperatures.	Y	N
1e	Verify Displayed Temperature	The temperature indicated on the touch screen display is measured at the outlet of the collector coil. A reference T-type thermocouple (red & blue wires with brown sheathing) can be accessed by removing the stainless steel front panel and read with an electronic thermocouple meter. Does the display correlate to the reference gauge/meter +/- 4°C? Ref. Instrument? _____ If the temperature does not correlate, see User's Manual or contact Labconco Product Service for calibration procedure.	Y N/A	N

1f	Vacuum Leaks	Verify that the system is leak-free by continuously running the vacuum pump with the refrigeration system ON. The rate that the freeze dryer (without samples) achieves a low level of vacuum, (less than 0.133 mbar), is dependent upon many factors: Inside volume & surface area of the system. Cleanliness or cleaners used on interior. Condition & size of the vacuum pump. Period of time the parts have been exposed to environmental conditions. Based on the 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. Does the system reach a displayed vacuum level less than or equal to 0.040 mbar in 18 hours?	Y	N

1g	Verify Displayed Vacuum	The vacuum level indicated on the touch screen display is measured between the collector and the vacuum pump. 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. 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. Before any adjustments are made to the factory calibration of the vacuum measurement, answer positively to these questions: 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? Does the vacuum display correlate to the reference gauge? Ref. Instrument? _____ If vacuum is to be calibrated, see User's Manual or contact Labconco Product Service.	Y N/A	N
1h	Defrost	Check defrost operation. With the refrigeration (i.e. collector) OFF, press the "COLLECTOR" button, press the "Defrost Options" button, then press the "start" button. Does the collector coil become warm to the touch?	Y N/A	N

1i	Shell Freezer Option (**if installed**)	Fill the Shell Freezer to the proper level with alcohol (see User's Manual). Press the "SHELL FREEZER" button. Do the rollers rotate?	Y N/A	N
		Does the bath temperature shown on the display reach –40°C in 2 hours?	Y N/A	N
		Verify the display reading by placing a thermocouple inside the center of the bath almost touching the bottom of the chamber. Does the display correlate with the reference gauge/meter +/- 2° C? Ref Instrument?_____	Y N/A	N
1j	Vacuum Control	Check vacuum control operation. With refrigeration running and collector temperature < -40°C and vacuum operating at < 0.075 mbar, set the vacuum level at 0.500 mbar. Within a 5 minute period, the vacuum shown on the display should not vary beyond 0.350 to 0.650 mbar. Are these readings achieved?	Y N/A	N
1k	Mini Chamber Option (**if installed**)	Some 6, 12 and 18L console freeze dryers have a vacuum chamber built into the top surface next to collector chamber. If the freeze dryer is equipped with a Mini Chamber, check its operation. Securely tape a thermocouple to the center of the chamber. Set the Mini Chamber temperature for 40°C and allow the chamber temperature to stabilize. Does the display correlate with the reference gauge / meter +/- 3°C ? Ref Instrument?_____	Y N/A	N

1l	Moisture Sensor	Check moisture sensor operation. Turn refrigeration (collector) and vacuum pump off. Pour water into the collector to cover the bottom. Press the "COLLECTOR" button, then "Start". Press the "VACUUM" button, then "Start". The refrigeration and vacuum should be inoperable. Are they disabled? NOTE: Deionized (DI) water may not cause the moisture sensor to activate due to the low conductivity (high purity) water.	Y N/A	N
		Is there an alert on the display that reads "Collector Moisture"?	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. Do not use grease on the flat gaskets used to seal freeze dry valves to the chamber. Is vacuum grease readily available and documented? Type of grease used? _____	Y	N

2b	Vacuum Pump Oil	The vacuum pump oil should be changed as needed. Change oil that appears cloudy or discolored. As a general rule, oil should be changed every 1000 hours of service. An alarm can be set (from 1 hour to 9999 hours) on the freeze dryer to alert personnel when the set hours of operation has been reached. Has there been a preventive maintenance plan established for the vacuum pump? Type of oil to be used? _____	Y	N
2c	Inspect for Wear & Damage	Is there a procedure to periodically inspect the interior metal surfaces for corrosion due to acids?	Y	N
2d	Inspect for Wear & Damage Refrigeration System Cleaning	Is there awareness and a maintenance procedure to check the clear acrylic and glass parts for chips, cracks, deep scratches or chemical attack? WARNING: This is a safety issue. Implosion can occur with damaged or corroded components!	Y	N
2e	Inspect for Wear & Damage	Will all the rubber components be periodically inspected so that they are free from drying, cracks or deterioration?	Y	N
2f	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

3	**Personnel Training**			
3a	User Training Related to Equipment	Have personnel that will use the FreeZone Freeze Dryer been adequately trained? Are personnel familiar with: Touch screen display in the control panel; Collector capacity limits before defrosting; Defrosting and draining methods; Safe handling of solvents drained; The various alerts on the touch screen; The use of vacuum grease; Opening, closing and venting sample valves; Setting the vacuum level; Setting the Mini Chamber temperature; Using the Shell Freezer; Cleaning of the freeze dryer and neutralization of acids?	Y	N
3b	User's Manual	Are the personnel who are to use or maintain the Freeze Dryer 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 www.labconco.com	Y	N

C. Summary

Labconco FreeZone Freeze Dryer IQ/OQ Document 1065800 Revision D

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