IQ/OQ Protocol
Installation Qualification/ Operation Qualification

FreeZone® Freeze Dry Systems

(To be used with FreeZone Systems manufactured prior to August, 2004- see model number chart inside.)

Labconco No: 1058900 Rev. B ECO C414
Available at www.labconco.com
or by e-mail in Word 2000 document

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Purpose and Scope IQ and OQ

This Qualification Protocol is solely intended to be used with Labconco FreeZone Freeze Dry Systems, which are new or relocated. FreeZone Tray Dryers are covered in a separate document, #1058901.

Design changes occurred in 2004 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 dark gray (almost black) control panel label and painted front panel. Newer models have a blue control panel label and stainless steel front panel. Use document #1059500 to perform the IQ/OQ on newer models.

Models: FreeZone Freeze Dry Systems

7670000	*7752000*	*7754000*	*7755500*	*7960000*
7670001	*7752001*	*7754001*	*7755501*	*7960001*
	7752003	*7754003*	*7755503*	*7960002*
7670500		*7754010*	*7755510*	*7960003*
7670501	*7753000*	*7754011*	*7755511*	*7960010*
7670503	*7753001*	*7754013*	*7755513*	*7960011*
	7753003			*7960012*
7750000	*7753010*	*7754500*	*7934000*	*7960013*
7750001	*7753011*	*7754501*	*7934001*	
7750003	*7753013*	*7754503*	*7934002*	
7750004		*7754510*	*7934003*	
7751000	*7753500*	*7754511*	*7934010*	
	7753501	*7754513*	*7934011*	
7751001	*7753503*		*7934012*	
7751003	*7753510*	*7755000*	*7934013*	
7751004	*7753511*	*7755001*		
	7753513	*7755003*		
		7755010		
		7755011		
		7755013		

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 Dry Systems 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 Dry System 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 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
		230V models are not shipped with a power cord plug. Is one available to match the service outlet 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 150 Liters/min free-flow for 6-, 12- and 18-Liter models, at least 110 Liters/min free-flow for 2.5, and 4.5-Liter models, 0.2 x 10^{-3} mBar ultimate vacuum, 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.) (230V pumps for the 6-, 12- and 18-L models should have a 15-amp NEMA 6-15P plug to match the outlet on the freeze dryer. All 2.5- and 4.5-L models as well as the 6-L Benchtop use a reverse IEC 320 plug.)	Y	N

1d	Manifolds	With the exception of the 4.5-Liter Benchtop model, 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
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	Teflon Coated	If aggressive acids are to be used within this freeze dryer, Teflon-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	Manifold Installation	Place the desired drying chamber or manifold onto the 3-inch diameter port located on the top of the freeze dryer. (4.5-L models have a drying chamber permanently installed.) Larger drying chambers are to be held in place with a stainless steel pin provided.	Y	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 large rubber hose and clamps provided?	Y	N
	Vacuum Pump Electrical	Is the vacuum pump plugged into the rear 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, turn the Main Power Switch ON. Press the button labeled "Refrigeration Auto." Does the refrigeration system start? Record the time it started. _____	Y	N
1b	Power to Vacuum Pump	For systems without 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 with the Purge Valve option, the vacuum pump should start 2 seconds after pressing the "Refrigeration Auto" switch. 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 FreeZone Freeze Dryers does the collector temperature reach –47°C in less than 15 minutes? (With the system under vacuum and 21°C ambient temperature.) Or, for FreeZone Plus Cascade Freeze Dryers does the collector temperature reach –84°C in less than 20 minutes? (With the system under vacuum and 21°C ambient temperature.)	Y	N

1e	Verify Displayed Temperature	The temperature indicated on the LCD display is measured at the outlet of the collector coil. The value was calibrated at the factory by correlating its reading with that of a reference gauge attached to a thermocouple. The J-type (red/white) thermocouple can be accessed outside the bottom of the insulated collector chamber. Does the display correlate to the reference gauge/meter +/- 2°C? Ref. Instrument? _____ If the temperature does not correlate, contact Labconco Product Service for calibration procedure.	Y N/A	N
1f	Temperature Wave Display	The temperature "wave" graph of indicator lights on the control panel is a quick reference of the collector temperature. Verify these lights are operating properly. Does the last green light illuminate when the system reaches < 39°C?	Y	N
1g	Vacuum Leaks	Verify that the system is leak-free by continuously running the vacuum pump with the refrigeration system ON. The rate the freeze dryer without samples achieves a low level of vacuum, (less than 133 x 10^{-3} 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 of less than 50 x 10^{-3} mBar in 18 hours?	Y	N

1h	Vacuum Wave Display	The control panel's vacuum "wave" graph of indicator lights is a quick reference of vacuum level. Verify these lights are operating. Does the last green light flash when the system reaches < 450 x 10^{-3} mBar? And, does the last green light remain illuminated when the system reaches < 133 x 10^{-3} mBar?	Y	N
1i	Verify Displayed Vacuum	The vacuum level indicated on the LCD display is measured on the underside of the collector. 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 10 x 10^{-3} mBar. 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. 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, contact Labconco Product Service for calibration procedure.	Y N/A	N

1j	Defrost Option	If the freeze dryer is equipped with a defrost heater, check its operation. With the refrigeration switches OFF, press the "defrost" button ON. Do the interior sides of the collector chamber become warm to the touch?	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. 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. At a minimum, oil should be changed every 1000 hours of service. An alarm can be set on the freeze dryer to alert personnel when 1000 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
		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
		Will all the rubber components be periodically inspected so that they are free from drying, cracks or deterioration?	Y	N
2d	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 Dry System been adequately trained? Are personnel familiar with: All the buttons and displays on the front; Collector capacity limits before defrosting; Defrosting and draining methods; Safe handling of solvents drained; The various alarms on the control panel; The use of vacuum grease; Opening, closing and venting sample valves; 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 Tray Dryers able to locate the User's Manual for the machine?	Y	N

C. Summary

Labconco FreeZone Freeze Dry System IQ/OQ Document 1058900 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.

Step	Deficiency followed by Corrective Action	Initial

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