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IQ/OQ Protocol Installation Qualification/ Operation Qualification

Protector[®] Controlled Atmosphere Glove Box

Purpose and Scope

This Qualification Protocol is intended to be used with Labconco Protector Controlled Atmosphere Glove Boxes only, which are new or relocated.

Models:

Protector® Controlled Atmosphere Glove Boxes

Base Catalog Model Number	Operation Type	Liner Material	Liner Width	(Last Two Digits of Configured Catalog Number) Electrical Receptacle Voltage/Frequency				
				North America 100-115V	British (UK) 230V	Schuko 230V	China Australia 230V	North America 230V
				50/60 Hz	50/60 Hz	50/60 Hz	50/60 Hz	60 Hz Only
50600	Manual	Fiberglass	Single	10	31	35	40	45
50601	Manual	Stainless Steel	Single	10	31	35	40	45
			Double	12	33	37	42	47
50800	Auto	Fiberglass	Single	10	31	35	40	45
50801	Auto	Stainless Steel	Single	10	31	35	40	45
			Double	12	33	37	42	47
50800	Combination	Fiberglass	Single	60	65	70	75	80
50801	Combination	Stainless Steel	Single	60	65	70	75	80
			Double	62	67	72	77	82

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

Responsibilities

End-User – The ultimate user or otherwise appointed personnel in the lab is responsible to ensure the Controlled Atmosphere Glove Box 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 cautious 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 use of the Controlled Atmosphere Glove Box. Records should be stored in a safe, easily retrievable location. The location of the Controlled Atmosphere Glove Box, preventive maintenance and certification schedules should be documented in the company's quality system.

Manufacturer – Labconco Corporation, certified ISO-9001, is responsible to fully test the Controlled Atmosphere Glove Box prior to shipment. The manufacturer must retain these

records. Their staff of Product Service Representatives and Product Specialists can assist with information on the purchase, delivery and installation. Labconco is not responsible for carrying out the actual installation or validation processes.

Performance Qualification

Once the Controlled Atmosphere Glove Box has been checked for proper installation and operation, its performance may 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 Controlled Atmosphere application.

In general this requires establishing acceptance criteria, inspecting and testing the results with calibrated equipment and qualified personnel. Some basic suggestions are included after the Operational Qualification section.

A. Installation Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	Site Planning			
1a	Level Surface	Have accommodations been made for placement of the Controlled Atmosphere Glove Box on a reasonably level work surface?	Y	N
1b	Space Requirements	Refer to Appendix B in User's Manual. Has adequate floor space been provided for placement of the Controlled Atmosphere Glove Box and its stand?	Y	N
		Is there proper right-side clearance for the transfer chamber of the Controlled Atmosphere Glove Box? There should be 12" inches, (305 mm) to the right-side of the exterior transfer chamber door.	Y	N
1c	Electrical Service	Refer to the Electrical Requirements section of the User's Manual for a list of model numbers and their corresponding electrical ratings. Are services available for the Controlled Atmosphere Glove Box to be connected to a dedicated circuit with over-current protection of adequate size and the proper voltage?	Y	N
1d	Delivery Requirements	If the Controlled Atmosphere Glove Box has not been delivered yet, have arrangements been made with the facility or delivery agent to have equipment capable of handling a packaged skid of this size and weight?	Y	N
		The Controlled Atmosphere Glove Box is delivered on a shipping pallet. Accessory base stands are available to mount the glove box on. Is there a clear path from the loading platform to the final destination in the lab?	Y	N
2	Prior to Operation			
2a	Damage Claims	Has the Controlled Atmosphere Glove Box been inspected for any signs of damage that may have occurred while in transit or within the building? Keep packaging materials until inspection is complete. If so, refer to the User's Manual for information on shipping damage claims.	Y	N

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2b	Set Up	Is the Controlled Atmosphere Glove Box set at a suitable height for the operator to work ergonomically?	Y	N
		<p>Before attempting to operate verify that;</p> <ul style="list-style-type: none"> • The inert gas and vacuum pump service tubing has been connected to the main chamber valves and transfer chamber valves. • If applicable, has inert gas and vacuum pump service tubing been connected to the four auto pressure controller valves properly? • Have the gloves been installed correctly with the outer o-rings showing over the gloves and the clamps secured on the outer rings? • If applicable, has the AtmosPure Re-Gen Gas Purifier (O₂/H₂O removal system) been installed properly? <p>See Installation Instructions in the User's Manual for details.</p>	Y	N
		The User's Manual is shipped within the Controlled Atmosphere Glove Box. Has it been unpacked and stored for future use?	Y	N
2c	Electrical Connections	Is the Controlled Atmosphere Glove Box connected to a dedicated electrical circuit of proper voltage and amperage? See identification plate on the rear of the glove box.	Y	N
		Is the interior duplex receptacle controlled by the front panel Auxiliary electrical switch?	Y	N
2d	Electrical Operational Checks	Does the front panel electrical switch or Auto Pressure Controller, control the rear panel exterior electrical outlet for vacuum pump operation?	Y	N
		Does the front panel Fluorescent Light operate when the light switch is turned ON?	Y	N
2e	Transfer Chamber	Do the transfer chamber doors and door latches operate?	Y	N
2f	Pressure Relief Bubbler on Main Glove Chamber	Has the Bubbler (over/under pressure relief device) on the rear wall of the main chamber of the glove box been identified and filled with vacuum pump oil? If applicable, is the pressure relief device properly vented to the outside and/or filtered with a HEPA and/or carbon filter.	Y	N

B. Operational Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	Certification			
1a	Initial Certification	<p>Prior to use, the Controlled Atmosphere Glove Box can be tested by the user or a qualified certifier for leaks?</p> <p>The User's Manual describes several ways to leak test the glove box with and without test equipment.</p>	Y	N
2	Training			
2a	User Training	Have all users been properly trained on the benefits, theory of operation and limitations of the Controller Atmosphere Glove Box?	Y	N
		<p>Do all users understand the techniques for:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Establishing an inert atmosphere. <input type="checkbox"/> Operation of the transfer chamber for material transfers into an inert atmosphere. <input type="checkbox"/> Pressure limitations of the main chamber and the transfer chamber? 	Y	N
3	Cleaning			
3a	Exterior Cleaning	Has the exterior been cleaned of dust that accumulated throughout shipment and installation?	Y	N

C. Performance Qualification

NOTE: This Performance Qualification section is only a recommendation of some basic items to consider for your protocol. Your protocol should include tests and inspections that are pertinent to the applications performed within the equipment.

Step	Description	Suggested Criteria	Result	
			YES	YES
1	Periodic Certification			
1a	Glove Box Performance	Leak testing should be done at a minimum annually. An experienced user or certifier can verify the glove box performance to manufacturer's specifications. Is the Controlled Atmosphere Glove Box current certification within the acceptable timeframe set by your organization?	Y	N
		Has there been a procedure established if a cabinet is found to have exceeded its certification due date?	Y	N
		Is the next required certification noted in your quality system's preventive maintenance or certification schedule?	Y	N
2	Maintenance			
2a	Cleaning	The Controlled Atmosphere Glove Box exterior and interior should be cleaned weekly with an application compatible cleaner.	Y	N
2b	Fluorescent Lamp	Regular maintenance should ensure that the Fluorescent Lamp is operating properly.	Y	N

D. Summary

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Equipment Location _____

Serial. 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