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IQ/OQ Protocol

Installation Qualification/ Operation Qualification

Protector[®] HEPA Filtered and ULPA Filtered Glove Boxes

Purpose and Scope

This Qualification Protocol is intended to be used with Labconco Protector HEPA & ULPA Filtered Glove Boxes only, which are new or relocated.

Models: Protector® HEPA & ULPA Filtered Glove Boxes

Base Catalog Model No.	Liner Material	Filter Type	Liner Width	Electrical Receptacle Voltage/Frequency				
				North America 100-115V 50/60 Hz	British (UK) 230V 50/60 Hz	Schuko 230V 50/60 Hz	China/ Australia 230V 50/60 Hz	North America 230V 60 Hz only
50650	Fiberglass	HEPA	Single	-10	-31	-35	-40	-45
50655	Stainless Steel	ULPA	Single	-10	-31	-35	-40	-45
50655	Stainless Steel	ULPA	Double	-12	-33	-37	-42	-47

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 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 glove box. Records should be stored in a safe, easily retrievable location. The location of the glove box, preventive maintenance and certification schedules should be documented in the company's quality system.

Glove Box Certifier – All glove boxes utilizing HEPA or ULPA Filters to control particulate levels should be certified prior to use. A qualified certifying technician must do this process with calibrated instruments. The HEPA or ULPA Filters should be certified upon installation, on a scheduled annual basis and whenever the glove box is moved to a new location. Certification is the key requirement of this protocol.

Manufacturer – Labconco Corporation, certified ISO-9001, is responsible to fully test the glove boxes 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 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 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 glove box on reasonably level flooring?	Y	N
1b	Space Requirements	Has adequate floor space been provided for placement of the glove box?	Y	N
		Is there proper right-side clearance for the glove box? There should be 12-inches, (300 mm) to the right of the outer transfer chamber door for access to the transfer chamber interior.	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 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 glove box has not been delivered yet, have arrangements been made with the facility or delivery agent to have equipment capable of gently handling a packaged skid of this size and weight?	Y	N
		The glove box is delivered in a carton, on shipping pallet. Accessory base stands are available to mount the glove box on. Is there a clear path from the building loading platform to the final destination of the glove box in the laboratory?	Y	N
2	Prior to Operation			
2a	Damage Claims	Has the 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	The glove box must be placed on a stand or the work surface of a cabinet. Has the height of the stand or the cabinet been set to provide the operator an ergonomically correct work station?	Y	N
		Before attempting to operate verify that; <ul style="list-style-type: none"> The gloves have been installed correctly with the outer o-rings showing over the gloves and the clamps secured on the outer o-rings. The interior work surface is clean. See cleaning instructions in the User's Manual for details.	Y	N
		The User's Manual is shipped within the glove box. Has the manual been unpacked and stored for future use?	Y	N
2c	Electrical Connections	Is the glove box connected to a dedicated electrical circuit of proper voltage and amperage? See identification plate on the top of the cabinet.	Y	N
		Is the duplex receptacle mounted on the right side wall inside the glove box operational?	Y	N
		Is the interior duplex receptacle controlled by the front panel Auxiliary electrical switch?	Y	N
2d	Basic Operational Checks	Does the Blower operate when the Power Switch is turned on?	Y	N
		Does the Fluorescent Light operate when the Light Switch is turned on?	Y	N
3e	Air Flow Control	Does the blower speed dial increase and decrease the volume of air flowing through the glove box? If applicable, is the blower exhaust properly vented to the outside or an accessory FilterMate Portable Exhauster to remove chemical vapors not trapped by the HEPA filter.	Y	N
3f	Transfer Chamber	Do the transfer chamber doors and door latches operate?	Y	N
3g	Main Chamber	Does the airflow pressure monitor operate and indicate properly with the blower turned on and the transfer chamber doors closed? Consult the instruction manual for proper airflow and pressure.	Y	N

B. Operational Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	Certification			
1a	Initial Certification	Prior to use, has a qualified certifier tested the inlet and outlet HEPA/ULPA filters for leaks?	Y	N
		Have the exhaust volumes been measured as described in the User's Manual.		
		Certification should be done annually. Has the next required certification been added to your quality system's preventive maintenance or certification schedule?	Y	N
2	Training			
2a	User Training	Have all users been properly trained on the theory of operation and limitations of the HEPA/ULPA filtered glove boxes?	Y	N
		Do all users understand techniques for: <ul style="list-style-type: none"> <input type="checkbox"/> Start up of the glove box. <input type="checkbox"/> Dilution of internal particulate contamination levels. <input type="checkbox"/> Surface cleaning objects that will be transferred out of the glove box. <input type="checkbox"/> Shutting down the glove box? 	Y	N
		Are users aware of ergonomic factors that can cause unnecessary fatigue or personal discomfort?	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	NO
1	Periodic Certification			
1a	Glove Box Performance	Certification should be done at a minimum annually. An experienced certifier can verify the HEPA/ULPA filter performance to manufacturer's specifications. Is the glove box current certification within the acceptable timeframe set by your organization?	Y	N
		Has there been a procedure established if a glove box 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	HEPA Filters	The disposable HEPA/ULPA filters located on top of the glove box should be leak checked annually. The HEPA/ULPA filters should be replaced when internal air volume dilution rate drop below acceptable levels after the blower speed control has been set to its maximum.	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