



LABCONCO CORPORATION

8811 Prospect Avenue
Kansas City, MO 64132
(800) 821-5525, (816) 333-8811
(816) 363-0130 fax
labconco@labconco.com

IQ/OQ/PQ Protocol Installation Qualification/ Operation Qualification/ Performance Qualification

Purifier[®] Logic[®] Vue Class II Enclosures

Purpose and Scope

This Qualification Protocol is solely intended to be used with Labconco Purifier Logic Vue Class II Enclosures, which are new or relocated. 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.

Models:

33006 Series

Responsibilities

End-User – The end user or equipment owner is responsible for ensuring that the enclosure 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 enclosure. Records should be stored in a safe, easily retrievable location. The location of the enclosure, preventive maintenance and certification schedules should be documented in the company's quality system.

Enclosure Certifier – All Class II enclosures must be certified prior to use. A qualified certifying technician must perform this process with calibrated instruments. The enclosure must be certified upon installation, and again on at least an annual basis, or whenever the enclosure 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 Purifier Logic Vue to performance requirements adapted from NSF 49 prior to shipment and must retain these records. Labconco's Product Service Representatives and Application 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 Purifier Logic Vue has been checked for proper installation and operation, its performance may be validated. Labconco cannot recommend specific procedures to perform additional validation. Any performance validation should be designed to meet the specifications and accuracy required of the Vue's application.

In general, additional validation may involve 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	Proper airflows	Is the Logic Vue to be located in a room with windows that will remain closed?	Y	N
		Is the enclosure to be located away from heavy foot traffic, doors, fans, ventilation registers and any other air-handling devices that could disrupt its airflow patterns?	Y	N
1b	Space Requirements	Refer to Appendix B in User's Manual. Has adequate floor space been provided for placement of the enclosure?	Y	N
		Is there proper overhead clearance for the Logic Vue? There must be 6-inches, (150 mm) above the supply inlet.	Y	N
		Are 36-inches (914 mm) of clearance provided in front and behind the Logic Vue? If the rear sash is not to be used, 24-inches of clearance is required (610 mm) between the Vue and the nearest object to the rear.	Y	N
1c	Exhaust Requirements	Certain applications require the enclosure to be exhausted to the outside. Have the applications been evaluated and reviewed with the responsible Safety Officer?	Y	N
		For enclosures to be connected to exhaust systems, has a facilities manager or qualified HVAC professional reviewed and approved the site plans for placement of exhaust duct?	Y N/A	N

		For units requiring exhausting to the outside, have the exhaust blower, ductwork, dampers, and canopy connection been ordered?	Y N/A	N
		Has the room/building been evaluated for adequate air changes with the device?	Y	N
		Has the heating and cooling load been considered in the planning?	Y N/A	N
		6' Logic Vue = 3242 BTU/hr		
1d	Gas Services	If gas/vacuum service is to be used with the Logic Vue, has the facilities manager been consulted with regard to gas/vacuum requirements?	Y N/A	N
		Does the enclosure have service valves to match application requirements? Connections to service valves are 1/4" OD metal and require a shut-off valve. WARNING: The use of flammable gasses or solvents within the Logic Vue should be avoided. Excessive heat may alter the laminar airflow and could potentially damage the HEPA filter. A Safety Officer should approve the use of flammable materials within the enclosure.	Y N/A	N
1e	Electrical Service	Refer to Electrical Requirements in Section 2 of the User's Manual for a list of model numbers and their corresponding electrical ratings. Are services available for the Logic Vue to be connected to a dedicated circuit with over-current protection of adequate size and proper voltage?	Y	N
1f	Delivery Requirements	If the Logic Vue 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
		Is there a clear path from the loading platform to the final destination in the lab?	Y	N

Labconco Purifier Logic Vue Class II Enclosure's IQ/OQ/PQ Protocol #1058605 Revision A

		When required, will there be equipment to move the enclosure into the final installation location? (Refer to Section 4 of the User's Manual.)	Y	N
2	Prior to Operation		Y	N
2a	Damage Claims	Has the Logic Vue 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
2b	Set Up	Has the enclosure been installed in an area with level ground and been checked for level? If casters are not level, install Levelling Feet.	Y	N
		Is the enclosure set at a suitable height for the operator to work ergonomically? If not, adjust enclosure to desired height.	Y	N
		The User's Manual and Small Parts Kit are shipped attached to the work surface. Unpack and store these items for future use.	Y	N
		Does the application require the full weight capacity of 250 lbs/2ft (113 kg/61 cm) of worksurface width, and/or require seismic restraint mounting? If yes, have the shipping casters removed and replaced with the supplied levelling feet.	Y	N
2c	Electrical Connections	Is the enclosure connected to a dedicated electrical circuit of proper voltage and amperage? See identification plate on the electrical access panel on the right upper side of the enclosure.	Y	N
2d	Equipment Connections	If instrumentation is to be used within the enclosure, have all connections including service lines, data cables, and power cords been safely made through the provided pass-through ports?	Y	N

Labconco Purifier Logic Vue Class II Enclosure's IQ/OQ/PQ Protocol #1058605 Revision A

		If automated instrumentation will be used within the enclosure, is a Safety Interlock required for user protection? Install the safety interlock cable detailed in Section 9 of the User's Manual.	Y	N
2e	Gas Services	Has a qualified technician has installed the gas/vacuum services and checked for leaks?	Y N/A	N
		Have the valves been labeled for the proper gas/vacuum?	Y N/A	N
2f	Exhaust System	If exhausted to the outside, has a qualified installer has completed the connections to the enclosure?	Y N/A	N
		If exhausted to the outside, is the exhaust system to the enclosure is ON whenever the enclosure blowers are active?	Y N/A	N
2g	Basic Operational Checks	Press the Light Switch ON. Do both LED lights illuminate the interior of the enclosure?	Y	N
		Does the Blower operate with the Blower Switch ON and the sash open?	Y	N
		Do the sashes raise and lower smoothly?	Y	N
		If equipped with one or more factory-installed Access Door, with the blowers on, and the unit operating normally, open each door. Does the "Alarm - Sash Height" message screen appear when any door is opened?	Y	N
		With the blowers on, and the unit operating normally, do the audible and visual alarms indicate when more than one lower sash has been raised, or when either full sash has been raised?	Y	N
		Does the Alarm Mute button stop the audible alarm for approximately 5 minutes when pressed?	Y	N
		Has the enclosure been posted with warnings to not be used until certified?	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 enclosure to manufacturer's specifications? Has the certifier labeled the enclosure with the successful certification date?	Y	N
		Certification should be done at least once 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 safety, theory of operation and limitations of the enclosure?	Y	N
		Do all users understand techniques for: <ul style="list-style-type: none"> <input type="checkbox"/> Cleaning & disinfection of the enclosure's interior <input type="checkbox"/> Loading supplies and equipment <input type="checkbox"/> Avoiding cross contamination <input type="checkbox"/> Not disturbing the laminar flow <input type="checkbox"/> Spill control and clean up <input type="checkbox"/> Shutting down the enclosure 	Y	N
3	Cleaning			
3a	Exterior Cleaning	Has the exterior of enclosure been cleaned of dust that accumulated throughout installation?	Y	N
3b	Interior Cleaning	Have the enclosure's interior surfaces been cleaned and disinfected appropriately for the work that is about to be performed inside the enclosure?	Y	N
4	Alarm Operation			
4a	Sash Position Alarm	Open one sash, turn on the blower, raise lower sash. Does the enclosure signal a "Alarm - Sash Height" message screen? Close both sashes. Does the alarm repeat when either front or rear full sash is raised?	Y	N

Labconco Purifier Logic Vue Class II Enclosure's IQ/OQ/PQ Protocol #1058605 Revision A

4b	Airflow Alert	Using a notebook or cardboard block the large series of airflow slots on the worksurface perimeter air intake slots. <input type="checkbox"/> Does the internal motor/blower audibly increase speed? <input type="checkbox"/> Does the enclosure signal an “Alert – Airflow” message screen?	Y	N
4c	Airflow Monitor (Optional)	If the enclosure has been equipped with the optional airflow sensor, block the air intake at the top of the enclosure. Does the airflow value drop?	Y	N
4d	Canopy Alarm (Optional)	If the enclosure has been equipped with the optional Canopy Connection – with the enclosure blowers on, raise any exhaust flap on the canopy until the side inlet relief valve closes. Does the enclosure signal an “Alarm – Canopy” message screen?	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
1	Periodic Certification	
1a	Enclosure Performance	<p>Certification should be done annually at a minimum. A qualified certifier can verify the enclosure's performance.</p> <ul style="list-style-type: none"> ❑ Is the enclosure's current certification within the acceptable timeframe set by your organization? ❑ Has there been a procedure established if the enclosure is found to have exceeded its certification due date? <p>Is the next required certification noted in your quality system's preventive maintenance or certification schedule?</p>
2	Maintenance	
2a	Pre-filters	The supply pre-filter should be checked for any foreign debris, and replaced regularly.
2b	LED Lights	Ensure that the LED lights are operating properly regularly.
2c	Work surface and drip trays	Regularly clean and disinfect the drip tray located on top of the work surface, all pieces of the work surface, and the sump spill trough beneath the work surface.
2d	Prefilter	Inspect the condition of the prefilter on the top of the enclosure, and replace regularly.
2e	Canopy (optional)	For enclosures connected to exhaust through a canopy - the alarm function of the canopy should be exercised regularly for proper operation.

D. Summary

Labconco Purifier Logic Vue Class II Enclosure IQ/OQ/PQ Document 1058605 Revision A

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