

IQ/OQ Protocol Installation Qualification/ Operation Qualification

PuriCare[®] Procedure Station

Labconco No: 1058601 Rev. -

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Purpose and Scope

This Qualification Protocol is solely intended to be used with Labconco PuriCare Procedure Stations, which are new or relocated.

Models:

38000 Series
38100 Series

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.

Responsibilities

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

Cabinet Certifier – All Procedure Stations must be certified prior to use. A qualified certifying technician must do this process with calibrated instruments. The cabinet must be certified upon installation, on a scheduled annual basis and whenever the cabinet 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 Procedure Station 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 Procedure Station 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	Proper airflows	Is the Procedure Station to be located in a room with windows that will remain closed?	Y	N
		Is the cabinet 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	Mounting Surface	Have accommodations been made for placement of the Procedure Station on cabinetry or stand of suitable strength and proper height?	Y	N
1c	Space Requirements	Refer to Appendix B in User's Manual. Has adequate floor space been provided for placement of the cabinet?	Y	N
		Is there proper overhead clearance for the Procedure Station? There must be 6-inches, (150 mm) above the exhaust cover for units not connected to exhaust systems.	Y	N
1d	Exhaust Requirements	Certain applications require the Procedure Station to be exhausted to the outside. Have the applications been reviewed with the Safety Officer?	Y	N
		For cabinets to be connected to exhaust systems, has a facilities manager or qualified HVAC person 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? Series 38000 = 142 BTU/hr 38100 = 222 BTU/hr	Y N/A	N

1d	Gas Services	Has the facilities manager been consulted with regard to gas/vacuum requirements?	Y N/A	N
		Does the Procedure Station ordered/received have service valves to match expectations? 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 Procedure Station 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 cabinet.	Y N/A	N
1e	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 Procedure Station to be connected to a dedicated circuit with over-current protection of adequate size and the proper voltage?	Y	N
1f	Delivery Requirements	If the Procedure Station 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? (Refer to Chapter 3 of the User's Manual.)	Y	N
		Is there a clear path from the loading platform to the final destination in the lab?	Y	N
		When required, will there be equipment to move the cabinet onto the final mounting surface/stand? (Refer to the Getting Started section of User's Manual)	Y	N
2	Prior to Operation		Y	N
2a	Damage Claims	The Procedure Station has 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	The cabinet has been mounted to a substantial supporting stand or cabinet that has been checked for level?	Y	N
		The cabinet or stand is set at a suitable height for the operator to work ergonomically?	Y	N
		Before attempting to operate the sash, remove the side panels and verify that; <ul style="list-style-type: none"> ❑ the sash cables are centered on the pulleys, ❑ the weight restraining bolt under each weight has been removed and discarded, ❑ the sash stop screws and spacers are installed on the lower front corners of the cabinet, See Installation Instruction Sheet affixed to the sash for photos and details.	Y	N
		The User's Manual and Small Parts Kit is shipped within the cabinet. These have been unpacked and stored for future use.	Y	N
2c	Drain Valve	If the optional Drain Valve provided is to be installed, it has been sealed and fastened to the underside of the work surface per the User's Manual.	Y N/A	N
2d	Electrical Connections	Is the Procedure Station connected to a dedicated electrical circuit of proper voltage and amperage? See identification plate on the front-lower surface on the cabinet.	Y	N
		Duplex receptacle(s) inside the cabinet are operational? If equipped, do the GFI test and reset buttons work properly?	Y	N
2e	Gas Services	A qualified technician has installed the gas/vacuum services? Checked for leaks?	Y N/A	N
		Verified that valves are labeled for the proper gas/vacuum?	Y N/A	N
2f	Exhaust System	If exhausted to the outside, a qualified installer has completed the connections to the Procedure Station?	Y N/A	N
2g	Basic Operational Checks	With the System Power Switch ON, does the Fluorescent Light illuminate the interior of the cabinet?	Y	N

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		Does the Blower(s) operate with the System Power Switch ON and the sash open? (Alarm will sound for several seconds when started.)	Y	N
		If equipped, does the U.V. Light, mounted in the upper-rear of the interior, operate when the System Power Switch is turned to U.V. and the sash is fully closed?	Y N/A	N
		Does the audible and visual alarms indicate when the sash has been raised above the 12-inch positioning mark?	Y	N
		Does the Alarm Silence button stop the audible alarm for approximately 5 minutes when pressed?	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 cabinet to the manufacturer’s specifications? Has the certifier labeled the cabinet with the successful certification date?	Y	N
		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 safety, theory of operation and limitations of the Procedure Station?	Y	N
		Do all users understand techniques for: <ul style="list-style-type: none"> <input type="checkbox"/> Cleaning & Disinfection of the cabinet’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 station? 	Y	N
		Are users aware of ergonomic factors that can cause unnecessary fatigue or personal discomfort? (Refer to the Safety and Comfort section of the User’s Manual.)	Y	N
3	Cleaning			
3a	Exterior Cleaning	Has the exterior of the station been cleaned of dust that accumulated throughout installation?	Y	N
3b	Interior Cleaning	Has the Procedure Station’s interior surfaces been cleaned and disinfected appropriately for the work that is about to be performed in it?	Y	N
3c	Prefilters	Have the prefilters, located in the rear under the worksurface been checked and cleaned of any foreign debris?	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	Cabinet Performance	<p>Certification should be done at a minimum annually. An experienced certifier can verify the cabinet’s performance. Is the Procedure Station’s current certification within the acceptable timeframe set by your organization? Has there been a procedure established if a cabinet is found to have exceeded its certification due date?</p> <p>Is the next required certification noted in your quality system’s preventive maintenance or certification schedule?</p>
2	Maintenance	
2a	U. V. Lamp	If equipped, the U.V. Lamp should be replaced annually to remain effective.
2b	Prefilters	The Prefilters (located in the rear under the worksurface) should be checked for any foreign debris when the cabinet is cleaned.
2c	Fluorescent Lamp	Regular maintenance should ensure that the Fluorescent Lamp is operating properly.

D. Summary

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Equipment Location _____

PuriCare Procedure Station 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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