



LABCONCO CORPORATION

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

IQ/OQ Protocol Installation Qualification/ Operation Qualification

Purifier[®] Vertical Clean Benches & Filtered PCR Enclosures

Purpose and Scope

This Qualification Protocol is intended to be used with Labconco Purifier® Vertical Clean Benches (VCB's) and Filtered PCR Enclosures (PCR's) only, which are new or relocated.

Models:

3970200	2-foot VCB	115 VAC, 50/60 Hz, 3 Amps
3970201	2-foot VCB w/ UV Lamp	115 VAC, 50/60 Hz, 3 Amps
3970202	2-foot PCR w/ UV Lamp	115 VAC, 50/60 Hz, 3 Amps
3970203	2-foot VCB w/ Airflow Monitor	115 VAC, 50/60 Hz, 3 Amps
3970204	2-foot VCB w/ UV Lamp, Airflow Monitor	115 VAC, 50/60 Hz, 3 Amps
3970205	2-foot PCR w/ UV Lamp & Airflow Monitor	115 VAC, 50/60 Hz, 3 Amps
3970220	2-foot VCB	230 VAC, 50/60 Hz, 2 Amps
3970221	2-foot VCB w/ UV Lamp	230 VAC, 50/60 Hz, 2 Amps
3970222	2-foot PCR w/ UV Lamp	230 VAC, 50/60 Hz, 2 Amps
3970223	2-foot VCB w/ Airflow Monitor	230 VAC, 50/60 Hz, 2 Amps
3970224	2-foot VCB w/ UV Lamp, Airflow Monitor	230 VAC, 50/60 Hz, 2 Amps
3970225	2-foot PCR w/ UV Lamp & Airflow Monitor	230 VAC, 50/60 Hz, 2 Amps
3970300	3-foot VCB	115 VAC, 50/60 Hz, 3 Amps
3970301	3-foot VCB w/ UV Lamp	115 VAC, 50/60 Hz, 3 Amps
3970302	3-foot PCR w/ UV Lamp	115 VAC, 50/60 Hz, 3 Amps
3970303	3-foot VCB w/ Airflow Monitor	115 VAC, 50/60 Hz, 3 Amps
3970304	3-foot VCB w/ UV Lamp, Airflow Monitor	115 VAC, 50/60 Hz, 3 Amps
3970305	3-foot PCR w/ UV Lamp & Airflow Monitor	115 VAC, 50/60 Hz, 3 Amps

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3970320	3-foot VCB	230 VAC, 50/60 Hz, 2 Amps
3970321	3-foot VCB w/ UV Lamp	230 VAC, 50/60 Hz, 2 Amps
3970322	3-foot PCR w/ UV Lamp	230 VAC, 50/60 Hz, 2 Amps
3970323	3-foot VCB w/ Airflow Monitor	230 VAC, 50/60 Hz, 2 Amps
3970324	3-foot VCB w/ UV Lamp, Airflow Monitor	230 VAC, 50/60 Hz, 2 Amps
3970325	3-foot PCR w/ UV Lamp & Airflow Monitor	230 VAC, 50/60 Hz, 2 Amps
3970400	4-foot VCB	115 VAC, 50/60 Hz, 5 Amps
3970401	4-foot VCB w/ UV Lamp	115 VAC, 50/60 Hz, 5 Amps
3970402	4-foot PCR w/ UV Lamp	115 VAC, 50/60 Hz, 5 Amps
3970403	4-foot VCB w/ Airflow Monitor	115 VAC, 50/60 Hz, 5 Amps
3970404	4-foot VCB w/ UV Lamp, Airflow Monitor	115 VAC, 50/60 Hz, 5 Amps
3970405	4-foot PCR w/ UV Lamp & Airflow Monitor	115 VAC, 50/60 Hz, 5 Amps
3970420	4-foot VCB	230 VAC, 50/60 Hz, 3 Amps
3970421	4-foot VCB w/ UV Lamp	230 VAC, 50/60 Hz, 3 Amps
3970422	4-foot PCR w/ UV Lamp	230 VAC, 50/60 Hz, 3 Amps
3970423	4-foot VCB w/ Airflow Monitor	230 VAC, 50/60 Hz, 3 Amps
3970424	4-foot VCB w/ UV Lamp, Airflow Monitor	230 VAC, 50/60 Hz, 3 Amps
3970425	4-foot PCR w/ UV Lamp & Airflow Monitor	230 VAC, 50/60 Hz, 3 Amps
3660600	6-foot VCB	115 VAC, 50/60 Hz, 5 Amps
3660601	6-foot VCB w/ UV Lamp	115 VAC, 50/60 Hz, 5 Amps
3660603	6-foot VCB w/ Airflow Monitor	115 VAC, 50/60 Hz, 5 Amps
3660604	6-foot VCB w/ UV Lamp, Airflow Monitor	115 VAC, 50/60 Hz, 5 Amps
3660620	6-foot VCB	230 VAC, 50/60 Hz, 3 Amps

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3660621	6-foot VCB w/ UV Lamp	230 VAC, 50/60 Hz, 3 Amps
3660623	6-foot VCB w/ Airflow Monitor	230 VAC, 50/60 Hz, 3 Amps
3660624	6-foot VCB w/ UV Lamp, Airflow Monitor	230 VAC, 50/60 Hz, 3 Amps

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 VCB or PCR 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 VCB or PCR. Records should be stored in a safe, easily retrievable location. The location of the VCB or PCR, 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 VCB or PCR 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 VCB or PCR has been checked for proper installation and operation, its performance may be validated. Labconco cannot instruct customers on the specific procedures to test the HEPA filters performance and validate the airflow speed. The performance validation should be designed to meet the specifications and accuracy required by 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 location	Is the VCB or PCR location planned away from heavy foot traffic, doors, fans, ventilation registers and any other air-handling devices that could disrupt its operation?	Y	N
1b	Level Surface	Have accommodations been made for placement of the VCB or PCR on a level work surface?	Y	N
1c	Space Requirements	Refer to the Manual, Appendix B. Has adequate floor space been provided for placement of the VCB or PCR and its base stand or cabinet?	Y	N
		If the VCB or PCR will be installed on a Labconco Base Stand, refer the manual and base stand instruction sheet for installation instructions. Is the stand or cabinet set to the proper height for use with the VCB or PCR?	Y	N
		In order for the VCB or PCR to operate properly, there should be at least six inches (150 mm) of clearance from any overhead obstructions when the bench is in its final operating position. Does the installation location have the proper overhead clearance?	Y	N
1d	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 VCB or PCR to be connected to a dedicated outlet with appropriately sized circuit breaker?	Y	N
1e	Delivery Requirements	If the VCB or PCR 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 VCB or PCR is delivered on a shipping pallet. Is there a clear path from the loading platform to the final destination in the lab?	Y	N

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2	Prior to Operation			
2a	Damage Claims	The VCB or PCR as 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	Is the VCB or PCR set at a suitable height for the operator to work ergonomically?	Y	N
		The User's Manual is shipped within the VCB or PCR. Has it been unpacked and stored for future use?	Y	N
2c	Electrical Connections	Has the VCB or PCR connected to a dedicated electrical circuit of proper voltage and amperage? See identification plate on the rear of the VCB or PCR.	Y	N
		Is the electrical receptacle(s) inside the VCB or PCR operational?	Y	N
2d	Electrical Operational Checks	Does the Blower(s) operate when the Blower Switch is turned ON?	Y	N
		Does the Fluorescent Light operate when the Light Switch is turned ON?	Y	N
2e	Resetting the Circuit Breaker	The circuit breaker is located next to the power cord on the upper rear panel of the bench as shown in Figure 6-1 of the product manual. If the circuit breaker trips, it can be reset by pressing the white button in. Has the circuit breaker been located and identified?	Y	N
2f	Electrical Operational Checks on units with Ultra Violet Light	The Ultra Violet Light operation is interlocked with the fluorescent light and blower switches to prevent UV operation and personnel exposure while the unit is in operation. Does the Ultra Violet Light operate when the Light Switch is pushed to the UV position, and the Blower Switch is in the OFF position and the sash opening cover is installed?	Y	N NA

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2g	Service Valve Plumbing Connections on units with Service Valve	<p>Service lines should be quarter inch outside diameter, metal, and equipped with an accessible shut-off valve. If the service line pressure exceeds 40 PSI, it must be equipped with a pressure regulator to reduce the line pressure. Refer to the user's manual for specific plumbing instructions. The use of flammable gases or solvents should be avoided in the clean bench.</p> <p>Has the proper size and pressure service line been connected to the Service Valve?</p>	Y	N
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B. Operational Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	Certification			
1a	Initial Certification	<p>Prior to use, all Purifier VCB's or PCR's should be certified by a qualified certifier. Under normal operating conditions, the Purifier VCB or PCR should be recertified at least annually and when moved or serviced. The certifier should perform the following tests, as recommended in Institute of Environmental Sciences and Technology, IEST RP-CC0002:</p> <ul style="list-style-type: none"> • Airflow Velocity Test • HEPA Filter Leak Test • Airborne Particle Count (when appropriate) • Lighting Intensity Test (when appropriate) <p>In addition, the following tests should also be performed at the user's discretion by a qualified electrician:</p> <ul style="list-style-type: none"> • Electrical Leakage and Ground Circuit Resistance Test • Smoke Test to determine airflow patterns 	Y	N
2	Training			
2a	Safety Officer Evaluation	<p>Because air from the work area is dispersed directly into the operators breathing zone, the VCB or PCR should not be used in conjunction with biohazardous material, toxins, or radionuclides.</p> <p>Have operators and qualified safety officer(s) carefully assess the risk associated with any operation performed in the VCB or PCR?</p>	Y	N

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2b	User Training	<p>To maintain sterile sample conditions thoroughly understand the operation procedures for the VCB or PCR before beginning work. Refer to the product manual section, "Use of the VCB or PCR" for detailed operation guide. Have all users been properly trained on the benefits, theory of operation and limitations of the VCB or PCR?</p>	Y	N
		<p>Do all users understand techniques for:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Initial start-up and decontamination of work surfaces operations. <input type="checkbox"/> Sterile Product manipulation in a sterile air flow. <input type="checkbox"/> Material transfers into and out of the Sterile Airflow. 	Y	N
2c	HEPA Filter Static Pressure Gauge	<p>The Static Pressure gauge in the VCB or PCR measures the total system operating pressure (the negative pressure below the prefilters, plus the positive pressure on the HEPA filter). The gauge allows the user to monitor the total pressure differential of the cabinet. As the HEPA filters loads with particulates, the reading on the gauge will increase. If the user obstructs the inlet grilles the pressure reading of the gauge will increase. A large hole in one of the HEPA filters or a malfunction of a motor/blower would result in a decrease in the gauge's reading. The pressure reading of the gauge will gradually increase (due to HEPA filter loading) when the cabinet is maintained and operated correctly. The rate of HEPA filter loading will depend upon the cleanliness of the room air, the amount of time the clean bench is operating.</p> <p>The gauge reading should be periodically recorded during use.</p> <p>Has a weekly log chart been prepared for recording the static pressure gauge readings?</p>	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	Cabinet Performance	<p>The VCB or PCR should be certified by a qualified certification technician before its initial use. Certification testing of the HEPA filter, and air flow velocity in a VCB or PCR should be done at a minimum, annually.</p> <p>Labconco's Quality Assurance Test Report is included with each unit, located in the manual packet.</p> <p>An experienced user or certifier can verify the cabinet's performance to manufacturer's specifications (see Chapter 3, Setting Downflow Velocity with the Speed Control Adjustment).</p> <p>Has the Factory Quality Assurance Test Report been filed for reference?</p>	Y	N
		Is the current certification of the VCB or PCR 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 Schedule	Under normal operation, your Purifier VCB or PCR will require little routine maintenance. The following schedule is recommended:		
2a	Cleaning	<p>Weekly</p> <ul style="list-style-type: none"> • Wipe down the interior surfaces of the clean bench with a mild household detergent, cleaner or 70% IPA and allow to dry. Using a damp cloth, clean the exterior surfaces of the clean bench, particularly the front and top of the clean bench to remove any accumulated dust. <p>Monthly (or more often as required)</p> <ul style="list-style-type: none"> • Check all service valves, if so equipped, for proper operation. • Check the prefilters and replace if necessary. The prefilters should be replaced at least quarterly. • All weekly activities. <p>Quarterly Replace the prefilter. See user's manual for ordering information. All monthly activities.</p> <p>Annually</p> <ul style="list-style-type: none"> • Have the VCB or PCR recertified by a qualified certification technician. • All quarterly activities. <p>Biannually</p> <ul style="list-style-type: none"> • Replace the fluorescent lamp if required. • Replace the UV lamp (if included). • All annual activities. 		

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