



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

**XPert[®] Balance Enclosure,
XVS[™] Ventilation Station &
FilterMate[™] Portable Exhauster**

Purpose and Scope

This qualification protocol is solely intended to be used with Labconco XPert Balance Enclosures or XVS Ventilation Stations with or without a FilterMate Portable Exhauster.

XPert Balance Enclosures:

39302 Series
39303 Series
39304 Series
39715 Series
39716 Series
39718 Series

XVS Ventilation Station Models:

48620 Series
48630 Series
48640 Series
48650 Series
48660 Series
48680 Series

XPert Balance Enclosure Systems:

39602 Series
39603 Series
39604 Series

FilterMate Portable Exhauster Models:

39700 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 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 verification schedules should be documented in the company's quality system.

Certifier, Servicer or Safety Personnel – All ventilated enclosures should be tested prior to use. A qualified technician can perform this process with proper instruments. The enclosure should be tested on a scheduled annual basis and whenever it is moved to a new location.

Manufacturer – Labconco Corporation, certified ISO-9001, is responsible to ensure the XPert Balance Enclosure, XVS Station and FilterMate are suitable for use prior to shipment. The manufacturer must retain these records. Their staff of Labconco 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 XPert Balance Enclosure, XVS Ventilation Station and FilterMate have been checked for proper installation and basic 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 tolerances required of the application.

In general this requires establishing acceptance criteria, inspecting and testing the results with calibrated equipment and qualified personnel.

A. Installation Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	Site Planning			
1a	Proper airflows	Will the XPert Enclosure or XVS Station 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? (Cross drafts should be kept less than 1/3 the face velocity per ANSI Z9.5)	Y	N
1b	Mounting Surface	Have accommodations been made for placement of the XPert Balance Enclosure or XVS Ventilation Station on cabinetry or a balance table of suitable strength, minimal vibration and proper height?	Y	N
1c	Space Requirements	Refer to Appendix B in User's Manual. Has adequate floor or counter space been provided for placement of the enclosure and/or FilterMate?	Y	N

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1d	Exhaust Requirements (External)	Certain applications require the enclosure to be exhausted to the outside. Have the applications been reviewed with the Safety Officer?	Y	N
		For enclosures to be connected to building 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 enclosures requiring exhausting to the outside without the FilterMate, have the exhaust blower, ductwork, dampers, been ordered? (See Chapter 3 of the Balance Enclosure/Ventilation Station User's Manual.)	Y N/A	N
		Has the room/building been evaluated for adequate air changes with the device?	Y N/A	N
		Has the safety officer investigated the need to HEPA filter the exhaust prior to releasing to the outside?	Y N/A	N
		For enclosures requiring exhausting to the outside with the FilterMate, have the exhaust blower, ductwork, and the model with the thimble connection been ordered? (See Chapter 6 of the FilterMate User's Manual.)	Y N/A	N
1e	Exhaust Requirement (Internal back into the room)	If plans are to circulate the exhaust back into the room, has the FilterMate product been specified?	Y N/A	N
1f	Filtration - Activated Carbon	An activated carbon filter kit is available for low-level, low risk chemicals or nuisance odors. Has the need for a carbon filter been considered for this application?	Y N/A	N
1g	Electrical Service for FilterMate	Are services available for the FilterMate of adequate size and proper voltage? FilterMate: 115v, 10 amps 230v, 10 amps	Y N/A	N

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1h	Electrostatics	Do you anticipate that static electricity will be an issue with the handling of powders and have accommodations been made to mitigate electrostatics? Higher humidity control or the application of ionizers is recommended.	Y N/A	N
1i	Delivery Requirements	When delivered, will there be personnel to move the enclosure onto the final mounting surface? (Requires two individuals to carry the enclosure or FilterMate.)	Y	N
2	Prior to Operation			
2a	Damage Claims	Has the enclosure 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	Has the enclosure been mounted to a substantial supporting bench or balance table that will minimize vibration?	Y	N
		Has a vibration-dampening mount, like a marble slab been considered for additional stability?	Y	N
		Is a suitable non-porous, easy-to-clean benchtop or worksurface installed under the enclosure?	Y	N
		Is the bench or table set at a suitable height for the operator to work ergonomically?	Y	N
2c	Electrical Connections	If the FilterMate is used, is it connected to an electrical circuit of proper voltage and amperage? See identification plate on the rear of the housing.	Y N/A	N
2d	Exhaust System	If exhausted to the outside, has a qualified installer completed the connections to the enclosure?	Y N/A	N
		If exhausted to the outside, is the exhaust system to the enclosure ON all the time?	Y N/A	N

B. Operational Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	Verification			
1a	Test Airflow	Prior to use, has a qualified technician tested the airflow through the enclosure prior to use? Your Safety Officer may have acceptance criteria for face velocity. Labconco recommends 60 to 80 fpm; see Chapter 3 of the Balance Enclosure/Ventilation Station User's Manual.	Y	N
1b	Calibrate Airflow Monitor	Has the airflow monitor been calibrated to alarm at a level prescribed by the Safety Officer?	Y N/A	N
1c	Inspect for Filter Leaks	If FilterMate is installed, has a qualified technician scanned the HEPA filter for leaks? See FilterMate User's Manual Chapter 5 for details.	Y N/A	N
1d	Documentation	Has the verification of proper airflow been documented and filed?	Y	N
1e	Next Required Verification	Verification should be done at least annually. Has the next required testing 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 XPert Balance Enclosure, XVS Ventilation Station and/or FilterMate?	Y	N
		Do all users understand: ❑ Cleaning/Decontamination of the enclosure's interior ❑ Where to work within the enclosure ❑ HEPA (and if equipped, carbon) filter maintenance ❑ The operation and warning provided by the airflow alarm?	Y	N

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		Are users aware of ergonomic factors that can cause unnecessary fatigue or personal discomfort?	Y N/A	N
3	Cleaning			
3a	Exterior Cleaning	Has the exterior of the enclosure been cleaned of dust that accumulated throughout installation?	Y	N
3b	Interior Cleaning	Have the enclosure's interior surfaces been cleaned appropriately for the work that is about to be performed in it?	Y	N

C. Summary

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Equipment Location _____

XPert Balance Enclosure Ser. No. _____ Model No. _____

XVS Ventilation Station Ser. No. _____ Model No. _____

FilterMate Ser. No. _____ Model No. _____

User Protocol _____ Revision (or Date published) _____

Dept. or Co.	Print Name	Title	Signature	Date

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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Step	Deficiency followed by Corrective Action	