



# **IQ/OQ Protocol Installation Qualification/ Operation Qualification**

## **PuriCare<sup>®</sup> Bedding Disposal Station**

*Labconco No: 1059602 Rev-*

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## **Purpose and Scope**

This qualification protocol is solely intended to be used with PuriCare Bedding Disposal Stations with the following catalog numbers.

### **PuriCare Bedding Disposal Stations**

38400-00

38400-20

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 facility 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 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 PuriCare products 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 PuriCare Disposal Station has 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**

<b>Step</b>	<b>Description</b>	<b>Specification or Acceptance Criteria</b>	<b>Result</b>	
			<b>YES</b>	<b>NO</b>
<b>1</b>	<b>Site Planning</b>			
1a	Proper airflows	Will the enclosure 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	Space Requirements	Refer to Appendix B in User’s Manual. Has adequate floor, counter space or overhead space been provided for placement of the enclosure?	Y	N
1c	Electrical Service for The Enclosure	Are services available for the enclosure of adequate size and proper voltage?  PuriCare Disposal Station: 115v, 3 amps 230v, 3 amps	Y  N/A	N
1d	Delivery Requirements	When delivered, will there be personnel to move the enclosure onto the final mounting surface? (Requires three individuals to attach the casters.)	Y	N
<b>2</b>	<b>Prior to Operation</b>			
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	Electrical Connections	Is the enclosure connected to an electrical circuit of proper voltage and amperage? See identification plate on the rear of the housing.	Y	N

## B. Operational Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
<b>1</b>	<b>Verification</b>			
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 50 to 60 fpm; see appendix of the User's Manual.	Y	N
1b	Inspect for Filter Leaks	Has a qualified technician scanned the HEPA filter for leaks? See the User's Manual Chapter 6 for details.	Y N/A	N
1c	Documentation	Has the verification of proper airflow been documented and filed?	Y	N
1d	Next Required Verification	Verification/Certification 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
<b>2</b>	<b>Training</b>			
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: <ul style="list-style-type: none"> <li><input type="checkbox"/> Cleaning/Decontamination of the enclosure's interior</li> <li><input type="checkbox"/> HEPA, prefilter and carbon filter maintenance</li> <li><input type="checkbox"/> Recommended personal protection to be used with the station.</li> </ul>	Y	N
		Are users aware of ergonomic factors that can cause unnecessary fatigue or personal discomfort?	Y N/A	N
<b>3</b>	<b>Cleaning</b>			
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

## D. Summary

**Labconco PuriCare Bedding Disposal IQ/OQ Document 1059202 Revision -**

**Equipment Location** \_\_\_\_\_

**Enclosure Ser. No.** \_\_\_\_\_ **Model No.** \_\_\_\_\_

**User Protocol** \_\_\_\_\_ **Revision (or Date published)** \_\_\_\_\_

<b>Dept. or Co.</b>	<b>Print Name</b>	<b>Title</b>	<b>Signature</b>	<b>Date</b>

**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.**

<b>Step</b>	<b>Deficiency followed by Corrective Action</b>	<b>Initial</b>
<b>Step</b>	<b>Deficiency followed by Corrective Action (cont.)</b>	<b>Initial</b>


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