



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

SteamScrubber[®] & FlaskScrubber[®] Laboratory Glassware Washers

Purpose and Scope IQ and OQ

This Qualification Protocol is solely intended to be used with Labconco FlaskScrubber® and SteamScrubber® Laboratory Glassware Washers, which are new or relocated.

Models: SteamScrubbers

<i>44003 SERIES</i>
<i>44004 SERIES</i>
<i>457800 SERIES</i>

FlaskScrubbers

<i>44203 SERIES</i>
<i>44204 SERIES</i>
<i>457810 SERIES</i>

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.

The use of this document does not replace the need for the Glassware Washer User’s Manual (#4591100). Information within the User’s Manual is required to complete this IQ/OQ Protocol.

Responsibilities

End-User – The ultimate user or otherwise appointed personnel in the lab is responsible to ensure the Glassware Washer 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 careful 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 applying the Washer. Records should be stored in a safe, easily retrievable location. The location of the Washer and required validation should be included in the company’s quality system.

Installer – A qualified technician should perform the installation per the User’s Manual. If the manual has been misplaced, copies can be obtained from the manufacturer or downloaded from their website, www.labconco.com.

Manufacturer – Labconco Corporation, certified ISO-9001, is responsible to fully test each FlaskScrubber and SteamScrubber prior to shipment. The manufacturer must retain these records. Labconco’s staff of Product Service Representatives and Product Specialists can assist with information on the purchase, delivery and installation. Labconco is not responsible for the actual installation or validation processes.

Performance Qualification

Once the washer 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, making several runs 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	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 clearance for the washer if installed undercounter?	Y N/A	N
1b	Local Codes	Are there any unique local codes with regard to electrical or plumbing connections to be considered prior to installation?	Y	N
1c	Plumbing Requirements	Is there an adequate supply of hot water near the proposed installation site?	Y	N
		Can the washer be connected into the building’s drain plumbing where proposed?	Y	N
		Have accommodations been considered for connection to a purified water source?	Y N/A	N
		If connecting to a purified water source, will there be sufficient rate and volume?	Y N/A	N
		Has the heating and cooling load been considered in the planning? (Refer to Appendix C of User’s Manual)	Y	N
1d	Electrical Service	Refer to the User’s Manual for a list of model numbers and their corresponding electrical requirements. Are services available for the washer to be connected to a dedicated circuit of adequate size and proper voltage?	Y	N
1e	Delivery Requirements	If the washer has not been delivered, 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 User’s Manual)	Y	N

Labconco SteamScrubber & FlaskScrubber Washer IQ/OQ Protocol #1058702 Revision D

2	Prior to Operation			
2a	Damage Claims	Has the washer 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 damaged, refer to the User's Manual for information on shipping damage claims.	Y	N
2b	Set Up	Have the washer's leveling feet or casters been installed?	Y	N
		The washer in its final site has been leveled and the door opens and closes with minimal interference to the sides of the tank?	Y N/A	N
		If an "undercounter" model, has it been secured to the underside of the countertop for stability when the door is open?	Y N/A	N
2c	Plumbing	Has hot water been plumbed to the washer and checked for leaks?	Y	N
		If desired, has a purified water source been plumbed? (Or, will the purified rinse come from a portable container?)	Y N/A	N
2d	Drain Connection	Does the drain hose have a rise in the line per the User's Manual and is it connected to the building's drain system?	Y	N
		Does the drain hose have an air gap to prevent backflow into the washer?	Y	N
2e	Electrical Connections	Has the unit been connected to a dedicated grounded circuit of appropriate size?	Y	N
2f	Set Up Controller	Refer to the User's Manual to perform the following steps.		
	Washer Voltage	Does the voltage shown on the display agree with the voltage shown on the washer I.D. tag? Press ▼ to continue.	Y	N
2g	Temperature Units	Are the displayed temperature units the desired units? Press ▼ to continue.	Y	N

Labconco SteamScrubber & FlaskScrubber Washer IQ/OQ Protocol #1058702 Revision D

2h	DI Pump	<p>If pure water will be used for rinse cycles, is the DI pump enabled?</p> <p>Press ▼ to continue.</p>	<p>Y</p> <p>N/A</p>	N
2i	Light	<p>If the washer has a window, do you want the light to be ON when the washer is operating? Is the displayed selection correct?</p> <p>Press ▼ to continue.</p>	<p>Y</p> <p>N/A</p>	N
2j	Liquid Detergent Dispenser	<p>If the optional liquid detergent dispenser has been installed, has the control been set to ON?</p> <p>Press RUN to save settings.</p>	<p>Y</p> <p>N/A</p>	N
2k	<p>Run Diagnostics Test:</p> <p>Water Fill</p>	<p>Refer to the User's Manual to perform this diagnostic test in the following steps. With water and power to the washer connected, close the detergent cup and start the diagnostic mode.</p> <p>Does hot tap water enter the washer when display reads TAP WATER VALVE? (Listen for water flow.)</p> <p>Allow tap water to enter the washer for approximately 1 minute.</p>	<p>Y</p>	N
2l	Tap Water Temperature	<p>Verify the tap water temperature entering the washer is at least 120°F? (49 °C)</p> <p>Measured with what? _____</p> <p>Press the ▼ button to advance the test.</p>	<p>Y</p>	N
2m	Pure Water/ Fill Level	<p>If pure water will be used, allow pure water to enter the washer until it automatically shuts off.</p> <p>If pure water will not be used, allow tap water to enter the washer until it automatically shuts off.</p> <p>Open the door and verify that the washer filled to the proper level.</p> <p>At the front of the washer, does the water contact the bottom of the heater?</p>	<p>Y</p>	N

Labconco SteamScrubber & FlaskScrubber Washer IQ/OQ Protocol #1058702 Revision D

		At the front of the washer, is the water below the top of the heater? Press the ▼ button to advance the test.	Y	N
2n	Wash Pump	Does the main washer pump activate when the display reads PUMP-ON WASH? (Listen for the water spray on the inside of the washer.) Press the ▼ button to advance the test.	Y	N
2o	Detergent Cup	Within a minute of the display showing DETERGENT CUP, can the sound of the cup opening be heard? Press the ▼ button to continue the test.	Y	N
2p	Heater	Measure the water temperature. Turn the HEATER “ON” for 10-15 minutes. Has the water temperature increased? Measured with what? _____ Press ▼ to continue test.	Y	N
2q	Drain Pump	Does the tank drain when the display indicates DRAIN/COOL? (Listen for a change in the sound of the draining water to indicate draining is complete.) Press the ▼ button to advance the test.	Y	N
2r	Blower	Can the dryer blower be heard when the display reads DRY BLOWER? Press the ▼ button to advance the test.	Y	N
2s	Liquid Detergent Pump Option	For washers with the Liquid Detergent Pump installed and activated in the Set Up of the Controller. Can the pump be heard to run when the display shows LIQ DETER PUMP? Note: If the volume to be dispensed needs to be verified, a wash cycle needs to be run after this series of tests. Press ▼ to continue the test.	Y N/A	N

Labconco SteamScrubber & FlaskScrubber Washer IQ/OQ Protocol #1058702 Revision D

2t	Light	For washers with a window only. Does the light turn on when LIGHT is displayed? Press ▼ to continue the test.	Y N/A	N
2u	Cooling Fan	Can the fan inside the toe kick panel be heard to operate when COOL FAN is displayed?	Y	N
2v	Overfill	Verify that the overfill sensor turns the water off before water overflows out of the washer. This completes diagnostics. Open the door to exit.	Y	N
2w	Run Cycle Detergent Pump (if applicable)	The detergent pump operation was verified earlier. The dispense volume can be verified by following the following procedure. Remove the 1 gallon detergent jug and replace with a graduated cylinder of water. Run the LIQUID DETERGENT PUMP diagnostics letting the pump run for about 1 minute. Record the volume of water left in the graduate. Select the “GLASS” wash cycle. Set the detergent dispense to 20 ml. Start the cycle. The water in the graduate should be 34/46 ml less than the at the start. (There are two dispenses.) Display setting _____ Total Volume Dispensed _____ Volume/Dispense = Total/2 _____	Y N/A	N
2x	Tap Water Flow Rate	The fill level was verified earlier, however the flow rate of water entering must be at least 1.25 gal/min, (4.7 L/min). Start the “GLASS” wash cycle. Note the time it takes for the filling tap water to stop. Is this time less than 2.8 minutes?	Y	N
2y	Pure Water Flow Rate	Verify the flow rate of purified water is adequate by noting the time it takes for the purified water fill. The DI Pump should be heard to run from outside the washer. Did the purified water complete filling in less than 5 minutes? The cycle can be CANCEL'd after this test.	Y	N

Labconco SteamScrubber & FlaskScrubber Washer IQ/OQ Protocol #1058702 Revision D

2z	Temperature Calibration	<p>The temperature shown on the display may be verified. Open the door and secure a thermocouple to the temperature probe. Close the door allowing the thermocouple lead to pass between the door and the seal so the meter is outside the washer. Press the ◀ button and latch the door. The displayed temperature should not vary from the meter by more than $\pm 4^{\circ}\text{C}$ when temperature readings have stabilized.</p> <p>Display Temperature _____ Meter Temperature _____</p>	Y	N
----	-------------------------	---	---	---

B. Operational Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	Accessories			
1a	Racks & Types of Glassware	The best results often depend upon the washer being equipped with the proper accessories. Refer to Appendix A in the User's Manual.		
		Are the appropriate racks and baskets available for the type of glassware to be washed?	Y	N
		The position of the upper rack can be adjusted or the rack removed. Has the optimal upper rack position been selected?	Y	N
		Are spindles on the lower spindle rack of the FlaskScrubber models arranged for your type of glassware? Are the ports without spindles plugged? (Optional upper spindle rack too.)	Y N/A	N
1b	Detergent	Has a non-foaming powder or liquid detergent specifically formulated for laboratory washers been procured for this application?	Y	N
		Has the detergent dispenser been filled per the User's Manual?	Y	N
1c	Acid Neutralizer	If desired, is there neutralizing acid available for use with this washer?	Y N/A	N
		Optional, is the neutralizing acid dispenser filled and set per the User's Manual?	Y N/A	N

Labconco SteamScrubber & FlaskScrubber Washer IQ/OQ Protocol #1058702 Revision D

2	Wash Cycle			
2a	Selecting Program	<p>Refer to Appendix C in the User’s Manual.</p> <p>Choosing the factory-set program or customizing your own program to obtain better wash results generally involves trial runs and inspection of the glassware for cleanliness.</p> <p>Has a procedure for the selection of an optimal cycle, detergent and neutralizing acid been adopted?</p>	Y	N
2b	Cleanliness	<p>After trial runs, have successful results been obtained for typical wash requirements?</p> <p>Have the preferred detergent and neutralizing acid been proven to have satisfactory results?</p> <p>Have the brands, types, volumes been documented? Have other brands been removed from the area to avoid confusion?</p>	Y Y Y	N N N
2c	Drying	The rate at which the washed items dry is a function of their material, mass, humidity and rinse temperature. If drying is important to your process, has adequate dry time been provided in the selected program?	Y N/A	N
2d	Documentation	Has the desired factory-set cycle or custom cycle parameters been documented and stored?	Y	N
3	Personnel Training			
3a	User Training	<p>Have all users been properly trained on the operation and limitations of the washer?</p> <p>Do all users understand: Which programs and racks are to be used; Proper way to load each type of glassware; How and when to fill detergent and neutralizing acid dispensers; How to start and interrupt cycles; Where washer manual and procedures are kept?</p>	Y	N

C. Summary

Labconco FlaskScrubber & SteamScrubber Washer IQ/OQ Protocol 1058702, Rev. D

Instrument 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