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IQ/OQ Protocol Installation Qualification/ Operation Qualification

SteamScrubber® and FlaskScrubber® Series Glassware Washers

Purpose and Scope IQ and OQ

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

SteamScrubber Models: 4010010xx, 4011010xx, 402001xx, 4021010xx

FlaskScrubber Models: 4110010xx, 4111010xx, 4120010xx, 4121010xx

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 SteamScrubber and FlaskScrubber Series Washer User's Manual (#4676800). 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 SteamScrubber or FlaskScrubber 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 down loaded from their website, www.labconco.com

Manufacturer – Labconco Corporation, certified ISO-9001, is responsible to fully test each washer 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 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

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 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 installation, 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	Has the drain hose been installed as detailed in 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.		
	Temperature Units	Are the displayed temperature units the desired units?	Y	N
2g	DI Pump	If pure water will be used for rinse cycles, is the DI pump enabled?	Y N/A	N

2h	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>Go to Accessories to turn light off.</p>	<p>Y</p> <p>N/A</p>	N
2i	<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 you preform Fill All the Way (FATW)? (Listen for water flow.)</p>	Y	N
2j	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>_____</p>	Y	N
2k	Pure Water/ Fill Level	<p>If pure water will be used, perform Pure Fill All The Way (PFATW) and 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>Does the water contact the bottom of the heater/heaters?</p> <p>Is the water below the top of the heater/heaters?</p>	<p>Y</p> <p>Y</p>	<p>N</p> <p>N</p>
2l	Wash Pump1	Does the main washer pump activate when Wash Pump 1 test is ran? (Listen for the water spray on the inside of the washer.)	Y	N

2m	Detergent Cup	Does the detergent cup door open when Detergent Cup test is ran?	Y	N
2n	Heater	Does the heater/heaters heat up when Heater 1 and Heater 2&3 tests are ran?	Y	N
2o	Drain Pump	Does the tank drain when the Drain All The Way (DATW) test is ran? (Listen for a change in the sound of the draining water to indicate draining is complete. DATW will run for approx. 3 minutes or until stopped.	Y	N
2p	Blower	Does the dry blower come on when Dry Blower 1 test is ran?	Y	N
2q	Liquid Detergent Pump Option	If installed does the detergent pump come on when Detergent Pump 1 test is ran? Note: If the volume to be dispensed needs to be verified, a wash cycle needs to be run after this series of tests.	Y N/A	N
2r	Light	For washers with a window only. Does the light come on when LED Light test is ran?	Y N/A	N
2s	Cooling Fan	Does the cooling fan come on when Electronic Cooling Fan test is ran?	Y	N
2t	Rinse Aid Pump Option	If installed does the rinse aid pump come on when Rinse Aid Pump 1 test is ran? Note: If the volume dispensed needs to be verified, a wash cycle needs to be run.	Y N/A	N
2u	Door Latch	With the door shut, does the door latch actuate when Door Latch test is ran?	Y	N
2v	Optional Detergent	The detergent pump operation was verified earlier. The dispense volume can be verified by with following procedure.	Y N/A	N

	Dispense Pump	<p>Remove the 1 gallon detergent jug and replace with a graduated cylinder filled with water. Run the LIQUID DETERGENT PUMP diagnostics letting the pump run for about 1 minute. Record the volume of water left in the graduate.</p> <p>Select the "GLASS" wash cycle. The detergent dispense is set to 20 ml. Start the cycle. After the Wash 1 fill water in the graduate should be 16 to 24 ml less than at the start.</p> <p>Programed setting _____</p> <p>Total Volume Dispensed _____</p>		
2w	Optional Rinse Aid Dispense Pump	<p>Remove the container and replace with a graduated cylinder of water. Run the RINSE AID PUMP diagnostics letting the pump run for at least 1 minute. Record the volume of water left in the graduate.</p> <p>Select the "GLASS" wash cycle. The rinse aid dispense is set to 4 ml. Start the cycle. After the Rinse 1 fill water in the graduate should be 2/6 ml less than at the start.</p> <p>Programed setting _____</p> <p>Total Volume Dispensed _____</p>	Y N/A	N
2x	Tap Water Flow Rate	<p>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).</p> <p>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?</p>	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	Y	N

		<p>heard running. Did the purified water complete filling in less than 5 minutes?</p> <p>The cycle can be Cancelled after this test.</p>		
2z	Temperature Verification	<p>The temperature shown on the display may be verified. Open the door and secure a thermocouple to the temperature probe on the back wall of the wash. Close the door allowing the thermocouple leads to pass between the door and the seal so the meters are outside the washer. Go to the Sensor screen. The unit temperature will be displayed.</p> <p>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 _____</p> <p>Meter Temperature _____</p> <p>If needed, refer to the User's Manual Chapter 6 to learn to calibrate this sensor</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 Chapter 9 in the User's Manual.		
		Optional racks and inserts are available.		
		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 removed. Has the optimal upper rack position been selected?	Y	N
		Are spindles on the lower spindle rack 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 low-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

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	Recording Data	<p>For a successful wash, record the "data" as described in the User's Manual.</p> <p>Wash Water Temp. from Washer? _____</p> <p>Wash Water Temp. Measured? _____</p> <p>Final Rinse Water Temp. from Washer? _____</p> <p>Final Rinse Water Temp. Measured? _____</p> <p>Use the above recorded parameters as reference in the future to validate performance of the washer. Have the above values been recorded?</p>	Y N/A	N

2d	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
2e	Documentation	Has the desired factory-set cycle or custom cycle parameters been documented and stored?	Y	N
2f	Low Detergent Level Alarm Optional	Low Detergent alarm is activated by the lack of fluid within the 1-gal. detergent container if auto dispense is installed. Does the alarm activate when the float inside the bottle is lowered?	Y	N
2g	Low Acid Rinse Level Alarm	Low Acid Rinse alarm is activated by the lack of fluid within the 1-L container if auto dispense is installed. Does the alarm activate when the float inside the bottle is lowered?	Y N/A	N
2h	Data Collection	If the data acquisition feature via Ethernet or USB is to be utilized, has it been properly set up and tested? Are the procedures in place for the observation and storage of the measured parameters?	Y N/A	N
2i	Email Alerts	If the Email Alerts feature is to be utilized, has the Ethernet connection and Email Alerts feature been set up and tested?		
2j	Printer	If the optional printer is to be utilized, has it been installed and tested. Has the proper print format been selected?	Y NA	N

3	Personnel Training			
3a	User Training	<p>Have all users been properly trained on the operation and limitations of the washer? Do all users understand:</p> <ul style="list-style-type: none"> • 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? 	Y	N
4	Preventive Maintenance	Add the following item(s) to the company's preventive maintenance plan?		
4a	Sump Screen	Inspect and clean sump screen as required	Y	N

C. Summary

Labconco FlaskScrubber or SteamScrubber Series Washer IQ/OQ Protocol
1058704, Rev. A

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