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IQ/OQ Protocol Installation Qualification/ Operation Qualification

ScrubAir™ Pipette Washer/Dryers

Purpose and Scope IQ and OQ

This Qualification Protocol is solely intended to be used with ScrubAir Pipette Washer/dryer/Dryers, which are new or relocated.

Models: ScrubAir Basic

4612020	4612030
4612040	4612060
4612070	4612080

ScrubAir Heated

4612021	4612031
4612041	4612061
4612071	4612081

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 ScrubAir Pipette Washer/Dryer User's Manual (#4612200). 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 ScrubAir Pipette Washer/Dryer 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 ScrubAir Pipette Washer/Dryer. Records should be stored in a safe, easily retrievable location. The location of the ScrubAir Pipette Washer/Dryer 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 ScrubAir Pipette Washer/Dryer 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/Dryer 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 counter space been provided for placement of the unit?	Y	N
		Is there proper head clearance for the removal of the washer/dryer's clear cover?	Y	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/dryer be connected into the building's drain plumbing where proposed?	Y	N
		Have accommodations been considered for connection to a purified water source if required?	Y N/A	N
		If connecting to a purified water source, will there be sufficient rate and volume?	Y N/A	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/dryer to be connected circuit of adequate size and proper voltage?	Y	N
1e	Air Requirements	Is there an adequate supply of pressurized air near the proposed installation site?	Y	N
1f	Delivery Requirements	If the washer/dryer has not been delivered, have arrangements been made with the facility or delivery agent to have equipment capable of gently handling a package of this size and weight? (Refer to User's Manual)	Y	N

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2	Prior to Operation			
2a	Damage Claims	Has the washer/dryer 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	The washer/dryer in its final site and setting level?	Y	N
2c	Plumbing	Has the factory installed water supply and drain tube assembly been connected to a faucet as detailed in the Users Manual? If hard plumbed have the main water supply and drain hoses been installed as detailed in the manual?	Y	N
		Has the plumbing been checked for leaks?	Y	N
		If required, has a purified water source been plumbed and checked for leaks?	Y N/A	N
2d	Air Connection	Has the air supply hose been connected to an acceptable air supply per the User's Manual?	Y	N
2e	Electrical Connections	Has the unit been connected to a grounded circuit of appropriate size?	Y	N
2f	Run Diagnostics Test:	Refer to the User's Manual to perform the diagnostic test.		
	Tap Water Fill	Does air and water enter tank and turn off when tank full?	Y	N
2g	Pure Water Fill	If pure water is not connected continue to next step.	Y	N
		Does air and water enter tank and turn off when tank is full?	N/A	
2h	Air Valve	Does the air valve come on and force water and then air bubbles up through the pipettes?	Y	N

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2i	Heater	If unit is not a heated model continue to next step. Does heater come on?	Y N/A	N
2j	Drain	Does water come out of the drain line?	Y	N
2k	Lid Check	Does lid sensor work?	Y	N
2l	Temperature Sensor Check	If unit is not a heated model continue to next step. Insert and secure a thermocouple or thermometer down through the holes in the pipette guide assembly to the bottom of the tank. Run the Standard Wash cycle. Temperature should reach 60°C before the end of the 30 minute wash and should not vary more than +5°C and -10°C when temperature readings have stabilized. Max. Temperature _____ Min. Temperature _____	Y NA	N

B. Operational Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	Accessories			
1a	Detergent	Has a non-foaming liquid detergent specifically formulated for laboratory washer/dryers been procured for this application?	Y	N

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2	Wash Cycle			
a	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, and detergent 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 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/dryer?</p> <p>Do all users understand: Which programs and racks are to be used; Proper way to load each type of pipettes; How and when to dispense detergent; How to start and interrupt cycles; Where washer/dryer manual is kept?</p>	Y	N

C. Summary

Labconco ScrubAir Pipette Washer/Dryer IQ/OQ Protocol 1064200, 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