

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

RapidVap<sup>®</sup> Vacuum Evaporation Systems

Labconco No. – 1058802, Rev. A, ECO L395 Available at **labconco.com** 

## Purpose and Scope IQ and OQ

This Qualification Protocol is solely intended to be used with new or relocated Labconco RapidVap Vacuum Systems. RapidVap  $N_2$  and  $N_248$  Systems are covered in a separate document, #1058803.

Models: RapidVaps			
7900000	7900001	7900002	7900003
7900010	7900011	7900012	7900013

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 product.

The use of this document does not replace the need for the RapidVap User's Manual (#7490100). Information within the User's Manual is required to complete this IQ/OQ Protocol. If the manual has been misplaced, copies can be obtained from the manufacturer or down-loaded from their website, www.labconco.com

## Responsibilities

**End-User** – The ultimate user or otherwise appointed personnel in the lab is responsible to ensure the evaporator 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 RapidVap. Records should be stored in a safe, easily retrievable location. The location of the equipment and required validation should be included in the company's quality system.

**Manufacturer** – Labconco Corporation, certified ISO-9001, is responsible to fully test each RapidVap 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 evaporator has been checked for proper installation and basic operation, it may be decided to validate its performance. 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.

Step	Description	Specification or Acceptance Criteria	Res	Result	
			YES	NO	
1	Site Planning				
1a	Space Requirements	Refer to Appendix B in the User's Manual for dimensions of the model(s) you have chosen. Has adequate counter space been provided for placement of the equipment?	Y	N	
1b	Vacuum Pump Selection	Is there a vacuum pump with appropriate flow and ultimate vacuum available or purchased for this application?	Y	Ν	
		Vacuum Pump ID			
		Can the vacuum pump accommodate the <sup>1</sup> / <sub>2</sub> - inch ID hose to the equipment?	Y	Ν	
		Is the pump the same voltage as the RapidVap? 115V requires a standard NEMA 5-15P plug.	Y	Ν	
		230V must have a "reverse" IEC 320 plug.			
		If intentions are to evaporate flammable solvents, has a vacuum pump with an	Y	N	
		explosion-proof motor been considered?	N/A		
1c	Electrical Service	Refer to the User's Manual for a list of model numbers and their corresponding electrical requirements. Are services available for the equipment to be connected to an electrical circuit of adequate size and the proper voltage?	Y	Ν	

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## **A.Installation Qualification**

		230V models are shipped with a CEE 7/7 power cord plug, (it may need to be removed and replaced). Is one available to match the service outlet at the installation site?	Y N/A	N
1d	Exhaust Requirements	Refer to the User's Manual 7490100 Chapter 2. Have accommodations been made to vent the RapidVap safely?	Y	N
2	Prior to Operation			
2a	Damage Claims	<ul><li>Have the delivered products been inspected for any signs of damage that may have occurred while in transit? Keep packaging materials until inspection is complete.</li><li>If damaged, refer to the User's Manual for information on shipping damage claims.</li></ul>	Y	N
2b	Vacuum Connections	Have the vacuum connections been made between the RapidVap and pump? Are the connections secured with clamps? (See section 2a of the Operation Qualification section of this protocol before making final connection.)	Y	N
2c	Venting of fumes	Is the vacuum pump outlet vented to an appropriate exhaust source such as a fume hood?	Y	N
2d	Pump - Electrical	The vacuum pump is to be controlled by the RapidVap, has the pump been plugged into the back of the RapidVap with the pump's switch ON?	Y	N
2e	Glassware Block	Does the sample block match the size of tubes you wish to use in this evaporator?	Y	N
		Has the block been placed into the RapidVap 's chamber and secured with the three nuts?	Y	N
2f	Handling Solvents	Has the Safety Officer, or equivalent, reviewed the safe handling, venting and disposal of solvents evaporated?	Y	N

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	RapidVap			
1a	Preheat	Activate the Preheat feature. With the lid closed, does the chamber heat up?	Y	Ν
1b	Heat and Run	Select any program and set a higher than ambient temperature and set the Run Time to one minute to check operation.	Y	N
		Did the chamber oscillate and heat when the lid is closed?		
1c	Run Timer	Did the alarm sound and oscillation stop after one minute?	Y	Ν
1d	Interrupt Cycle	Repeat the one-minute cycle, except this time, press the STOP button to interrupt the cycle. Did the oscillation stop? When Run is pressed, did the cycle resume?	Y	N
1e	Temperature Control	Set the speed to zero. Attach a thermocouple wire on the top of the sample block next to the retaining nut at the 7:00 position. Without vacuum, close the lid and allow the block to heat. With the Temp. Control set at 45 °C: RapidVap Display Temperature: (Display should be between 44 and 46 °C) Reference Device Temperature: (Device should read between 42 and 48 °C) With the Temp. Control set at 95 °C: RapidVap Display Temperature: (Display should be between 94 and 96 °C)	Y	Ν
		Reference Device Temperature: (Device should read between 91 and 99 °C) Ref. Device ID		

#### **B.** Operational Qualification

1f	Vortex Speed	Place a piece of aluminum tape on the top of the	Y	Ν
	(Optional, this step requires a calibrated tachometer to	sample block. Set the following speeds and measure with a calibrated optical tachometer. Does the RapidVap operate at RPM's in the allowable tolerance?	N/A	
	complete)	Set Pt. Display Allowable Tach. Allowable   0 0 0 0   12% 12 105/135   100% 98/102 970/1030		
		Tachometer I.D.		
1g	RS-232 Optional Accessory	Refer to the User's Manual 7490100 for instructions on connections and operation of the RS-232	Y	Ν
	Communications Port	communications with the RapidVap. To test the connections and output, use cable #7484800. Send each of the RS-232 commands listed in the User's Manual and observe the results. Did the RapidVap respond correctly to the commands?	N/A	
2	Vacuum Pump			
2a	Vacuum Level	Has the vacuum pump been checked with a calibrated gauge to determine the ultimate vacuum capability of the pump? Gauge reading on pump alone? Description of gauge used?	Y N/A	N
		Acceptance criteria for future pump validation?		
2b	Vacuum Control & Calibration (Optional, this step requires a calibrated vacuum sensor to complete)	Install a reference vacuum sensor by configuring a "tee" at the point where the vacuum hose connects to the RapidVap. Only use a high vacuum rotary vane pump. Place the RapidVap in calibrate mode by pressing the Vacuum Release Button and turning on the Main Power Switch at the same time. With the vacuum at zero, adjust the displayed vacuum reading with the up and down arrows. Store the adjusted reading by pressing Run. Now set the vacuum level to 100 mBar. Does the unit hold between 85 and 115 mBar as shown on the display? Vacuum Sensor ID	Y N/A	N

2c	Start of Vacuum	Close the lid to the RapidVap. Press RUN. Did the vacuum pump start after the chamber reached operating speed?	Y	Ν
3	Personnel Training			
3a	User Training	Have personnel to use the RapidVap been adequately trained?	Y	N
		Are personnel familiar with:		
		Volume limits of samples in vials;		
		Loading of vials in heated block;		
		Safe handling of solvents and vapors;		
		Programming time, temp. & vacuum parameters;		
		Cleaning and maintenance of the RapidVap?		

#### **C. Summary**

Labconco RapidVap Vacuum System IQ/OQ Document 1058802 Revision				
Equipment Location				
RapidVap Ser. 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