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IQ/OQ Protocol Installation Qualification/ Operation Qualification

CentriVap[®] Centrifugal Concentrators & Cold Trap Systems

Purpose and Scope IQ and OQ

This Qualification Protocol is solely intended to be used with new or relocated Labconco CentriVap Centrifugal Concentrators, separate Cold Traps, and Mobile Consoles with built-in Cold Trap. CentriVap DNA Systems are covered in a separate document, #1058801.

Models: CentriVaps and Cold Trap Systems

<i>73100XX Series</i>	<i>74750XX Series</i>	<i>79820XX Series</i>
<i>73150XX Series</i>	<i>78100XX Series</i>	<i>79830XX Series</i>
<i>73850XX Series</i>	<i>78110XX Series</i>	<i>79840XX Series</i>
<i>74600XX Series</i>	<i>78120XX 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 CentriVap and Cold Trap User's Manual (#7539800), Mobile Console User's Manual (#7396603), CentriVap Refrigerated Centrifugal Concentrator User's Manual (#7310605) or the CentriVap Complete User's Manual (#7314000). 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 Concentrator and Cold Trap are 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 Concentrator/Cold Trap. 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 CentriVap and Cold Trap 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 Concentrator and Cold Trap have been checked for proper installation and operation, it may be decided to validate their 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.

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 for dimensions of the model(s) you have chosen. Has adequate counter or floor 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? Min recommended requirements Aqueous samples 82 L/min, <2 mbar Volatile solvents 42 L/min, 200 mbar	Y	N
		Can the vacuum pump accommodate the 0.5-inch ID hose to the equipment?	Y	N
		Is the pump the same voltage as the Concentrator (and Cold Trap)? 115V requires a standard NEMA 5-15P plug. 230V must have a “reverse” IEC 320 plug.	Y	N
		With aggressive solvents internal wetted parts of the pump must be Teflon®* or Teflon-coated. Has this been confirmed?	Y N/A	N
		If intentions are to evaporate flammable solvents, has an explosion-proof vacuum pump been considered?	Y N/A	N
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	N
		Does the service outlet match the power cord plug?	Y N/A	N
1d	Exhaust Requirements	Refer to the User’s Manual. Have accommodations been made to vent the CentriVap safely?	Y	N

* Teflon is a registered trademark of E.I. duPont de Nemours

2	Prior to Operation			
2a	Damage Claims	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. If damaged, refer to the User's Manual for information on shipping damage claims.	Y	N
2b	Set Up	Have the vacuum connections been made between the Concentrator, (Cold Trap), and pump? Are the connections secured with clamps?	Y	N
2c	Electrical	If the vacuum pump is to be controlled by the CentriVap, has the pump been plugged into the back of the Concentrator with the pump's switch ON?	Y N/A	N
2d	Rotor	Does the rotor match the size of tubes you wish to use in this Concentrator?	Y	N
		Has the rotor been placed into the Concentrator's chamber so that the hub is seated all the way down on the drive pin?	Y	N
2e	Secondary Trap	The secondary trap is standard on some of the models, optional on others. Has the appropriate type of chemical cartridge been procured for the samples to be run? Refer to the User's Manual.	Y N/A	N
2f	Handling Solvents	Has the Safety Officer or equivalent reviewed the safe handling, venting and disposal of solvents trapped?	Y N/A	N
2g	Glass Lid	If the solvents to be used attack acrylic, has the optional glass lid been considered?	Y N/A	N
2h	Glass Trap Insert	For solvents that would attack acrylic or the stainless steel trap, has the glass trap insert been considered? (Glass container that fits inside the Cold Trap condensing chamber.) Refer to the User's Manual.	Y N/A	N

B. Operational Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	Concentrator			
1a	Preheat	Activate the Preheat feature. With the lid closed, does the chamber heat up?	Y	N
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. Does the rotor turn and the chamber heat when the lid is closed?	Y	N
1c	Cool and Run (Refrigerated Concentrator Only)	Select any program and set a lower than ambient temperature and set the Run Time to one minute to check operation. Does the rotor turn and the chamber cool when the lid is closed?	Y	N
1d	Run Timer	Did the alarm sound and rotor stop after one minute?	Y	N
1e	Interrupt Cycle	Repeat the one-minute cycle, except this time; press the STOP button to interrupt the cycle. Did the rotor stop? When Run is pressed, did the cycle resume?	Y	N
1f	Shaft Speed	If rotor shaft speed is important to your work, measure with a calibrated tachometer. To do this, remove the rotor and measure the shaft rotation through the closed lid. (Typically reflective tape is attached to the top surface of the drive shaft.) Does the speed measure at least: 1650 RPM for the 115V, 1350 RPM for the 230V? Speed _____ RPM's Measured with _____	Y N/A	N

2	Cold Trap			
2a	Ready Light	Turn ON the Cold Trap. Did the “READY” light illuminate within 30 minutes signifying that the system has reached operating temperature? Or, on CentriVap Mobile Console models, is there a steady, non-flashing “Y” shown on the display?	Y	N
3	Vacuum Pump			
3a	Start of Vacuum	Close the lid to the Cold Trap and the CentriVap. Press RUN. Did the vacuum pump start after the rotor reached operating speed?	Y	N
3b	Vacuum leaks	Check for vacuum leaks on the entire system. Compare vacuum readings of the system to the ultimate vacuum of the pump alone. Gauge reading on the entire system? _____ Gauge reading on pump alone? _____ Type of gauge used? _____	Y N/A	N
4	Personnel Training			
4a	User Training	Have personnel that use the CentriVap and Cold Trap been adequately trained? Are personnel familiar with: Volume limits of samples in vials; Symmetric loading of vials in rotor; Safe handling of solvents and vapors; Programming time and temp. parameters; Cleaning of the CentriVap and Cold Trap?	Y	N

C. Summary

Labconco CentriVap/Cold Trap IQ/OQ Document 1058800 Revision H

Equipment Location _____

CentriVap Ser. No. _____ Model No. _____

Cold Trap Ser. No. _____ Model No. _____

(Cold Trap built-in on Mobile Console models)

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