



IQ/OQ Protocol Installation Qualification/ Operation Qualification

**RapidVap[®] Vacuum
Evaporation Systems**

Labconco No: 1058802 Rev. -

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Purpose and Scope IQ and OQ

This Qualification Protocol is solely intended to be used with new or relocated Labconco RapidVap Vacuum Systems. RapidVap N₂ and N₂48 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.

A. Installation Qualification

| Step | Description | Specification or Acceptance Criteria | 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? Vacuum Pump ID _____ | Y | N |
| | | Can the vacuum pump accommodate the ½-inch ID hose to the equipment? | Y | N |
| | | Is the pump the same voltage as the RapidVap? 115V requires a standard NEMA 5-15P plug. 230V must have a “reverse” IEC 320 plug. | Y | N |
| | | If intentions are to evaporate flammable solvents, has a vacuum pump with an explosion-proof motor 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 |

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|----------|---------------------------|---|----------|---|
| | | 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 | 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 | 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 |

B. Operational Qualification

| 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 | 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. Did the chamber oscillate and heat when the lid is closed? | Y | N |
| 1c | Run Timer | Did the alarm sound and oscillation stop after one minute? | Y | N |
| 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) Reference Device Temperature: _____ (Device should read between 91 and 99 °C) Ref. Device ID _____ | Y | N |

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|----------|--|--|---------------------|-----------|-----------|-------|-----------|---|-------|---|-------|---|-----|-------|----|-------|---------|------|-------|--------|-------|----------|---------------------|----------|
| 1f | <p>Vortex Speed</p> <p>(Optional, this step requires a calibrated tachometer to complete)</p> | <p>Place a piece of aluminum tape on the top of the sample block. Set the following speeds and measure with a calibrated optical tachometer. Does the RapidVap operate at RPM's in the allowable tolerance?</p> <table border="0" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">Set Pt.</td> <td style="width: 15%;">Display</td> <td style="width: 15%;">Allowable</td> <td style="width: 15%;">Tach.</td> <td style="width: 15%;">Allowable</td> </tr> <tr> <td>0</td> <td>_____</td> <td>0</td> <td>_____</td> <td>0</td> </tr> <tr> <td>12%</td> <td>_____</td> <td>12</td> <td>_____</td> <td>105/135</td> </tr> <tr> <td>100%</td> <td>_____</td> <td>98/102</td> <td>_____</td> <td>970/1030</td> </tr> </table> <p>Tachometer I.D. _____</p> | Set Pt. | Display | Allowable | Tach. | Allowable | 0 | _____ | 0 | _____ | 0 | 12% | _____ | 12 | _____ | 105/135 | 100% | _____ | 98/102 | _____ | 970/1030 | <p>Y</p> <p>N/A</p> | <p>N</p> |
| Set Pt. | Display | Allowable | Tach. | Allowable | | | | | | | | | | | | | | | | | | | | |
| 0 | _____ | 0 | _____ | 0 | | | | | | | | | | | | | | | | | | | | |
| 12% | _____ | 12 | _____ | 105/135 | | | | | | | | | | | | | | | | | | | | |
| 100% | _____ | 98/102 | _____ | 970/1030 | | | | | | | | | | | | | | | | | | | | |
| 1g | <p>RS-232 Optional Accessory Communications Port</p> | <p>Refer to the User's Manual 7490100 for instructions on connections and operation of the RS-232 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?</p> | <p>Y</p> <p>N/A</p> | <p>N</p> | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |
| 2 | Vacuum Pump | | | | | | | | | | | | | | | | | | | | | | | |
| 2a | <p>Vacuum Level</p> | <p>Has the vacuum pump been checked with a calibrated gauge to determine the ultimate vacuum capability of the pump?</p> <p>Gauge reading on pump alone? _____</p> <p>Description of gauge used? _____</p> <p>Acceptance criteria for future pump validation? _____</p> | <p>Y</p> <p>N/A</p> | <p>N</p> | | | | | | | | | | | | | | | | | | | | |
| 2b | <p>Vacuum Control & Calibration</p> <p>(Optional, this step requires a calibrated vacuum sensor to complete)</p> | <p>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.</p> <p>With the vacuum at zero, adjust the displayed vacuum reading with the up and down arrows. Store the adjusted reading by pressing Run.</p> <p>Now set the vacuum level to 100 mBar. Does the unit hold between 85 and 115 mBar as shown on the display?</p> <p>Vacuum Sensor ID _____</p> | <p>Y</p> <p>N/A</p> | <p>N</p> | | | | | | | | | | | | | | | | | | | | |

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|----------|---------------------------|--|---|---|
| 2c | Start of Vacuum | Close the lid to the RapidVap. Press RUN. Did the vacuum pump start after the chamber reached operating speed? | Y | N |
| | | | | |
| 3 | Personnel Training | | | |
| 3a | User Training | Have personnel to use the RapidVap been adequately trained? 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? | Y | N |

C. Summary

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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 |
|------|--|---------|
| | | |
| | | |
| | | |
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