

# Installation Qualification/Operational Qualification Protocols and Instructions

AquaLab VSA  
Vapor Sorption Analyzer



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# Section 1 – Introduction

This Qualification protocol is solely intended to be used with new or relocated AquaLab Vapor Sorption Analyzer systems. It is written to assist the end-user in validation of predetermined specifications.

The use of this document does not replace the need for the AquaLab VSA User's Manual. 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 downloaded from their website, [www.aqualab.com](http://www.aqualab.com)

Qualification of instrumentation is a formal process of documenting that an instrument is fit for its intended use and that it is kept maintained and calibrated.

## Responsibilities

The instrument qualification carried out onsite is the sole responsibility of the instrument owner/user. However, Decagon Devices supports their customers in performing the qualification by providing the instrument qualification dedicated documentation and offering a qualification service. In this regard, the following responsibilities are defined:

### **Performance of Qualification**

Execution of the instrument qualification and entire qualification of the installed system covered in this document is performed by the Decagon Devices trained and authorized service personnel if ordered from a customer.

### **Review and final qualification approval**

Final approval for the qualification has to be completed after review of the qualification documentation filled out during performance of the qualification procedures (IQ/OQ protocols). The customer representative then signs the approved form.

## Installation Qualification (IQ)

Installation qualification is documented proof that the instrument was received as designed and specified by the manufacturer, that it is properly installed in the selected environment, and that this environment is suitable for the operation and use of the instrument. The IQ section therefore describes and documents the instrument installation in the pre-determined environment. Further, the IQ verifies and ensures that all ordered parts and documentation are in place and that all supplied items are in working order and condition.

## Operational Qualification (OQ)

The operational qualification serves as proof that the equipment operates as designed and intended as well as fulfills acceptance criteria defined and stated in the Operational Qualification documentation. These criteria are defined and are based on the equipment technical specifications of the manufacturer.

## Performance Qualification (PQ)

Performance qualification is documented proof that an instrument consistently performs according to the specifications appropriate for its routine use. Monitoring of equipment during routine operation is essential for ensuring that the ongoing performance is within specifications. The performance qualification, execution

and frequency are solely under responsibility of the user. Performance validation should be designed to meet the specifications and accuracy for a given application.

## **Equipment familiarization and operator training records**

All equipment users are to be instructed in basic operation, functionality, instrument parameters, as well as on basic hardware features of the installed system including routine maintenance and cleaning procedures. Please contact Decagon Devices to learn about available training and seminars.

Authorized support specialists perform the qualification services offered by Decagon Devices.

# Section 2 – Installation Qualification (IQ)

## Initial Qualification and Requalification

The IQ protocols described below are dedicated to initial qualification and/or to requalification. Installation Qualification tests should be performed, 1) when the system is installed, 2) when the system is moved to a new location, 3) prior to running OQ tests.

This section describes the procedure for receiving, unpacking, and installing the AquaLab VSA.

The purchased AquaLab VSA undergoing qualification is located at:

Company Name: \_\_\_\_\_

Department: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_

Country: \_\_\_\_\_

Zip code/Postal Code: \_\_\_\_\_

Phone Number: \_\_\_\_\_

### 2.1 Equipment identification

Fill out this section after unpacking the VSA and corresponding accessories.

Manufacturer: DECAGON DEVICES \_\_\_\_\_

Model Number: AquaLab VSA \_\_\_\_\_

Serial Number: \_\_\_\_\_

#### Decagon Devices Authorized Representative

Name: \_\_\_\_\_

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

Initials: \_\_\_\_\_

### 2.2 Receiving and Unpacking

Verify that the external packaging was not damaged during shipment in a way that the internal package content might be damaged.

External package condition       Satisfactory       Not Satisfactory

Remarks:  N/A  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Compare shipment list with supplied items to ensure completeness of order.

VSA Benchtop Unit	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Quick Start Guide	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
User's Manual	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Moisture Analysis Toolkit Software	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
VSA Humidity & Temperature Table	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Certificate of Calibration	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
MCC Standard	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Desiccant Tubes (3)	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Trial Verification Standards	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
SDS Documents	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Power Cable	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
USB Cable	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
2 g Standard Weight	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Weight Certificate	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Stainless Steel Sample Cups (2)	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Black Water Tank Plug	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Filters	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Chamber Pan	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Air Cylinder	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
125 ml Bottles (2)	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Wrench 5/16"	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Tweezers	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A

Remarks:  N/A

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All parts were received as ordered and the delivery is complete.  Yes  No

Any parts that were missing at the time of this supply verification and reported as Not Complete must be delivered to complete the shipment. Any parts marked as Not Complete must be indicated below and reviewed with the customer. Minor parts or accessories that do not impact the installation or qualification procedure or the functionality of the instrument can be accepted, if agreed upon by the customer in order to complete the remainder of the IO/OO process. Completed can be marked once the item has been received.

Item:			Date	Initials
_____	<input type="checkbox"/> Accepted	<input type="checkbox"/> Completed	_____	_____
_____	<input type="checkbox"/> Accepted	<input type="checkbox"/> Completed	_____	_____
_____	<input type="checkbox"/> Accepted	<input type="checkbox"/> Completed	_____	_____
_____	<input type="checkbox"/> Accepted	<input type="checkbox"/> Completed	_____	_____
_____	<input type="checkbox"/> Accepted	<input type="checkbox"/> Completed	_____	_____
_____	<input type="checkbox"/> Accepted	<input type="checkbox"/> Completed	_____	_____

Remarks:  N/A  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Qualified by: \_\_\_\_\_  
Date: \_\_\_\_\_ Initials: \_\_\_\_\_

### 2.3 Visual Inspection

After unpacking, verify that there is no physical damage to the instrument, cables, and accessories. Note all observed damage in the Remarks section. Minor defects that do not affect functionality can be marked as accepted, if approved by the customer.

VSA Instrument	<input type="checkbox"/> Satisfactory	<input type="checkbox"/> Not Satisfactory	<input type="checkbox"/> Accepted
Documentation	<input type="checkbox"/> Satisfactory	<input type="checkbox"/> Not Satisfactory	<input type="checkbox"/> Accepted
Other	<input type="checkbox"/> Satisfactory	<input type="checkbox"/> Not Satisfactory	<input type="checkbox"/> Accepted

Remarks:  N/A  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Qualified by: \_\_\_\_\_  
Date: \_\_\_\_\_ Initials: \_\_\_\_\_

Severe damage to any of the delivered parts interrupts the installation qualification until the part is replaced. Completion of the installation qualification after replacement is documented below.

VSA Instrument	<input type="checkbox"/> Satisfactory	<input type="checkbox"/> Not Satisfactory	<input type="checkbox"/> N/A
Documentation	<input type="checkbox"/> Satisfactory	<input type="checkbox"/> Not Satisfactory	<input type="checkbox"/> N/A
Other	<input type="checkbox"/> Satisfactory	<input type="checkbox"/> Not Satisfactory	<input type="checkbox"/> N/A

Remarks:  N/A

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Qualified by:

Date: \_\_\_\_\_ Initials: \_\_\_\_\_

## 2.4 Environmental Conditions

Installation of the AquaLab VSA includes placing the instrument on a level surface in a location where the temperature remains fairly stable. This location should be well away from air conditioner and heater vents, open windows, outside doors, or other items that may cause rapid temperature fluctuation or vibration. Humidity of the room should be monitored and verified to be within the range that is acceptable according to Appendix B in the VSA User's Manual.

Location	<input type="checkbox"/> Satisfactory	<input type="checkbox"/> Not Satisfactory
Adequate Power	<input type="checkbox"/> Satisfactory	<input type="checkbox"/> Not Satisfactory
Stable Surface	<input type="checkbox"/> Satisfactory	<input type="checkbox"/> Not Satisfactory
Temperature	<input type="checkbox"/> Satisfactory	<input type="checkbox"/> Not Satisfactory
Humidity	<input type="checkbox"/> Satisfactory	<input type="checkbox"/> Not Satisfactory

Remarks:  N/A

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Qualified by:

Date: \_\_\_\_\_ Initials: \_\_\_\_\_



## 2.5 Power Up and Scale Stability Test

After finding a good location for the AquaLab VSA, plug the power cord into the back of the unit and a standard AC outlet. The ON/OFF switch is located in the lower left corner of the AquaLab VSA's back panel. Install the 2 desiccant tubes, the air cylinder and the weighing pan according to manufacturer's recommendations.

Instrument is powered upon switching on  Yes  No

Remarks:  N/A  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Ensure the instrument is level using the bubble level on the base plate. Scale stability is tested by navigating to the diagnostics screen and scrolling down to the screen that shows the weight. Readings should vary no more than 0.5 mg with the chamber lid closed. Lightly tap the table with one finger. If the readings vary more than 0.5 mg after tapping, the table is too unstable for accurate readings or the scale is out of alignment.

Instrument is level	<input type="checkbox"/> Satisfactory	<input type="checkbox"/> Not Satisfactory
Scale readings within 0.5 mg	<input type="checkbox"/> Satisfactory	<input type="checkbox"/> Not Satisfactory
Scale readings while tapping table or surface vary < 0.5 mg	<input type="checkbox"/> Satisfactory	<input type="checkbox"/> Not Satisfactory

Remarks:  N/A  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Qualified by:

Date: \_\_\_\_\_ Initials: \_\_\_\_\_

## Completeness of Installation Qualification (IQ)

Installation Qualification was completed and documented according to manufacturers guidelines.

Initial Qualification       Requalification

### Decagon Devices Authorized Representative

Name: \_\_\_\_\_

Function: \_\_\_\_\_

Company: \_\_\_\_\_

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

Initials: \_\_\_\_\_

Installation Qualification was reviewed by the representative of the system owner.

Reviewed and approved by:

Name: \_\_\_\_\_

Function: \_\_\_\_\_

Company: \_\_\_\_\_

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

Initials: \_\_\_\_\_

# Section 3 – Operational Qualification (OO)

This section describes tests that are to be executed for Operational Qualification of the AquaLab VSA in order to prove proper operation of the installed instrument.

## 3.1 Hardware testing

Display is functional  Yes  No

Keypad is functional  Yes  No

Remarks:  N/A  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Qualified by:

Date: \_\_\_\_\_ Initials: \_\_\_\_\_

## 3.2 System Information

AquaLab VSA Information

Manufacturer: \_\_\_\_\_  
Model Number: \_\_\_\_\_  
Serial Number: \_\_\_\_\_  
Firmware Version: \_\_\_\_\_

### 3.2.1 Scale Alignment Check

Proper scale function is dependent upon the scale rod being correctly aligned. The scale rod/cap should be centered in the lower bore hole of the lower block. When the weigh pan is in place, the pan should be centered in the bore hole and not shifted to one side. Test the actuator function by navigating to the diagnostics menu and scrolling down until the option ACT displays on the bottom of the screen. Pressing the ACT button activates the actuation of the system and lifts the air cylinder. Pressing the ACT button a second time deactivates the actuation system and the air cylinder should drop down completely.

- |   |                                       |   |
|---|---------------------------------------|---|
| Visual inspection of scale rod alignment            | <input type="checkbox"/> Satisfactory | <input type="checkbox"/> Not Satisfactory |
| Air cylinder able to spin                           | <input type="checkbox"/> Satisfactory | <input type="checkbox"/> Not Satisfactory |
| Air cylinder moves freely when ACT button activated | <input type="checkbox"/> Satisfactory | <input type="checkbox"/> Not Satisfactory |
| Weigh pan centered                                  | <input type="checkbox"/> Satisfactory | <input type="checkbox"/> Not Satisfactory |
| Weight reading stable $\leq 0.50$ mg drift          | <input type="checkbox"/> Satisfactory | <input type="checkbox"/> Not Satisfactory |

Remarks:  N/A

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Qualified by:

Date: \_\_\_\_\_ Initials: \_\_\_\_\_

### 3.2.2 Scale Accuracy Test

The VSA uses a magnetic force balance to gravimetrically track the weight of the sample during the isotherm test. The performance of this balance is verified against a NIST traceable 2 g standard weight. Ideally, your VSA should be allowed a warm-up for a period of 24 hours to provide the most accurate readings. The weight should be within  $\pm 0.50$  mg of the 2000 mg weight. To measure the weight, navigate to the diagnostics screen and scroll down until weight is showing. Press the scale icon at the bottom of the screen to zero the scale. Place the 2 g standard weight on the weigh pan and close the lid. Record the weight and repeat.

- |                       |           |       |
|-----------------------|-----------|-------|
| Weight Verification 1 | 2000.0 mg | _____ |
| Weight Verification 2 | 2000.0 mg | _____ |

Weight Verification Standard Within Specification:  Yes  No

Remarks:  N/A

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If the scale reading is out of specification, follow the weight calibration procedure to calibrate the scale.

Navigate to the calibration menu and select weight calibration. Follow the on-screen prompts. After calibration, repeat verification procedures.

Weight Verification 1                      2000.0 mg \_\_\_\_\_

Weight Verification 2                      2000.0 mg \_\_\_\_\_

Weight Verification Standard Within Specification:       Yes       No       N/A

Remarks:  N/A  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Qualified by:

Date: \_\_\_\_\_ Initials: \_\_\_\_\_

### Section 3.2.3 Sensor Verification

The AquaLab VSA uses both a capacitance relative humidity sensor and a chilled mirror dew point technique to determine water activity. The performance of the sensors is verified by measuring specially prepared calibration standards that have a specific molality and water activity. Performance Verification Standards come in four water activity levels for the VSA: 0.250, 0.500, 0.760, and 0.920  $a_w$ . The AquaLab dew point sensor will read each standard within  $\pm 0.005 a_w$  of the stated value. The capacitance (volatiles) sensor will read each standard within  $\pm 0.02 a_w$  of the stated value. To measure the water activity of the standards, navigate to the measurement screen of the VSA and follow the instructions in the User's Manual. Repeat to complete testing on all standards.

Standard @ 25°C		Lot #	Dew Point Sensor		Volatiles Sensor	
			$a_w \pm 0.005$	°C	$a_w \pm 0.02$	°C
13.41m LiCl	0.250					
	0.250					
8.57m LiCl	0.500					
	0.500					
6.0m NaCl	0.760					
	0.760					
2.33m NaCl	0.920					
	0.920					

Water Activity Verification Standards Within Specification:       Yes       No

Remarks:  N/A  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

If verification standards are out of specification, clean the instrument and follow the procedure in the Operator's Manual to perform a linear offset. Repeat the verification process on fresh standards.

Standard @ 25°C		Lot #	Dew Point Sensor		Volatiles Sensor	
			$a_w \pm 0.005$	°C	$a_w \pm 0.02$	°C
13.41m LiCl	0.250					
	0.250					
8.57m LiCl	0.500					
	0.500					
6.0m NaCl	0.760					
	0.760					
2.33m NaCl	0.920					
	0.920					

Water Activity Verification Standards Within Specification:     Yes     No     N/A

Remarks:  N/A

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Qualified by:

Date: \_\_\_\_\_ Initials: \_\_\_\_\_

### 3.2.4 Equipment Familiarization

This section ensures that the instrument operators receive appropriate equipment training to ensure proper operation, maintenance, and generation of results with the AquaLab VSA. Product familiarization covers instruction on basic operations, functionality and features of the instrument, routine maintenance including cleaning procedures, and use of the software component for data retrieval. Appendix 1 on page 16 is an attached training documentation form.

Equipment familiarization and training completed for the AquaLab VSA

Yes

No

Qualified by:

Date: \_\_\_\_\_ Initials: \_\_\_\_\_

### Completeness of Operational Qualification (OO)

Operational Qualification was completed and documented according to manufacturers guidelines.

Initial Qualification

Requalification

Qualifications met Vendor Acceptance Criteria:

Yes

No

If any deficiencies are found, fill out the instructions for a corrective action on Pg. 17 of this document.

### Decagon Devices Authorized Representative

Name: \_\_\_\_\_

Function: \_\_\_\_\_

Company: \_\_\_\_\_

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

Initials: \_\_\_\_\_

Operational Qualification was reviewed by the representative of the system owner.

Reviewed and approved by:

Name: \_\_\_\_\_

Function: \_\_\_\_\_

Company: \_\_\_\_\_

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

Initials: \_\_\_\_\_

# Appendix 1

## Training Record

This training record is for instruction in basic operation, functionality, instrument parameters, as well as on basic hardware features of the installed system including routine maintenance and cleaning procedures. Please contact Decagon Devices to learn about available training and seminars.

Authorized support specialists perform the qualification services offered by Decagon Devices.

Name: _____	Date: _____
Name: _____	Date: _____
Name: _____	Date: _____
Name: _____	Date: _____
Name: _____	Date: _____
Name: _____	Date: _____
Name: _____	Date: _____
Name: _____	Date: _____
Name: _____	Date: _____
Name: _____	Date: _____

## Decagon Devices Authorized Representative

Name: \_\_\_\_\_  
Function: \_\_\_\_\_  
Company: \_\_\_\_\_  
Date: \_\_\_\_\_

Signature: \_\_\_\_\_  
Initials: \_\_\_\_\_

Reviewed and approved by:

Name: \_\_\_\_\_  
Function: \_\_\_\_\_  
Company: \_\_\_\_\_  
Date: \_\_\_\_\_

Signature: \_\_\_\_\_  
Initials: \_\_\_\_\_



# Appendix 2

## Deficiencies and Corrective Actions

If any deficiencies were found, they are to be followed with an instruction for Corrective Action. Once acceptable results are obtained, the deficiency is accepted by checking the "accepted" box under the deficiency.

Deficiency: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Corrective Action:     Accepted            Initial \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Deficiency: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Corrective Action:     Accepted            Initial \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## Decagon Devices Authorized Representative

Name: \_\_\_\_\_

Function: \_\_\_\_\_

Company: \_\_\_\_\_

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

Initials: \_\_\_\_\_