

# Installation Qualification/Operational Qualification Protocols and Instructions

AquaLab PRE



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# Section 1 – Introduction

This Qualification protocol is solely intended to be used with new or relocated AquaLab Water Activity instruments. 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 PRE 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 a Decagon Devices trained and authorized service personnel when 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 a PRE AquaLab Water Activity instrument.

The purchased AquaLab Water Activity instrument 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 AquaLab instrument and corresponding accessories.

Dewpoint     Volatiles

Manufacturer: DECAGON DEVICES  
Model Number: \_\_\_\_\_  
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.

Water Activity Instrument	<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
Certificate of Calibration	<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/Serial Cable	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Filters (Volatiles only)	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Cleaning Kit	<input type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
LDPE Sample Cups and Lids	<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 IQ/OQ 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	_____	_____

			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	_____	_____

Remarks:  N/A

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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.

AquaLab 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

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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.

AquaLab 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 Water Activity instrument 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.

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

Remarks:  N/A

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Qualified by:

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

## 2.5 Power Up Test

After finding a good location for the AquaLab Water Activity meter, plug the power cord into the back of the unit and a standard AC outlet. The ON/OFF switch is located on the back panel.

Instrument is powered upon switching on  Yes  No

Remarks:  N/A

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## Completeness of Installation Qualification (IQ)

Installation Qualification was completed and documented according to manufacturer's 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: \_\_\_\_\_

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

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

# Section 3 – Operational Qualification (OQ)

This section describes tests that are to be executed for Operational Qualification of the AquaLab Water Activity instrument 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 Water Activity Instrument Information

Manufacturer: \_\_\_\_\_

Model Number: \_\_\_\_\_

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

Firmware Version: \_\_\_\_\_

### 3.2.1 Sensor Verification

The AquaLab PRE line of instruments contain a chilled mirror dewpoint sensor for determining water activity. The Volatiles option contains a capacitance relative humidity sensor. The performance of the sensors is verified by measuring specially prepared calibration standards that have a specific molality and water activity. Performance Verification Standards in four water activity levels are used for qualification: 0.250, 0.500, 0.760, 1.000  $a_w$ . The AquaLab dew point sensor will read each standard within  $\pm 0.001 a_w$  of the stated value. The capacitance (volatiles) sensor will read each standard within  $\pm 0.015 a_w$  of the stated value. To measure the water activity of the standards, follow the instructions in the User's Manual for taking a reading.

Standard @ 25°C		Lot #	Dew Point Sensor		Volatiles Sensor	
			$a_w \pm 0.01$	°C	$a_w \pm 0.015$	°C
13.41m LiCl	0.250					
	0.250					
8.57m LiCl	0.500					
	0.500					
6.0m NaCl	0.760					
	0.760					
Steam Distilled H <sub>2</sub> O	1.00					
	1.00					

Water Activity Verification Standards Within Specification  Yes  No

Remarks:  N/A

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

Standard @ 25°C		Lot #	Dew Point Sensor		Volatiles Sensor	
			$a_w \pm 0.01$	°C	$a_w \pm 0.015$	°C
13.41m LiCl	0.250					
	0.250					
8.57m LiCl	0.500					
	0.500					
6.0m NaCl	0.760					
	0.760					
Steam Distilled H <sub>2</sub> O	1.00					
	1.00					

Water Activity Verification Standards Within Specification  Yes  No  N/A

Remarks:  N/A

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Qualified by:

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

### 3.2.2 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 instrument. Product familiarization covers instruction on basic operations, functionality and features of the instrument, and routine maintenance including cleaning procedures.

Equipment familiarization and training completed for the AquaLab.

Yes

No

Qualified by: \_\_\_\_\_

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

### Completeness of Operational Qualification (OQ)

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. 14 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:

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

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Deficiency:

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

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## Decagon Devices Authorized Representative

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

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

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

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

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

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