

Installation Qualification/Operational Qualification Protocols and Instructions

AquaLab 4TE, 4TEV
4TE DUO and 4TEV DUO



Table of Contents

Section 1	Introduction	Pg. 3
Section 2	Installation Qualification (IQ)	Pg. 5
Section 2.1	Equipment Identification	Pg. 5
Section 2.2	Receiving and Unpacking	Pg. 5
Section 2.3	Visual Inspection	Pg. 7
Section 2.4	Environmental Conditions	Pg. 8
Section 2.5	Power Up Test	Pg. 8
Section 3	Operational Qualification (OQ)	Pg. 10
Section 3.1	Hardware testing	Pg. 10
Section 3.2	System information	Pg. 10
Section 3.2.1	Sensor Verification	Pg. 10
Section 3.2.2	Equipment Familiarization	Pg. 12
Appendix 1	Training Record	Pg. 13
Appendix 2	Deficiencies and Corrective Actions	Pg. 14

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 Series 4 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.

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 Series 4 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.

☐ 4 ☐ 4TE ☐ 4TEV ☐ 4TE DUO ☐ 4TEV DUO

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	☐ Complete	☐ Not Complete	☐ N/A
Quick Start Guide	☐ Complete	☐ Not Complete	☐ N/A
User's Manual	☐ Complete	☐ Not Complete	☐ N/A
AquaLink 4 Software	☐ Complete	☐ Not Complete	☐ N/A
Certificate of Calibration	☐ Complete	☐ Not Complete	☐ N/A
Trial Verification Standards	☐ Complete	☐ Not Complete	☐ N/A
SDS Documents	☐ Complete	☐ Not Complete	☐ N/A
Power Cable	☐ Complete	☐ Not Complete	☐ N/A
USB Cable	☐ Complete	☐ Not Complete	☐ N/A
Filters (TEV only)	☐ Complete	☐ Not Complete	☐ N/A
Cleaning Kit	☐ Complete	☐ Not Complete	☐ N/A
LDPE Sample Cups and Lids	☐ Complete	☐ Not Complete	☐ N/A
DUO Quick Start Guide (DUO only)	☐ Complete	☐ Not Complete	☐ N/A

Remarks: ☐ N/A

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
_____	☐ Accepted	☐ Completed	_____	_____
_____	☐ Accepted	☐ Completed	_____	_____
_____	☐ Accepted	☐ Completed	_____	_____

			Date	Initials
_____	☐ Accepted	☐ Completed	_____	_____
_____	☐ Accepted	☐ Completed	_____	_____
_____	☐ Accepted	☐ 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.

AquaLab Instrument	☐ Satisfactory	☐ Not Satisfactory	☐ Accepted
Documentation	☐ Satisfactory	☐ Not Satisfactory	☐ Accepted
Other	☐ Satisfactory	☐ Not Satisfactory	☐ 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.

AquaLab Instrument	☐ Satisfactory	☐ Not Satisfactory	☐ N/A
Documentation	☐ Satisfactory	☐ Not Satisfactory	☐ N/A
Other	☐ Satisfactory	☐ Not Satisfactory	☐ N/A

Remarks: ☐ N/A

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	☐ Satisfactory	☐ Not Satisfactory
Adequate Power	☐ Satisfactory	☐ Not Satisfactory
Stable Surface	☐ Satisfactory	☐ Not Satisfactory
Temperature	☐ Satisfactory	☐ Not Satisfactory

Remarks: ☐ N/A

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 in the lower left corner of the back panel.

Instrument is powered upon switching on ☐ Yes ☐ No

Remarks: ☐ N/A

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 Series 4 line of instruments contain a chilled mirror dewpoint sensor for determining water activity. The 4TEV model contains both the chilled mirror sensor and 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 aw. The AquaLab dew point sensor will read each standard within +/- 0.003 aw of the stated value. The capacitance (volatiles) sensor will read each standard within +/- 0.015 aw of the stated value. To measure the water activity of the standards, follow the instructions in the User's Manual for taking a reading.

		Dew Point Sensor		Volatiles Sensor (TEV only)	
Standard @ 25°C	Lot #	$a_w \pm 0.003$	°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 ₂ O	1.00				
	1.00				

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 User's Manual to perform a linear offset. Repeat the verification process with fresh standards.

		Dew Point Sensor		Volatiles Sensor (TEV only)	
Standard @ 25°C	Lot #	$a_w \pm 0.003$	°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 ₂ O	1.00				
	1.00				

Water Activity Verification Standards Within Specification

☐ Yes

☐ No

☐ N/A

Remarks: ☐ N/A

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: _____

Corrective Action: ☐ Accepted Initial _____

Deficiency: _____

Corrective Action: ☐ Accepted Initial _____

Decagon Devices Authorized Representative

Name: _____

Function: _____

Company: _____

Date: _____

Signature: _____

Initials: _____