

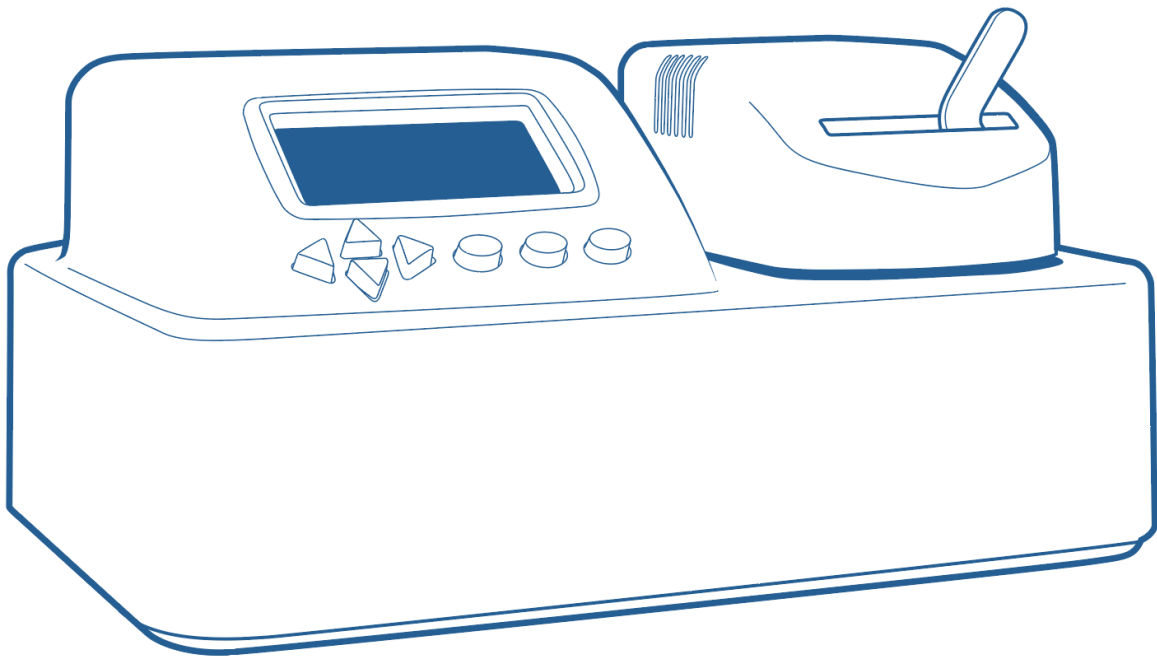


**METER**

# **AQUALAB® 4TE, 4TEV, 4TE DUO, 4TEV DUO**

**BENCHTOP WATER ACTIVITY**

**Installation Qualification + Operational Qualification  
Protocols and Instructions**





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# 1. Introduction

This Qualification protocol is solely intended to be used with new or relocated AQUALAB® 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 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 [metergroup.com/food](http://metergroup.com/food). 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, METER Group, Inc. USA 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 METER Group Inc., USA trained and authorized service personnel when ordered from a customer.

### Review and final qualification approval

Final approval for the qualification must 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 METER Group Inc., USA to learn about available training and seminars. Authorized support specialists perform the qualification services offered by METER Group, Inc. USA.

The IQ/OQ will not commence without acknowledgement of METER Group, Inc. USA’s Terms and Conditions, your signature, and date below. Please fill out this form as completely as possible.

- I agree to METER Group, Inc. USA’s Service terms, Payment terms, and Terms and Conditions  
For more information visit [metergroup.com/terms-conditions](http://metergroup.com/terms-conditions)

Signature

Date

Name/Title



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## 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 an AQUALAB 4 Water Activity instrument.

The purchased AQUALAB 4 Water Activity instrument undergoing qualification is located at:

#### Company Information

Company \_\_\_\_\_

Department \_\_\_\_\_

Street Address \_\_\_\_\_

City \_\_\_\_\_

State \_\_\_\_\_

Zip \_\_\_\_\_

#### Contact Information

First Name \_\_\_\_\_

Last Name \_\_\_\_\_

Email \_\_\_\_\_

Phone \_\_\_\_\_

#### 2.1 Equipment identification

Fill out this section after unpacking the AQUALAB 4 instrument and corresponding accessories.

Manufacturer METER Group, Inc. USA \_\_\_\_\_

Model \_\_\_\_\_

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

**METER Group, Inc. USA**  
**Authorized Representative**

Signature \_\_\_\_\_

Date \_\_\_\_\_

Name/Title \_\_\_\_\_

Initials \_\_\_\_\_



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## 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 packaging conditions**     Satisfactory                       Not Satisfactory

Notes & remarks about receiving and packing.

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### Checking Contents

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

AQUALAB® Instrument	<input checked="" type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Quick Start Guide	<input checked="" type="checkbox"/> Complete	<input type="checkbox"/> Not complete	<input type="checkbox"/> N/A
User's Manual	<input checked="" type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Certificate of Calibration	<input checked="" type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Trial Verification Standards	<input checked="" type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
SDS Documents	<input checked="" type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Power Cable	<input checked="" type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
USB Cable	<input checked="" type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Filters (TEV only)	<input checked="" type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
Cleaning Kit	<input checked="" type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
AQUALAB Qualification Kit	<input checked="" type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
LDPE Sample Cups and Lids	<input checked="" type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A
DUO Quick Start (DUO only)	<input checked="" type="checkbox"/> Complete	<input type="checkbox"/> Not Complete	<input type="checkbox"/> N/A

Notes & remarks from checking contents.

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## Order Completeness

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 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	_____	_____	_____
<input type="checkbox"/> Accepted	<input type="checkbox"/> Completed	_____	_____	_____
<input type="checkbox"/> Accepted	<input type="checkbox"/> Completed	_____	_____	_____
<input type="checkbox"/> Accepted	<input type="checkbox"/> Completed	_____	_____	_____

Notes & remarks about order completeness.

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## 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.

<b>AQUALAB® Instrument</b>	<input type="checkbox"/> Satisfactory	<input type="checkbox"/> Not Satisfactory	<input type="checkbox"/> Accepted
<b>Documentation</b>	<input type="checkbox"/> Satisfactory	<input type="checkbox"/> Not Satisfactory	<input type="checkbox"/> Accepted
<b>Other</b>	<input type="checkbox"/> Satisfactory	<input type="checkbox"/> Not Satisfactory	<input type="checkbox"/> Accepted

Notes & remarks about the visual inspection.

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Qualified by:

Signature	Date
Name/Title	Initials



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## 2.4 Environmental Conditions

Installation of the AQUALAB instrument includes placing the instrument on a level surface in a location where the temperature remains 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.

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

Notes & remarks about the visual inspection.

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**Qualified by:**

<b>Signature</b>	<b>Date</b>
<b>Name/Title</b>	<b>Initials</b>

## 2.5 Power Up Test

After finding a good location for the AQUALAB instrument, plug the power cord into the back of the unit and the other end into a standard AC outlet.

Instrument is powered upon switching on.  Yes  No

Notes & remarks about the visual inspection.

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## Completeness of Installation Qualification (IQ)

Installation Qualification was completed and documented according to the manufacturer's guidelines.

Yes                       No

Notes & remarks about the completeness of the Installation Qualification.

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### METER Group, Inc. USA Authorized Representative

Signature

Date

Name/Title

Initials

Installation Qualification was reviewed by the representative of the system owner.  
Reviewed and approved by:

Signature

Date

Name/Title

Initials





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## 3. Operational Qualification (OQ)

Description of tests that are to be executed for Operational Qualification of the AQUALAB® 4 to prove proper operation of the installed instrument.

### 3.1 Hardware Testing

The display is functional  Yes  No

The keypad is functional  Yes  No

Notes & remarks about the visual inspection.

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#### Qualified by:

<b>Signature</b>	<b>Date</b>
_____	_____
<b>Name/Title</b>	<b>Initials</b>
_____	_____

### 3.2 System Information

<b>Manufacturer</b> METER Group, Inc. USA	<b>Firmware Version</b>
_____	_____
<b>Model</b>	<b>Serial Number</b>
_____	_____

#### 3.2.1 System Information

The AQUALAB 4 line of instruments contain a chilled mirror dew point sensor for determining water activity. The AQUALAB 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, and 1.000<sub>a<sub>w</sub></sub>. The AQUALAB dew point sensor will read each standard within ± 0.003<sub>a<sub>w</sub></sub> of the stated value. The capacitance (volatiles) sensor will read each standard within ± 0.015<sub>a<sub>w</sub></sub> of the stated value. To measure the water activity of the standards, follow the instructions in the User Manual for taking a reading.

Standard @ 25 °C	Lot	Dew Point Sensor <i>a<sub>w</sub></i> ± 0.003	Temperature °C	Volatiles Sensor <i>a<sub>w</sub></i> ± 0.015 (4TEV only)	Temperature °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	1.000	_____	_____	_____	_____
	1.000	_____	_____	_____	_____



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Water Activity Standards are within specification.

Yes

No

Notes & remarks about the testing against the Water Activity Standards.

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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 $a_w \pm 0.003$	Temperature °C	Volatiles Sensor $a_w \pm 0.015$ (4TEV only)	Temperature °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	1.000				
	1.000				

Water Activity Standards are within specification.

Yes

No

Notes & remarks about the verification process and testing.

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Qualified by:

Signature

Date

Name/Title

Initials



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

Equipment familiarization and training was completed for the AQUALAB®  Yes  No

#### Qualified by:

<b>Signature</b>	_____	<b>Date</b>	_____
<b>Name/Title</b>	_____	<b>Initials</b>	_____

#### Completeness of Operational Qualification (OQ)

Operational Qualification was completed and documented according to manufacturers' guidelines.

Initial Qualification  Requalification

Qualification met the Vendor Acceptance Criteria  Yes  No

**NOTE: If any deficiencies are found, fill out the instructions for a corrective action on Page 13 of this document.**

#### METER Group, Inc. USA Authorized Representative

<b>Signature</b>	_____	<b>Date</b>	_____
<b>Name/Title</b>	_____	<b>Initials</b>	_____

Operational Qualification was reviewed by the representative of the system owner.  
Reviewed and approved by:

<b>Signature</b>	_____	<b>Date</b>	_____
<b>Name/Title</b>	_____	<b>Initials</b>	_____



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## ii. Appendix: 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 METER Group, Inc. USA to learn about available training and seminars.

Authorized support specialists perform the qualification services offered by METER Group, Inc. USA.

Name	Date
Name	Date
Name	Date
Name	Date
Name	Date
Name	Date
Name	Date
Name	Date
Name	Date
Name	Date
Name	Date
Name	Date
Name	Date
Name	Date
Name	Date

### METER Group, Inc. USA Authorized Representative

Signature	Date
Name/Title	Initials

Operational Qualification was reviewed by the representative of the system owner.  
Reviewed and approved by:

Signature	Date
Name/Title	Initials



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## iii. Appendix: Deficiencies + 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.

### Deficiency 1

Explain the deficiency.

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Corrective Action

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The deficiency was reviewed and corrective action was taken and accepted.  Accepted

### Deficiency 2

Explain the deficiency.

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Corrective Action

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The deficiency was reviewed and corrective action was taken and accepted.  Accepted

**METER Group, Inc. USA**  
**Authorized Representative**

Signature \_\_\_\_\_

Date \_\_\_\_\_

Name/Title \_\_\_\_\_

Initials \_\_\_\_\_