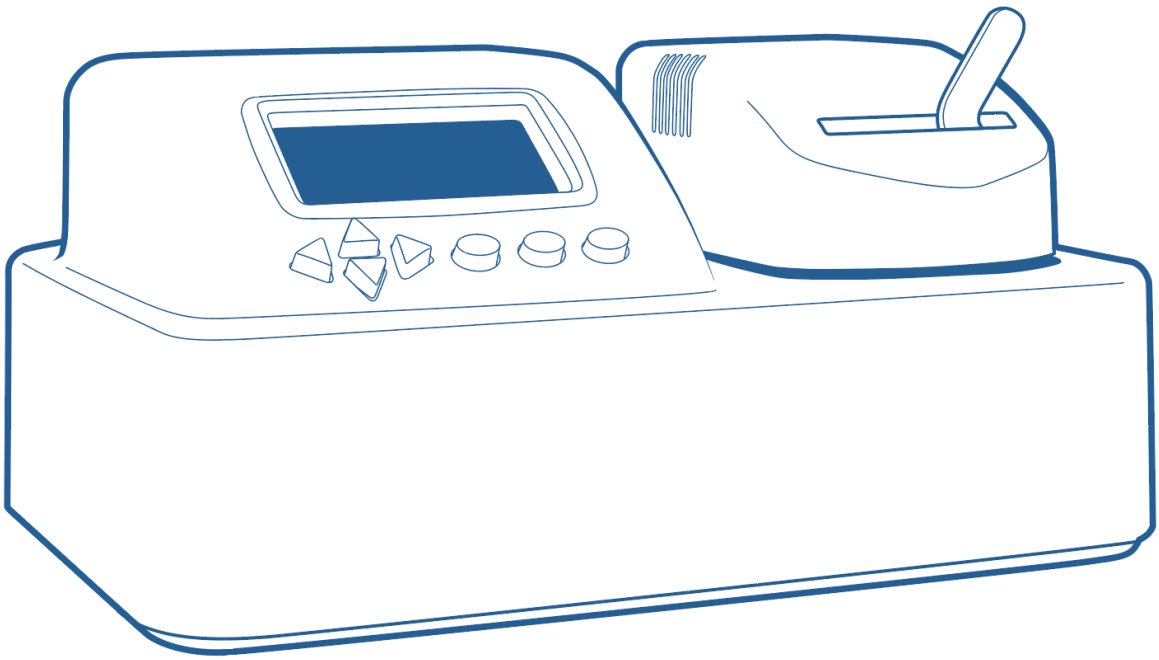
METER

# AQUALAB® TDL/TDL 2

## BENCHTOP WATER ACTIVITY METER

**Installation Qualification and Operational Qualification (IQ/OQ) Protocols and Instructions**



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# TABLE OF CONTENTS



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# 1. Introduction

This qualification protocol is solely intended to be used with new or relocated AQUALAB® TDL or TDL 2 Water Activity Meters. It is written to assist the user in validation of predetermined specifications. The use of this document does not replace the need for the AQUALAB TDL User Manual.

Information within the user 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/TDL-support. 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 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 authorized METER Group, Inc. USA service specialists 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 predetermined 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 the sole 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.

Please identify which instrument this IQ/OQ applies to by marking either AQUALAB TDL or TDL 2.

☐ AQUALAB TDL ☐ AQUALAB TDL 2

The IQ/OQ will not commence without acknowledgement of METER Group, Inc. USA *Terms and Conditions*, signature, and date below. Please fill out this form as completely as possible. Please refer to metergroup.com/terms-conditions for details.

☐ I agree to the METER Group, Inc. USA Service terms, Payment terms, and Terms and Conditions.

**Signature** _____ **Date** _____

**Name/Title** _____

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# 2. Installation Qualification (IQ)

The Installation Qualification (IQ) protocols described in this section are dedicated to initial qualification and/or to requalification. IQ tests should be performed in the following instances:

1. When the system is installed
2. When the system is moved to a new location
3. Prior to running Operational Qualification (OQ) tests

This section describes the procedure for receiving, unpacking, and installing an AQUALAB TDL/TDL 2 Water Activity Meter.

## 2.1 Initial Qualification and Requalification

Fill out the company information below after unpacking the AQUALAB TDL/TDL 2 Water Activity Meter and corresponding accessories.

### Company Information

**Company**

**Department**

**Street Address**

**City** **State** **Zip**

### Contact Information

**First Name** **Last Name**

**Email** **Phone**

## 2.2 Equipment Identification

Fill out this section after unpacking the AQUALAB TDL/TDL 2 Water Activity Meter 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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## 2.3 Receiving and Unpacking

Fill out the information below, verifying the condition of the external packaging (make note if any damage during shipment in a way might have damaged the internal package content).

**External packaging conditions** ☐ Satisfactory ☐ Not Satisfactory

Notes and remarks about receiving and packaging.

## Checking Contents

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

| | | | |
|---|---|---|---|
| **AQUALAB TDL Benchtop Unit** | ☐ Complete | ☐ Not Complete | ☐ NA |
| **Quick Start Guide** | ☐ Complete | ☐ Not complete | ☐ NA |
| **User Manual** | ☐ Complete | ☐ Not Complete | ☐ NA |
| **Certificate of Calibration** | ☐ Complete | ☐ Not Complete | ☐ NA |
| **Trial Verification Standards** | ☐ Complete | ☐ Not Complete | ☐ NA |
| **SDS Documents** | ☐ Complete | ☐ Not Complete | ☐ NA |
| **Power Cable** | ☐ Complete | ☐ Not Complete | ☐ NA |
| **USB Cable** | ☐ Complete | ☐ Not Complete | ☐ NA |
| **Cleaning Kit** | ☐ Complete | ☐ Not Complete | ☐ NA |
| **AQUALAB Qualification Kit** | ☐ Complete | ☐ Not Complete | ☐ NA |
| **LDPE Sample Cups and Lids** | ☐ Complete | ☐ Not Complete | ☐ NA |

Notes and 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 meter 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 |
|---|---|---|---|---|
| ☐ Accepted | ☐ Completed | | | |
| ☐ Accepted | ☐ Completed | | | |
| ☐ Accepted | ☐ Completed | | | |
| ☐ Accepted | ☐ Completed | | | |
| ☐ Accepted | ☐ Completed | | | |
| ☐ Accepted | ☐ Completed | | | |

Notes and remarks about order completeness.

## 2.4 Visual Inspection

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

| | | | |
|---|---|---|---|
| **AQUALAB TDL / TDL 2 Meter** | ☐ Satisfactory | ☐ Not Satisfactory | ☐ Accepted |
| **Documentation** | ☐ Satisfactory | ☐ Not Satisfactory | ☐ Accepted |
| **Other** | ☐ Satisfactory | ☐ Not Satisfactory | ☐ Accepted |

Notes and remarks about the visual inspection.

**Qualified by:**

**Signature** **Date**

**Name/Title** **Initials**

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## 2.5 Environmental Conditions

The AQUALAB TDL / TDL 2 Water Activity Meter should be installed 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.

| | | | |
|---|---|---|---|
| **Location** | ☐ Satisfactory | ☐ Not Satisfactory | ☐ Accepted |
| **Adequate Power** | ☐ Satisfactory | ☐ Not Satisfactory | ☐ Accepted |
| **Stable Surface** | ☐ Satisfactory | ☐ Not Satisfactory | ☐ Accepted |
| **Temperature** | ☐ Satisfactory | ☐ Not Satisfactory | ☐ Accepted |

Notes and remarks about the visual inspection.

**Qualified by:**

**Signature** _____ **Date** _____

**Name/Title** _____ **Initials** _____

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## 2.6 Power-Up Test

After finding a suitable location for the AQUALAB TDL/TDL 2, plug the power cord into the back of the unit and the other end into a standard AC outlet.

**AQUALAB TDL /TDL 2 is powered upon switching on.** ☐ Yes ☐ No

Notes and remarks about the power-up test.

## Completeness of Installation Qualification (IQ)

**IQ was completed and documented according to METER guidelines.** ☐ Yes ☐ No

Notes and remarks about the completeness of the IQ.

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

**Signature** **Date**

**Name/Title** **Initials**

IQ was reviewed by the representative of the system owner.

**Qualified by:**

**Signature** **Date**

**Name/Title** **Initials**

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# 3. Operational Qualification (OQ)

This section contains descriptions of tests that are to be executed for the Operational Qualification (OQ) of the AQUALAB TDL/TDL 2 Water Activity Meter to prove proper operation.

## 3.1 Hardware Testing

| | | |
|---|---|---|
| **The display is functional** | ☐ Yes | ☐ No |
| **The keypad is functional** | ☐ Yes | ☐ No |

Notes and remarks about the visual inspection.

**Qualified by:**

**Signature** _____ **Date** _____

**Name/Title** _____ **Initials** _____

## 3.2 System Information

**Manufacturer** METER Group, Inc. USA **Firmware Version** _____

**Model** _____ **Serial Number** _____

### 3.2.1 Sensor Verification

The AQUALAB TDL/TDL 2 Water Activity Meter utilizes a tunable diode laser to determine water activity. The performance of the laser 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 $a_w$, 0.500 $a_w$, 0.760 $a_w$, 1.000 $a_w$. The AQUALAB TDL will read each standard within ± 0.005 $a_w$ of the stated value. To measure the water activity of the standards, follow the instructions for taking a reading in the user manual.

| Standard @ 25 ˚C | | Lot | $a_w$ ± 0.005 | Tunable Diode Laser ˚C |
|---|---|---|---|---|
| 13.41m LiCl | 0.250 | | | |
| | 0.250 | | | |
| 8.57m LiCl | 0.500 | | | |
| | 0.500 | | | |
| 6.0m NaCl | 0.760 | | | |
| | 0.760 | | | |
| Steam Distilled $H_20$ | 1.000 | | | |
| | 1.000 | | | |

**Water Activity Standards are within specification.** ☐ Yes ☐ No

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Notes and remarks about the verification standards measurement inspection.

If verification standards are out of specification, clean the AQUALAB TDL/TDL 2 and follow the procedure in the user manual to perform a linear offset. Repeat the verification process with fresh standards.

| Standard at ˚C | | Lot | $a_w$ ± 0.005 | Tunable Diode Laser ˚C |
|---|---|---|---|---|
| 13.41m LiCl | 0.250 | | | |
| | 0.250 | | | |
| 8.57m LiCl | 0.500 | | | |
| | 0.500 | | | |
| 6.0m NaCl | 0.760 | | | |
| | 0.760 | | | |
| Steam Distilled $H_20$ | 1.000 | | | |
| | 1.000 | | | |

**Water Activity Standards are within specification.** ☐ Yes ☐ No

Notes and remarks about the verification standards measurement inspection.

**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 TDL/TDL 2 Water Activity Meter. Product familiarization covers instruction on basic operations, functionality, and meter features, and routine maintenance, including cleaning procedures.

**Equipment familiarization and training was completed for the AQUALAB TDL.** ☐ Yes ☐ No

**Qualified by:**

**Signature** _____ **Date** _____

**Name/Title** _____ **Initials** _____

### Completeness of Operational Qualification (OQ)

**OQ was completed and documented according to METER guidelines.** ☐ IQ ☐ 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**

**Signature** _____ **Date** _____

**Name/Title** _____ **Initials** _____

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

**Qualified by:**

**Signature** _____ **Date** _____

**Name/Title** _____ **Initials** _____

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# Appendix A: Training Record

This training record is for instruction in basic operation, functionality, meter 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 |

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

| Signature | Date |
|---|---|
| Name/Title | Initials |

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

**Qualified by:**

| Signature | Date |
|---|---|
| Name/Title | Initials |

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# Appendix B: Deficiencies and Corrective Actions

If any deficiencies were found, a corrective action will be opened. Once acceptable results are obtained, the results of the corrective action are accepted by checking the Accepted box below.

## Deficiency 1

**Explain the deficiency.**

**Corrective Action**

**The deficiency was reviewed, and corrective action was taken and accepted.** ☐ Accepted

## Deficiency 2

**Explain the deficiency.**

**Corrective Action**

**The deficiency was reviewed, and corrective action was taken and accepted.** ☐ Accepted

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

**Signature** **Date**

**Name/Title** **Initials**

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