

Decagon Devices, Inc.

Annual Calibration Operating Procedure

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1. AquaLab: Annual Calibration and Validation Service

1.1 Purpose

The purpose of the Annual Calibration Service is to validate and document that all AquaLab models perform within Decagon operating specifications. All AquaLabs will perform to Decagon specifications before they are returned to the customer, thus ensuring accurate product analysis.

1.2 Annual Calibration and Validation Service Overview

Each AquaLab enrolled in the Annual Calibration and Validation Service will undergo the following procedure:

1. Calibration Service Order Recorded
2. Loaner Unit Prepared and Shipped (if requested)
3. Customers Unit Received
4. Customers Unit Factory Inspected, Cleaned, Repaired (if necessary) & Calibrated
5. Customer Unit Quality Control Certified and Documented
6. Customer Unit Returned
7. Loaner Unit Received and Checked

1.3 Annual Calibration and Validation Service Procedure

1.3.1 Calibration Service Order Recorded

The customer order will be recorded in M3 and a return material authorization (RMA) will be sent to the customer.

1.3.2 Loaner Unit Prepared and Shipped (if requested)

A loaner request form is completed by the customer and returned to Decagon. Upon availability of a loaner unit, a convenient shipment date will be scheduled with the customer. The calibration of the loaner unit will be verified before shipment to the customer. A calibrated loaner unit will be taken to Shipping/Receiving with the appropriate shipping paperwork.

1.3.3 Customers Unit Received

The customer unit will be received and recorded into the M3. The customer unit will be taken to the Repair Department.

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1.3.4 Customers Unit Factory Inspected, Cleaned & Calibrated

The unit will be visually inspected. The instrument is thoroughly inspected for any damage or excessive wear. The results are recorded in the RMAREC in M3. The unit is cleaned. The instrument will be repaired if necessary to pass calibration. A Calibration text file will be started for the customer unit. The unit is then calibrated using a 4-point linear adjustment (if necessary). A 4-point verification procedure is run to ensure the accuracy and repeatability of the instrument. All calibration and verification data is recorded. The customer unit will be sent to Quality Control for final inspection and documentation.

1.3.5 Customer Unit Quality Control Certified and Documented

The unit will be visually inspected to guarantee that all parts are properly assembled and in good working condition. A Calibration Certificate will be completed for the customer unit. A Calibration Sticker will be completed by the Repair Technician and applied to the front panel of the AquaLab. The customer unit will be taken to Shipping/Receiving with the Calibration Certificate and appropriate shipping paperwork for return to the customer.

1.3.6 Customer Unit Returned

The customer unit will be prepared for return to the customer. The Calibration Certificate will be included with the customer AquaLab unit.

1.3.7 Loaner Unit Received and Checked

The loaner unit will be received and recorded in M3. The loaner unit will be taken to the Repair Department. The loaner unit will be visually inspected for any damage. The loaner unit will be cleaned and calibrated. The loaner unit will be stored in inventory until future need. An invoice will be issued to the customer for the Annual Factory Calibration Service and loaner if applicable.