

# Pipette Tracker Pro™ Validation Toolkit



The Pipette Tracker Pro Validation Toolkit is available to assist in your validation procedure. The toolkit provides the appropriate documentation and test procedures required to complete an IQ/OQ (Installation Qualification and Operation Qualification) validation of the software. The documentation and test procedures related to IQ/OQ include the following:

## Installation Qualification

### Hardware Verification

Checklist with required specifications (e.g., RAM, hard disk space).

### Software Verification

Checklist with required specifications (e.g., operating system, version numbers, location of install media).

### System Documentation

Checklist that lists all relevant manuals, verifies that the manuals are available and records where they are located.

### Installation Protocol

Complete installation directions.

### File Verification

Checklist of filenames, sizes and dates.

### Domain Verification

Verification of Logins and User Rights.

### Installation Qualification Verification Summary

Yes/No checklist to verify that the above tests were performed and that the results are included.

## Operational Qualification

### System Setup Options

Verify the settings and instruments selected for use in the Qualification tests.

### Method/Test Plan Validation and Versioning

Verify the validation of a method and test plan, the recording of the validated status and incremental versioning of a method and test plan.

### Calibration Verification

Using the pre-defined method, actual results will be compared against expected results.

### Verify Manual Data calculation

Verify calculations by confirming that entering data manually produces correct and accurate results.

### Report Verification

Verify that the reports (and database) provide accurate results (input and output) that reflect the data entered by the user and the calculated results.

### Print Validation

Print reports and verify that the data on the printout reports is correct.

### Operational Qualification Verification Summary

Yes/No checklist to verify that the above tests were performed and that the results are included.

A Deficiency Report and a Validation Certification document complete the package.  
The Pipette Tracker Pro Validation Toolkit is a valuable assistant for any laboratory that is required to perform IQ and OQ on their new Pipette Tracker Pro installation.

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