

Calibration - Easing the Burden of ISO/IEC 17025 Compliance

Like any laboratory instrument, regular testing and calibration of pipettes is fundamental to ensuring the quality and integrity of laboratory testing results. Using an uncalibrated pipette for liquid handling can compromise test results, resulting in unnecessary costs for the laboratory due to time spent on problem identification, investigation and resolution.

ISO 17025, “General requirements for the competence of testing and calibration laboratories”, is an international standard that specifies all of the requirements that laboratories have to meet when carrying out testing and calibration procedures.

In this article, we will look at how Pipette Tracker Pro from Labtronics Inc. assists laboratories in fulfilling the requirements of ISO 17025 “to demonstrate that they operate a management system, are technically competent and are able to generate technically valid results” when they are testing and calibrating their pipettes.

Pipette Calibration - What is the risk?

A study, conducted several years ago, determined that over 2/3 of the pipettes being used in laboratories failed to meet required standards for precision and accuracy. A survey conducted by Labtronics Inc. determined that on average 36% of regularly calibrated pipettes submitted to calibration service providers failed the “as found” test - a test that is typically only performed on pipettes that appear to be in good working order.

Those results indicate that at any given time, there are pipettes in use in your laboratory that are not meeting requirements for accuracy and precision. Under those conditions, any analysis that involves liquid handling runs a very significant risk that the test results will be compromised by the pipette. (For this reason Labtronics has added a “Quick Check”

... over 2/3 of the pipettes being used in laboratories failed to meet required standards for precision and accuracy.



function to their Pipette Tracker software. Quick Check can be run on a daily basis to verify that your pipettes are performing as expected.)

Pipette Calibration - Minimizing Risk

A well-managed program for regular and frequent testing and calibration of pipettes is the most effective way for a laboratory to minimize the risk of compromising test results due to the use of uncalibrated pipettes.

Ideally this testing and calibration will be carried out under regular laboratory working conditions, as the accuracy and precision of a pipette can be affected by environmental factors such as temperature, barometric pressure and relative humidity. Unfortunately, the amount of time and effort required to meet the stringent requirements of ISO 17025 can discourage laboratories from implementing a program of frequent testing and calibration.

Fortunately, a pipette calibration program like Pipette Tracker Pro provides a level of automation that makes it easier for laboratories to follow a regular testing and calibration program that fully meets the requirements of ISO 17025.

Pipette Tracker Pro and ISO 17025

ISO 17025 considers the factors that can influence “the correctness and reliability of the tests and/or calibrations performed by a laboratory”.

These factors include:

- human factors
- accommodation and environmental conditions
- test and calibration methods and method validation
- equipment
- measurement traceability
- sampling
- the handling of test and calibration items

Pipette Tracker Pro helps laboratories to minimize the impact of these factors on the reliability of pipette calibrations, while reducing the administrative workload involved in managing the technical requirements of their calibration program.

To understand how that works on a day-to-day basis, let's consider some specific sections of the ISO 17025 standard.



Qualified Personnel

Section 5.2.1 of ISO 17025

Requires that only competent operators perform testing and calibration.

- Pipette Tracker Pro uses a User ID and password to control access to calibration methods.
- Users can be automatically blocked from accessing a calibration procedure that they are not qualified to execute.

Environmental Conditions

Section 5.3.2 of ISO 17025

Requires monitoring, controlling and recording of environmental conditions that can influence testing or calibration results.

- Temperature, barometric pressure and relative humidity have a significant influence on pipette calibration.
- ISO 8655-6 “Gravimetric methods for the determination of measurement error” requires in Section 7.1.4 that environmental parameters be recorded for the weighing procedure.
- Section 8.3 of the same document provides the calculations that apply this data to calculate the conversion of the corrected mass to volume, known as the “Z-factor”.
- Pipette Tracker Pro provides three different ways for recording these environmental factors - either by use of a constant value or by entering a value at run-time or by automatically collecting the environmental data from any measuring devices that are equipped with RS232 or TCP/IP Ethernet ports.
- Pipette Tracker Pro automatically uses that data to perform mass-to-volume calculations, in accordance with ISO 8655-6, as sample results arrive at the computer from the balance.

Method & Test Plan Validation

Section 5.4.1 of ISO 17025

Requires that only appropriate methods and procedures are used for testing and calibration.

- Pipette Tracker Pro meets GLP and ISO/EN requirements and conforms to the procedures. recognized by ISO/EN 8655, 17025, ASTM E1154.
- Users can develop, validate and assign a version number to their methods or test plans.
- As new versions are created and validated, previous versions are archived for easy reference.
- Pipette Tracker Pro prevents users from using non-validated methods or test plans.

Calculate Uncertainty

Section 5.4.6 of ISO 17025

Requires an estimate of the uncertainty of measurement for all calibrations.

- Pipette Tracker Pro automatically calculates the expanded uncertainty of measurement associated with the mean volume, as described in ISO/TR 20461:200(E) "Determination of uncertainty for volume measurements made using the gravimetric method". The expanded uncertainty of the mean is stored along with the calibration data and added to reports.

Traceability

Section 5.6.1 of ISO 17025

Requires a program and procedure for ensuring that only calibrated equipment is used for all tests and calibrations.

- Pipette Tracker Pro supports scheduling and calibration tests for other devices such as balances, environmental monitors, etc.
- Information including the serial number, manufacturer, device name and device location is permanently recorded into the database for each device.

- Pipette Tracker Pro automatically schedules calibration testing for all pipettes and devices.
- Maintains a complete calibration history for all pipettes and devices.
- Devices or Standards that are calibrated externally can be included in the system, along with their certificates of calibration attached as an electronic file.

Quality Control

Section 5.6.1 of ISO 17025

Requires that laboratories have procedures for monitoring the validity of tests and calibrations.

- Real-time interactive graphing of data quickly identifies when samples fall outside accuracy limits.
- Notification when maintenance tasks fall outside their recommended action limits.
- Pipette Tracker Pro automatically calculates all of the statistical results for pipette calibrations using formulae and tables provided in ISO 8655-6.
- All test results are saved for each device providing a full calibration history in the system, which can be accessed at any time.

Reporting

Section 5.6.1 of ISO 17025

Requires clear, accurate reporting of results for all tests and calibrations.

- Pipette Tracker Pro standard reports include worklists, inventory lists, summary and detail calibration reports, device calibration history reports, test plan and method documentation, etc.
- Reports can be modified to suit specific requirements.
- Reports can be previewed, printed, generated in Excel®, PDF, Text, Word®, HTML and TIF formats.

Conclusion

A frequent and regular calibration program for pipettes is essential to ensuring the quality of any preparation procedures or analyses that involve liquid handling. However, implementing and executing a comprehensive calibration program can be a significant undertaking for a laboratory if it is done manually.

Pipette Tracker Pro provides automated execution and documentation capabilities that ease the burden for laboratories that want to implement a calibration program that is in full compliance with the requirements of ISO 17025.

Laboratories can keep their focus on their analytical work with full confidence that their pipette calibration program, driven by Pipette Tracker Pro, is fully supporting the quality of results that they and their clients demand.

Learn more about Pipette Tracker Pro at
<http://www.labtronics.com>.

References

ASTM International. Standard Specification for Piston- or Plunger-Operated Volumetric Apparatus. ASTM E1154. ASTM International, West Conshohocken, Pennsylvania, 1997.

Connors, M. and Curtis, R. H. Pipetting error: A real problem with a simple solution. Part 2, American Laboratory News (Dec 1999) 31(25):12.

How are your pipettes performing today?
http://www.labtronics.com/DI/resources/ar_t138_pt.asp

ISO. Piston-Operated Volumetric Apparatus: Part 6: Gravimetric methods for the determination

of measurement error. ISO 8655-6. ISO, Geneva, Switzerland, 2002

ISO/IEC General requirements for the competence of testing and calibration laboratories. ISO/IEC 17025:2005(E) ISO, Geneva, Switzerland, 2005

ISO/TR Determination of uncertainty for volume measurements made using the gravimetric method. ISO/TR 20461:2000(E) ISO, Geneva, Switzerland, 2000