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# Pipette Calibration and Standards

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## Abstract

Pipetting results are critically depending on the maintenance and calibration of the pipette. The most import International Stardardization Organization (ISO) standards related to pipetting are ISO8655 and ISO17025 and these standards set the guidelines how and in which conditions calibration should be performed. Regular cleaning and maintenance according to guidelines also prolongs the lifetime of the pipette.

**Find out more:** www.sartorius.com/en/products/pipetting-and-dispensing

# Introduction

Taking proper care of your pipettes is one of the most critical factors affecting the quality of your work. Pipette performance can deteriorate over time due to drift of calibration, leakage, part wear or contamination. Although cleaning and maintenance help to eliminate these sources of incorrect dispensing, the accuracy and precision of pipettes must be checked at regular intervals. This application note outlines what is involved in calibration and maintenance and the various standards and concepts associated with these procedures.

**What is Calibration and Preventive Maintenance?**
All pipette manufacturers recommend preventive maintenance and calibration programs to maintain reliable pipetting results and to maximize the lifetime of the pipette.

Pipette calibration is a fundamental part of Good Laboratory Practice (GLP) and quality systems, and must be considered as a vital part of any laboratory workflows where precise volumes of fluids need to be transferred. Pipette performance is measured as accuracy and precision, meaning how close the dispensed volumes are to the target and how close the results are to each other.

Calibration is predominantly undertaken by gravimetric analysis of the dispensed volumes and the results are compared against specifications provided by manufacturer or defined by ISO 8655 standard. Calibration should always be done for the pipette-tip combination used in the actual lab work and it is important to keep in mind that pipette manufacturer's specifications are valid only in combination with the manufacturer's tips.

Preventive maintenance consists of cleaning and greasing the piston and tip cone of the pipette and replacement of worn parts to guarantee long lifetime and accurate and precise results. Just like any other devices, pipettes may need repairing from time to time. It is usually worth investing in repairs rather than simply disposing of pipettes. Professional service teams can supply spare parts and repair services for any make and model, or an offer for replacements if repairing the pipettes is deemed uneconomical.

Pipette maintenance consists of:
- Cleaning and decontamination
- Opening, cleaning and greasing pistons, tip cones and any associated seals
- Checking the operation of the pipette for any jams, leakages or other faults

Pipette calibration consists of:
- Checking the accuracy and precision of the pipette using 4 – 10 measurements per volume at 1 – 4 different volumes (usually selected from minimum or 10%, 50%, and 100% of the nominal volume of the pipette)
- Calculation of results and comparison against pass/fail limits
- Issuing of a calibration certificate.

For maintenance a maximum interval of one year is recommended, with calibration being performed a minimum of once per year, but ideally every 3 – 6 months.

**Accreditation and Quality Systems:**
Different quality systems and industry requirements pose different demands for the control of work quality. Most laboratory work is done under various standards such as ISO 9000-series, ISO 17025 accreditation and Good Laboratory Practice (GLP) guidelines. All have a central theme of controlling the performance of instruments in use with a regular and documented program.

A reference often used in the laboratory work is GLP guidelines which dictate that precision tools like pipettes must be maintained and calibrated at regular intervals by a competent body:

"Apparatus used in a study should be periodically inspected, cleaned, maintained, and calibrated according to Standard Operating Procedures. Records of these activities should be maintained. Calibration should, where appropriate, be traceable to national or international standards of measurement."

Good Laboratory Practice (OECD 2005)

**What is ISO 8655?**
The International Standard ISO 8655 specifies the requirements for pipettes and pipette calibration laboratories, providing detailed guidance for the respective environmental conditions, procedures, and equipment. For example pipette calibration in accordance with ISO 8655 is performed using a reliable measurement equipment, such as a high-quality balance, in a carefully controlled environment without any drafts or vibrations.

ISO 8655 sets guidelines for:
- Characteristics, features, and marking of pipettes
- Responsibilities of pipette users and manufacturers
- Pipette testing equipment, conditions, and procedures

**What is ISO 17025?**
The ISO 17025 standard specifies the general requirements for the competence of calibration laboratories to carry out tests and calibrations. A pipette calibration laboratory with ISO 17025 accreditation provides the highest level of reliability and confidence in pipette calibration, as proven by the uncertainty of measurement provided for each calibration when required. Achieving and maintaining ISO 17025 accreditation requires extensive testing of personnel, procedures, and facilities, with the accreditation reviewed in an annual audit by the relevant body.

Using an ISO17025 accredited calibration laboratory is essential for all laboratories where quality and reliability of results are important as it guarantees the following:

- All measurements are traceable to national and international methods and standards
- The uncertainty of both the pipette and the measuring process are taken into account
- You can be sure exactly which part of the uncertainty is due to pipette performance and which is due to the uncertainty of measuring process, for example the balance used
- The laboratory issuing the certificate has been approved by independent experts and authorities (e.g. DaKKs, UKAS, A-Class, COFRAC, UKAS, JCSS, FINAS, or Rosstandart).

All European accreditation bodies are members of the European Cooperation for Accreditation (EA) and signatories to the Multilateral Recognition Agreements (MRA). European Cooperation for Accreditation (EA) is recognized body of International Laboratory Accreditation Cooperation (ILAC), linking the European accreditation bodies to Inter American Accreditation Cooperation (IAAC), Asia Pacific Laboratory Accreditation Coopertion Inc (APLAC), Arab Accreditation Cooperation (ARAC), and African Accreditation Cooperation (AFRAC). This means that accredited pipette calibration certificate from one of the calibration laboratory part of the Multilateral Recognition Agreement (MRA) is widely accepted around the world.

## Conclusion

Laboratories using pipettes should be familiar with the relevant standards as well as maintenance & calibration tasks associated with pipettes. Pipette calibration and maintenance should be performed regularly, at minimum annually or more often. The basic requirement for all laboratories to follow is the ISO 8655 standard, which outlines the calibration of pipettes and other piston-operated liquid handling instruments. For accredited laboratories and laboratories requiring traceability of measurement, the golden standard is ISO 17025, which provides the best possible confidence in results and quality of work.

Do you need support in pipette service and maintenance? Contact Sartorius for a Pipetting Academy training, go to www.sartorius.com/pipetting-academy

## References

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