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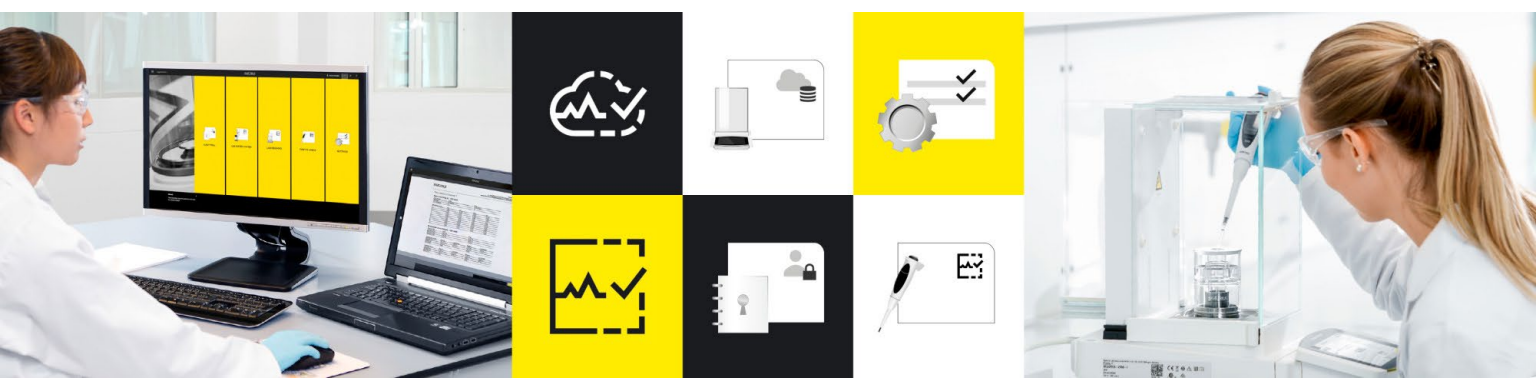
Pipette Calibration Resource Guide

How to effectively perform, manage, and maintain ISO-compliant pipette calibrations



The Ingenix Suite

Bolster data integrity, lab efficiency, and compliance with data and fleet management software

Tracking tools and equipment can consume substantial time and resources in the lab. Regulatory compliance and collaboratively used equipment add an additional level of complexity. Many labs face the problem of mounting paperwork and data management to ensure they meet data integrity, and compliance requirements necessary for continued operations. In addition, when equipment is shared between multiple laboratory groups, centralized reports are needed.

Together, this places considerable work on laboratory staff. Ingenix Suite by Sartorius is designed to address this problem by providing a central, digital database for storage of compliance and routine calibration data and measurement readouts for easy access and organization. The Ingenix Suite Fleet Manager is a platform now enhanced by the newly introduced Ingenix Suite Advanced Pipette Calibration Module.

Utilizing the advanced pipette calibration module

The Advanced Pipette Calibration Module, which is ISO 8655:2022 compliant, offers improved digital calibration management for greater efficiency in the lab. The module can be used with pipettes from any other brand in addition to Sartorius©. The Advanced Pipette Calibration Module can manage your pipette calibration data automatically, organizing your readouts and reports, keeping the lab compliant with current regulations, and scheduling calibration reminders ahead of time, preventing a lapse in calibration assessments. Ingenix Suite can also be used in conjunction with Laboratory Information Management System (LIMS) or as a standalone platform.

Keeping pipette work compliant with Ingenix suite

Two modules complete the Ingenix suite for pipettes. The Pipette Check Module enables a convenient means to check the performance of your pipettes during the daily routine, before sensitive applications. The GxP Compliance Module can be used to track overall system- and instrument-level events around all weighing measurements and balance or pipette calibrations. It includes the full audit trail of all audit relevant events and provides the ability to review and approve digital reports, according to the 21 CFR part 11 and EMA Annex 11 needs.

Why choose Ingenix suite

Using the Ingenix suite modules together offers maximum benefits. Streamlined digital management expedites categorization and facilitation of calibration and compliance documents and identifies equipment problems. Ingenix Software also makes inter-lab sharing of equipment and data easier by creating one localized file repository for documents associated with a piece of equipment. Increase the efficiency, performance, and reliability of your data by utilizing Ingenix Suite to track calibration and compliance documents for pipettes and balances.

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Protecting Data Integrity—Evaluating Instruments in the Lab

Compliance with data integrity regulations begins with all data-generating instruments and extends throughout lab systems—evaluate your instruments and procedures with this checklist

What does data integrity mean for labs?

In the current age of digital transformation, improving operational efficiencies, streamlining workflows, and eliminating paper requires connected workflows with fully integrated equipment and systems. Maintaining data integrity forms a primary concern, particularly as auditors increasingly call for fully electronic data handling to improve security, contributing to the digitalization trend.

An expanding regulatory network affects an increasing number of labs as they connect to the highly regulated life science, biotech, pharmaceutical, and food industries, such as the fine chemical companies supplying pharmaceutical and biotech product pipelines. Non-compliance can result in shutdowns, product recalls, or delayed drug approvals, is costly, and places the organization's reputation at risk. The challenge of remaining compliant centers the need for improved data handling.

Beyond avoiding regulatory violations, data integrity measures that ensure the correct recording and handling of data increase workflow automation, minimizing errors common to manual or hybrid data entry, like transcription errors and data breaks. They increase reproducibility, efficiency, and time and cost savings, impacting important timelines like discovery time and time to market. Eliminating the need to repeat work because of inaccurate data or reporting helps organizations remain competitive.

Protecting data integrity

Compliance with FDA 21 Part 11 CFR guidelines, and the EU Annex 11 in Europe, requires supporting features for all electronic instruments in the lab within either native OEM software or third-party bridging software. Features supporting compliance include audit trails, access control with personalized user and role management, electronic signatures, data backup, and safe data transfer options for laboratory information management systems (LIMS), electronic lab notebooks (ELN), or other system integrations.

Most violations of FDA 21 Part 11 CFR guidelines, as indicated through FDA warning letters, arise from data integrity issues (79 percent). The majority of these involve access and role management, missing or incomplete audit trails, improper data handling, or failure to follow procedures. Personalized user accounts that limit access to functions specific to their role are required to meet user traceability and access control guidelines. A common violation arises from the use of a universal account, frequently with administrative permissions that allow users to change or manipulate data. Maintaining complete audit trails is critical and requires backups of all data generated, regardless of whether the data are correct. Complete traceability requires documentation of every instrument-related event, including adding new users or changing operational settings. Nonconformance to audits also frequently arises from transcription errors that occur when data are entered manually into LIMS and ELN.

Beginning with a top-down, systems view of operations helps ensure compliance is maintained across the lab through identifying gaps in data integrity measures and fostering a quality culture centered on compliance. Focusing primarily on specific instruments or software is likely to result in missing other key systems or problems where systems interface. The top-down approach ensures start-to-end traceability by first identifying all GxP-relevant

processes in the lab, then sub-processes, followed by individual activities with standalone systems and instruments. While analytical equipment is most often top-of-mind when considering data integrity measures, a detailed examination of processes typically identifies supporting lab equipment that must be included for complete traceability. Lab balances, for example, are foundational to data accuracy but frequently overlooked or only considered secondarily with the implementation of third-party software.

The value of instrument-based compliance support features

Some lab instruments come with native compliance support, negating the need for middleware, which reduces operating costs and simplifies qualification processes. The integration of data integrity features on an instrument like a lab balance improves data quality, helps bring control to the entire lab process, removes the ability to falsify process data or signatures, and reduces costs associated with rework. When acquiring new electronic lab equipment, considering the current and future needs of the lab throughout the digitalization process helps inform purchasing decisions.

A compliance-ready instrument needs to have technical control features, comprehensive audit trail features, and effective and compliant connection to LIMS, ELN, and other IT systems. FDA guidelines on data integrity require that data be complete, accurate, and consistent, and recommend following the ALCOA framework: attributable, legible, contemporaneously recorded, original or a true copy, and accurate. Instruments can be fully evaluating using the 21 CFR Part 11 compliance checklist provided below.

What does compliance support look like on an instrument?

The design elements required for onboard compliance support can be illustrated using the **Sartorius Cubis® II** lab balance. Designed using the ALCOA framework, the Cubis II with the QApp pharma package incorporates all technical control features required for adherence to CFR Part 21, Part 11 guidelines. A full walk-through of these features and how they support compliance follows.

Ensuring data are attributable requires inclusion of metadata, such as user ID, balance ID, sample and batch information, date and time, software version, etc. This relies on comprehensive user management and access control, which the Cubis II provides through local user management and centralized "single sign-on" user management options. Password and login security measures can be set in line with company policies. Final weighing reports including the relevant metadata can be printed or exported electronically with electronic signatures, which are tied to secure username and password combinations.

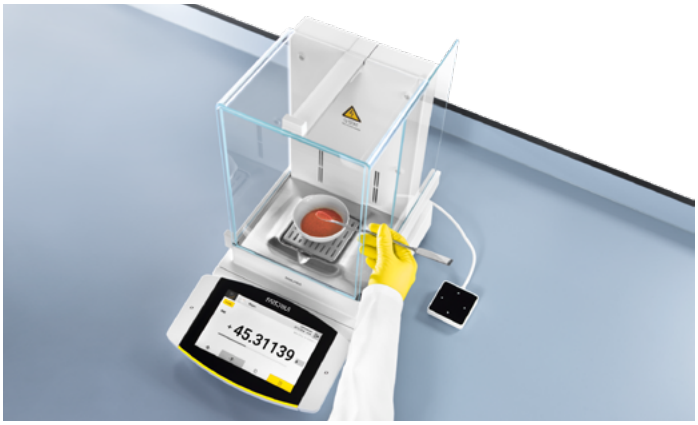
Full traceability is achieved with audit trails and advanced reporting. Audit trails consist of complete, tamper-protected, time-stamped data files that reflect all events relating to creation, modification, and deletion of records. The Cubis II is configured to deliver these data in filterable, exportable reports that are easy to read and understand. Additionally, it retains separate, immutable records of the last 150,000 datapoints in weighing data raw ("Alibi") memory.

Data must be recorded contemporaneously (at the time of generation) with accurate timestamps that are traceable to UTC. The Cubis II offers automatic time synchronization via network time protocol to ensure accuracy in metadata.

Origin, content, and meaning are preserved through file metadata and protected using a calculated MD5 checksum for each file by the Cubis II. This allows other IT systems, like LIMS, to verify authenticity and trustworthiness of data files.

Ensuring data are accurate and complete also requires proper documentation of all mistakes and corrections. The Cubis II allows users to mark incorrect datasets and add explanatory comments. Invalid datasets are clearly displayed using crossed out text accompanied by the correct dataset.

Full compliance requires additional procedural controls and long-term data storage systems in the lab. Data backup and archival are integral to protecting data in both the short and long term. Cubis II backups can be automatically scheduled and include audit trails, printouts, log files, Alibi memory, and configuration data. Archival can easily be performed by IT in a compliant manner, as records are readable without system-specific software.



Safe data transfer is an important capability for ensuring unbroken data integrity across systems. The Cubis II allows secure data transfer via multiple options, such as FTPS (secure file transfer protocol), SMB (Windows file server protocol), or external hard drive connection. It integrates easily and seamlessly with existing IT infrastructure, connecting securely to ELN, LIMS, and LDAP (Lightweight Directory Access Protocol) servers.

Full compliance heavily relies on human behavior, as well. The Cubis II further supports compliance through safety features like the "safe weighing" settings and through QApps (quality assurance project plans) that provide clear user guidance. This includes appropriate limits, tolerances, and best practices for reliable weighing results.

Compliance with data integrity guidelines requires correct recording, archival, and sharing of data. As digitalization transforms lab operations and regulations expand and evolve, it's increasingly important for labs to implement solutions that meet both current and future operational needs. Taking measures to protect data integrity helps organizations not only meet regulatory requirements but improve workflow efficiency and reduce costs.

How well do your lab instruments support data integrity compliance? Evaluate them using the checklist below.

For an example of the compliance checklist in action, **see how the Sartorius Cubis II stacks up.**

ISO 8655:2022 – Pipette Calibration and Standards

Setting the requirements for calibration of pipette and piston-operated volumetric apparatus

ISO 8655:2022 details requirements for producing and in-use control of piston-operated volumetric apparatus (POVA) including testing methods, testing environment, testing equipment, reporting requirements, requirements for measurement uncertainty, and general requirements for how POVAs work.

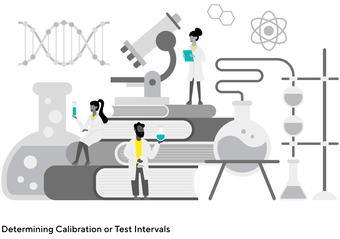
Taking proper care of your pipettes is one of the critical factors affecting the quality of your work. Pipette performance can deteriorate over time due to drift of calibration, leakage, part wear, or contamination. The accuracy and precision of pipettes must be checked at regular intervals. Calibrating your pipettes is the only way to ensure they still work as intended.

ISO 8655 is different from ISO 17025. The former describes how the calibration of a POVA is performed while the latter defines the requirements a calibration laboratory must meet to achieve valid calibration results

POVA Testing and Calibration

Calibration and test are operations that describe the relationship between the delivered volume and the corresponding selected volume of the apparatus. Measurement results are only comparable under the same conditions.

All variables that affect liquid properties must be controlled to ensure valid comparisons, POVA testing, and calibration.



Determining Calibration or Test Intervals

Factors to consider:

- Risk of application
- Frequency of use
- Number of users
- Type of liquid delivered and its vapors
- Acceptable maximum permissible errors
- Manufacturer information
- Liquid handling process

What is new in ISO 8655:2022?

Two different reference measurement procedures for volume determination:

(i) Gravimetric (Part 6)

(ii) Photometric (Part 8)

Recommendation: Follow the new ISO once it is officially published in a country.

Adapting to calibration and maintenance tolerances

An as-found calibration or test should be carried out and a metrological confirmation should be considered before and after the maintenance or repair of a POVA. This can be done against the ISO 8655, manufacturer, or customer/user tolerances to ensure the ISO standard is fulfilled.

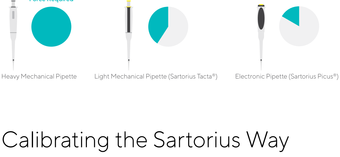
ISO parts 2, 6 and 7 require tolerances for the nominal volume, 50% of nominal volume, and 10% of nominal volume. The tests must be done with at least 10 repetitions per tested volume and at three points, minimum.

Additionally, part 6 gives the new minimum requirements for balances used for gravimetric calibration. The requirements were adapted and now ask for lower readabilities for pipettes up to 200 µL.

ISO 8655 Part 7 A.2 allows for deviations in test liquid and volumes.

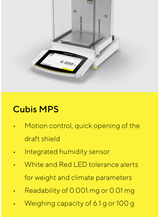
Recommendation: When using third-party pipette tips, it is recommended that the tip manufacturer proves that the whole system, pipette, and tip together meet the requirements and maximum permissible errors of ISO 8655. Pipette tips must be changed at least once per calibrated volume when performing calibration or testing under ISO 8655 Parts 6 – 8. This is not required for ISO 8655 Part 7 A.2.

Pipetting constitutes a large portion of bench time and can affect data reliability and the well-being of laboratory workers. Sartorius has combined ergonomic solutions with proper pipetting techniques enabling minimizations of errors due to fatigue and the risk of repetitive strain injuries.



Calibrating the Sartorius Way

Sartorius' Cubis MPS and Speedcal Mobile systems combine accuracy, precision, speed, and convenience to provide professional pipette calibration.



Cubis MPS

- Motion control, quick opening of the draft shield
- Integrated humidity sensor
- White and Red LED tolerance alerts for weight and climate parameters
- Readability of 0.001 mg or 0.01 mg
- Weighing capacity of 6.1 g or 100 g

Speedcal Mobile

- Calibrates multi-channel pipettes
- Parallel connections up to 12 balances within 10 minutes
- Available with 4, 8, or 12 channels
- Conforms to ISO 17025 and ISO 8655 regulations
- Integrated web service interface for mobile service
- Weighing capacity of 21 g per channel
- Resolution of 0.01 mg
- Stabilization time < 4 s

POVAs constitute a large portion of laboratory equipment. ISO 8655:2022 details the relevant methods for testing and calibration of POVAs to meet a precision lab's needs and requirements. Sartorius' Cubis MPS and Speedcal Mobile systems provide an accurate, precise, fast, and convenient means of professional pipette calibration that enhance your lab's standards.

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White Paper

February 2023

Keywords:
ISO 8655:2022, test and calibration of piston-operated volumetric apparatus, environmental conditions, tip change during test and calibration

Gravimetric Calibration and Testing of Piston-Operated Volumetric Apparatus (POVA) According to Part 6 and 7 of the ISO 8655:2022

How to Perform a Norm Compliant Calibration or Test

Axel Taube, Joni Ake, Dr. Ellen Hage, Dr. Lars Wallbaum
Sartorius Lab Instruments GmbH & Co. KG, Otto-Brenner-Strasse 20, 37079 Goettingen, Germany

Correspondence
E-mail: metrology@sartorius.com

Abstract

Reliable and reproduceable liquid handling results depend crucially on the regular test and calibration of the instruments. The globally most accepted International Standardization Organization (ISO) standard that details requirements for producing and in-use control of piston-operated volumetric apparatus (POVA) is the ISO 8655.

The aim of this white paper is to present the requirements for gravimetric calibration and testing of piston-operated volumetric apparatus (POVA) according to part 6 and part 7 of the ISO 8655 revised in 2022.

This white paper presents the differences between calibration and testing according to chapters 6 and 7, describes the testing method as well as testing environment, testing equipment and reporting requirements.

Introduction

Liquid handling products are used daily in most laboratories to prepare samples, controls, and assay reagents.
As mechanical and electronical liquid handling products affect virtually every experiment, accuracy and repeatability are extremely important. Metrological confirmation by calibration or testing of all piston-operated volumetric apparatus (POVA) shall therefore be performed on a regular basis to ensure that the apparatus meets the requirements for its intended use.

The most important international standard on piston-operated volumetric apparatus (POVA) is the ISO 8655. It is applicable to pipettes, burettes, dilutors, dispensers and manually operated precision laboratory syringes for volumes up to two liters.

The ISO 8655 standard was developed and published by the International Organization for Standardization (ISO), an international, independent, non-governmental organization. In 2022 a second edition of the ISO 8655 was published. The ISO 8655:2022 series has now nine parts (a part 10 is in preparation) and replaces the first edition from 2002.

ISO 8655 series is addressing the needs of POVA manufacturers as well as calibration laboratories and POVA users performing calibration or tests on POVAs.

The aim of this white paper is to describe the requirements for a gravimetric calibration or test according to part 6 and part 7 of the ISO 8655:2022. This includes testing methods, testing environment, testing equipment, and reporting requirements.

Part 6 and Part 7 of the ISO 8655:2022

Part 6 and 7 of the ISO 8655:2022 specifies gravimetric measurement procedures for the determination of volume of piston-operated volumetric apparatus (POVA).

Figure 1: *Gravimetric Calibration of a Pipette on a Single Channel Balance*

Part 6 of the ISO 8655 describes the gravimetric reference measurement procedure for the determination of volume.

Conformity with Part 6 can only be given if all the requirements described in this part are met. Part 7 specifies alternative measurement procedures for the determination of volume. Annex A of part 7 of the ISO is entitled with “Gravimetric procedure”.

Both in part 6 and part 7 the test procedures apply to the entire system which comprises the basic apparatus and all disposable (e.g.: pipette tips) or reusable parts that are selected for use with the apparatus. This means calibration and test results according to the ISO 8655 are only valid for the entire system. Thus, when different types of disposable or reusable parts or disposable or reusable parts from different manufacturers are used, different systems are in use, and each requires its own calibration or testing.

Part 6 and Part 7 of the ISO 8655 distinguish between calibration, test, and routine testing. All are defined as a set of operations that establish the relationship between the delivered volume and the corresponding selected volume of the apparatus. The difference between calibration and test according to the ISO 8655 is that the calculation of the measurement uncertainties is required for a calibration, while this is optional when testing a POVA. As measurement results are, strictly speaking, incomplete if they are not accompanied by a statement of the associated measurement uncertainty and measurement uncertainty is also crucial in measurement comparison and measurement traceability, calibration has a much higher value then just testing.

According to the ISO 8655:2022 a metrological confirmation of a POVA shall be performed on a regular basis to ensure that the apparatus meets the requirements for its intended use. Such a metrological confirmation can be given by both calibration and test and as well under Part 6 and Part 7 of the ISO 8655.

The ISO 8655:2022 clearly states that an as-found calibration or test should be carried out and a metrological confirmation should be considered before and after the maintenance or repair of a POVA.

While the main target of calibration and test lays at the metrological confirmation routine testing shall be performed at shorter time intervals than metrological confirmations and follows Part 7 of the ISO 8655.

	ISO 8655-6	ISO 8655-7	ISO 8655-7 A.2
Test Types	Calibration, Test	Calibration, Test, Routine testing	Calibration, Test, Routine testing
Metrological confirmation	Yes	Yes, if the measurement procedure is validated by comparison to the reference procedure	Yes, if the measurement procedure is validated by comparison to the reference procedure and at least 10 measurements per volume are taken

Balance Used for Gravimetric Calibration and Test

Gravimetric calibration and tests are performed by dispensing the test liquid several times on a balance. Single-channel balances can be used for calibration and test of single and multi-channel instruments while a multi-channel balance shall only be used for multi-channel pipettes.

The minimum requirements for the balance used for calibration and test are the same under Part 6 and Part 7 of the ISO. The following minimum requirements need to be met:

Nominal Volume of the POVA	Resolution (d) (mg)	Repeatability (s) (mg)	Expanded Uncertainty in use (U_{gl} [W]) (mg)
0.5 µL ≤ V < 20 µL	0.001[a] 0.01[b]	0.006 [a] 0.03[b]	0.012[a] 0.06 [b]
20 µL ≤ V < 200 µL	0.01	0.025	0.05
200 µL ≤ V ≤ 10 mL	0.1	0.2	0.4
10 mL <V ≤ 1,000 mL	1	2	4
1,000 mL < V ≤ 2,000 mL	10	10	40

[a] Single-channel balance
[b] Multi-channel balance (to be used below 20 µL only if the expanded uncertainty in use is less than ¼ of the maximum permissible systematic error of the apparatus)

Resolution is quite simple – when knowing the nominal volume of the POVA the needed resolution | scale interval (d) of the balance can directly be taken from the table above.

An evaluation if the balance meets the requirements on repeatability (s) and the expanded uncertainty in use (U_{gl} [W]) is only possible by taking these values from an actual calibration certificate of the balance. It is important that the balance has been calibrated at the place of use and that both values, the repeatability (s) as well as the expanded uncertainty in use are stated in the calibration certificate.

In particular the expanded measurement uncertainty in use (U_{gl} [W]) is not specified on calibration certificates from all service providers. It is represented by a formula and allows the measurement uncertainty to be calculated for all loads. In contrast to the measurement uncertainty that is given on a calibration certificate for the calibration result, the formula of the expanded uncertainty in use takes additional uncertainty contributions into account, such as effects when taring the balance, environmental influences or rounding effects.

Calibration certificates from Sartorius that follow the EURAMET cg-18 guideline do always state the expanded uncertainty in use. With a special attachment to the calibration certificate the Sartorius service can provide a document confirming the use of the balance for calibrations of POVAs of different nominal volumes.

Test Equipment Used for Gravimetric Calibration and Test

The minimum requirements for the test equipment to measure the environmental condition during calibration or test slightly differ between Part 6 and Part 7 of the ISO 8655:2022. The following minimum requirements shall be met:

	ISO 8655-6	ISO 8655-7	ISO 8655-7 A.2
Test equipment	All measurements done by test equipment shall be traceable to the International System of Units (SI) and shall meet the uncertainty requirements of ISO 8655-6	Shall be chosen such that the required uncertainty of measurement can be obtained	
Air temperature	Minimum requirements to be met: ▪ Resolution: 0.1 °C ▪ Expanded uncertainty of measurement (k = 2): 0.3 °C		
Water temperature	Minimum requirements to be met: ▪ Resolution: 0.1 °C ▪ Expanded uncertainty of measurement (k = 2): 0.2 °C	Minimum requirements: ▪ Resolution: 0.1 °C ▪ Expanded uncertainty of measurement (k = 2): 0.3 °C	
Air humidity	Minimum requirements to be met: ▪ Resolution: 1% relative humidity ▪ Expanded uncertainty of measurement (k = 2): 5% relative humidity		
Air pressure	Minimum requirements to be met: ▪ Resolution: 0.1 kPa ▪ Expanded uncertainty of measurement (k = 2): 1 kPa		
Test liquid	Minimum requirements to be met: ▪ Distilled or deionized water conforming at least grade 3 as specified in ISO 3696:1987		

Test Conditions

The environmental conditions need to be measured and reported during gravimetric calibration and test of a POVA. The following environmental conditions must be met:

	ISO 8655-6	ISO 8655-7	ISO 8655-7 A.2
Test conditions in test room	▪ Draft free ▪ Stable environment ▪ Relative Humidity: 45 % – 80 % relative humidity ▪ Temperature: (20 ± 3) °C ▪ Air pressure: to be recorded ▪ Temperature variation during test ≤ 0.5 K	▪ Draft free ▪ Stable environment ▪ Relative Humidity: to be recorded ▪ Temperature: to be recorded ▪ Air pressure: to be recorded ▪ Temperature variation during test ≤ 0.5 K	
Test liquid	The water temperature shall be within 0.5 K of ambient air temperature	Test liquid shall be acclimatized to the test room temperature	Not specified

Test Procedure

Depending on the part of the ISO 8655 and the test type the requirements on the measurement procedure differ. The following requirements are given under the different parts of the ISO and for the different test types:

	ISO 8655-6	ISO 8655-7	ISO 8655-7 A.2
Test volumes	**Calibration and test** At least at the following 3 volumes: ▪ nominal volume ▪ 50 % of the nominal volume ▪ The lower limit of the usable volume range or 10% of the nominal volume (whichever is greater).	**Calibration and test** At least at the following 3 volumes: ▪ nominal volume ▪ 50 % of the nominal volume ▪ The lower limit of the usable volume range or 10% of the nominal volume (whichever is greater). **Routine testing** Fewer than 3 volumes might be tested	**All test types** At least 1volume
Number of measurements	**Calibration and test** At least 10 measurements per volume	**Calibration and test** At least 10 measurements per volume **Routine testing** At least 4 measurements per volume	**All test types** At least 4 measurements per volume
Tip change	At least once per volume	At least once per volume	No tip change required
Specific requirement when testing a multi-channel pipettes	▪ All channels must be tested individually ▪ All channels shall be tested on a multi-channel balance in parallel ▪ When testing on a single-channel balance test liquid shall be aspirated by all channels together. The volume of the channel to be measured shall be delivered into the weighing vessel, while the volumes from all other channels shall be discarded		

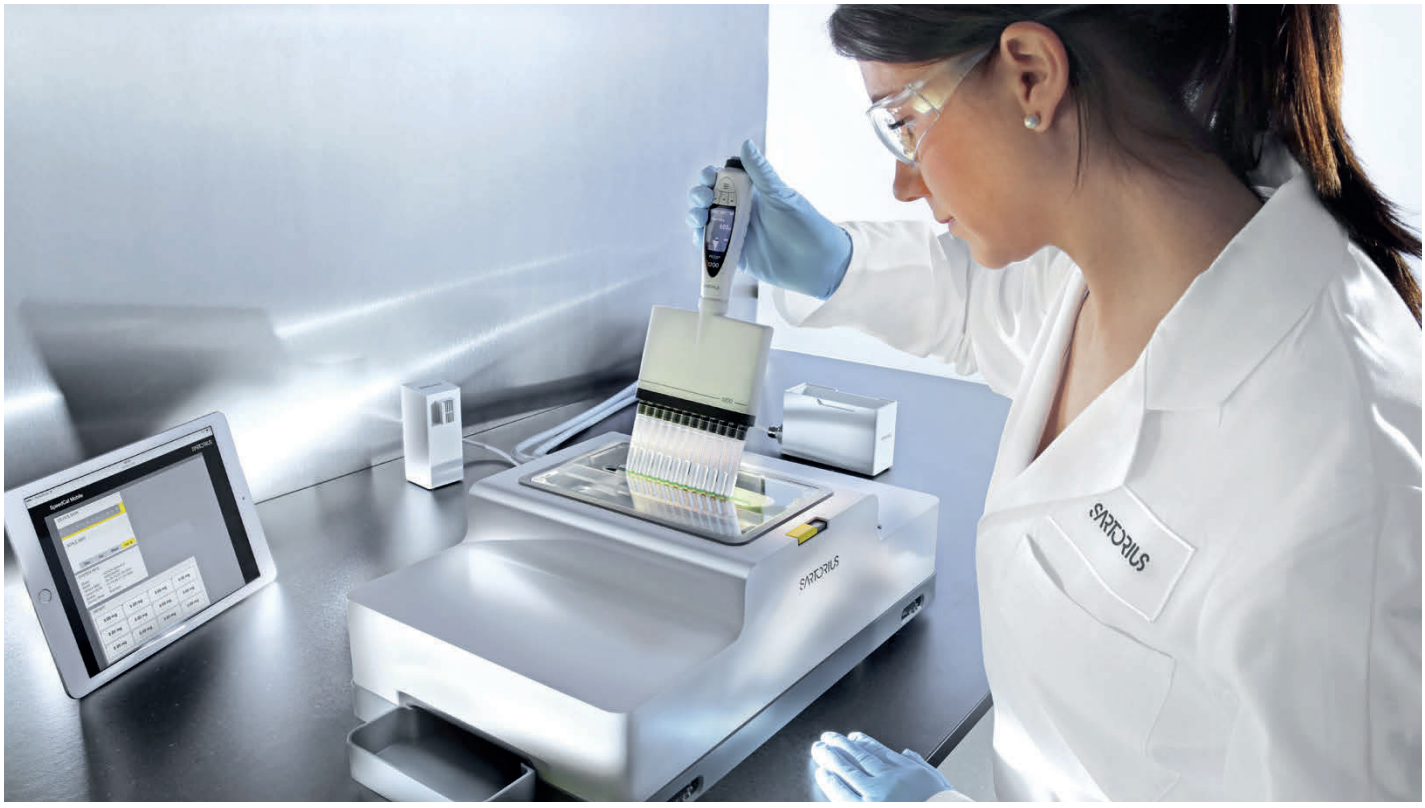

Figure 2: *Gravimetric Calibration on a Speedcal Mobile Multi Channel Balance*

Test Evaluation and Reporting of Results

	ISO 8655-6	ISO 8655-7	ISO 8655-7 A.2
Volume calculation	The corrected weighing values shall be converted to volume by using the general formula 2 according to ISO 8655-6 or using the Z correction table		
Systematic error of measurement	$e_s = \overline{V} - V_s$ e_s is the systematic error of measurement, expressed in units of volume V_s is the selected test volume at the POVA under test $\overline{V}$ is the average of the measured volume		
Random error of measurement	$s_r = \sqrt{\frac{\sum_{i=1}^{n} (V_i - \overline{V})^2}{n-1}}$ where s_r is the standard deviation, expressed in units of volume		
Tolerances	Results can be compared against following tolerances: ▪ ISO 8655 (given in the technology related chapters of the ISO) ▪ Manufacturer ▪ Own customer requirements		
Reporting of results	▪ Identification of the POVA ▪ Identification of tips | exchangeable parts ▪ Basis of the test (Ex) or (In) ▪ Reference temperature and cubic thermal expansion coefficient γ, if a correction for cubic thermal expansion of the POVA is made ▪ Test conditions under which the test was performed ▪ Volumetric measurement results for each delivered volume ▪ Total number of replicate measurements made per selected volume ▪ Systematic and random measurement errors ▪ Tolerances to which the test results are compared, if applicable ▪ Expanded uncertainty of the mean delivered volume, for each selected volume and channel, if required ▪ Date of the test ▪ Identification of the operator performing the test		
	▪ Reference to ISO 8655-6:2022 ▪ Any variation from the reference measurement procedure specified under ISO 8655-6 ▪ Reference to the formula used to convert weighing values into volume	▪ Reference to ISO 8655-7:2022 ▪ Any deviation from the employed procedure described under ISO 8655-7 ▪ Type of test liquid ▪ Recommendation for the next test date (if agreed upon	▪ Reference to ISO 8655-7:2022, A.2 ▪ Any deviation from the employed procedure described under ISO 8655-6 ▪ Type of test liquid ▪ Recommendation for the next test date (if agreed upon)

Conclusion and Sartorius Recommendations

- Testing and calibration are only valid for the entire system (basic apparatus and all disposable or reusable parts) – therefore when using different kinds of disposable or reusable parts with your POVA the test or calibration must be performed separately per entire system
- Balances that are used for calibration and test of POVA need to meet the requirements on resolution | scale interval (d), repeatability (s) and the expanded uncertainty in use (U_{gl} [W])
- A metrological confirmation should be considered before and after the maintenance or repair of a POVA.
- When performing calibration or test the requirements for the balance and all other test equipment must be met
- When performing a calibration, the calculation and reporting of measurement uncertainties is required
- Test and calibration according to part 6 and 7 of the ISO 8655:2022 require at least one tip change per measured volume
- The test results can be compared against ISO 8655:2022, manufacturer, or customer tolerance settings

References

ISO 8655:2022 Piston-operated volumetric apparatus
Part 1: Terminology, general requirements and user recommendations
Part 2: Pipettes
Part 6: Gravimetric reference measurement procedure for the determination of volume
Part 7: Alternative measurement procedures for the determination of volume
International Organization for Standardization, Geneva, Switzerland

Version History

Version	Date	Changes
01	February 2023	Initial Version
02	April 2023	Required Balance Load

Germany
Sartorius Lab Instruments GmbH & Co. KG
Otto-Brenner-Straße 20
37079 Göttingen
Phone +49 551 308 0

For further information, visit
www.sartorius.com