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Frequently Asked Questions (FAQ)

The new ISO 8655:2022 "Piston-Operated Volumetric Apparatus"

1. What does the new ISO 8655:2022 contain?

ISO 8655:2022 contains requirements for producing and in-use control of piston-operated volumetric apparatus (POVA). This includes testing methods, testing environment, testing equipment, reporting requirements, requirements for measurement uncertainty, and general requirements for how POVAs work. The ISO 8655:2022 is applicable to pipettes, burettes, dilutors, dispensers and manually operated precision laboratory syringes.

2. What are the main differences between the new ISO 8655:2022 and the previous version?

ISO 8655:2022 consists of nine parts total, which is two more parts then in the previous version. There are major and minor changes to all parts. Part 9 of the new ISO 8655:2022 describes a new instrument class - manually operated precision laboratory syringes.

The ISO 8655:2022 describes two different reference measurement procedures for the determination of volume (a gravimetric procedure in part 6 and a photometric procedure in part 8). In addition to the reference measurement procedures, part 7 (new chapter) describes alternative procedures.

3. When does the new ISO 8655:2022 become effective for me?

Unlike laws, standards are only legally binding when stipulated in legislation or in contracts. For an accredited calibration laboratory, the ISO 8655:2022 becomes binding when this standard is named in the accreditation certificate. However, even where standards are not expressly named in a contractual agreement or law, they are used to settle legal disputes, especially in product liability cases. In this way, standards provide legal certainty. Therefore, it is recommended to follow the new ISO 8655:2022 after it is officially published in a country.

4. The new ISO 8655:2022 describes two reference measurement procedures. Which one applies to me?

In former versions of the ISO 8655 the gravimetric measurement procedure for volume determination has been described as the "gold standard". The gravimetric procedure (Part 6 in the ISO 8655:2022) is now losing this unique position. The photometric procedure (Part 8 in the ISO 8655:2022) is now given equal status as the second reference measuring procedure.

Currently, the ISO does not favor one method over the other.

5. Next to the reference measurement procedures, the new ISO 8655:2022 describes an alternative measurement procedure. What are the differences?

Following a reference measurement procedure, calibrations and tests must be performed following strict requirements. Deviations from these requirements when referring to part 6 (gravimetric reference procedure) or part 8 (photometric reference procedure) are not permitted.

However, it is not always possible to fulfill the environmental requirements described in Parts 6 and 8, especially when calibrating or testing a POVA on the customer site. The alternative measurement procedure allows deviations from these strict requirements within limits.

6. What is the difference between calibration or test according to Part 7 and Part 7 A.2 of the new ISO 8655:2022?

Calibrations and tests under Part 7 require specific environmental conditions, repetitions and test volumes.

Tests and calibrations under Part 7 A.2 allow use of the gravimetric reference measurement procedure according to Part 6 of the ISO 8655:2022, when all deviations from the reference measurement procedure are recorded and reported. This allows for example to vary the test liquid, the tested volumes, the replicates or the tip changes.

7. Can a metrological confirmation of a POVA only be given when calibration or test follows a reference measurement procedure?

Calibrations and tests done under ISO 8655 Part 7 can also be used as a metrological confirmation of POVA if at least 10 replicate measurements are performed per selected volume and the measurement procedures are validated by comparison to one of the reference measurement procedures.

8. The new ISO 8655:2022 distinguishes between calibration and test. What are the differences?

A metrological confirmation can be done by both a calibration or test and should be performed according to one of the reference measurement procedures described in ISO 8655 Part 6 and ISO 8655 Part 8, or according to an alternative measurement procedure described in ISO 8655 Part 7.

Both calibration and test are defined as a set of operations that establish the relationship between the delivered volume and the corresponding selected volume of the apparatus. While the estimate of measurement uncertainties is required for a calibration, this is optional when testing a POVA.

9. How often do I have to perform a metrological confirmation of my POVA?

The ISO states that a metrological confirmation of all POVA shall be performed regularly to ensure that the apparatus meets the requirements for its intended use.

The recommended frequency is based on the risks associated with using the POVA. The maintenance interval is affected by such factors as pipetting frequency, liquids dispensed and the age/model of the pipette. A minimum maintenance interval of one year is suggested, with calibration done annually or more often, such as every 3 – 6 months. In some circumstances, such as when dispensing volatile liquids or solvents, more frequent maintenance is advised.

10. What should I take into account when defining the calibration or test intervals?

The following factors should be considered:

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

11. Is there a need to perform an as-found calibration or test prior to a maintenance or repair of a POVA?

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. Maintenance or repairs can affect the performance of a POVA and the as-found calibration is needed to interpret results obtained beforehand.

12. Can a calibration or test according to the new ISO 8655:2022 also be carried out against customer or manufacturer tolerances?

Calibration and test under the ISO 8655:2022 can be done against the ISO 8655, manufacturer or customer/user tolerances. A test against the ISO 8655 tolerances is necessary to prove that the ISO standard is fulfilled. If the manufacturer or customer/user tolerances are stricter or equal to the ISO 8655 tolerances, then the standard is fulfilled. Deviations that are not within the ISO 8655 tolerances do not prove that the ISO standard is fulfilled.

Calibration and test according to ISO 8655 Part 6, Part 7 and Part 8 require tolerances for the nominal volume, 50 % of the nominal volume and 10 % of the nominal volume (or the lower limit if the min is > 10 % of the nominal volume). If no manufacturer or customer/user tolerances for these volumes are available, only a test according to ISO 8655 Part 7 A.2 is possible.

13. Can the number of repetitions and the tested volumes be adapted to my needs?

Calibration and testing under ISO 8655 Part 6, Part 7 and Part 8 must be done with at least 10 repetitions per tested volume and at three points, minimum. They must be set to the nominal volume, 50 % of the nominal volume and 10 % of the nominal volume (or the lower limit if min is > 10 % of the nominal volume).

Only the ISO 8655 Part 7 A.2 allows for the calibration or testing of the POVA with other, or less calibration volumes, and less than 10 repetitions.

14. The new ISO 8655:2022 describes tolerances for the system of POVA and tip. What does this mean?

Some POVA require the use of exchangeable parts during typical use (e.g., disposable pipette tips). The new ISO 8655 describes the POVA and the exchangeable part as a system and requires that these exchangeable parts constitute an integral part of the POVA under test. Therefore, the calibration results are only valid for the tip type used during the calibration. In case the POVA is used with different tip types, a separate calibration should be performed with each tip type.

15. Can I use my pipette with tips from other manufacturers?

The new ISO 8655:2022 clearly describes that the maximum permissible errors apply to the total system of pipette and tip. Before a pipette tip is placed on the market, the tip manufacturer must prove that the whole system, pipette and tip, fulfills the requirements and maximum permissible errors of the new ISO 8655. Using the tip is not recommended if the manufacturer of a third-party tip has not provided this validation.

16. The new ISO 8655:2022 requires changing the tip at least once per calibrated/tested volume. Why is that?

According to ISO 8655 Part 6, Part 7 and Part 8 the tip must be changed at least once per calibrated volume when performing calibration or testing, in order to detect damaged or incorrectly manufactured tips. When performing the calibration under ISO 8655 Part 7 A.2, the tip does not need to be changed mandatorily.

17. Why are POVA tested and calibrated under special conditions and not in standard laboratory conditions?

Measurement results can only be compared if they are taken under the same conditions. Common laboratory conditions fluctuate and are never completely standard. To enable comparison of results from different calibration laboratories, all variables that affect liquid properties, such as temperature, humidity and air pressure, must be controlled.

18. What is the difference between an ISO 8655 and an accredited ISO 17025 pipette calibration?

In short, ISO 8655 describes how the calibration of a POVA is performed, while ISO 17025 entitled "General requirements for the competence of testing and calibration laboratories" defines the requirements that a calibration laboratory must meet to work competently and achieve valid calibration results. Within the accreditation process, the calibration laboratory must prove to an independent accreditation body that it is complying with the corresponding national and international standards, laws and guidelines and therefore is operating at a globally comparable level.

One important section within the ISO 17025 describes the traceability of the test equipment. This means that all test equipment that is used for calibration or as part of a calibration must be traceable to international standards. This ensures that an accredited calibration certificate alone is always recognized as proof of traceability.

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