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Piston-operated volumetric apparatus —

Part 1: Terminology, general requirements and user recommendations

Appareils volumétriques à piston —

Partie 1: Définitions, exigences générales et recommandations pour l'utilisateur

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 48, *Laboratory equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 332, *Laboratory equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 8655-1:2002), which has been technically revised. It also incorporates the Technical Corrigendum ISO 8655-1:2002/Cor.1:2008.

The main changes are as follows:

— ISO 8655-7, ISO 8655-8, and ISO 8655-9 have been added as normative references;

— abbreviated terms have been introduced as Clause 4;

— terms and definitions have been revised and some new ones included;

— general requirements for frequency of calibration, reporting measurement errors, exchangeable parts, metrological confirmation, routine testing, and maintenance and repair, suitability of statements on performance and determination of pass/fail status have been added in Clause 6.

A list of all parts in the ISO 8655 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The ISO 8655 series addresses the needs of:

— manufacturers, as a basis for quality control including, where appropriate, the issuance of manufacturer's declarations;

— calibration laboratories, test houses, users of the equipment and other bodies as a basis for independent calibration, testing, verification and routine tests.

The tests specified in the ISO 8655 series are intended to be carried out by trained personnel.

Piston-operated volumetric apparatus —

Part 1: Terminology, general requirements and user recommendations

1 Scope

This document specifies general requirements for piston-operated volumetric apparatus (POVA). It is applicable to pipettes, burettes, dilutors, dispensers and manually operated precision laboratory syringes. It furthermore defines terms for the use of piston-operated volumetric apparatus and gives user recommendations.

This document does not apply to medical products intended for use on humans, e.g. for medical syringes.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8655-2, *Piston-operated volumetric apparatus — Part 2: Pipettes*

ISO 8655-3, *Piston-operated volumetric apparatus — Part 3: Burettes*

ISO 8655-4, *Piston-operated volumetric apparatus — Part 4: Dilutors*

ISO 8655-5, *Piston-operated volumetric apparatus — Part 5: Dispensers*

ISO 8655-6, *Piston-operated volumetric apparatus — Part 6: Gravimetric reference measurement procedure for the determination of volume*

ISO 8655-7, *Piston-operated volumetric apparatus — Part 7: Alternative measurement procedures for the determination of volume*

ISO 8655-8, *Piston-operated volumetric apparatus — Part 8: Photometric reference measurement procedure for the determination of volume*

ISO 8655-9, *Piston-operated volumetric apparatus — Part 9: Manually operated precision laboratory syringes*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
adjustment
⟨POVA⟩ set of operations carried out so that the delivered volume more closely corresponds to the nominal or selected volume

Note 1 to entry: Information about the correct adjustment method can be found in the manufacturer's instruction manual. Some devices have more than one adjustment method. Some have none at all.

3.2
balance
⟨POVA⟩ device used to determine the mass of a delivered volume

3.3
bandpass filter
optical filter used to selectively transmit a band of wavelengths from the total spectrum while rejecting shorter and longer wavelengths than those within the transmission band

3.4
calibration
⟨POVA⟩ set of operations that establish the relationship between the delivered volume and the corresponding selected volume of the apparatus with associated measurement uncertainties

Note 1 to entry: Calibration requires no operation which permanently modifies the apparatus and does not require adjustment of the device.

3.5
coefficient of variation
random error expressed as a percentage of the mean delivered volume

3.6
correction
mathematical compensation of a systematic effect

Note 1 to entry: In the context of this document, a systematic error can be mathematically compensated by subtracting it from the selected volume.

Note 2 to entry: The correction is applied when the user is setting the indication to deliver the corrected intended volume.

3.7
chromophore
compound which absorbs photons of a specific energy

3.8
dead air volume
headspace
captive air volume
air cushion
⟨air displacement pipettes⟩ air volume between the piston and the surface of the liquid in the tip

3.9
dead volume
⟨POVA⟩ amount of liquid that does not belong to the delivered volume and which is contained during operation in aspiration or expelling tubes, valves and within the cylinder

3.10
evaporation trap
accessory used in a balance that minimizes evaporation of test liquid from the weighing vessel

3.11
immersion depth
⟨piston pipette⟩ depth of the tip orifice of the piston pipette below the liquid surface

3.12
liquid handling process tolerance
user-specified tolerance defining the maximum acceptable uncertainty in use of the delivered volume

Note 1 to entry: A POVA is fit for its intended purpose if its uncertainty in use is smaller than or equal to the liquid handling process tolerance.

Note 2 to entry: The liquid handling process tolerance is typically expressed as a percentage of the nominal or selected volume.

3.13
maximum permissible systematic error
permitted extreme value for the deviation of the mean delivered volume from the nominal volume or selected volume

Note 1 to entry: The maximum permissible systematic errors of piston-operated volumetric apparatus are specified in ISO 8655-2 to ISO 8655-5, and ISO 8655-9.

3.14
maximum permissible random error
permitted extreme value for the variation of the delivered volumes around the mean of the delivered volumes

Note 1 to entry: The maximum permissible random errors of piston-operated volumetric apparatus are specified in ISO 8655-2 to ISO 8655-5 and ISO 8655-9.

3.15
mean delivered volume
arithmetic mean of multiple replicate delivered volumes obtained by the measurement method

3.16
measurement
process of experimentally obtaining one or more quantity values that can be reasonably attributed to a quantity

3.17
measurement accuracy
accuracy
⟨POVA⟩ closeness of agreement between delivered volume and the nominal volume or selected volume

Note 1 to entry: The concept 'measurement accuracy' is not given as a numerical value. A measurement is said to be more accurate when it offers a smaller measurement error.

Note 2 to entry: The term 'measurement accuracy' is not the same as 'measurement trueness' or 'measurement precision'.

3.18
measurement repeatability
measurement precision under a set of repeatability conditions of measurement

3.19
measurement uncertainty
⟨volume as delivered by a POVA⟩ non-negative parameter, associated with the delivered volume, that characterizes the dispersion of the volumes that could reasonably be attributed to the delivered volume based on the information used

Note 1 to entry: When POVA are calibrated according to one of the procedures in ISO 8655-6, ISO 8655-7, or ISO 8655-8, the uncertainty of the mean delivered volume is usually estimated and reported.

Note 2 to entry: When POVA are used in the laboratory the uncertainty in use of a single delivered volume can be estimated and is discussed further in ISO 8655-10. This uncertainty is likely to be larger than the uncertainty of the mean delivered volume.

Note 3 to entry: ISO/TR 20461 and ISO/TR 16153 provide examples of the estimation of the uncertainty of the mean delivered volume and the uncertainty in use of a single delivered volume.

3.20
measuring system
set of one or more measuring instruments, and often other devices, including any reagents and supplies, assembled and adapted to give information used to generate measured volumes within specified intervals for quantities of specified kinds

[SOURCE: ISO/IEC Guide 99:2007, 3.2, modified — Note to entry was deleted, and definition has been modified for the purpose of the POVA standard]

3.21
measuring system uncertainty
value related to the method used for the determination of volume, which does not include the uncertainty of the POVA under test or the operator effect

3.22
metrological confirmation
set of operations required to ensure that the POVA conforms to the requirements for its intended use

Note 1 to entry: Metrological confirmation generally includes calibration and verification, and any necessary adjustment or repair, and subsequent recalibration, comparison with the metrological requirements for the intended use of the POVA, as well as any required sealing and labelling.

Note 2 to entry: The requirements for intended use include such considerations as range, resolution, and maximum permissible errors.

Note 3 to entry: Metrological requirements are usually distinct from, and are not specified in, product requirements.

[SOURCE: ISO 9000:2015, 3.5.6, modified — definition and Note 1 to entry have been modified for the purpose of the POVA standard, Note 2 to entry has been deleted and following notes to entries were renumbered.]

3.23
metrological traceability
property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty

[SOURCE: ISO/IEC Guide 99:2007, 2.41, modified — Notes to entry have been deleted.]

3.24
nominal volume
⟨POVA⟩ upper limit of the usable volume range as specified by the manufacturer

Note 1 to entry: For specific piston-operated volumetric apparatus, this definition is further qualified in the applicable parts of ISO 8655.

3.25
photometric repeatability
standard deviation of at least 10 absorbance measurements at a specific wavelength using a glass filter calibration standard

3.26
precision
⟨POVA⟩ closeness of agreement between replicate delivered volumes obtained under repeatability conditions

Note 1 to entry: The error characterizing precision is the *random error* (3.27).

3.27
random error
⟨POVA⟩ variation of the delivered volumes around the mean of the delivered volumes

Note 1 to entry: General definitions for random error are given in the ISO/IEC Guide 99 and ISO 3534-2. The term "random error" as used in ISO 8655 refers to the net effect of all random errors.

Note 2 to entry: The random error is ascertained by taking the repeatability standard deviation of multiple measurements.

Note 3 to entry: This definition corresponds to measurement repeatability as the term measurement repeatability is defined in the ISO/IEC Guide 99: measurement precision under a set of identical conditions of measurement.

Note 4 to entry: Equations for calculation of the random error are given in ISO 8655-6, ISO 8655-7, and ISO 8655-8.

3.28
reference measurement procedure
⟨POVA⟩ measurement procedure accepted as providing volume measurement results fit for use in assessing systematic and random errors

3.29
safe liquid handling range
volume range of a POVA in which the measurement uncertainty in use of a single delivered volume is smaller than or equal to the required liquid handling process tolerance

3.30
selected volume
target volume
test volume
⟨variable-volume volumetric apparatus⟩ volume set by the user, in order to deliver the chosen volume

Note 1 to entry: For a fixed-volume POVA, the selected volume is equal to the nominal volume.

3.31
spectrophotometer
instrument measuring the amount of light transmitted through a sample solution at specific wavelengths

3.32
systematic error
⟨POVA⟩ difference between the mean delivered volume and the selected volume

Note 1 to entry: According to the ISO/IEC Guide 99, a measuring device can have multiple different measurement errors, each of which can be random or systematic. The term "systematic error" as used in ISO 8655 refers to the net effect of all systematic errors.

Note 2 to entry: For piston-operated volumetric apparatus, the systematic error is ascertained by taking the difference between the mean of multiple measurements and the selected volume.

Note 3 to entry: According to ISO/IEC Guide 99, this definition corresponds to measurement error, measured quantity value (mean delivered volume) minus a reference quantity value (selected volume).

Note 4 to entry: Equations for calculation of the systematic error are given in ISO 8655-6, ISO 8655-7, and ISO 8655-8.

3.33
tare
device for setting the indication of a balance to zero when a load is placed on the balance pan
3.34
test liquid
liquid used for the volume determination

Note 1 to entry: Requirements for test liquids are given in ISO 8655-6, ISO 8655-7, and ISO 8655-8.

3.35
testing
⟨POVA⟩ set of operations that establish the relationship between the delivered volume and the corresponding nominal or selected volume of the apparatus with or without the estimation of the measurement uncertainty

Note 1 to entry: Testing requires no operation which permanently modifies the apparatus and does not require adjustment of the device.

3.36
trueness
⟨POVA⟩ closeness of agreement between the mean delivered volume and the selected volume

Note 1 to entry: The error characterizing trueness is the systematic error. Equations for calculation of systematic error are given in ISO 8655-6, ISO 8655-7 and ISO 8655-8.

Note 2 to entry: The term 'accuracy' is different from 'trueness' and should not be used for 'trueness'.

Note 3 to entry: The definition based on ISO/IEC Guide 99: 2007, 2.14, which was modified for the purpose of the POVA standard.

3.37
usable volume range
volume range commensurate with the liquid handling process tolerance or with the manufacturer's specifications

Note 1 to entry: When liquid handling process tolerances are considered, the lower end of the usable volume range of the POVA is defined as the volume below which the relative expanded measurement uncertainty in use becomes larger than the liquid handling process tolerance. In this case, the usable volume range equals the safe liquid handling range.

3.38
wavelength reproducibility
standard deviation of at least 10 consecutive wavelength maximum measurements at the peak wavelength of the reference standard

4 Abbreviated terms

The following are abbreviated terms used in this document and the ISO 8655 series of standards.

POVA Piston-operated volumetric apparatus

GUM Guide for the Expression of Measurement Uncertainty (ISO/IEC Guide 98: 2008)

5 Types of piston-operated volumetric apparatus

5.1 General

POVA includes a range of devices intended to aspirate or deliver specific volumes of liquids; they can be manually or semi-automatically operated and are controlled by mechanical, electro-mechanical or electronic means.

5.2 Pipettes

Pipettes are used to aspirate and deliver liquids. Single-channel pipettes have one piston/cylinder assembly. Multi-channel pipettes have a piston/cylinder assembly for each channel; the same volume of liquid can be delivered into several receptacles simultaneously (e.g. the wells of a microplate). Pipettes can be of fixed or variable volume.

Pipettes can be of positive displacement or air-displacement type (see ISO 8655-2).

5.3 Burettes

Burettes are designed to deliver liquid progressively until the volume delivered is sufficient to satisfy external (usually analytical) criteria such as change of colour, pH, conductivity, or polarization of the analyte. The volume delivered can be read from a display or recorded from the apparatus by other means (see ISO 8655-3).

5.4 Dilutors

Dilutors are used to deliver mixtures of liquids of defined volumetric proportions. The intended volumes of sample and dilution fluid, chosen to provide a combined volume of the required dilution ratio, are user-selected prior to the uptake and delivery of the liquids. According to ISO 8655-4, dilutors can be constructed with or without valves and may be of fixed or variable volume.

5.5 Dispensers

Dispensers are used for the repetitive delivery (dispensing) of a measured volume of liquid. Single-stroke dispensers provide a single delivery from each filling stroke. Multiple delivery dispensers or ratchet-based systems provide multiple deliveries from each filling stroke (see ISO 8655-5).

5.6 Syringes

Manually operated precision laboratory syringes are instruments used for delivering liquids and/or gases (see ISO 8655-9).

6 General requirements

6.1 Frequency of calibrations and tests

Metrological confirmation, including calibration or testing, shall be performed on a regular basis and at least once every 12 months (see 6.4). Routine tests shall be performed on a regular basis, preferably at shorter time intervals than metrological confirmations (see 6.5). The frequency of metrological confirmations and routine tests for POVA shall be based on a risk assessment and determined so that the continued fitness of the POVA for its intended use is documented. Industry- or organization-specific frequency requirements shall be followed.

If a POVA fails to meet the performance requirements, re-examining or voiding all results in which this POVA has been used since the last passing test result should be considered. The number of results at risk of being voided can be reduced by performing more frequent tests. Frequent and regular testing provides assurance of performance.

6.2 Reporting measurement errors

The systematic error in the ISO 8655 standard series is based on historic convention within the pipetting industry, and is opposite to ISO/IEC Guide 99:2007, because in this series of standards, the selected volume of the POVA is considered as the reference value.

6.3 Exchangeable Parts

Some POVA require the use of exchangeable parts during typical use (e.g. disposable pipette tips). These exchangeable parts constitute an integral part of the POVA under test.

Metrological confirmation and routine tests of the POVA should be performed using the type of exchangeable parts, which are used during the typical operation of the POVA.

Handling of exchangeable pipette tips shall be minimised, e.g., when fitting or changing tips, to avoid any thermal transfer, which can introduce volumetric errors.

Documentation of the exchangeable or disposable part shall include make, model, and if available, lot or serial number.

6.4 Metrological confirmation

Metrological confirmation of all POVA shall be performed on a regular basis to ensure that the apparatus meets the requirements for its intended use.

Metrological confirmation of POVA should be performed according to one of the reference measurement procedures described in ISO 8655-6 and ISO 8655-8. Metrological confirmation may also be performed according to one of the alternative measurement procedures described in ISO 8655-7, provided that the measurement procedure meets the requirements of ISO 8655-7:2022, 4.1.

6.5 Routine testing

The routine testing of the POVA shall be performed at regular intervals as part of test equipment monitoring or analytical quality control routines, for example, every three months (see 6.1). Other time intervals may be adopted giving due consideration to the following factors:

— risk of application;

— frequency of use;

— number of users of the POVA;

— aggressive nature of the liquid to be delivered and its vapours;

— acceptable maximum permissible errors;

— manufacturer's information;

— number of dispenses performed on each occasion of use;

— liquid handling process requirements.

The determination of the delivered volume shall be done following the procedures specified in ISO 8655-6 and ISO 8655-8, or by the adoption of other methods in accordance with ISO 8655-7.

6.6 Maintenance and repair

If maintenance or repair is to be carried out, metrological confirmation should be considered before and after such actions. No assumption shall be made that such actions do not change the performance of the device and results obtained before maintenance or repair will have no relevance if this is not performed.

6.7 Suitability to give statements on performance

ISO 8655-2, ISO 8655-3, ISO 8655-4, ISO 8655-5, and ISO 8655-9 provide product requirements for maximum permissible systematic and random errors. The reference measurement procedures of ISO 8655-6 and ISO 8655-8 are considered suitable for determining whether these requirements are met.

Alternative measurement procedures are provided in ISO 8655-7. These procedures are suitable for determining that maximum permissible systematic and random error requirements are met provided that the requirements of ISO 8655-7:2022, 4.1, are fulfilled.

6.8 Determination of pass/fail status

Appropriate performance tolerances for POVA, which reflect its fitness for its intended purpose, shall be defined.

The pass/fail status may be evaluated by comparing the determined systematic and random errors against the maximum permissible systematic and random errors defined by:

a) POVA product tolerances, for example those provided in ISO 8655-2, ISO 8655-3, ISO 8655-4, ISO 8655-5, and ISO 8655-9;

b) POVA product tolerances provided by the POVA manufacturer; or

c) other values established by the POVA user.

For routine testing, the determined measurement uncertainty in use of a single delivered volume may be assessed against liquid handling process tolerances defined by the POVA user.

Further guidance on the determination of pass/fail status can be found in ISO/TR 20461, ISO/TR 16153 and ISO 8655-10.

7 Product information

7.1 User information

Information essential to the proper use of the apparatus and its accessories shall be provided when making a POVA available on the market. Additional information can be found in ISO 8655-2, ISO 8655-3, ISO 8655-4, ISO 8655-5, and ISO 8655-9.

7.2 Decontamination and sterilisation

Information on how to dismantle the POVA for decontamination shall be provided.

Information on how to sterilise the POVA shall be provided.

If no such information is included in the user information, then the POVA shall be understood not to be sterilisable or intended to be dismantled for decontamination.

Additional information can be found in ISO 8655-2, ISO 8655-3, ISO 8655-4, ISO 8655-5, and ISO 8655-9.

7.3 Chemical resistance

The supplier(s) shall, upon request, provide information regarding the chemical resistance of the POVA and exchangeable parts against organic and inorganic solutions and solvents.

8 Factors affecting choice of piston-operated volumetric apparatus

8.1 Interaction with liquids

The range of applications of POVA is determined, among other factors, by the workmanship and choice of the materials from which they are made. The liquid to be delivered can affect the metrological performance of the apparatus.

The apparatus can, by the transfer of substances or trace elements, or through catalytic effects, affect the characteristics of the delivered liquid, without measurably altering the metrological performance of the apparatus.

Before use, it should be verified that the POVA, and if applicable, its disposables are resistant to the liquid that it is intended to handle, and that no contamination of the liquid takes place. This can be

accomplished, for example, by referring to resistance tables or, if necessary, by undertaking tests on the apparatus, and if applicable, the consumables and the liquid in question.

8.2 Use of air displacement pipettes

In order to achieve the most accurate measurements, the instructions for use provided should be noted and observed. Special care shall be taken to avoid the aspiration of liquid or vapour that can affect the interior workings of the pipette or lead to contamination of the instrument and other samples.

ISO 8655-2:2022, Annex B provides comprehensive information on possible sources of error and how to avoid them.

Tips made of plastic for piston pipettes with air interface are designed for single use. They shall not be cleaned for reuse as their metrological characteristics will no longer be reliable.

Single use of a pipette tip means mounting the tip on the pipette only once, and then discarding it after use. While the tip is mounted on the pipette, it can be used to handle several replicate aspiration and delivery cycles, as long as a tight seal between the tip and pipette's tip cone is maintained.

The piston pipettes should not be used below the lower limit of the usable volume range or 10 % of the nominal volume, whichever is the greater, due to the decreased accuracy.

9 Marking

Marking of the individual POVA shall be done in accordance with ISO 8655-2, ISO 8655-3, ISO 8655-4, ISO 8655-5, or ISO 8655-9, as appropriate.

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