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Piston-operated volumetric apparatus —

Part 1: **Terminology, general requirements and user recommendations**

illen SIA Appareils volumétriques à piston — E 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 <u>Clause 4</u>;
- 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 <u>Clause 6</u>.

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 <u>www.iso.org/members.html</u>.

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.

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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 9179-08e285b90d3d/iso-

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 <u>https://www.electropedia.org/</u>

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 8655-12022

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

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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

 $\langle \text{POVA}\rangle$ 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

 $\langle \text{POVA} \rangle$ 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).