

**SLOVENSKI STANDARD
SIST EN ISO 8655-7:2022****01-julij-2022****Nadomešča:****SIST EN ISO 8655-7:2006****SIST EN ISO 8655-7:2006/AC:2009**

Volumetrične naprave, delujoče na bat - 7. del: Nadomestni merilni postopki za določanje prostornine (ISO 8655-7:2022)

Piston-operated volumetric apparatus - Part 7: Alternative measurement procedures for the determination of volume (ISO 8655-7:2022)

Volumenmessgeräte mit Hubkolben - Teil 7: Alternatives Prüfverfahren zur Bestimmung des Volumens (ISO 8655-7:2022)

Appareils volumétriques à piston - Partie 7: Modes opératoires de mesure alternatifs pour la détermination de volumes (ISO 8655-7:2022)

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ICS:

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71.040.20	Laboratorijska posoda in aparati	Laboratory ware and related apparatus

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Supersedes EN ISO 8655-7:2005, EN ISO 8655-7:2005/AC:2009

English Version

Piston-operated volumetric apparatus - Part 7: Alternative measurement procedures for the determination of volume (ISO 8655-7:2022)

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Volumenmessgeräte mit Hubkolben - Teil 7: Alternatives Prüfverfahren zur Bestimmung des Volumens (ISO 8655-7:2022)

This European Standard was approved by CEN on 13 February 2022.

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Contents	Page
European foreword.....	3

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[SIST EN ISO 8655-7:2022](https://standards.iteh.ai/catalog/standards/sist/de613e86-c508-44d0-9b50-ac4046c4f64b/sist-en-iso-8655-7-2022)

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European foreword

This document (EN ISO 8655-7:2022) has been prepared by Technical Committee ISO/TC 48 "Laboratory equipment" in collaboration with Technical Committee CEN/TC 332 "Laboratory equipment" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2022, and conflicting national standards shall be withdrawn at the latest by November 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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INTERNATIONAL
STANDARD

ISO
8655-7

Second edition
2022-04

**Piston-operated volumetric
apparatus —**

Part 7:

**Alternative measurement procedures
for the determination of volume**

Appareils volumétriques à piston —

*Partie 7. Modes opératoires de mesure alternatifs pour la
détermination de volumes*

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Contents

	Page
Foreword.....	v
Introduction.....	vi
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	2
4 General requirements.....	2
4.1 Metrological confirmation.....	2
4.2 Uncertainty of measurement.....	2
4.3 Operator qualification.....	2
5 Performance requirements.....	3
5.1 Performance tolerances.....	3
5.2 Operator impact.....	3
6 Test conditions.....	3
6.1 General.....	3
6.2 Test equipment.....	3
6.3 Test room, environmental conditions.....	3
6.4 Test volumes.....	4
6.4.1 Fixed volume POVA.....	4
6.4.2 Adjustable volume POVA.....	4
6.5 Number of measurements per test volume.....	4
6.6 Test liquids.....	5
7 Evaluation.....	5
7.1 Mean volume.....	5
7.2 Systematic error of measurement.....	5
7.3 Random error of measurement.....	6
8 Test methods.....	6
8.1 General.....	6
8.2 Gravimetric method.....	7
8.3 Dual-dye ratiometric photometric method.....	7
8.4 Single dye photometric method.....	8
8.5 Hybrid photometric/gravimetric method for multichannel POVA.....	8
8.6 Titration method.....	8
8.7 Batch testing.....	8
9 Dispense procedures.....	8
9.1 General.....	8
9.2 Preparation.....	9
9.3 Single-channel air displacement pipettes (in accordance with ISO 8655-2).....	9
9.3.1 General.....	9
9.3.2 Test cycle.....	9
9.4 Multi-channel pipettes (in accordance with ISO 8655-2).....	10
9.5 Positive displacement pipettes (in accordance with ISO 8655-2).....	11
9.6 Burettes (in accordance with ISO 8655-3).....	11
9.7 Dilutors (in accordance with ISO 8655-4).....	12
9.7.1 General.....	12
9.7.2 Test cycle.....	12
9.8 Dispensers (in accordance with ISO 8655-5).....	13
9.9 Syringes (in accordance with ISO 8655-9).....	13
9.9.1 General.....	13
9.9.2 Test cycle.....	13
10 Reporting of results.....	14

ISO 8655-7:2022(E)

Annex A (normative) Gravimetric procedure	16
Annex B (normative) Dual-dye ratiometric photometric procedure	21
Annex C (normative) Single dye photometric procedure	29
Annex D (normative) Photometric/gravimetric hybrid procedure	33
Annex E (normative) Titrimetric procedure	41
Annex F (normative) Conversion of liquid mass to volume	45
Bibliography	48

**iTeh STANDARD
PREVIEW
(standards.iteh.ai)**

[SIST EN ISO 8655-7:2022](https://standards.iteh.ai/catalog/standards/sist/de613e86-c508-44d0-9b50-ac4046c4f64b/sist-en-iso-8655-7-2022)

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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 8655-7:2005), which has been technically revised. It also incorporates the Technical Corrigendum ISO 8655-7:2005/Cor.1:2008.

The main changes are as follows:

- a gravimetric test method was added (see [8.2](#));
- a photometric/gravimetric hybrid test method was added (see [8.5](#));
- a batch testing method was added (see [8.7](#));
- measurement procedures for all methods are given in normative [Annexes A](#) to [E](#);
- standard dispense procedures for POVA described in ISO 8655-2, ISO 8655-3, ISO 8655-4, ISO 8655-5, and ISO 8655-9 were added (see [Clause 9](#));
- requirements for operator qualification have been added (see [4.3](#));
- requirements for testing of multi-channel POVA is described in more detail, with specific procedures given for these apparatus (see [8.5](#), and [Annex D](#));
- [Annexes A](#), [B](#), and [C](#) of the first edition have been deleted and replaced.

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.

ISO 8655-7:2022(E)**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 7:

Alternative measurement procedures for the determination of volume

1 Scope

This document specifies alternative measurement procedures for the determination of volume of piston-operated volumetric apparatus.

The procedures are applicable to complete systems comprising the basic apparatus and all parts selected for use with the apparatus, disposable or reusable, involved in the measurement by delivery process (Ex). Methods described in this document are suitable for various maximum nominal volumes of piston-operated volumetric apparatus. It is the responsibility of the user to select the appropriate method.

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 1042, *Laboratory glassware — One-mark volumetric flasks*

ISO 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 3951-1, *Sampling procedures for inspection by variables — Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL*

ISO 8655-1, *Piston-operated volumetric apparatus — Part 1: Terminology, general requirements and user recommendations*

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 8655-8, *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*

ISO/IEC Guide 2, *Standardization and related activities — General vocabulary*

ISO 8655-7:2022(E)

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8655-1, ISO/IEC Guide 2, ISO/IEC Guide 99 and the following 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 acceptance quality limit AQL

<acceptance sampling> worst tolerable quality level

Note 1 to entry: This concept only applies when a sampling scheme with rules for switching and for discontinuation, such as in ISO 2859-1, ISO 3951-1 or ISO 3951-5 is used.

Note 2 to entry: Although individual lots with quality as bad as the acceptance quality limit may be accepted with fairly high probability, the designation of an acceptance quality limit does not suggest that this is a desirable quality level. Sampling schemes found in International Standards such as ISO 2859-1, ISO 3951-1 or ISO 3951-5, with their rules for switching and for discontinuation of sampling inspection, are designed to encourage suppliers to have process averages consistently better than the AQL.

4 General requirements (standards.iteh.ai)

4.1 Metrological confirmation

SIST EN ISO 8655-7:2022

Metrological confirmation of all POVA shall be performed on a regular basis to ensure the apparatus conforms to requirements for its intended use. The requirements of the methods and procedures described in this document are suitable to be used in the metrological confirmation of POVA. For calibrations and testing, no less than ten replicate measurements per selected volume shall be performed and the measurement procedures in this document shall be validated by comparison to one of the reference measurement procedures described in ISO 8655-6 or ISO 8655-8.

4.2 Uncertainty of measurement

When performing calibrations (ISO 8655-1:2022, 6.4) according to measurement procedures described in this document, the expanded measurement uncertainty of the mean delivered volume for each selected volume shall be estimated and reported (see [Clause 10](#) (m)).

When performing testing (ISO 8655-1:2022, 6.4) or routine tests (ISO 8655-1:2022, 6.5), it is optional to estimate and report the expanded measurement uncertainty.

NOTE For further information on uncertainty for the photometric and gravimetric methods, refer to ISO/TR 16153^[1] and ISO/TR 20461^[2] respectively.

4.3 Operator qualification

An operator who uses POVA for volumetric transfers, performs metrological confirmation or routine tests of POVA shall be adequately trained on the use of the type of POVA under test. Operator training and competence should be documented.

NOTE 1 Previously calibrated POVA can be used for the qualification of operators.

NOTE 2 Training and qualification requirements for operators of POVA are intended to be included in ISO 8655-10.

5 Performance requirements

5.1 Performance tolerances

Calibration, testing, and routine test results may be reported without comparison to performance tolerances. If the results are verified against performance tolerances, these tolerances shall be stated on the test report/certificate.

Performance tolerances may be based on the user's liquid handling process tolerances or the product tolerances given in the part of ISO 8655 corresponding to the type of POVA under test or the tolerances specified by the manufacturer, subject to them being fit for purpose.

5.2 Operator impact

Measurement of volumetric performance includes random and systematic errors of the POVA, as well as errors introduced by the device's operator. The performance of a hand-held pipette is inseparable from the performance of its operator.

NOTE More information about operator impact is given in ISO 8655-10.

6 Test conditions

6.1 General

Test conditions described in this clause shall be validated for their suitability for the selected test method and procedure. Test conditions, together with the test equipment and detailed test procedure, impact the uncertainty of measurement. Examples for the calculation of the expanded uncertainty of the mean volume and of the uncertainty in use of a single delivered volume are given in ISO/TR 16153^[1] and ISO/TR 20461^[2].

6.2 Test equipment

All equipment used for the testing of POVA, including for the preparation of test solutions, shall be chosen such that the required uncertainty of measurement can be obtained.

All test equipment used shall be of suitable readability, accuracy, reproducibility and stability, consistent with the required expanded uncertainty of measurement.

Deviations from the test equipment given in this document shall be taken into account when calculating the expanded measurement uncertainty and shall be proven to yield measurement results fit for the intended purpose.

6.3 Test room, environmental conditions

The following applies:

- a) The test room should be kept at a steady temperature throughout the entirety of the equilibration time for the test equipment and POVA (± 1 °C), and throughout the POVA testing time ($\pm 0,5$ °C). All test equipment, POVA, exchangeable parts (e. g. pipette tips), and reagents used shall be equilibrated to the test room temperature.
- b) The air temperature, relative humidity, and barometric pressure at the time of the test shall be recorded. At the start and at the end of the n replicate measurements, the temperature of the test liquid shall be recorded.