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Automated liquid handling systems —

Part 1: Vocabulary and general requirements

Systèmes automatisés de manipulation de liquides —

Partie 1: Vocabulaire et exigences générales

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Foreword

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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).

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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*.

This first edition of ISO 23783-1, together with ISO 23783-2 and ISO 23783-3, cancels and replaces IWA 15:2015.

A list of all parts in the ISO 23783 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

Globalization of laboratory operations requires standardized practices for operating automated liquid handling systems (ALHS), communicating test protocols, as well as analysing and reporting of performance parameters. IWA 15:2015 was developed to provide standardized terminology, test protocols, and analytical methods for reporting test results. The concepts developed for, and described in, IWA 15 form the foundation of the ISO 23783 series.

Specifically, this document addresses the needs of:

— users of ALHS, as a basis for calibration, verification, validation, optimization, and routine testing of trueness and precision;

— manufacturers of ALHS, as a basis for quality control, communication of acceptance test specifications and conditions, and issuance of manufacturer's declarations (where appropriate);

— test houses and other bodies, as a basis for certification, calibration, and testing.

The tests established in this document should be carried out by trained personnel.

Automated liquid handling systems —

Part 1:
Vocabulary and general requirements

1 Scope

This document defines terms relating to automated liquid handling systems (ALHS). This document also specifies general requirements for the use of ALHS. It describes types of ALHS and specific use requirements, settings, and adjustments for each ALHS type. It also specifies environmental requirements for the use of ALHS.

This document is applicable to all ALHS with complete, installed liquid handling devices, including tips and other essential parts needed for delivering a specified volume, which perform liquid handling tasks without human intervention into labware.

NOTE Measurement procedures for the determination of volumetric performance are given in ISO 23783-2. The determination, specification, and reporting of volumetric performance of automated liquid handling systems are described in ISO 23783-3.

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 23783-2, *Automated liquid handling systems — Part 2: Measurement procedures for the determination of volumetric performance*

ISO 23783-3:2022, *Automated liquid handling systems — Part 3: Determination, specification, and reporting of volumetric performance*

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
accuracy
accuracy of liquid delivery
<ALHS> closeness of agreement between the delivered volume and the target volume

Note 1 to entry: The concept "accuracy" is not given a numerical value. A liquid delivery is said to be more accurate when it is made with a smaller error.

Note 2 to entry: The term "accuracy" shall not be used for "trueness" and the term "precision" should not be used for ‘accuracy,’ which, however, is related to both of these concepts.

Note 3 to entry: The relationship between accuracy, systematic error, and random error of an automated liquid handling system is explained further in ISO 23783-3:2022, 5.1.

[SOURCE: ISO/IEC Guide 99:2007, 2.13, modified — definition and Notes 1 and 2 were modified for the context of automated liquid handling and Note 3 was replaced.]

3.2
air displacement
<piston-operated ALHS> liquid handling principle in which a body of air is contained between the piston and the test liquid

Note 1 to entry: It is possible to have a large air gap (piston systems), or a smaller air gap between the test liquid and the system liquid (liquid filled systems).

3.3
air gap
captive air volume
dead air volume
<piston-operated ALHS> air volume between the lower part of the piston and the surface of the aspirated liquid

Note 1 to entry: It is possible to have a large air gap (piston systems), or a smaller air gap for liquid filled systems.

3.4
automated liquid handling system
ALHS
system with a complete, installed liquid handling device, including tips and other essential components needed for delivering a specified volume without human intervention into labware

Note 1 to entry: Examples of automated liquid handling systems include automated pipetting systems (APS), and automated dispensing systems (ADS).

3.5
calibration
<ALHS> operation that, under specified conditions, establishes a relation between the target volume of the ALHS and the delivered volume

Note 1 to entry: A calibration may be expressed by a statement, a calibration curve or a calibration table. It may include a correction, but correction or adjustment is not a required element of a calibration.

[SOURCE: ISO/IEC Guide 99:2007, 2.39, modified — definition was simplified and modified for the context of automated liquid handling; Note 1 was simplified and Notes 2 and 3 were deleted.]

3.6
correction
mathematical compensation for a systematic effect

Note 1 to entry: The mathematical compensation can take different forms, such as an addend or a factor, or can be deducted from a table.

[SOURCE: ISO/IEC Guide 99:2007, 2.53, modified – added mathematical to the definition and Note 2, deleted estimated from the definition, and Note 1 was deleted.]

3.7
delivered volume
quantity delivered by a liquid handling system

Note 1 to entry: Delivered volume is a conceptual term and cannot be known with complete certainty due to measurement error.

3.8
dispense height
initial distance at which the test liquid is dispensed relative to a stated reference

Note 1 to entry: Dispensing from an initial fixed distance relative to the liquid surface will decrease the dispense height as the liquid level rises.

Note 2 to entry: Dispensing from a fixed distance relative to the well bottom will not change the dispense height over the course of the dispense.

Note 3 to entry: Dispensing and adjusting the distance relative to the liquid surface will not change the dispense height over the course of the dispense. This is an operational mode possible with some ALHS liquid level detection systems.

Note 4 to entry: Dispensing and adjusting the distance relative to the well bottom will increase the dispense height over the course of the dispense. This is an operational mode possible with some ALHS liquid level detection systems.

3.9
dispensing system
device for delivering liquids from a pre-filled liquid reservoir

3.10
disposable tip
component to transfer liquid, which is attached once and after use, as defined by the manufacturer, detached and intended to be discarded

Note 1 to entry: Disposable tips are usually made of plastic.

Note 2 to entry: Disposable tips are in contrast to *fixed tips* (3.13).

3.11
dry contact dispensing
transferring of liquid while the tip is in contact with a dry surface

3.12
factory acceptance testing
internal testing at the site of ALHS production to ensure ALHS performance to manufacturer's specifications

3.13
fixed tip
component to transfer liquid, which remains attached to the dispense head after use and is cleaned prior to its next use

Note 1 to entry: Fixed tips are in contrast to *disposable tips* (3.10).

3.14
forward mode pipetting
direct mode pipetting
process of liquid transfer where the entire aspirated volume is delivered

3.15
immersion depth
depth of the tip orifice below the liquid surface

Note 1 to entry: Immersion depth can be applied to both aspiration and dispensing (wet contact).

3.16
individually controlled channel
<ALHS> liquid handling channel that can be operated independently of other channels

3.17
inkjet type dispenser
dispensing system which uses technologies that deliver liquid volume as individual, free-flying droplets or jets (e.g. inkjet technology)

Note 1 to entry: For example, multiple volume increments as small as a few picolitres can be added up to dispense volumes of several microlitres.

3.18
labware
<ALHS> materials used in conjunction with liquid handling operations

Note 1 to entry: Labware includes, but is not limited to, disposable tips, reservoirs, receiving vessels, adapters and microplates.

3.19
liquid class
specific liquid or liquid type, which is defined by specific liquid characteristics that require specific settings of the liquid handler to achieve a desired volume delivery

3.20
maximum permissible error
upper or lower permitted extreme value for the deviation of the dispensed volume from the target volume

3.21
maximum specified volume
largest volume for which specifications are provided

3.22
measured volume
quantity reported by a volume measuring system

Note 1 to entry: In practice, all measurements contain some measurement error. The measured volume is a quantity value and serves as an estimate of the delivered volume which is not known with complete certainty.

3.23
minimum specified volume
smallest volume for which specifications are provided

3.24
measurement method
measurement procedure
detailed description of a measurement according to one or more measurement principles

Note 1 to entry: Sometimes, a distinction is drawn between a "'measurement method" and a "measurement procedure". In this document, the terms are used interchangeably.

Note 2 to entry: The measurement method descriptions in this document detail the steps needed to make a volume measurement and calculate certain descriptive statistics. Additional details needed to operate the ALHS are part of the *test process* (3.51). In this document, the measurement method is one of the components of a test process.

3.25
measurement uncertainty
<delivered volume> non-negative parameter characterizing the statistical dispersion of the delivered volumes

Note 1 to entry: The measurement uncertainty of the mean delivered volume and the measurement uncertainty of a single delivered volume are two distinct applications of this concept.

Note 2 to entry: The measurement uncertainty of the mean delivered volume and the measurement uncertainty of a single delivered volume include contributions from the random errors and uncorrected systematic errors of the ALHS.

Note 3 to entry: The measurement uncertainty includes contributions from the measuring system uncertainty, as well as the ALHS under test.

Note 4 to entry: These measurement uncertainties can be estimated according to ISO/IEC Guide 98-3.

3.26
measuring system uncertainty
non-negative parameter characterizing the statistical dispersion of the volume results of the measurement procedure, which does not include the uncertainty of the ALHS under test

Note 1 to entry: The measuring system uncertainty can be estimated according to ISO/IEC Guide 98-3.

3.27
metrological confirmation
set of operations required to ensure that the ALHS conforms to the requirements for its intended use

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

Note 2 to entry: Metrological confirmation is not achieved until and unless the fitness of the ALHS for the intended use has been demonstrated and documented.

Note 3 to entry: The requirements for intended use include such considerations as range, resolution and maximum permissible errors.

Note 4 to entry: Metrological requirements are usually distinct from, and are not specified in, product requirements.

[SOURCE: ISO 9000:2015, 3.5.6, modified — the terms 'measurement equipment' and 'equipment' were replaced by 'ALHS.']

3.28
metrological traceability
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

Note 1 to entry: Additional information can be found in the notes to definition (ISO/IEC Guide 99:2007, 2.41) and the related term 'metrological traceability chain' (ISO/IEC Guide 99:2007, 2.42).

[SOURCE: ISO/IEC Guide 99:2007, 2.41, modified — Notes 1 to 4 were deleted and a new Note 1 to entry was added.]

3.29
microplate
flat plate with an array of wells

Note 1 to entry: Some dimensions of microplates are defined in ANSI/SLAS standards[5–9].

3.30
multichannel head
<ALHS> group of liquid handling channels operated in common

Note 1 to entry: Common arrangements of multichannel heads include 8-, 96-, 384-, and 1 536-channel heads. Other arrangements are possible, e.g. 2-channel to 1 536-channel configurations.

3.31
multi-dispense
repeat dispense
sequential dispense
<ALHS> collection of dispenses without intervening aspiration

Note 1 to entry: First dispense can be different and is frequently wasted.

Note 2 to entry: Repeat dispenses usually dispense repeatedly the same volume, while sequential dispenses usually dispense different volumes.