

American National Standard



ANSI/AAMI ST55:2016/ (R)2023

Table-top steam sterilizers

Table-top steam sterilizers

Approved 7 October 2016 by
AAMI

Approved 1 November 2016 and reaffirmed 3 April 2023 by
American National Standards Institute, Inc.

Abstract: This standard establishes minimum construction and performance requirements for small table-top steam sterilizers that use saturated steam as the sterilizing agent and that have a volume less than or equal to 56.63 liters (2 cubic feet).

Keywords: distilled water, moist heat sterilization, process monitoring, saturated steam, steam sterilization

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Published by

AAMI
901 N Glebe Road, Suite 300
Arlington, VA 22203

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Printed in the United States of America

ISBN 978-1-57020-626-9

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Hospital Steam Sterilizer Working Group

This standard was developed by the AAMI Hospital Steam Sterilizer Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of this standard does not necessarily mean that all working group members voted for its approval.

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NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

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Acknowledgement

The working group thanks Mark N. Smith, who served as cochair through much of this revision to ANSI/AAMI ST55.

Foreword

This standard was developed by the AAMI Hospital Steam Sterilizer Working Group under the auspices of the AAMI Sterilization Standards Committee. The objective of this standard is to provide minimum labeling, safety, performance, and testing requirements to help ensure a reasonable level of safety and efficacy of table-top steam sterilizers that are intended for use in health care facilities and that have a volume less than or equal to 2 cubic feet.

This standard is the fourth edition of *Table-top steam sterilizers*, which was first published as an American National Standard in 1997 as ANSI/AAMI ST55:1997. In comparison to the second edition, which was approved in 2003, this new edition covers cassette sterilizers (which were excluded from the scope of previous editions), incorporates revisions of the methodology for testing the biological performance of table-top steam sterilizers with dental handpieces, and includes a requirement that certain sterilizers be tested for noncondensable gases.

Compliance with this standard does not guarantee that sterilization will be achieved, but it does help ensure that the steam sterilizer will be capable of providing the conditions necessary to achieve product sterility when operated according to appropriate procedures.

Compliance with this standard is voluntary. The existence of the standard does not preclude anyone from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard.

This voluntary standard is intended primarily for use by equipment manufacturers in the performance and design qualification of table-top steam sterilizers intended for use in health care facilities. The criteria defined in this standard might be useful to health care personnel and purchasing authorities in the acquisition process. However, the standard is not intended to provide guidelines for hospital receiving–inspection testing or for steam sterilization procedures in health care facilities. In addition, any problems with existing equipment should not be judged solely in terms of conformance to this standard.

As used within the context of this document, “shall” indicates requirements to be strictly followed in order to conform to the standard; “should” indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited; “may” is used to indicate that a course of action is permissible within the limits of the standard; and “can” is used as a statement of possibility and capability. “Must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

This standard should be considered flexible and dynamic. AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203

NOTE—This foreword does not contain provisions of the American National Standard, *Table-top steam sterilizers* (ANSI/AAMI ST55:2016), but it does provide important information about the development and intended use of the document.



Table-top steam sterilizers

1 Scope

1.1 General

This standard applies to steam sterilizers that are intended for use in health care facilities and that have a volume less than or equal to 56.63 liters (2 cubic feet [ft³]).

NOTE—For purposes of this standard, *health care facilities* refers to hospitals, nursing homes, extended-care facilities, freestanding surgical centers, clinics, and medical and dental offices. For convenience, the term *hospital* is sometimes used in this standard; in all instances, this term should be taken to encompass all other health care facilities.

1.2 Inclusions

This standard covers minimum labeling, safety, performance, and testing requirements for small steam sterilizers, including cassette sterilizers, that have a volume less than or equal to 56.63 liters (2 ft³), have automatic controls, and provide means of controlling time and temperature. Definitions of terms and normative references are also included, as well as an annex explaining the rationale for the provisions of the standard and other informative annexes.

NOTE—This standard is intended primarily for use by manufacturers in the performance and design qualification of table-top steam sterilizers that are intended for use in health care facilities. The criteria defined in this standard might be useful to health care personnel and purchasing authorities in the acquisition process. However, the standard is not intended to provide guidelines for receiving–inspection testing or steam sterilization procedures in health care facilities.

1.3 Exclusions

Manually controlled steam sterilizers (i.e., sterilizers without software control) and all other sterilizers not covered in 1.2 are excluded from the scope of this standard.

NOTE—Minimum labeling and performance requirements for large steam sterilizers (those having a volume greater than 56.63 liters [2 ft³]) are covered in ANSI/AAMI ST8. Guidelines for steam sterilization procedures in health care facilities, including typical steam sterilization cycle parameters, are provided in ANSI/AAMI ST79.

2 Normative references

The following documents contain provisions that, through reference in the text, constitute provisions of this standard. At the time of publication, the editions indicated were valid.

2.1 American Society of Mechanical Engineers. *Boiler and pressure vessel code*. New York: ASME (with current amendments).

2.2 Association for the Advancement of Medical Instrumentation. *Hospital steam sterilizers*. ANSI/AAMI ST8:2013.

2.3 Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization processes*. ANSI/AAMI/ISO 11138-3:2010. Arlington (VA): AAMI.

2.4 Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Chemical indicators—Part 5: Class 2 indicators for Bowie and Dick air removal test sheets and packs*. ANSI/AAMI/ISO 11140-5:2012. Arlington (VA): AAMI.

2.5 Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Moist heat—Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*. ANSI/AAMI/ISO 17665-1.

2.6 National Fire Protection Association. *National electrical code*. ANSI/NFPA 70. Current Edition. Quincy (MA): NFPA.

2.7 Underwriters Laboratories. *Electrical equipment for measurement, control, and laboratory use—Part 1: General requirements*. UL 61010-1. Current edition. Northbrook (IL): UL.

NOTE—For product conformity assessments, the Part 2 standard for steam sterilizers (Normative Reference 2.8) is to be used in conjunction with the applicable Part 1 standard for electrical equipment for laboratory use (Normative Reference 2.7).

2.8 International Electrotechnical Commission. *Electrical equipment for laboratory use—Part 2: Particular requirements for autoclaves using steam for the treatment of medical materials and for laboratory processes*. IEC 61010-2-040. Current edition. Geneva (Switzerland): IEC.

3 Definitions, symbols, and abbreviations

For the purposes of this standard, the following definitions apply.

3.1 accuracy: Extent to which the measured value of a quantity differs from the true value of the quantity measured.

3.2 cassette sterilizer: Sterilizer that uses a removable cassette as both the container to hold the items to be sterilized and the vessel that contains the sterilant (steam) for processing.

3.3 certification: Formal report of test results attesting to the satisfactory performance of a sterilizer and accompanied by a statement to this effect signed by the manufacturer's authorized representative.

3.4 certified laboratory standards: Standards traceable to the National Institute for Standards and Technology (NIST) or other recognized industry or government standards.

NOTE—The Quality System regulation states that “if national or international standards are not practical or available, the manufacturer shall use an independent reproducible standard. If no applicable standard exists, the manufacturer shall establish and maintain an in-house standard.” [21 CFR 820.72(b)(1)]

3.5 chamber: Portion of the sterilizer in which items are processed and that is sealed off from the ambient environment when the door is closed.

3.6 control-set temperature: Arbitrary temperature that serves as the operating reference for the sterilizer control system so that the chamber temperature will remain within the required range around the selected sterilization exposure temperature.

3.7 control system (sterilizer): System that regulates the sterilization conditions within a sterilization chamber.

3.8 cycle: Defined sequence of operational steps designed to achieve sterilization and carried out in a sealed chamber.

3.9 cycle, steam sterilization, dynamic-air-removal type: One of two types of sterilization cycles in which air is removed from the chamber and the load by means of a series of pressure and vacuum excursions (prevacuum cycle) or by means of a series of steam flushes and pressure pulses above atmospheric pressure (steam-flush pressure-pulse [SFPP] cycle).

3.10 cycle, steam sterilization, gravity-displacement type: Type of sterilization cycle in which incoming steam displaces residual air through a port or drain in or near the bottom (usually) of the sterilizer chamber.

NOTE—Typical operating temperatures are 121 °C to 123 °C (250 °F to 253 °F) and 132 °C to 135 °C (270 °F to 275 °F).

3.11 D value: Time or dose required to achieve inactivation of 90 % of a population of a test microorganism under stated conditions.

3.12 drying time: Time required to dry steam-sterilized items before they are handled.

3.13 handle: As the term is used in this standard, a hand-operated device used to open and close the chamber door or to lock or unlock the chamber. The term may also be applied to devices used to control the flow of steam, water, or power to the sterilizer.

3.14 holding time: Period for which the temperature at the control location for the sterilizer is held within the sterilization temperature band.

NOTE—Holding time follows immediately after the preconditioning phase. The length of the holding time is related to the sterilization temperature.

3.15 jacket: Portion of the sterilizer surrounding and affixed to the chamber through which steam is circulated and that functions to help maintain temperature in the chamber.

3.16 noncondensable gas: Air or other gas that will not liquefy under the conditions of a saturated steam process.

3.17 preconditioning phase: Phase of a steam sterilization cycle during which air is removed from and steam is injected into the sterilizer chamber.

3.18 pressure vessel: Sealed cavity capable of withstanding internal pressure above atmospheric pressure.

3.19 psi: Pounds per square inch. More specific designations are pounds per square inch absolute (psia, referenced to an absolute vacuum), pounds per square inch gauge (psig, referenced to atmospheric pressure), and kiloPascals (kPa, referenced to absolute vacuum). Typical values of pressure for saturated steam sterilization are given in Table 1:

Table 1—Conversions of saturated pressure units at sea level

psia	psig	kPa absolute	Temperature °C (°F)
29.8	15.1	205.5	121 (250)
41.9	27.2	288.9	132 (270)
45.4	30.7	313.0	135 (275)
53.3	38.6	367.5	141 (285)

3.20 probability of survival: See **sterility assurance level**.

3.21 process challenge device (PCD): Item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process.

3.22 recording and controlling instruments: Instruments designed to permit control of a parameter, such as temperature, and to provide a permanent record of the parameter being controlled.

3.23 saturated steam: Water vapor in a state of equilibrium between condensation and evaporation.

3.24 steam generator: Device that adds sufficient heat to water to convert it to steam.

3.25 sterility assurance level (SAL): Probability of a single viable microorganism occurring on an item after sterilization.

NOTE 1—SAL is normally expressed as 10^{-n} .

NOTE 2—A 10^{-6} SAL or an SAL providing a greater assurance of sterility (i.e., 10^{-7} , 10^{-8} , etc.) means that there is less than or equal to one chance in a million that a single, viable microorganism is present on a sterilized item. It is generally accepted that an SAL of 10^{-6} is appropriate for items intended to come into contact with compromised tissue (i.e., tissue that has lost the integrity of the natural body barriers). See also ANSI/AAMI ST67.

3.26 sterilization exposure temperature: Minimum temperature achieved and maintained during the holding time.

3.27 sterilizer: Apparatus used to sterilize medical devices, equipment, and supplies by direct exposure to the sterilizing agent.

3.28 sterilizer, steam: Sterilizing apparatus that uses saturated steam under pressure as the sterilizing agent.

3.29 timer: Mechanical or electronic device that, when set, controls the time during which the sterilizer is held at the selected sterilization conditions.

4 Requirements

4.1 Labeling

4.1.1 Device markings

4.1.1.1 Identification

Each sterilizer shall have labelling that is permanently affixed and reasonably accessible, that provides the following information:

- the manufacturer's name and address;
- the manufacturer's type and model designation;