American National Standard

ANSI/AAMI ST55:2016/(R)2023

Table-top steam sterilizers

AAMI
Advancing Safety in Health Technology

American National Standard

ANSI/AAMI ST55:2016/(R)2023
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Table-top steam sterilizers

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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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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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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 welcome. 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 [ft^3]).

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 ft^3), 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 ft^3]) 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.