

American
National
Standard



ANSI/AAMI
ST55:2016

Table-top steam sterilizers

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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Table-top steam sterilizers

Approved 7 October 2016 by
AAMI

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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

AAMI Standard

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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.

At the time this document was published, the **AAMI Hospital Steam Sterilizer Working Group** had the following members:

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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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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, 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633.

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.