American National Standard

ANSI/AAMI ST8:2026

Hospital steam sterilizers

AAMI
Advancing Safety in Health Technology

Hospital steam sterilizers

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Abstract: 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 in steam sterilizers that are intended for use in health care facilities and that have a volume greater than 56.63 liters (2 cubic feet).

Keywords: steam sterilizers, testing requirements, moisture retention tests, immediate-use steam sterilization, electronic recording devices, sterilization, instructions for use (IFU), product sterility

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Committee representation

Association for the Advancement of Medical Instrumentation

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This AAMI American National Standard (ANS) was developed by the AAMI Hospital Steam Sterilization Working Group.

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Foreword

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- "shall" and "shall not" are used to express requirements;
- "should" and "should not" are used to express recommendations;
- "may" and "may not" are used to express permission;
- "can" and "cannot" are used as statements of possibility or capability;
- "might" and "might not" are used to express possibility;
- "must" is used for external constraints or obligations defined outside the document; "must" is not an alternative for "shall".

Suggestions for improving this document are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

NOTE—This foreword does not contain provisions of ANSI/AAMI ST8:2026; *Hospital steam sterilizers,* but it does provide important information about the development and intended use of the document.

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Introduction

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 in steam sterilizers that are intended for use in health care facilities and that have a volume greater than 56.63 liters (2 cubic feet).

This standard is the seventh edition of *Hospital steam sterilizers,* which was first published as an American National Standard in February 1983 as ANSI/AAMI ST8:1982. The standard was updated and published in revised editions in 1988, 1994, 2001, 2008, and 2013. The current (seventh) edition:

a) requires moisture retention tests to be conducted separately from the biological performance tests and to utilize full sterilization cycles rather than half- cycles;

b) excludes drying time from being used during the biological performance testing;

c) incorporates the term "immediate-use steam sterilization" (IUSS) in place of the term "flash sterilization;"

d) allows for electronic recording devices to be provided instead of a printer with a printout; and

e) adds a requirement that the instructions for use (IFU) specify a process for cleaning the chamber and loading equipment.

Conformance 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.

This standard is intended primarily for use by equipment manufacturers in the performance and design qualification of steam sterilizers intended for use in health care facilities. The criteria defined in this standard can 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. This standard is not intended to apply to existing equipment already installed in health care facilities.

Hospital steam sterilizers

1 Scope

1.1 General

This standard applies to steam sterilizers that are intended for use in hospitals and other health care facilities and that have a volume greater than 56.63 liters (L) (2 cubic feet [ft^3]).

NOTE For purposes of this standard, *health care facilities* means 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 is intended to encompass all other health care facilities.

1.2 Inclusions

This standard covers minimum labeling, safety, performance, and testing requirements for steam sterilizers that have a volume greater than 56.63 L (2 ft^3), have automatic controls, generally use an external steam source (but might also have an integral electric boiler), and provide a means for automatically recording 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 steam sterilizers intended for use in health care facilities. The criteria defined in this standard can 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.

1.3 Exclusions

Sterilizers that generate steam inside the sterilizing chamber and all other sterilizers not covered in 1.2 are excluded from this standard. Likewise, this standard does not cover installation acceptance testing, sterilization procedures, machine-operator requirements, or sterility assurance testing in health care facilities.

NOTE 1 Minimum labeling and performance requirements for small steam sterilizers (those that are 56.63 L [2 ft^3] or less in volume) are covered in ANSI/AAMI ST55.

NOTE 2 Guidelines for the use of large and small health care steam sterilizers are provided in ANSI/AAMI ST79. ANSI/AAMI ST79 also covers in-hospital steam sterilization procedures and quality control, as well as the selection and use of containment devices intended for use in steam sterilization.

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.

ANSI/AAMI/ISO 11138-3, *Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization processes*

ANSI/AAMI/ISO 11140-5, *Sterilization of health care products—Chemical indicators—Part 5: Class 2 indicators for Bowie and Dick air removal test sheets and packs*

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