American National Standard

ANSI/AAMI ST40:2004/(R)2010

Table-top dry heat (heated air) sterilization and sterility assurance in health care facilities

Association for the Advancement of Medical Instrumentation

The 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 fume of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards health care 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.

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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.

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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.

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American National Standard

ANSI/AAMI ST40:2004/(R)2010
(Revision of ANSI/AAMI ST40:1992/(R)1998)

Table-top dry heat (heated air) sterilization and sterility assurance in health care facilities

Developed by
Association for the Advancement of Medical Instrumentation

Approved 7 October 2004 and reaffirmed 24 March 2010 by
American National Standards Institute Inc.

Abstract: This recommended practice provides guidelines for dry heat sterilization in health care facilities. It covers functional and physical design criteria for work areas; staff qualifications, education, and other personnel considerations; sterilization processing procedures; installation, care, and maintenance of table-top dry heat sterilizers; and quality control. Definitions, a bibliography, and annexes providing supplementary information are also included

Keywords: dry heat sterilization, quality control, table-top sterilizers

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International standards adopted in the United States may include normative references to other international standards. For each international standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the international standard. (Note: Documents are sorted by international designation.)

Other normatively referenced international standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1-2:2001 and Amendment 1:2004	ANSI/AAMI/IEC 60601-1-2:2001 and Amendment 1:2004	Identical
IEC 60601-2-04:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and Amendment 1:1996	ANSI/AAMI II36:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI II51:2004	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
ISO 5840:200x[1]	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002	ANSI/AAMI/ISO 10993-4:2002	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:2002	ANSI/AAMI BE78:2002	Minor technical variations
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical

[1] Currently at FDIS stage

International designation	U.S. designation	Equivalency
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995 and Amdt 1:2001	ANSI/AAMI/ISO 11137:1994 and A1:2002	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO TS 11139:2001	ANSI/AAMI/ISO 11139:2002	Identical
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations
ISO 11607:2003	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 11737-3:2004	ANSI/AAMI/ISO 11737-3:2004	Identical
ISO TR 13409:1996	AAMI/ISO TIR13409:1996	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	Identical
ISO 15223:2000, A1:2002, and A2:2004	ANSI/AAMI/ISO 15223:2000, A1:2001, and A2:2004	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000 and A1:2004	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO TR 15844:1998	AAMI/ISO TIR15844:1998	Identical
ISO 15882:2003	ANSI/AAMI/ISO 15882:2003	Identical
ISO TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 25539-1:2003	ANSI/AAMI/ISO 25539-1:2003	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

Dry Heat Sterilization Working Group

This recommended practice was developed by the AAMI Dry Heat Sterilization Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of this recommended practice 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 recommended practice does not constitute endorsement by the federal government or any of its agencies.

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Foreword

This recommended practice was developed by the AAMI Dry Heat Sterilization Working Group, under the auspices of the AAMI Sterilization Standards Committee. This document provides guidelines for dry heat sterilization in dentists' and physicians' offices, laboratories, ambulatory care facilities, and other health care facilities. These guidelines are intended to promote sterility assurance and assist health care personnel in the proper use of dry heat sterilization processing equipment.

This document is the second edition of the recommended practice, which was first published in 1992 as *Table-top dry heat (heated air) sterilization and sterility assurance in dental and medical facilities* and reaffirmed in 1998. In this edition, the recommendations have been updated, where necessary, to reflect current good practice; and information on user verification of cleaning processes and documentation of premature release of implants has been added.

This recommended practice reflects the conscientious efforts of health care professionals, in cooperation with sterilizer manufacturers, to develop recommendations for optimum performance in the processing of medical and dental devices to be dry heat sterilized. These recommendations are not intended to be construed as universally applicable to all circumstances. It is also recognized that in many cases these recommendations might not be immediately achievable. Therefore, the document should serve as a guide to desirable performance objectives, and all of the document's provisions should be considered and applied using professional judgment and experience.

As used within the context of this document, "shall" indicates requirements to be strictly followed to conform to the recommended practice; "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 recommended practice; 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.

The provisions of this recommended practice should be reviewed by office and departmental managers and adapted to the needs of their particular institutions. Written policies and procedures should be developed and implemented in consultation with appropriate departments, committees, and professionals (e.g., safety, infection control, hazardous materials). Policies and procedures should take into account federal, state, and local regulations; the recommendations of the Centers for Disease Control and Prevention; national voluntary standards and recommended practices; and device and equipment manufacturers' recommendations. The policies and procedures should be uniform throughout a health care facility, and compliance should be monitored.

The concepts incorporated in this recommended practice should be considered flexible and dynamic. The recommendations set forth in this document are reviewed and updated periodically to assimilate new data and advancements in technology. AAMI policies and procedures require that AAMI standards and recommended practices be reviewed and, if necessary, revised at least once every 5 years.

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—This foreword does not contain provisions of the American National Standard *Table-top dry heat (heated air) sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST40:2004), but it does provide important information about the development and intended use of the document.

Introduction: Need for this recommended practice

Preventing infection in persons undergoing dental, medical, or surgical treatment is important in avoiding human suffering and lessening health care costs. One aspect of the prevention of infection in health care facilities is the effective reprocessing or sterilization of reusable dental and medical devices by dry heat sterilization.

In dry heat sterilization, the energy of heated air is transferred to objects and kills microorganisms. Typically, devices to be sterilized are placed in a chamber that uses electrical elements as the heat source; hot, dry air at a specified temperature is circulated around the devices for a specified time.

Advances in dry heat sterilization technology have led to the increased use of this mode of sterilization in dental and medical offices, ambulatory care clinics, and other health care facilities. As many as 40,000 dental and medical facilities currently use dry heat sterilizers. Dental and medical offices and ambulatory care clinics might differ greatly from hospitals in their physical design and in their level of personnel training. Consequently, guidelines are needed for good processing practices, facility design, and personnel considerations that take into account the specific characteristics and needs of this segment of the health care community.

For any sterilization method, sterility assurance depends not only on the process itself but also on the ability to minimize bioburden before sterilization and to prevent contamination after sterilization. Consequently, in addition to processing recommendations, this recommended practice covers facility design considerations, personnel considerations, work practices, and other variables that affect the achievement and maintenance of sterility.

Although these guidelines are intended to help health care personnel accomplish dry heat sterilization safely and effectively, they are not intended to be a substitute for facility procedures or professional judgment.

NOTE—This introduction does not contain provisions of the American National Standard *Table-top dry heat (heated air) sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST40:2004), but it does provide important information about the development and intended use of the document.

Table-top dry heat (heated air) sterilization and sterility assurance in health care facilities

1 Scope

1.1 General

This recommended practice provides guidelines for decontamination and dry heat sterilization procedures used in dentists' and physicians' offices, laboratories, ambulatory care clinics, and other health care facilities. These guidelines are intended to promote the assurance of sterility by identifying the special considerations that apply to this method of sterilization and by providing recommendations on the proper use of table-top dry heat sterilization processing equipment. This recommended practice also covers facility design considerations, personnel considerations, work practices, and other variables that affect sterility assurance.

1.2 Inclusions

This recommended practice specifically addresses the following:

a) functional and physical design criteria for work areas;

b) staff qualifications, education, and other personnel considerations;

c) preparation and packaging of devices (wrapped and unwrapped methods);

d) sterilization procedures;

e) sterile storage and distribution;

f) installation, care, and maintenance of table-top dry heat sterilizers; and

g) quality control.

Definitions of terms, a bibliography, and annexes providing supplementary information about dry heat sterilization are also included.

1.3 Exclusions

This recommended practice does not cover

a) construction and performance criteria for table-top dry heat sterilizers (see ANSI/AAMI ST50);

b) conduction-type or radiation-type dry heat sterilization processes;

c) table-top sterilization processes that use sterilizing agents other than dry heat (such as ethylene oxide, steam, unsaturated chemical vapor, or peracetic acid); or

d) reprocessing of devices labeled for single use only.

2 Definitions, symbols, and abbreviations

For the purposes of this recommended practice, the following definitions apply.

2.1 ambulatory care: Short-term treatment of medical, dental, or surgical needs (within 24 hours) in an office or clinic type of environment.

2.2 bioburden: Population of viable microorganisms on a product and/or a package.

NOTE—When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units per single item.

2.3 biofilm: Matrix that contains cells, living and dead, as well as polysaccharide (sometimes referred to as *glycocalyx*), and that is exuded by microorganisms when they are growing in water or water solutions or *in vivo* (e.g.,