List of Titles

American National Standard

ANSI/AAMI ST50:2004

Dry heat (heated air) sterilizers

AAMI 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.

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 decisionmaking.

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 ST50:2004
(Revision of ANSI/AAMI ST50:1995)

Dry heat (heated air) sterilizers

Developed by
Association for the Advancement of Medical Instrumentation

Approved 7 April 2004 by
American National Standards Institute, Inc.

Abstract: This standard establishes minimum labeling and performance requirements for dry heat (heated air) sterilizers intended for use in dental and medical offices, laboratories, ambulatory-care clinics, hospitals, and other health care facilities.

Keywords: dry heat sterilization

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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. 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	ANSI/AAMI/IEC 60601-1-2:2001	Identical
IEC 60601-2-04:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 & Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:1998	Major technical variations
IEC TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
ISO 5840:1996	ANSI/AAMI/ISO 5840:1996	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001	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 10993-8:2000	ANSI/AAMI/ISO 10993-8:2000	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	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical

International designation	U.S. designation	Equivalency
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 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 14969:1999	ANSI/AAMI/ISO 14969:1999	Identical
ISO 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	Identical
ISO 15223:2000	ANSI/AAMI/ISO 15223:2000	Identical
ISO 15223/A1:2002	ANSI/AAMI/ISO 15223:2000/A1:2001	Identical
ISO 15223/A2:2004	ANSI/AAMI/ISO 15223:2000/A2:2004	Identical
ISO 15225:2000	ANSI/AAMI/ISO 15225:2000	Identical
ISO 15225/A1:2004	ANSI/AAMI/ISO 15225:2000/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 TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical
ISO 25539-1:2003	ANSI/AAMI/ISO 25539-1:2003	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Dry Heat Sterilization Working Group

This standard was developed by the AAMI Dry Heat Sterilization Working Group under the auspices of the AAMI Sterilization Standards Committee. Working group approval of the standard does not necessarily mean that all 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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Foreword

This standard was developed by the AAMI Dry Heat Sterilization 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 dry heat sterilizers that are intended for use in dental and medical facilities.

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

This document is the second edition of the standard, which was first published in 1995 as *Dry heat (heated air) sterilizers* (ANSI/AAMI ST50:1995). The current edition of the standard reflects general updating of reference material and editorial clarifications.

As used within the context of this document, “shall” indicates requirements strictly to be followed in order 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.

This standard should be considered flexible and dynamic. As technology advances and new data is brought forward, the standard will be reviewed and, if necessary, revised. 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 standard 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 *Dry heat (heated air) sterilizers* (ANSI/AAMI ST50), but it does provide important information about the development and intended use of the document.

American National Standard **ANSI/AAMI ST50:2004**

Dry heat (heated air) sterilizers

1 Scope

1.1 General

This standard applies to dry heat (heated air) sterilizers that are intended for use in dental and medical offices, laboratories, ambulatory-care clinics, hospitals, and other health care facilities.

1.2 Inclusions

This standard covers minimum labeling, safety, performance, and testing requirements for convection-type dry heat (heated air) sterilizers. Definitions of terms, normative references, and informative annexes (including an annex explaining the rationale for the provisions of this standard) are also included.

1.3 Exclusions

This standard does not cover conduction-type or radiation-type dry heat sterilizers, nor does it provide guidelines for sterilization or sterility assurance procedures within health care facilities.

NOTE—For guidelines on sterilization procedures, sterility assurance procedures, and other aspects of the use of dry heat sterilizers within health care facilities, see ANSI/AAMI ST40.

2 Normative references

2.1 NATIONAL FIRE PROTECTION ASSOCIATION. *National Electrical Code.* ANSI/NFPA 70:2002. Quincy (MA): NFPA, 2002. American National Standard.

2.2 UNDERWRITERS LABORATORIES. *Electrical equipment for laboratory use—Part 1: General requirements.* UL 61010A-1. Northbrook (IL): UL, 2002.

3 Definitions of terms

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

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

3.3 biological indicator (BI): Microbiological test system providing a defined resistance to a specified sterilization process.

NOTE—Biological indicators are intended to demonstrate whether or not the conditions were adequate to achieve sterilization. A negative BI does not prove that all items in the load are sterile or that they were all exposed to adequate sterilization conditions.

3.4 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.

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

3.6 chamber: Portion of a sterilizer in which items are processed and that is sealed off from the ambient environment during the sterilization cycle when the door is closed.

3.7 chemical indicator (CI): System that reveals change in one or more predefined process parameters based on a chemical or physical change resulting from exposure to a process.

NOTE—Chemical indicators are intended to detect potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. The “pass” response of a chemical indicator does not prove that the item accompanied by the indicator is sterile.

3.8 contaminated: State of having been actually or potentially in contact with microorganisms.

NOTE—As used in health care, the term generally refers to microorganisms that could be capable of producing disease or infection.

3.9 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.

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

3.11 culture: A growth of microorganisms in or on a nutrient medium; to grow microorganisms in or on such a medium.

3.12 culture medium: Substance or preparation used to grow and cultivate microorganisms.

3.13 cycle time reduction value: Time required to kill 90 % of spores on a biological indicator when the biological indicator is placed in a test pack.

3.14 D value: Time or radiation dose required to achieve inactivation of 90 % of a population of test microorganisms under stated exposure conditions.

NOTE 1—The larger the D value, the more resistant the microorganism is to destruction. The D value can be derived by plotting the logarithm of the number of microbial survivors against sterilization exposure time; the time corresponding to a 1-logarithm reduction in numbers can then be directly measured.

NOTE 2—For purposes of this standard, “radiation dose” does not apply.

3.15 dry heat sterilization: Sterilization process that utilizes dry heated air as the sterilizing agent.

3.16 exposure time: Period for which the process parameters are maintained within their specified tolerances.

3.17 F value: Measure of the microbiological inactivation capability of a heat sterilization process.

NOTE—The F value can be determined by a physical ($F_{(phys)}$) or biological ($F_{(bio)}$) method. The F value for a specific sterilization temperature and z value is referred to as F_H.

— $F_{(bio)}$: F_H determined by biological methods.

— F_H: For a dry heat sterilization process, the equivalent time, in minutes at 160 °C, that has been delivered to the product by the process and that assumes a z value of 20 °C.

— $F_{(phys)}$: F_H determined by physical methods.

3.18 Gram-negative bacteria: Bacteria that are decolorized when stained by Gram’s method, but take on the color of the counterstain.

3.19 Gram-positive bacteria: Bacteria that are not decolorized by Gram’s method, but retain the original violet color.

3.20 Gram’s method of staining: Method of differential staining used in microbiological identification.

NOTE—Gram’s method of staining is also called *Gram staining*.

3.21 heat sink: Heat-absorbent material; a mass that readily absorbs heat.

3.22 microorganism: An entity, encompassing bacteria, fungi, protozoa, and viruses, of microscopic size.

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

3.24 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.

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

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

NOTE 2—A SAL of 10^{-6} 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 a SAL of 10^{-6} is appropriate for items intended to come into contact with compromised tissue (that is, tissue that has lost the integrity of the natural body barriers). A SAL of 10^{-3} (a one in a thousand chance of a surviving microorganism) is considered acceptable for items not intended to come into contact with compromised tissue. See ANSI/AAMI ST67:2003.

3.26 sterilization: Validated process used to render a product free from viable microorganisms.

NOTE—In a sterilization process, the nature of microbiological death is described by an exponential function. Therefore, the presence of microorganisms on any individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

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

3.28 sterilizer, dry heat: Sterilizing apparatus that uses ambient, convected, or high-velocity hot air as the sterilant.

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

3.30 z value: Number of degrees of temperature (Fahrenheit or Celsius) required to obtain a 1-logarithm (to the base 10) change in the D value.

4 Requirements

4.1 Labeling

4.1.1 Device markings

4.1.1.1 Identification

Each sterilizer shall have one or more information plates that are permanently fastened and reasonably accessible and provide the following minimum information:

a) Manufacturer's name and address

b) Manufacturer's type and model designation

c) Serial number

d) Electrical supply requirements

e) Stamp or label of a nationally recognized certifying authority

4.1.1.2 Hazard labeling

Because the sterilizer uses high temperatures to kill microorganisms, certain high-temperature surfaces will be encountered on and around the sterilizer during operation, in both the closed-door and open-door configurations. Labels shall be applied to the sterilizer to alert the operator to these high-temperature surfaces and advise the user not to open the door until the cycle is completed (see also 4.4). Adequate written information shall be supplied with the sterilizer to alert the operator to areas of potential hazard (see 4.1.2).

4.1.2 Information manual

The sterilizer shall be accompanied by a manual containing the following minimum information:

a) Manufacturer's name and address

b) Manufacturer's type and model designation of the sterilizer

c) Instructions for the installation of the sterilizer, complete and comprehensive enough to ensure the safe and effective operation of the equipment, including such information as the required building system utilities and type of materials to be used for installation

d) Instructions for the safe and effective operation of the sterilizer, including recommended loading procedures, normal safety precautions to be taken during routine use, recommended sterilizer cycles, operating temperature range of the sterilizer (i.e., the sterilization exposure temperature and how far above that temperature the sterilizer will run), and the recommended test pack to be used during biological monitoring (see Annex B and ANSI/AAMI ST40)

e) Information regarding the types of devices, materials, and load configurations that were used by the manufacturer in simulated-use testing (see 5.7.3)

f) Instructions for inspection and preventive and routine maintenance, including a schedule for implementing inspection and routine maintenance procedures; a caution that these procedures should be carried out by trained personnel; specific directions concerning the maintenance of critical components such as timers, heaters, and/or fans, if applicable; and the name, address, and telephone number of the nearest authorized service agent or representative

NOTE—Information concerning the nearest service agent or representative need not be a permanent part of the information manual, but may be provided in the form of a sticker or insert affixed to the manual.

4.1.3 Service manual

The manufacturer shall make available to the user a complete service manual, comprehensive enough to ensure that the safety and effectiveness of the sterilizer can be maintained. Information about parts availability shall be supplied.

4.2 Electrical components

The sterilizer electrical system shall be designed, manufactured, and tested in accordance with UL 61010A-1 (see 2.2). The sterilizer electrical system shall be designed for installation in conformance to the *National Electrical Code* (see 2.1).

4.3 Loading accessories

Loading shelves, trays, baskets, cassettes, racks, and other accessories supplied by the sterilizer manufacturer shall be resistant to pitting, cracking, and other damage from the sterilizing agent.

4.4 Prevention of thermal hazards

The temperature of all handles or similar devices that will be used by the operator during normal operation of the sterilizer shall comply with UL 61010A-1 (see 2.2). See also 4.1.1.2.

4.5 Sterilizer controls for aborting cycles

A means of safely aborting or terminating a cycle in progress shall be readily accessible to the operator and clearly described in the operator's manual.

4.6 Process control and monitoring devices

4.6.1 Chamber temperature

4.6.1.1 Temperature control and monitoring

The sterilizer shall be equipped with a means of continuously indicating chamber temperature. There shall also be a means of connecting an optional time and temperature recorder. The indicating and recording means may be one and the same.

NOTE—The recorder may be a both recording and controlling instrument.

4.6.1.2 Positioning of temperature sensors

The temperature sensor(s) for the indicator(s) and recorder shall be positioned to ensure that the actual temperature of the chamber air is at or above the temperature indicated and recorded.

4.6.1.3 Accuracy of temperature measurement

When tested against certified laboratory standards (see 3.5), the temperature indicator(s) and recorder shall be accurate to within ± 1 °C (or ± 2 °F) over the sterilizer's designated operating range.

4.6.1.4 Resolution of temperature measurement

Temperature graduations on a recorder chart, if provided, shall not exceed 1 °C or 2 °F throughout the entire range from 5 °C or 10 °F above to 5 °C or 10 °F below the recommended sterilization temperature. Digital printouts shall be rounded to the nearest whole degree or truncated to whole degrees unless printed in tenths of a degree.

4.6.1.5 Sterilizer temperature control

The control-set temperature shall be selected and the control shall function so that the chamber temperature does not fall below the selected sterilization exposure temperature of 160 °C (320 °F) or higher. Any mechanism provided to the operator to select the sterilization exposure temperature shall be marked in, or adjustable to, increments no larger than 1 °C or 2 °F throughout the entire range from 5 °C or 10 °F above to 5 °C or 10 °F below the manufacturer's recommended sterilization exposure temperature. The temperature control system shall initiate sterilization exposure timing when the selected sterilization exposure temperature has been achieved, reset the timer if the chamber temperature falls 5 °C or 10 °F below the control-set temperature, and alert the operator to the occurrence of the under-temperature condition.

4.6.2 Sterilizer exposure timer

The sterilizer shall be equipped with an exposure timer. In the event of an electrical power failure or cycle interruption, the timer shall automatically reset or the cycle shall be aborted and the operator alerted, unless the controls are capable of determining that the temperature has not dropped below the limit established in 4.6.1.5. The timer shall have a minimum accuracy of ± 5 % of the set value.

4.6.3 Airflow

If mechanical airflow is integral to the function of the sterilizer, means shall be provided to ensure that the specified airflow is maintained during the cycle. In the event of a mechanical airflow failure independent from a generalized electrical power failure or cycle disruption, the cycle shall be aborted and the operator alerted.

4.6.4 Cooling

If cool-down is integral to the function of the sterilizer, means shall be provided to ensure that cool-down is accomplished. At least one bacteria-retentive filter, having a minimum filtration efficiency of 99.97 % for 0.3 micron particles, shall be installed in each air inlet or vent. Filters shall be readily accessible for routine maintenance.

4.7 Biological performance of sterilizers

When tested according to 5.7, the manufacturer's recommended cycle or cycles shall have a sufficient lethality to reduce a resistant biological indicator (BI) population to a 10^{-6} probability of a surviving organism, and the test results shall otherwise meet the acceptance criteria defined in 5.7.

4.8 Certification and record-keeping

Reports of tests performed according to this standard shall be certified by the sterilizer manufacturer and kept on file for the design life of the sterilizer. The manufacturer shall recertify the equipment design and performance of current production sterilizers at least every 24 months and upon any change in design that might affect the safety and efficacy of the sterilizer type.

4.9 Software quality assurance

4.9.1 Software developed in-house

When a dry heat sterilizer manufacturer incorporates software developed in-house, a software quality assurance (SQA) program shall be in place. This program shall outline a systematic approach to development that involves the following major goals:

a) Measuring the development process phase

b) Validating that the output of each phase satisfies requirements

c) Documenting and controlling any changes made

d) Revalidating

4.9.2 Custom-developed software

When a dry heat sterilizer manufacturer incorporates custom software purchased from contractors, the contractors shall have an SQA program that ensures that the major goals listed in 4.9.1 have been adequately achieved.

4.9.3 Off-the-shelf software

When a dry heat sterilizer manufacturer incorporates software from vendors or subcontractors, the SQA program shall ensure that the major goals listed in 4.9.1 have been adequately achieved.

5 Tests

This section provides referee test methods and procedures by which compliance with the requirements of section 4 can be verified. These tests are not intended for routine quality assurance testing or in-hospital installation, acceptance, or preventive maintenance testing. The paragraph numbers below correspond to those of section 4 except for the first digit (e.g., compliance with the requirement of 4.6.1.1 can be determined by the test method of 5.6.1.1).

Test apparatus and instruments. Apparatus and instruments used for testing sterilizers must be calibrated for accuracy. The quality assurance program establishing the frequency and method of calibration must be documented. The calibration of all test instruments must be traceable to primary standards as specified in the federal Quality System regulation (21 CFR 820.72).

Installation and operation of sterilizers. The sterilizers used in testing compliance with the requirements of section 4 shall be identical to and installed and operated in the same way as those that will be provided by the manufacturer to health care facilities.

5.1 Labeling

Compliance with the requirements of 4.1 can be verified by inspection.

5.2 Electrical components

Methods by which compliance with the electrical safety requirements of 5.2 can be verified are provided in UL 61010A-1 (see 2.2) and the *National Electrical Code* (see 2.1).

5.3 Loading accessories

Compliance with the requirements of 4.3 can be verified by inspection.

5.4 Prevention of thermal hazards

Temperature-measuring devices (e.g., thermocouples) are attached to the handwheels, handles, or similar devices used by the operator during normal sterilizer operation. The sterilizer is tested in a room in which the ambient temperature is maintained between 18 °C and 24 °C (65 °F and 75 °F). A normal sterilization cycle is run, and the temperatures are monitored for compliance with UL 61010A-1 (see 2.2).

5.5 Sterilizer controls for aborting cycles

Compliance with 4.5 can be verified by inspection.

5.6 Process control and monitoring devices

5.6.1 Chamber temperature

5.6.1.1 Temperature monitoring and recording

Compliance with 4.6.1.1 can be verified by inspection.

5.6.1.2 Positioning of temperature sensors

Compliance with 4.6.1.2 can be verified by inspection.

5.6.1.3 Accuracy of temperature measurement

Compliance with 4.6.1.3 can be verified by testing against calibrated standards.

5.6.1.4 Resolution of temperature measurement

Compliance with 4.6.1.4 can be verified by inspection.

5.6.1.5 Sterilizer temperature control

Compliance with 4.6.1.5 can be verified by placing calibrated temperature-measuring sensors with continuous temperature readout in the empty sterilizer chamber. The number of sensors may vary with chamber size and

configuration, but a minimum of five temperature sensors should be used in each of the following locations: lower front, upper front, center, lower rear, and upper rear of the cart or basket containing the load in the chamber. The intent of this temperature control is to ensure that the sterilizer is capable of providing steady-state thermal conditions within the chamber that are consistent with the desired sterility assurance level (SAL) in the load. The manufacturer of the sterilizer shall verify and document that at any place where an item could be positioned within the chamber, the temperature parameters of 4.6.1.5 are satisfied for recommended operating cycles and loads. The requirements of 4.6.1.5 for exposure timing, timer reset, and alarms can be verified by inspection.

5.6.2 Sterilizer exposure timer

Compliance with 4.6.2 can be verified by inspection and testing the timer against a certified laboratory standard traceable to the National Institute for Standards and Technology.

5.6.3 Airflow

Compliance with 4.6.3 can be verified by inspection.

5.6.4 Cooling

Compliance with 4.6.4 can be verified by inspection and making time and temperature measurements for the load and comparing them to the manufacturer's specifications. HEPA filters used for air inlets or vents should be tested routinely by a qualified testing service at intervals no less than those recommended by the hot air equipment manufacturer.

5.7 Biological performance of sterilizers

5.7.1 General considerations

The biological performance of dry heat sterilizers shall be evaluated by the manufacturer as part of initial design qualification and periodically thereafter (see 4.8) on production sterilizers; records shall be maintained in accordance with 4.8. The tests shall be performed both with maximum loads and with the chamber empty except for the test pack; three consecutive cycles, at the same operating parameters, shall be run for both the maximum-load and empty-chamber tests. The BIs used in testing shall contain *Bacillus atrophaeus* (formerly called *Bacillus subtilis*) spores (usually 10^6) or other spores whose resistance to the dry heat sterilization process has been shown to be equal to or greater than that of *B. atrophaeus*. The culturing and incubation conditions shall be in accordance with the instructions supplied by the BI manufacturer.

5.7.2 Biological-indicator challenge test pack

5.7.2.1 Construction and placement of the test pack

A challenge test pack, constructed in accordance with the manufacturer's recommendations to the user (see 4.1.2(d)) and containing one dry heat chemical indicator (CI) and one BI, is placed on the bottom shelf of the sterilizer at the front near the door. The sterilizer is fully loaded (in accordance with the manufacturer's instructions for a maximum load) with appropriately packaged instruments. A second series of three consecutive cycles is run with the chamber empty except for the test pack.

NOTE—A standard BI challenge test pack has not yet been developed and qualified for the dry heat sterilization process. However, Annex B describes a proposed test pack, a test protocol, and noncollaborative test data that dry heat sterilizer manufacturers may wish to consider as a reference in developing and recommending test packs for their equipment.

5.7.2.2 Cycle operation

A normal sterilization cycle is run according to the instructions that the manufacturer provides to health care facilities, but with exposure times appropriate for establishing compliance with the sterility assurance requirements of 4.7 and acceptance criteria of 5.7.2.4. The cycle time reduction value necessary to determine the SAL can be estimated from survival curve data (e.g., Pflug, 1973) or fraction-negative data (e.g., Pflug, 1977; Stumbo, 1973).

5.7.2.3 Incubation of BIs

See 5.7.1.

5.7.2.4 Acceptance criteria

The manufacturer shall demonstrate that the recommended cycle has a SAL of at least 10^{-6}. This SAL represents the inactivation of 12 logarithms of a microorganism with a minimum $D_{160\ °C}$ of 2.5 minutes and a reference z value of 20 °C; this results in a minimum F_H of approximately 30. The temperature sensor readings shall confirm the achievement of a time–temperature relationship during the cycle sufficient to produce an F_H of at least 30.

5.7.3 Simulated-use tests

5.7.3.1 Test items

The biological performance of the sterilizer also shall be tested under simulated-use conditions. That is, tests shall be performed using replicates of the devices and types of materials that the sterilizer manufacturer has indicated in the labeling are capable of being sterilized in the equipment. The test items should exhibit design configurations that will provide the greatest challenge to heat penetration. Characteristics that can affect heat penetration include the number, type, thickness, density, mass, and thermal conductivity of the various materials (heat barriers) making up the article. Simulated-use testing shall be performed with load configurations that are commonly used in the workplace.

5.7.3.2 Placement of BIs and temperature sensors

The sterilizer is fully loaded (in accordance with the manufacturer's instructions for a maximum load) with appropriately packaged (if applicable) instruments/materials. BIs are placed in the most-difficult-to-sterilize locations of the device. If it is not possible to reach these areas of the device with a spore strip or other inoculated substrate, then the device may be inoculated with a liquid spore suspension, which should be dried onto the device prior to subjecting it to the dry heat sterilization process. The test items are placed in the coolest portions of the chamber. Temperature sensors are placed throughout the load as per 5.6.1.5.

5.7.3.3 Cycle operation

See 5.7.2.2.

5.7.3.4 Incubation of BIs

See 5.7.1.

5.7.3.5 Acceptance criteria

See 5.7.2.4.

5.8 Certification and record-keeping

Compliance with 4.8 can be verified by inspection.

5.9 Software quality assurance

Guidelines for assessing software quality assurance programs can be found in numerous U.S. Food and Drug Administration (FDA) documents such as FDA (1987, 1989, 1992, 1993, 1995, 1996, 1997, 1998, 1999), as well as in the considerable literature on software development, quality assurance, and validation.

Annex A
(informative)

Rationale for the development and provisions of this standard

A.1 Introduction

This annex discusses the need to develop a standard to guide sterilizer manufacturers in the performance qualification of dry heat sterilizers intended for use in health care facilities. This annex also provides the rationale for each of the provisions of this standard.

A.2 An overview of dry heat sterilization

A.2.1 Historical perspective

Starting with Robert Koch in 1881, dry heat sterilization was branded with the twin epithet, “slow and problematic” (Koch and Wolffhuegel, 1881). Indeed, penetration of dry heat through coverings such as paper is much slower than penetration of moist heat. The application of dry heat in an oven is difficult to control, because the density of the air decreases rapidly as it is heated, promoting stratification. Even if a fan is used to mix cold and warm air, load temperature in ovens is likely to vary, because the specific heat of air is low (Hailer and Heicken, 1929). Not surprisingly, a marked aversion developed against this agent, as expressed by one prominent authority (Walter, 1948): “The use of dry heat is limited to the sterilization of articles which do not withstand the corrosive action of steam, anhydrous objects which are spoiled by moist heat, and anhydrous substances which prevent the bactericidal action of moist heat. Cutting edge instruments, surgical gut, ground glass, and dry chemicals such as greases, oils, and glycerine are examples.”

Early in this century, health care workers were confronted with a need for dry heat specifications, particularly temperature and time. Around 1930, an upper limit of 160 °C (320 °F) or thereabouts was set on the basis of metallurgy. The temper of surgical instruments heated much beyond that value could be altered (Jeffries and Archer, 1924). In regard to exposure time, quantitative experiments with dry spores in sand heated to 135 °C to 145 °C (275 °F to 293 °F) demonstrated a requirement of 15 minutes or less to destroy some 10^6 colony-forming units (Murray and Headlee, 1931; Murray, 1931; Headlee, 1931). In a 1940 study, Oag reported a thermal death time of 9 minutes when spores of *Bacillus anthracis* dried onto glass were heated at 160 °C (320 °F). These studies all show that dry heat can be an efficient means of sterilization if the conditions of exposure are diligently controlled.

Unfortunately, this line of quantitative research never progressed to table-top ovens. In the absence of hard facts, especially data concerning heat transfer within different kinds of loads, the widely accepted standard that did evolve seems more reasonable: 1 hour at 160 °C (320 °F). So popular was this formulation that it gained equal status with the conditions of steam sterilization most often cited: “In dry heat sterilization an exposure time of 60 min at 160 °C is approximately the equivalent of 15 min at 121 °C in moist heat” (McCulloch, 1945). The *United States Pharmacopeia*, 15th edition, recommended 170 °C (338 °F) for 120 minutes (USP, 1955).

Modern dry heat sterilizers (those manufactured since 1987) have incorporated improved heat transfer techniques using mechanical air circulation, high-speed laminar flow, and higher process temperatures. These improvements, coupled with extensive validation testing required by regulatory agencies, allow the use of fixed exposure cycles and shorter exposure and overall process times.

A.2.2 How dry heat (heated air) sterilization is accomplished

Dry heated air sterilization is accomplished through the transfer of heat energy to objects upon contact. Microbial destruction results from dehydration, which prevents the cell from reproducing, either by direct effects on the genetic system or disrupting the metabolic systems that provide the required stimulation and nutrient environment for reproduction.

A.2.3 Types of dry heat sterilizers

Some types of dry heat sterilizers work by convection heating, others by conduction heating, and still others by radiation heating. Conduction- and radiation-type dry heat sterilizers are not covered in this standard.

There are two basic methods of convective dry heat sterilization: batch and continuous. In a *batch process*, a predetermined quantity of items is simultaneously subjected to a convective dry heat sterilization cycle. In a *continuous process*, a predetermined quantity of items is processed at a predetermined rate through a convection cycle; an example of this type is a conveyorized dry heat process.

All known table-top dry heat sterilizers are of the batch type because they are simpler to manufacture, install, and operate. Almost all of the batch designs in use today use electrical heating elements as the energy source for heating air. A typical batch cycle is usually made up of three phrases: (a) heat-up, (b) exposure and hold, and (c) cool-down.

The simplest batch-type dry heat sterilizer is the *static air type*, in which heating is by natural convection (gravity). This type of sterilizer is usually preheated to the desired temperature, the load is placed into the heated chamber, the load is heated for an established period of time, and the load is then removed and allowed to cool naturally. (See Figure A.1.)

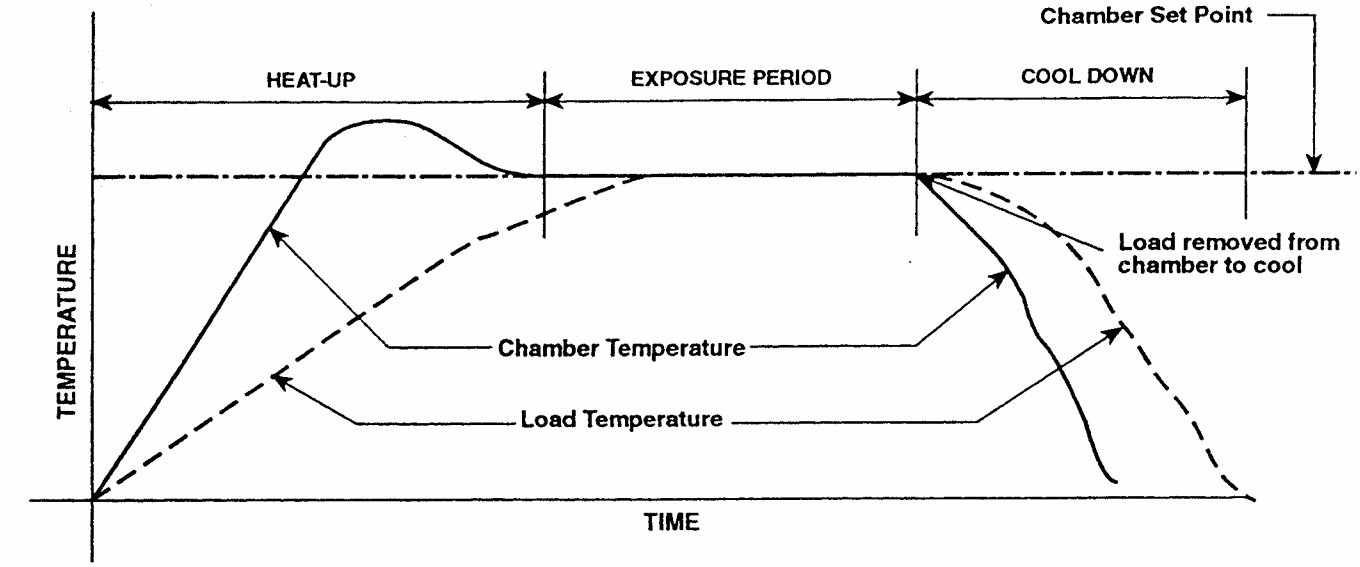

Figure A.1—Batch cycle: Convective dry heat (static air)
(Courtesy SPS Medical)

Other batch-type dry heat sterilizers operate by *forced air*; some of these sterilizers use *continuous heating* and some use *heating from ambient temperature*. In the continuous-heating type, continuous, high-velocity, heated air is circulated through the chamber. A load is placed into the continuously heated chamber and an exposure time is selected. The cool load causes the chamber temperature to decrease. The load and chamber are heated to the pre-established temperature and the selected exposure time commences once the chamber temperature recovers to its pre-established level. At the end of the exposure period, the load is removed from the chamber and allowed to cool. (See Figure A.2.)

In sterilizers using heating from ambient temperature, a load is placed in an otherwise cold (room temperature) sterilizer chamber, the processing conditions are selected, and the cycle is started. The chamber and load are simultaneously heated by high-velocity heated air. Exposure time commences when a pre-established chamber temperature is achieved. At the end of the exposure period, the load is allowed to cool in the chamber until it is safe to handle. (See Figure A.3.)

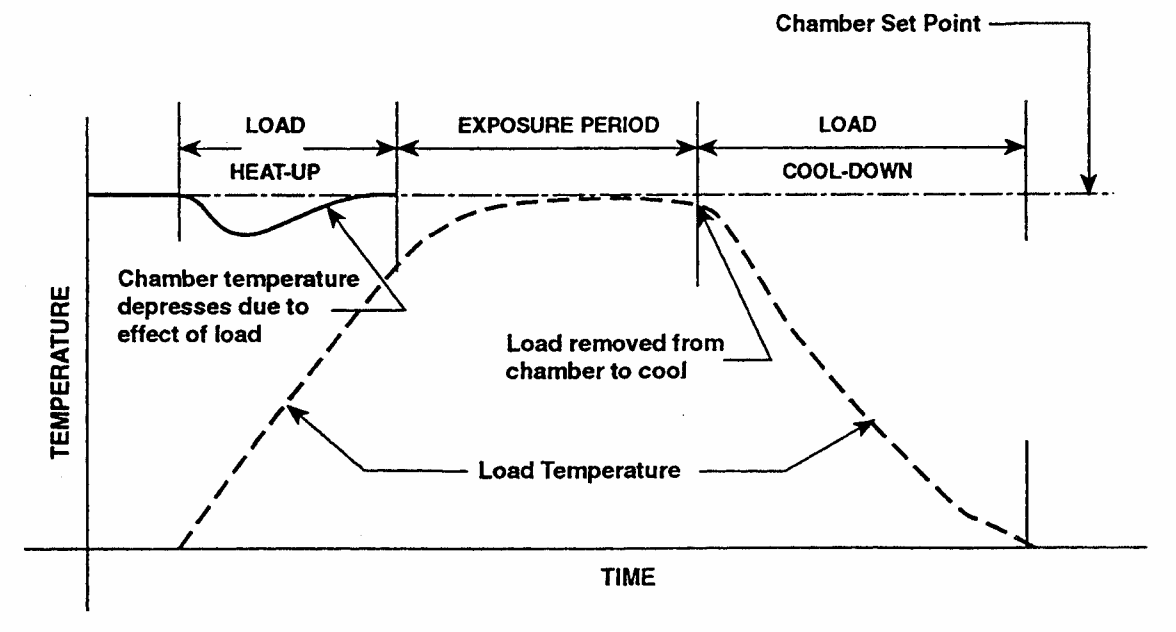

Figure A.2—Batch cycle: Convective dry heat (forced air) with chamber heat continuously maintained
(Courtesy SPS Medical)

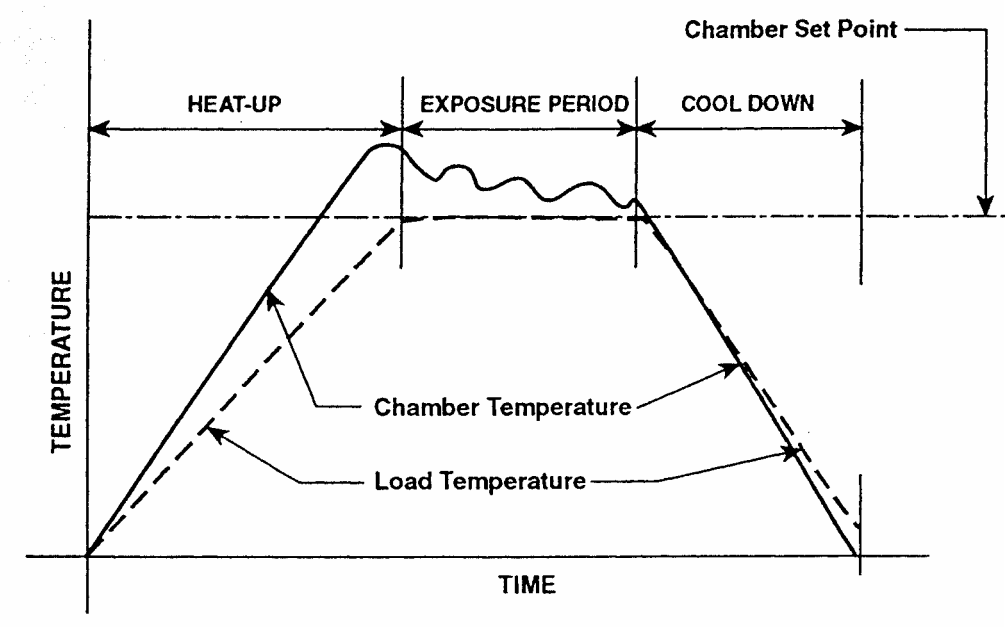

Figure A.3—Batch cycle: Convective dry heat (forced air); load remains in chamber during cool-down
(Courtesy SPS Medical)

A.2.4 Variables associated with the dry heat sterilization process

The major variables associated with dry heat sterilization are temperature, time, airflow rate and air distribution, and load configuration/distribution:

a) **Temperature.** The most important variable in dry heat sterilization is temperature. It is the measure of the heat energy level(s) available during the sterilization process. The effect of heat energy is a function of time. As the temperature is increased, the necessary exposure time is reduced.

b) **Time.** Sterilization science has defined time as the cumulative intervals over which microbial destruction takes place. This is also referred to as integrational lethality. To simplify this concept and provide a margin of safety, sterilization engineers used the term “exposure time” to mean the time at which a load has been exposed to a predetermined temperature profile or specified temperature designed to achieve sterilization.

c) **Airflow rate and air distribution.** Airflow, whether by convection or mechanical means, and air distribution are factors affecting heat energy transfer efficiency. The heated air must be distributed uniformly within the load. Optimal air velocity reduces microorganism resistance by means of dehydration, resulting in reduced sterilization times.

d) **Load configuration.** The size and density of the load, as well as the number and shapes of instruments contained in the load, can affect airflow rate and air distribution in the sterilizer.

The lethality of the dry heat sterilization process is also affected by the water content of the microorganisms, the physical and chemical properties of the microorganisms and adjacent support, the extent to which the microorganisms are protected from the sterilizing agent, and the gas atmosphere.

A.2.5 How dry heat sterilization is measured

As a load contaminated with microorganisms is heated, microbial destruction ensues at some minimum temperature and increases in rate as heating proceeds.

The most common method of measuring dry heat sterilization is to maintain a specified temperature for a prescribed time. This heat dosage is called “exposure time,” which is an indirect measurement of microbial destruction.

In some dry heat sterilizers, microbial destruction can be tracked as it occurs if the killing power (lethal rate) is known for the temperatures to which the load is exposed, and this information is programmed into the device. In practice, a load signals its temperature to a time-keeping microprocessor, which converts that temperature to a lethal rate and integrates that rate over the time held into quantitative lethality. As exposure continues, the cumulative sum of these incremental lethalities converges on sterilization.

A.2.6 Typical items sterilized by dry heat

Dry heat sterilization is commonly used for items that can withstand the high temperatures of this process, such as dental instruments, burrs, reusable needles, glass syringes, medical instruments, glassware, and heat-stable powders and oils. For any given item, the manufacturer’s written instructions should be consulted to verify that dry heat sterilization is appropriate.

A.3 Need for a standard for dry heat sterilizers

Advances in dry heat sterilization technology have led to the increased use of this mode of sterilization in dental and medical offices and ambulatory-care clinics. As many as 40,000 medical and dental facilities currently use dry heat sterilizers. As with any type of sterilizer, it is important to ensure that dry heat sterilizers perform effectively in order to avoid the potential for sterilization failures that could cause patient infections. Also, considering the high temperatures associated with dry heat sterilization, sterilizers must be labeled and designed with operator safety in mind.

The FDA’s General Hospital and Personal Use Device Classification Panel summarized its reasons for recommending Class II (performance standards) for dry heat sterilizers as follows:

> The Panel recommends that dry-heat sterilizers be classified into Class II because the Panel believes that performance standards are necessary to assure that the device maintains the correct temperature for a length of time adequate for proper sterilization of medical products. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel also recommends that the labeling of the device provide proper instructions for its use and describe the need for periodic performance testing using a sterilization indicator. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device, and that there is sufficient information to establish a standard to provide such assurance . . .

> Risks to health: Infection. If the dry-heat sterilizer fails to maintain the correct temperature for a length of time adequate to sterilize medical products properly, patients exposed to the products may experience infection. [FDA, 1979]

The specific rationale for each of the provisions of this standard is provided in A.4 of this annex, but, in summary, the standard is based on the following premise: To minimize the risk of patient infection, adequate control of sterilizing time and temperature is needed. Assurance of this control is best provided by defining criteria for use by the manufacturer in equipment qualification; therefore, this standard addresses the performance characteristics and instrumentation needed to provide adequate process control. With respect to potential safety hazards, the standard defines labeling and safety features necessary for reasonable protection of the operator.

In conclusion, the purpose of this standard is to help provide reasonable assurance that dry heat sterilizers intended for use in health care facilities will adequately sterilize medical products and materials through control of the necessary variables for dry heat sterilization, and that dry heat sterilizers can be used safely by health care personnel.

A.4 Rationale for the specific provisions of this standard

A.4.1 Labeling

The requirements of 4.1 are intended to help ensure that users of dry heat sterilizers will be given sufficient information by the manufacturer to enable them to correctly install, safely and effectively operate, and adequately maintain the equipment. In view of the relatively long life of a sterilizer, a permanently fastened identification plate (4.1.1.1) is required in order to permit the identification of essential characteristics if operating manuals have been lost. The labeling and markings required in 4.1.1.2 are intended to reduce the risk of operator burns from high-temperature surfaces. The information and service manuals defined in 4.1.2 and 4.1.3 are intended to help ensure the proper operation and maintenance of dry heat sterilizers. See Annex B regarding the requirement (4.1.2(d)) that the manufacturer recommend a test pack.

A.4.2 Electrical components

Compliance with UL 61010A-1 and the *National Electrical Code* helps protect sterilizer operators from electrical hazards.

A.4.3 Loading accessories

Loading accessories must be resistant to pitting and other damage in order to help prolong the useful life of the equipment, prevent loads from being contaminated, and ensure that the materials used will present a clean appearance that can be easily maintained over time.

A.4.4 Prevention of thermal hazards

The requirements of 4.4 are intended to ensure that surfaces touched by the operator during normal sterilizer operation cannot exceed a safe temperature.

A.4.5 Sterilizer controls for aborting cycles

In the event of an emergency, it could be necessary to abort or terminate a cycle in progress. For their own safety, operators should clearly understand how to accomplish this procedure.

A.4.6 Process control and monitoring devices

The efficacy of dry heat sterilization depends upon the exposure of the items to dry heat at a specified temperature for a specified time under specified airflow conditions. To ensure that the sterilizer will reliably provide these conditions, requirements are specified in 4.6.1.1, 4.6.1.2, 4.6.1.3, 4.6.1.4, 4.6.1.5, and 4.6.2 for the location, accuracy, and readability of the sterilization parameter indicating and recording system; airflow characteristics and cool-down are addressed in 4.6.3 and 4.6.4, respectively. Regarding temperature control in particular (4.6.1), the objective of the requirements is to ensure that at all points within the usable chamber, the temperature is within the control band of 4.6.1.5, so that the actual chamber temperature does not fall below the selected sterilization exposure temperature. The accuracy requirements should ensure uniform temperature control and exposure time readings; these requirements are considered realistic and consistent with an acceptable SAL. The air-break filter required in 4.6.4 is intended to help prevent recontamination of devices and materials before they are removed from the sterilizer.

A.4.7 Biological performance of sterilizers

Dry heat sterilizers must be biologically challenged to ensure the efficacy of the equipment and lethality of the recommended processing parameters.

The requirements and tests of 4.7 and 5.7 were designed for purposes of manufacturers' qualification testing, but they are intended to simulate the most difficult sterilization conditions that would normally be encountered in health care facilities. The methods for verifying the attainable SAL are conventional methods used in sterilization science.

To demonstrate that the sterilizer functions in a reproducible manner, three consecutive runs, both for the maximum-load configuration and with the chamber empty except for the test pack, are required for certification. Such studies must be repeated at least every 24 months or whenever a design change occurs that could affect performance (see A.4.8). Empty-chamber testing is required because, due to the lack of heat-sink effects, rapid heat-up to the chamber set temperature can be expected; it is necessary to verify that adequate lethality can be delivered to the test pack under these conditions.

If the sterilizers to be tested are installed and operated in a manner different from that recommended to the final user, the results might not be a valid representation of how the equipment will perform in actual use.

With respect to the requirements of 5.7.3, effective sterilization of a medical device requires adequate process parameters for biocidal efficacy (a SAL of 10^{-6}) and assurance that the sterilant can contact all surfaces of the device. This assurance can only be achieved by simulated-use tests.

A.4.8 Sterilizer performance certification and record-keeping

Section 4.8 requires the sterilizer manufacturer to document conformance to this standard as part of the original design qualification, every 24 months for production sterilizers of the originally qualified design, and upon any change in design. Certification is essential to help demonstrate that the sterilizer, as originally designed and qualified, is safe and efficacious. Recertification helps ensure that the safety and efficacy of production sterilizers do not deviate from the originally qualified design, and that any design changes do not affect safety and efficacy.

This standard also requires the sterilizer manufacturer to keep thorough test reports as proof and documentation that the sterilizer conforms to this standard. It is the purchaser's right to receive, upon request, a copy of these test reports from the manufacturer.

A.4.9 Software quality assurance

Since software may control critical functions of the equipment, it is essential that software used in dry heat sterilizers be developed and validated in accordance with currently accepted principles of software quality assurance.

Annex B
(informative)

Example of a biological-indicator challenge test pack for dry heat sterilizers

B.1 Introduction

As part of its review criteria for premarket notification (510(k)) submissions for sterilizers, FDA requires sterilizer manufacturers to use BI challenge test packs in the performance validation of their products and recommend challenge test packs to users for routine monitoring of sterilization cycles (FDA, 1993). There should be a test pack for each type of cycle indicated in the labeling.

Where "standard" test packs do not exist (i.e., consensus test packs such as those recommended for EO sterilizers and steam sterilizers in ANSI/AAMI ST41 and ANSI/AAMI ST46, respectively), sterilizer manufacturers must either develop and validate test packs for use with their equipment or establish test load conditions for purposes of routine monitoring. In a 510(k) submission, a sterilizer manufacturer must describe in detail the composition of the test pack(s) used in performance validation of the sterilizer and that will be used in routine performance monitoring by the user. The submission must also include a description of how the test pack(s) present a rigorous challenge to the sterilization process, the rationale for the composition of the test pack, and how the test pack itself was validated.

A standard BI challenge test pack has not yet been developed and qualified for the dry heat sterilization process. Based on preliminary work performed by one laboratory, however, this annex describes a proposed test pack, a test protocol, and noncollaborative test data that dry heat sterilizer manufacturers may wish to consider as a reference in developing and recommending test packs for their equipment. The test pack and test loads described here are simply examples, and it may be desirable for the manufacturer to use additional BIs in testing.

NOTE—Data discussed in this annex was derived from tests conducted at SPS Medical by Jack Scoville, formerly of SPS Medical.

B.2 Composition of a proposed test pack for dry heat sterilizers

The test pack consists of a 3 inch (in) x 3 in pouch fabricated from 3 in nylon tubing, 14 2 in x 2 in 8-ply cotton gauze sponges, 1 dry heat CI, and 1 dual-species dry heat BI packaged in a 30 # sterilizable blue glassine envelope. The BI and the CI are placed in the center of the stack of 14 gauze sponges (7 sponges above the indicators, 7 below). The stack of sponges is then placed in the 3 in x 3 in nylon pouch.

B.3 Test objective

The objective of the testing is to define a standard BI challenge test pack, consisting of easily obtained materials, that will present an adequate challenge to all types of dry heat sterilizers. The degree of challenge presented by the test pack is to be characterized by determining the thermal profile of the proposed test pack and correlating that profile with the results of fractional exposure testing using BIs and CIs.

B.4 Methods and materials

Biological indicators must have a $D_{160\,^{\circ}C}$ value that meets the criteria of the current edition of the *U.S. Pharmacopeia*.

All temperature-sensing devices must be calibrated to recognized standards, the degree of accuracy and reproducibility to be ± 1 °C (or ± 2 °F).

All sensing devices must be consistently placed. At least one sensing device must be located in the geometric center of the pack, and one sensor must be located outside the pack to monitor chamber temperature. Other sensors may be placed as necessary or desired.

New cotton gauze sponges and nylon film pouches must be used for each test.

B.5 Test procedure

The sterilizer is fully loaded in accordance with the manufacturer's loading instructions. The load should consist of instruments packaged in nylon film pouches. The BI test pack is placed on the lowest shelf at the front near the door or at the coolest chamber location as recommended by the manufacturer. Cycles are run in accordance with the manufacturer's recommendations and at fractional exposure times.

NOTE—Some of the preliminary test results reported in B.6 are half-cycle performance data. Sterilization scientists use the "half-cycle" as part of the "overkill" validation approach (see, for example, ANSI/AAMI/ISO 11135). The test load is seeded with BIs and processed under standard cycle conditions, but the cycle is interrupted at one-half the normal exposure time; one-half of the load,

with BIs, is retrieved. The cycle is then restarted and run to completion (normal time). Both sets of retrieved samples from the load are transferred to recovery media as per the current edition of the *U.S. Pharmacopeia*. The achievement of kill of 10^6 spores by the half-cycle means that the remaining half-cycle will kill another 10^6 spores and therefore yield a 10^{-6} SAL. If 10^6 spores are killed by the half-cycle and the full-cycle samples show no recovery, the cycle can be qualified.

B.6 Preliminary test data

NOTE—In the preliminary evaluation of the proposed test pack, four dry heat sterilizers were used, representing four of the most widely used models and processes.

B.6.1 Sterilizer A (static dry heat sterilizer)

The sterilizer and racks were preheated to 160 °C (320 °F). Six orthodontic pliers, weighing approximately 3.2 ounces each, were each packed in a nylon film package, placed three to a shelf in the chamber, and spread evenly. The BI test pack was placed at the center of the lower shelf at the front near the door (Figure B.1). Temperature profiles for the test pack are shown in Tables B.1 and B.2; Table B.3 shows BI and CI results.

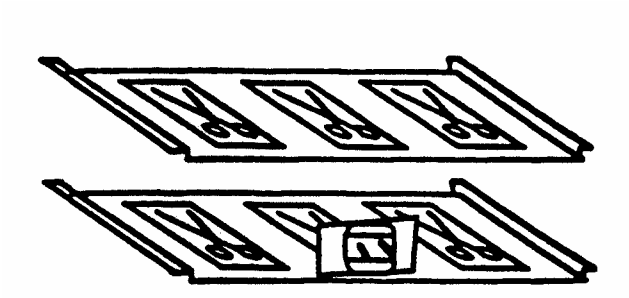

Figure B.1—Load configuration for Sterilizer A
(Courtesy SPS Medical)

Table B.1—Temperature profile for Sterilizer A (1 hour cycle)

Elapsed time	Test pack temperature	Chamber temperature	Sterilizer thermometer
17 minutes	280 °F	283 °F	320 °F
30 minutes	313 °F	301 °F	330 °F
37 minutes	320 °F	320.4 °F	335 °F
45 minutes	325 °F	325.4 °F	335 °F
60 minutes	327 °F	314 °F	338 °F

Table B.2—Temperature profile for Sterilizer A (30 minute cycle)

Elapsed time	Test pack temperature	Chamber temperature	Sterilizer thermometer
10 minutes	240 °F	271.5 °F	323 °F
20 minutes	283 °F	299 °F	330 °F
25 minutes	296.1 °F	305.9 °F	330 °F
30 minutes	303.4 °F	304.4 °F	330 °F

Table B.3—BI and CI results for Sterilizer A

Cycle	Spore strip*	Chemical indicator**	
		Strip	Tape
1 hour	0/1	C	C
30 minutes	1/1	C	C
Control	1/1		

* Number positive/number exposed.

** C = complete color change.

B.6.2 Sterilizer B (forced-air dry heat sterilizer)

The sterilizer was allowed to heat with an empty instrument drawer in place until the chamber reached the operating temperature of 375 °F. Six orthodontic pliers weighing approximately 3.2 ounces each were each packed in a nylon film package and then placed in the last six instrument rack locations. The BI test pack was placed in the seventh instrument rack location, facing the drawer handle (front) (Figure B.2). The empty heated drawer was removed and the loaded instrument rack was placed into the preheated sterilizer. The cycle time for “packaged goods” (12 minutes exposure time) was immediately selected. Figures B.3 and B.4 show the thermal profiles of the BI test pack and instrument rack for a 12 minute cycle and a 6 minute cycle (half-cycle), respectively. Table B.4 shows the BI and CI results.

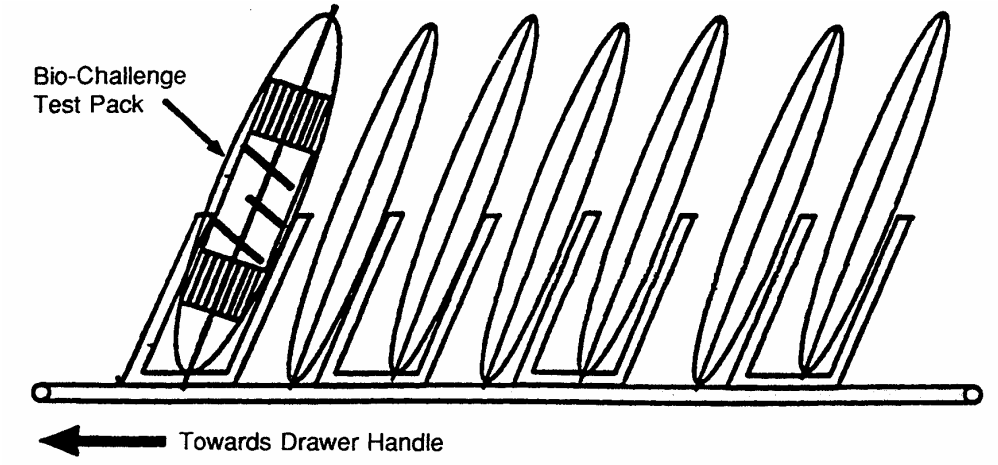

Figure B.2—Load configuration for Sterilizer B
(Courtesy SPS Medical)

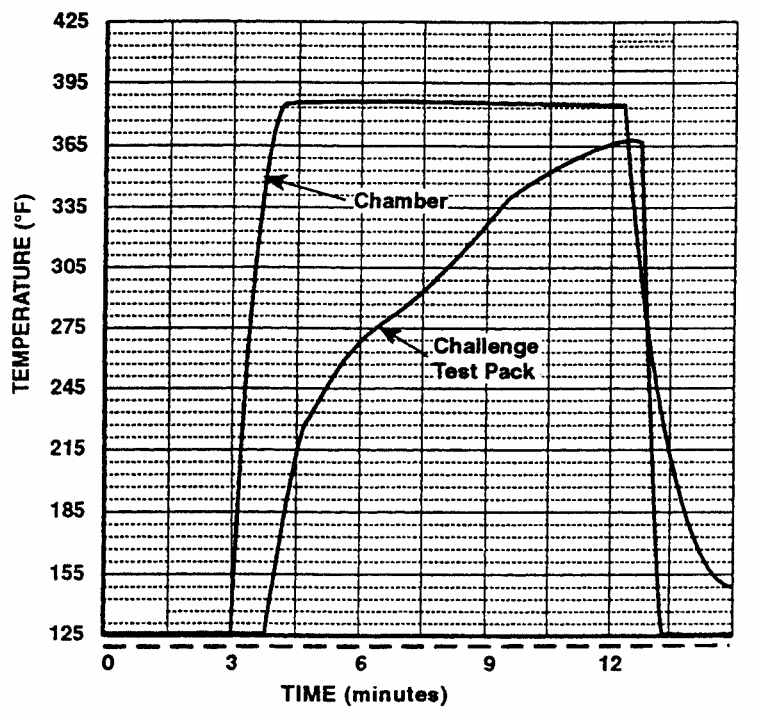

Figure B.3—Temperature profile for BI challenge test pack and instrument rack for Sterilizer B (12 minute cycle)
(Courtesy SPS Medical)

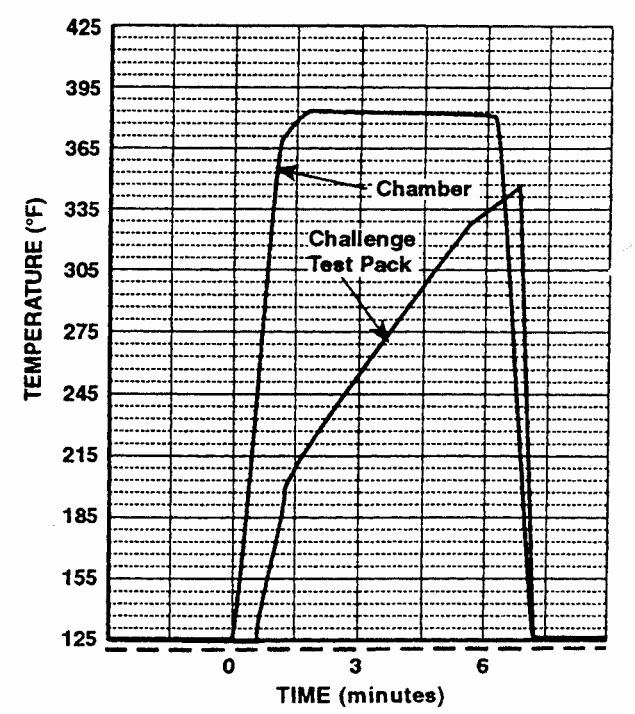

Figure B.4—Temperature profile for BI challenge test pack and instrument rack for Sterilizer B (6 minute cycle)
(Courtesy SPS Medical)

Table B.4—BI and CI results for Sterilizer B

Cycle	Spore strip*	Chemical indicator**	
		Strip	Tape
12 minutes	0/1	C	C
6 minutes	1/1	C	C
Control	1/1		

* Number positive/number exposed.

** C = complete color change.

B.6.3 Sterilizer C

Thirty-six orthodontic pliers weighing approximately 3.2 ounces each were placed on the four racks provided, nine pliers per rack. The BI challenge test pack was placed between racks #2 and #3 (numbered from left to right) at the front near the door (Figure B.5). A standard cycle was run according to the manufacturer's instructions and the following observations were made:

— Time to "sterilize light" on = 11 minutes, 34 seconds

— Actual exposure time = 6 minutes, 2 seconds

— Pack temperature at 12 minutes = 339 °F

— Chamber temperature at 12 minutes = 397 °F

— Time to cooling blower on = 17 minutes, 36 seconds

— Total elapsed time, including cool-down = 24 minutes, 54 seconds

— Pack temperature at end of cool-down = 143 °F

— Chamber temperature at end of cool-down = 87 °F

Table B.5 and Figure B.6 show temperature profiles for a half-cycle. Figure B.7 shows a temperature profile for a standard cycle. Table B.6 shows BI and CI results.

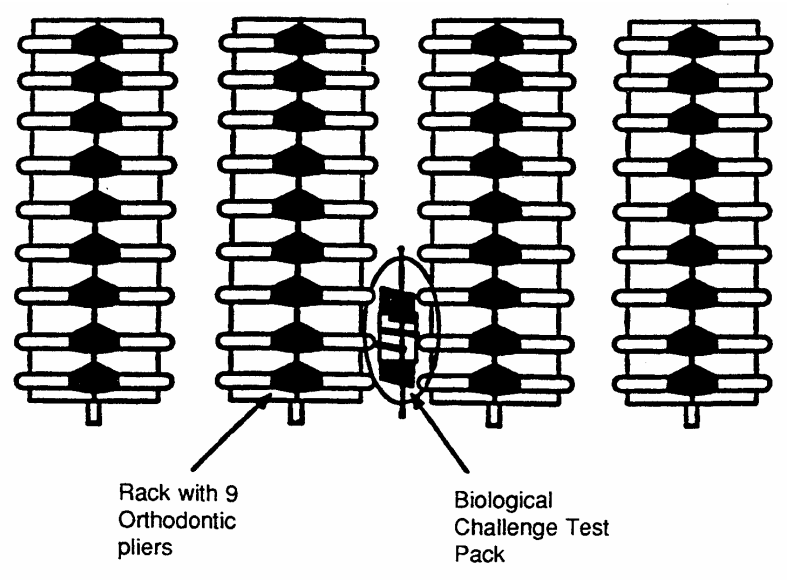

Figure B.5—Load configuration for Sterilizer C
(Courtesy SPS Medical)

Table B.5—Temperature profile for Sterilizer C (half-cycle)

Elapsed time	Test pack temperature	Chamber temperature
4 minutes	177 °F	208 °F
5 minutes	203 °F	339 °F
6 minutes	228 °F	269 °F
7 minutes	248 °F	293 °F
8 minutes	272 °F	321 °F
9 minutes	294 °F	344 °F
10 minutes	315 °F	365 °F
11 minutes	339 °F	388 °F
11 minutes, 21 seconds	349 °F	396 °F

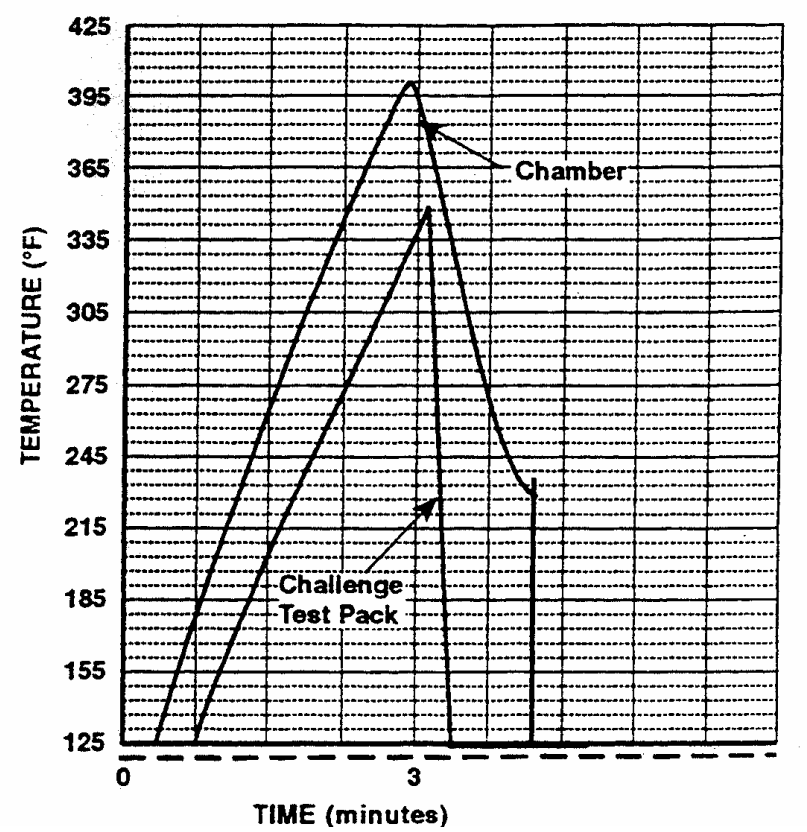

Figure B.6—Temperature profile for Sterilizer C (half-cycle)
(Courtesy SPS Medical)

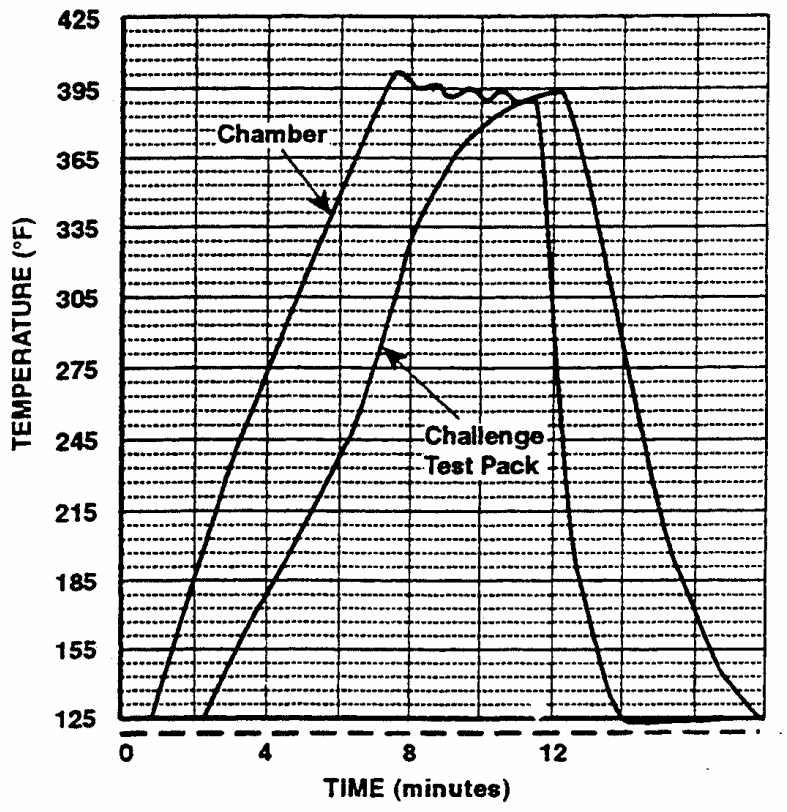

Figure B.7—Temperature profile for Sterilizer C (standard cycle)
(Courtesy SPS Medical)

Table B.6—BI and CI results for Sterilizer C

Cycle	Spore strip*	Chemical indicator**	
		Strip	Tape
Standard	0/1	C	C
Half-cycle	1/1	C	C
Control	1/1		

* Number positive/number exposed.

** C = complete color change.

B.6.4 Sterilizer D

Three tests were run. In test #1, 18 orthodontic pliers weighing approximately 3.2 ounces each were each packed in heat-resistant nylon tubing packaging material and secured at both ends with dry heat indicator tape. The 18 packaged pliers were then placed on the sterilizer instrument trays, six per tray. The BI challenge test pack was placed in the center of the lower tray near the door (front) (Figure B.8).

In test #2, 27 orthodontic pliers were packaged as in test #1 and placed on the sterilizer instrument trays, nine per tray. The BI challenge test pack was placed in the center of the lower tray near the door (front) (Figure B.9).

In test #3, 30 orthodontic pliers were packaged as in test #1 and placed on the sterilizer instrument trays, 10 per tray. The BI challenge test pack was placed at the left rear of the top tray (Figure B.10).

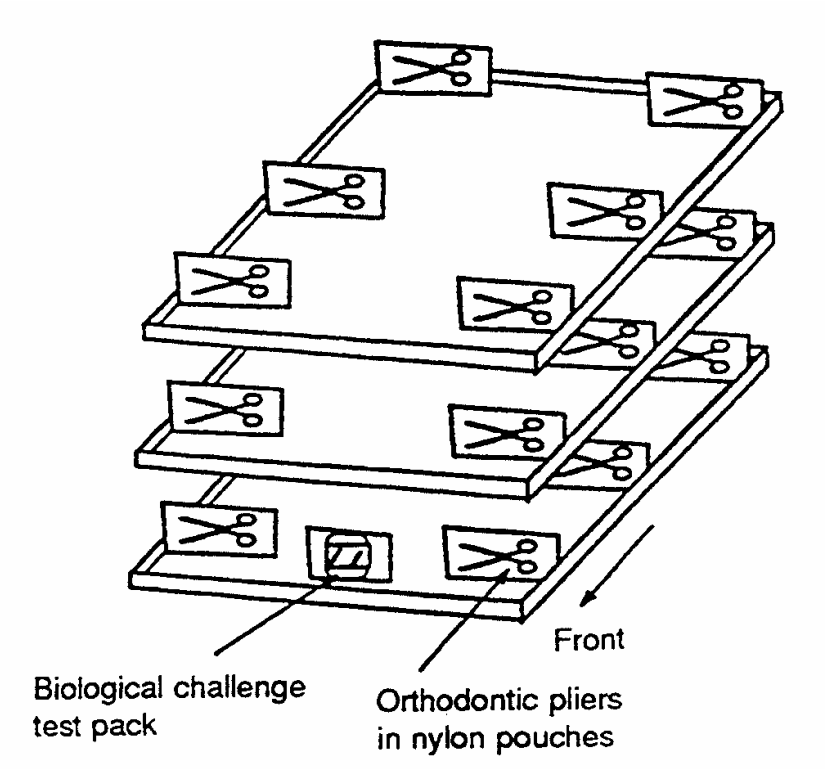

Figure B.8—Load configuration for Sterilizer D (test #1)
(Courtesy SPS Medical)

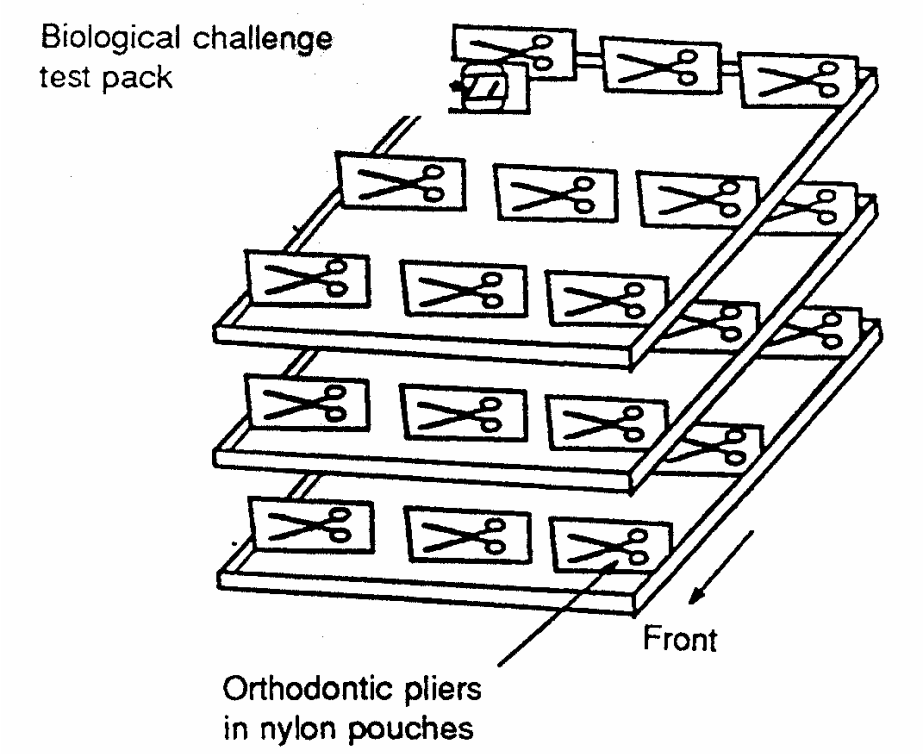

Figure B.9—Load configuration for Sterilizer D (test #2)
(Courtesy SPS Medical)

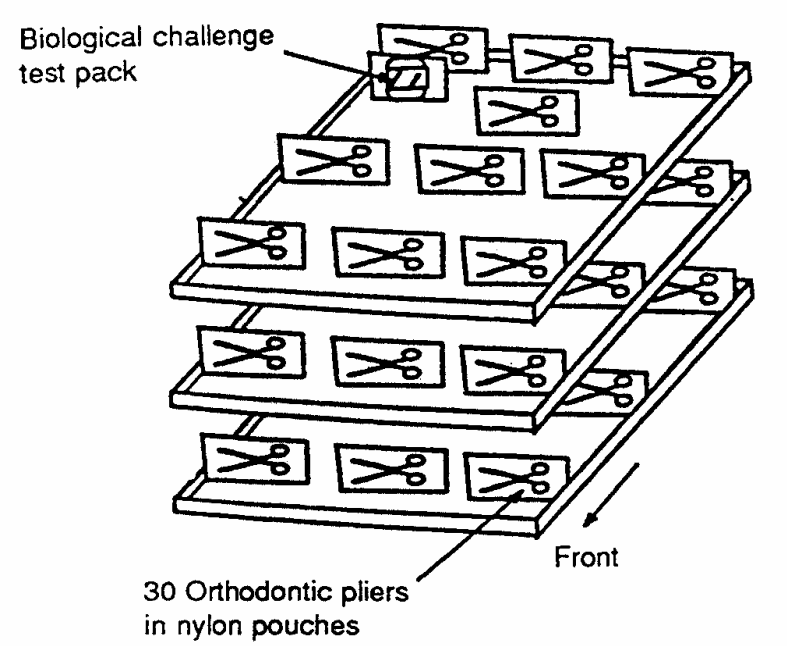

Figure B.10—Load configuration for Sterilizer D (test #3)
(Courtesy SPS Medical)

For the standard cycle, the digital exposure timer displayed 46 minutes. Test pack and chamber temperature observations for tests #1, #2, and #3 are shown in Tables B.7, B.8, and B.9, respectively. Table B.10 shows BI and CI results. Figures B.11, B.12, and B.13 show temperature profiles for a 46 minute cycle, an 18 minute cycle, and a 16.5 minute cycle, respectively.

Table B.7—Temperature profile for Sterilizer D (test #1)

Elapsed time	Test pack temperature	Chamber temperature
10 minutes	340 °F	374 °F
15 minutes	393 °F	401 °F

Table B.8—Temperature profile for Sterilizer D (test #2)

Elapsed time	Test pack temperature	Chamber temperature
5 minutes	181 °F	232 °F
10 minutes	257 °F	347 °F
15 minutes	322 °F	390 °F
18 minutes	364 °F	399 °F

Table B.9—Temperature profile for Sterilizer D (test #3)

Elapsed time	Test pack temperature	Chamber temperature
15 minutes	361 °F	391 °F
16 minutes	370 °F	394 °F
16 minutes, 30 seconds	377 °F	369 °F

Table B.10—BI and CI results for Sterilizer D

Cycle	Load configuration	Spore strip*	Chemical indicator**	
			Strip	Tape
46 minutes	18 pliers	0/1	C	C
18 minutes	27 pliers	0/1	C	C
16 minutes, 30 seconds	30 pliers	1/1	C	C
Control		1/1		

* Number positive/number exposed.

** C = complete color change.

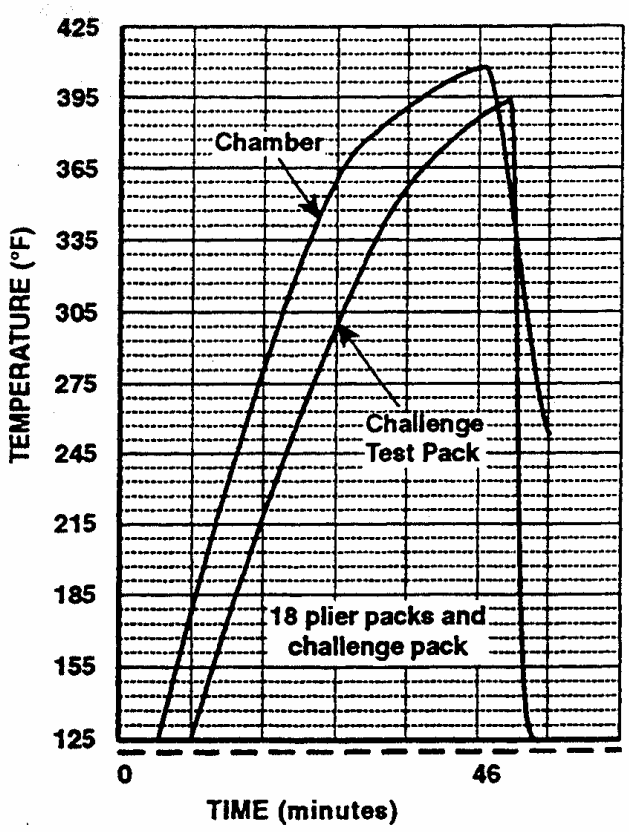

Figure B.11—Temperature profile for Sterilizer D (46 minute cycle)
(Courtesy SPS Medical)

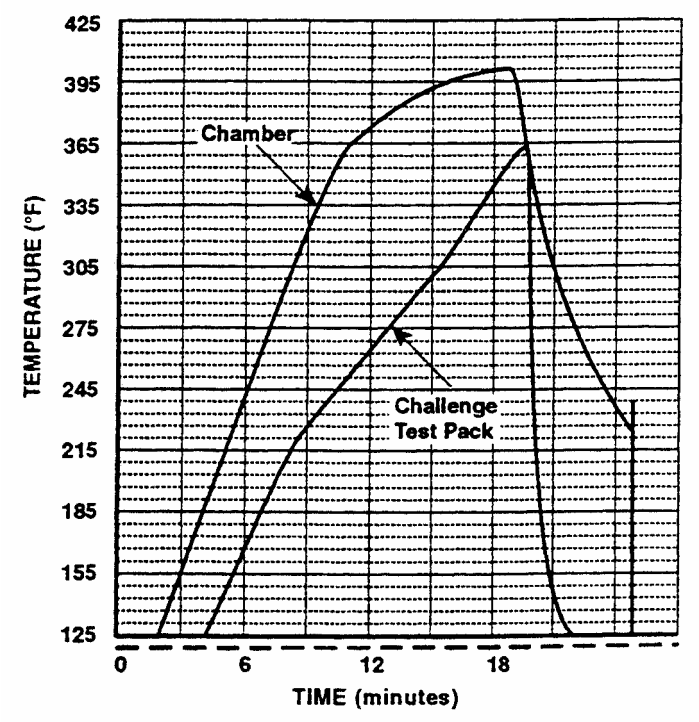

Figure B.12—Temperature profile for Sterilizer D (18 minute cycle)
(Courtesy SPS Medical)

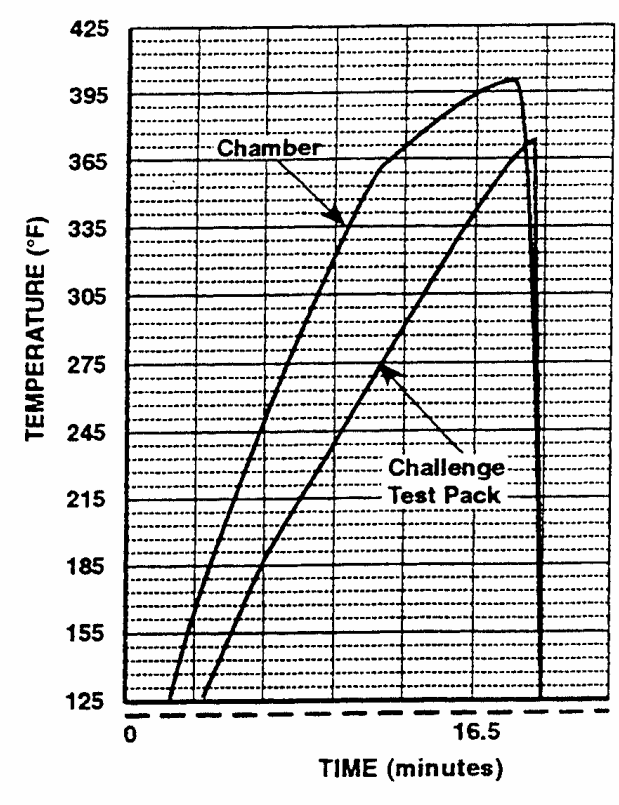

Figure B.13—Temperature profile for Sterilizer D (16.5 minute cycle)
(Courtesy SPS Medical)

Annex C
(informative)

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AAMI Standards Publications

List of Titles

	QUALITY MANAGEMENT, GENERAL SAFETY, AND DESIGN
ANSI/AAMI ES1:1993	Safe current limits for electromedical apparatus, 3ed
AAMI HE48:1993	Human factors engineering guidelines and preferred practices for the design of medical devices, 2ed
ANSI/AAMI HE74:2001	Human factors design process for medical devices, 1ed
ANSI/AAMI SW68:2001	Medical device software—Software life cycle processes, 1ed
ANSI/AAMI/IEC 60601-1-2:2001	Medical electrical equipment, Part 1-2: General requirements for safety—Collateral standard: Electromagnetic compatibility—Requirements and tests, 1ed
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ANSI/AAMI/ISO 15223:2000; 15223/A1:2001; 15223/A2:2004	Medical devices—Symbols to be used with medical device labels, labeling, and information to be supplied, 2ed and Amendments 1 and 2
ANSI/AAMI/ISO 15225:2000 and 15525/A1:2004	Nomenclature—Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange, 1ed and Amendment
AAMI TIR18:1997	Guidance on electromagnetic compatibility of medical devices for clinical/biomedical engineers—Part 1: Radiated radio-frequency electromagnetic energy, 1ed
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