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American National Standard

ANSI/AAMI ST50:1995

Dry heat (heated air) sterilizers

AAMI Association for the Advancement of Medical Instrumentation

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Association for the Advancement of Medical Instrumentation
1110 N. Glebe Rd., Suite 220
Arlington, VA 22201-4795

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ST50 Dry Heat (Heated Air) Sterilizers

Dry heat (heated air) sterilizers

American National Standard

ANSI/AAMI ST50—1995

Developed by
Association for the Advancement of Medical Instrumentation

Approved 12 January 1995 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 physician's offices, laboratories, ambulatory-care clinics, hospitals, and other health care facilities.

Committee representation

Association for the Advancement of Medical Instrumentation

Sterilization Standards Committee

This standard was developed by the Dry Heat Sterilization Working Group of the AAMI Sterilization Standards Committee. Committee approval of the standard does not necessarily imply that all committee and working group members voted for its approval.

The **AAMI Sterilization Standards Committee** has the following members:

Cochairs:
Carl W. Bruch, PhD
Virginia C. Chamberlain, PhD

Members:
Carl W. Bruch, PhD, Consultant, Hudson, WI
Virginia C. Chamberlain, PhD, Center for Devices and Radiological Health, Food and Drug Administration
Neal E. Danielson, HCA Wesley Medical Center, Wichita, KS
Judith Dowler, Medical Device Bureau, Health Canada, Ottawa, ON
Frank B. Engley, Jr., PhD, University of Missouri, Columbia, MO
Collette Keyser, RN, Alexandria, VA (Colonel, U.S. Army, Retired)
Robert Morrissey, PhD, Johnson & Johnson
Barry F.J. Page, Consultant, Garner, NC
Marimargaret Reichert, RN, Reichert Consulting
Janet K. Schultz, RN, AMSCO Healthcare
James Whitbourne, Sterilization Technical Services
James L. Whitby, MB, PhD, University of Western Ontario, London, ON

The Committee's **Dry Heat Sterilization Working Group** has the following members:

Cochairs:
Chris H. Miller, PhD

Jack Scoville

Members:
Thomas A. Augurt, PhD, Propper Manufacturing Company
Carl W. Bruch, PhD, Consultant, Hudson, WI
M. Keith Cox, DDS, Cox Sterile Products
Douglas D. Davie, Sterilization Validation Services
Barbara J. Goodman, RN, James Lawrence Kernan Hospital, Baltimore, MD
Charles O. Hancock, MDT Corporation
Arthur Jones, American Dental Association
Robert A. Kolstad, PhD, Baylor College of Dentistry, Dallas, TX
Sandra A. Lee, RN, AMSCO Healthcare
Darlene K. McLeod, RN, Alexandria, VA (Colonel, U.S. Army, Retired)
Chris H. Miller, PhD, Office Sterilization and Asepsis Research Foundation
John A. Molinari, PhD, University of Detroit Dental School, Detroit, MI
Lillian Nicolette, RN, Association of Operating Room Nurses
Robert R. Runnells, DDS, University of Utah Medical School, Fruitful Heights, UT
Jack Scoville, Cottrell, Ltd.
Linda A. Slone, RN, Sibley Memorial Hospital, Gaithersburg, MD
Timothy Ulatowski, Center for Devices and Radiological Health, Food and Drug Administration
Richard Wood, PhD, Pfizer

Alternate: Janet K. Schultz, RN, AMSCO Healthcare

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.

Acknowledgments

The Committee wishes to gratefully acknowledge SPSmedical for providing the illustrations of figures A.1, A.2, and A.3 in annex A and the data described in annex B. The Committee is also grateful for the contributions of Margaret Larson, RN, who formerly represented the Association of Operating Room Nurses on the AAMI Dry Heat Sterilization Working Group.

Foreword

This standard was developed by the 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 assure that the dry heat sterilizer will be capable of providing the conditions necessary to achieve product sterility when operated according to appropriate procedures.

This standard should be considered flexible and dynamic. As technology advances and as new data are brought forward, the standard will be reviewed and, if necessary, revised.

As used within the context of this document, "shall" indicates requirements strictly to be followed in order to conform to the standard; "should" indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited; "may" is used to indicate that a course of action is permissible within the limits of the standard; and "can" is used as a statement of possibility and capability. "Must" is used only to

describe "unavoidable" situations, including those mandated by government regulation.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

NOTE—This foreword does not contain provisions of the AAMI standard, *Dry heat (heated air) sterilizers* (AAMI ST50—1995), but it does provide important information about the development and intended use of the document.

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 physician's 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 and normative references are also included, as well as an annex explaining the rationale for the provisions of the standard.

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 AAMI (1993).

2 Normative references

The following documents contain provisions that, through reference in the text, constitute provisions of this standard. At the time of publication, the editions indicated were valid.

2.1 AMERICAN SOCIETY OF MECHANICAL ENGINEERS. *Boiler and pressure vessel code*. New York: ASME, 1992.

2.2 NATIONAL FIRE PROTECTION ASSOCIATION. *National electrical code.* ANSI/NFPA 70—1993. NFPA, 1993. American National Standard.

2.3 UNDERWRITERS LABORATORIES. *Standard for medical and dental equipment*. UL 544. Northbrook (Ill.): UL, 1993.

3 Definitions

For the purpose of this standard, the following definitions apply.

3.1 accuracy: The extent to which the measured value of a quantity differs from the true value of the quantity measured.

3.2 bioburden: The number and types of viable microorganisms with which an item is contaminated; also known as *bioload* or *microbial load*. When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units per single item.

3.3 biological indicator: A sterilization process monitoring device consisting of a standardized, viable population of microorganisms (usually bacterial spores) known to be resistant to the mode of sterilization

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

3.4 certification: A 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 or other recognized industry or government standards.

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

3.7 chemical indicator: A sterilization process monitoring device designed to respond with a characteristic chemical or physical change to one or more of the physical conditions within the sterilizing chamber. Chemical indicators are intended to detect potential sterilization failures that may 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: The state of having been actually or potentially in contact with microorganisms. As used in health care, the term generally refers to the presence of microorganisms that may be capable of producing disease or infection.

3.9 control set temperature: The 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): The system that regulates the sterilization conditions within a sterilization chamber.

3.11 culture: 1. A growth of microorganisms in or on a nutrient medium. 2. To grow microorganisms in or on such a medium.

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

3.13 cycle time reduction value: The 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: The exposure time required under a defined set of conditions to cause a 1-logarithm or 90% reduction in the population of a particular microorganism. The larger the D value, the more resistant the microorganism to destruction. The 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 may then be directly measured.

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

3.16 exposure time: The period of time during a sterilization process in which items are exposed to the sterilant at the specified sterilization parameters. In a dry heat sterilization process, exposure time is the period during which items are heated at a particular temperature or temperature range.

3.17 F value: A measure of the microbial inactivation capability of a heat sterilization process. The F value is calculated by determining the lethal rate per minute (min) at each process temperature using the z value of the microorganism.

3.18 F_0 value: The F value representing the process equivalent time at temperature T. When the reference temperature (T) is 170°C, the F_T value is referred to as F_H (Morrissey & Phillips, 1993).

3.19 gram-negative bacteria: Bacteria that are decolorized when stained by Gram's method but take on the color of the counterstain.

3.20 gram-positive bacteria: Bacteria that are not decolorized by Gram's method but retain the original violet color.

3.21 Gram's method of staining: A method of differential staining used in microbiological identification. Gram's method of staining is also simply called *Gram staining*.

3.22 heat sink: A heat-absorbent material; a mass that readily absorbs heat.

3.23 heat-up time: As the term is used in relation to dry heat sterilization, the time required for the entire load to reach the exposure temperature or temperature range.

3.24 microorganisms: Animals or plants of microscopic size. As used in health care, the term generally refers to bacteria, bacterial spores, fungi, and viruses.

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

3.26 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.

3.27 sterility assurance level (SAL): The probability of survival of microorganisms after a terminal sterilization process, and a predictor of the efficacy of the process. For example, a probability of microorganism survival of 10^{-6} means that there is less than or equal to one chance in a million that a particular item is contaminated or nonsterile. It is generally accepted that a sterility assurance level 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 sterility assurance level 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.

3.28 sterilization: A process designed to remove or destroy all viable forms of microbial life, including bacterial spores, to an acceptable sterility assurance level.

3.29 sterilizer: An apparatus used to sterilize medical devices, equipment, and supplies by direct exposure to the sterilizing agent.

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

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

3.32 z value: The number of degrees of temperature required for a one-logarithm change in the D value. A z value can be obtained from a thermal resistance curve; D values are plotted against temperature, and the reciprocal of the slope is determined as the z 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, permanently fastened and reasonably accessible, which identify the device as a sterilizer and which provide the following minimum information:

a) the manufacturer's name;

b) the manufacturer's type and model designation;

c) the serial number;

d) the electrical supply requirements;

e) the stamp or label of a nationally recognized certifying authority.

4.1.1.2 Safety 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 provided on the sterilizer to alert the operator to these high-temperature surfaces and to 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 information:

a) the name and address of the manufacturer;

b) the 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 the 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, and a recommended test pack to be used during biological monitoring (see annex B and AAMI [1993]);

e) 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 an insert affixed to the manual.

4.1.3 Service manual

The manufacturer shall make available to the user a complete service manual, sufficiently comprehensive to ensure that the safety and effectiveness of the device 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 544, *Standard for medical and dental equipment* (see 2.3). The sterilizer electrical system shall be designed for installation in conformance to the *National Electrical Code* (see 2.2).

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 544 (see 2.3). (See also 4.1.1.2.)

4.5 Sterilizer controls for aborting cycles

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

4.6 Process control and monitoring devices

4.6.1 Chamber temperature

4.6.1.1 Temperature monitoring and recording

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 both a recording and a controlling instrument.

4.6.1.2 Positioning of temperature sensors

The sensor(s) for the indicators(s) and recorder shall be positioned to assure 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 (±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 (2°F) within a range of ±5°C (±10°F) of the manufacturer's 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 Temperature control

The control set temperature shall be selected and the control shall function so that the chamber temperature is within +5°C (+10°F) and -0°C (-0°F) of the selected sterilization exposure temperature at exposure temperatures of 160°C (320°F) or higher. The mechanism used by the operator to select the sterilization exposure temperature shall be marked in, or adjustable to, increments no larger than 1°C (2°F) within a range of ±5°C (±10°F) of the manufacturer's recommended sterilization exposure temperature. The temperature control system shall initiate sterilization exposure timing when the selected sterilization exposure temperature is achieved and shall reset the timer when the chamber temperature falls 5°C (10°F) below the control set temperature and alert the operator to the occurrence of the undertemperature condition.

4.6.2 Sterilizer exposure timer

Each 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 Air flow

If mechanical air flow is integral to the function of the sterilizer, means shall be provided to ensure that the specified air flow is maintained during the cycle.

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. If cool-down is accomplished by forced air, 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. 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 biological indicator 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 recordkeeping

Reports of tests satisfactorily 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, or upon any change in design that might affect the safety or efficacy of the sterilizer type.

4.9 Software quality assurance

4.9.1 Software developed inhouse

When a dry heat sterilizer manufacturer incorporates software developed inhouse, a software quality assurance (SQA) program should be in place. This program should 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 should ensure, through appropriate testing prior to use in production, that the software is adequate for its intended application.

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 for inhospital installation, acceptance, or preventive maintenance testing. The paragraph numbers below correspond to those of section 4 except for the first digit (e.g., conformance with the requirement of 4.2 can be determined by the test method of 5.2).

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 federal regulations for good manufacturing practices (GMPs) (21 CFR Part 820).

Installation and operation of sterilizers. The sterilizers used in testing compliance with the requirements of section 4 must 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 4.2 can be verified are provided in 2.1 and 2.2.

5.3 Loading accessories

See 2.1.

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 monitored for compliance with 2.3.

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 certified standards.

5.6.1.4 Resolution of temperature measurement

Compliance with 4.6.1.4 can be verified by inspection.

5.6.1.5 Temperature control

Compliance with 4.6.1.5 can be verified by placing calibrated temperature-measuring sensors with continuous temperature readout in the sterilizer chamber. The number of sensors may vary with chamber size and configuration, but a minimum of five temperature sensors should be placed in the 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 assure that the sterilizer is capable of providing steady-state thermal

conditions within the chamber that are consistent with the predicted sterility assurance level in the load. The manufacturer of the sterilizer must determine and record that at any place a load may be positioned within the chamber, the temperature parameters of 4.6.1.5 are satisfied for recommended operating cycles and loads.

5.6.2 Sterilizer exposure timer

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

5.6.3 Air flow

Compliance with 4.6.3 can be determined by measuring air flow within the sterilizer during the cycle.

5.6.4 Cooling

Compliance with 4.6.4 can be determined by inspection and by making time and temperature measurements for the load and comparing them to the manufacturer's specifications.

5.7 Biological performance of sterilizers

The biological performance of dry heat sterilizers must be evaluated by the manufacturer as part of initial design qualification and periodically thereafter (see 4.7) on production sterilizers; records must be maintained in accordance with 4.8. The tests must be performed both with maximum loads and with the chamber empty except for the test pack; three consecutive cycles must be run for both the maximum-load and empty-chamber tests. The biological indicators used in testing shall contain *Bacillus subtilis* spores or other spores whose resistance to the dry heat sterilization process has been shown to be equal to or greater than that of *B. subtilis*. The culturing and incubation conditions shall be in accordance with the instructions supplied by the manufacturer of the biological indicator.

5.7.1 Biological indicator challenge test pack

5.7.1.1 Construction and placement of 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 and one biological indicator, 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 biological indicator challenge test pack has not yet been developed and qualified for the dry heat sterilization process. The AAMI Dry Heat Sterilization Working Group is engaged in developing and round-robin testing such a test pack, but consensus recommendations are not expected to be available for some time. Based on preliminary work performed by one laboratory, however, annex B describes a proposed test pack, a test protocol, and noncollaborative test data that dry heat sterilizer manufacturers may wish to use as a reference in developing and recommending test packs for their equipment.

5.7.1.2 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 the acceptance criteria of 5.7.1.4. The cycle time reduction value necessary to determine the sterility assurance level can be estimated from survival curve data (e.g., Pflug, 1973) or via fraction-negative methods (e.g., Pflug, 1977; Stumbo, 1973).

5.7.1.3 Incubation of biological indicators

See 5.7.

5.7.1.4 Acceptance criteria

The manufacturer shall demonstrate that the recommended cycle has a sterility assurance level of at least 10^{-6}. This sterility assurance level represents the inactivation of 12 logarithms of a microorganism with a $D_{160\ C}$ in the range of 3 to 5 min; this results in a minimum product F_H of approximately 12 (based on a reference Z value of 20°C). The temperature sensor readings shall confirm the achievement of a time-at-temperature sufficient to produce an F_T of at least 12.

5.7.2 Simulated-use tests

The biological performance of the sterilizer must also be tested under simulated-use conditions. That is, tests must 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 the penetration of the sterilant (e.g., lumens, mated surfaces, hinges, knurled surfaces).

5.7.2.1 Placement of biological indicators 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. Biological indicators 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, then the device may be inoculated with a liquid spore suspension. 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.

5.7.2.2 Cycle operation

See 5.7.1.2.

5.7.2.3 Incubation of biological indicators

See 5.7.

5.7.2.4 Acceptance criteria

See 5.7.1.4.

5.8 Certification and recordkeeping

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 FDA documents, such as FDA (1987a, 1987b, 1989, 1990, 1991), 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

NOTE—The data discussed in this annex were derived from tests conducted at SPSmedical by Jack Scoville, formerly of SPSmedical.

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 the 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 is 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. Surgical instruments heated much beyond that value could lose their temper (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 point out 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 tabletop 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 most 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 minutes at 160°C is approximately the equivalent of 15 minutes at 121°C in moist heat" (McCulloch, 1945). Not to be outdone, the *United States Pharmacopeia*, 15th edition, recommended 170°C (338°F) for 120 min (USP, 1955). Similarly, the American Dental Association, to this day, recommends 160°C (320°F) for 120 min (ADA, 1984).

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 by 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. A *batch process* is one in which a predetermined quantity of items is simultaneously subjected to a convective dry heat sterilization cycle. A *continuous process* is one in which a predetermined quantity of items is processed at a

predetermined rate through a convection cycle. An example of this type would be a conveyorized dry heat process.

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

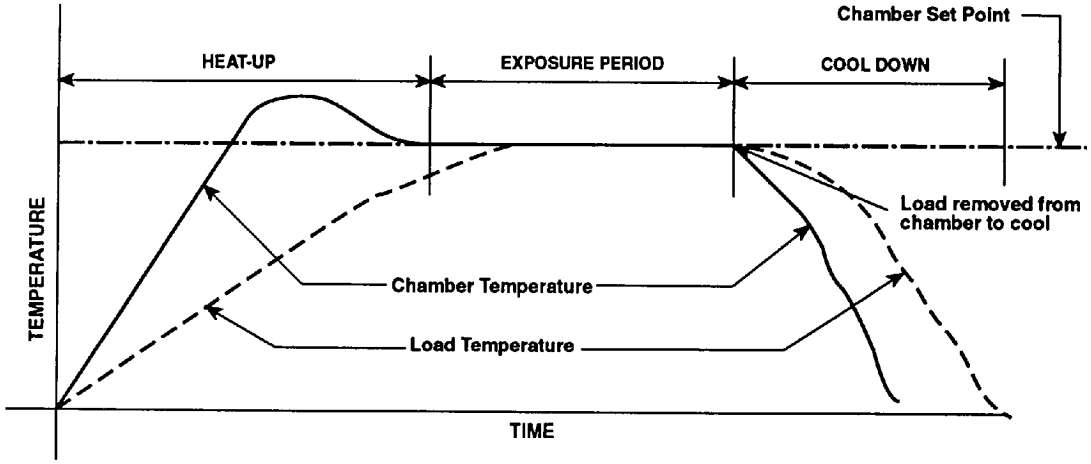

Figure A.1—Batch cycle: Convective dry heat (static air) (Courtesy SPSmedical)

Other batch-type dry heat sterilizers operate by *forced air*; some of these sterilizers utilize *continuous heating*, and some utilize *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 safe to handle. (See figure A.3.)

A.2.4 Variables associated with the dry heat sterilization process

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

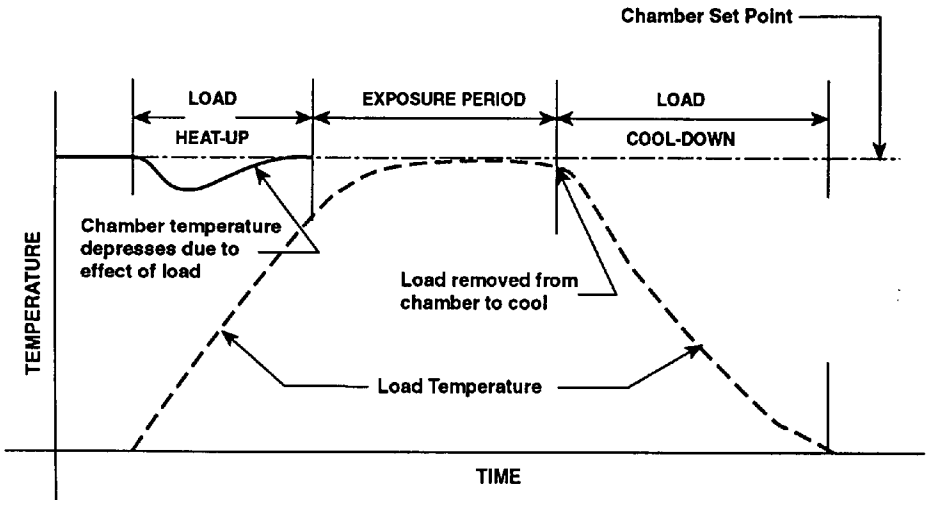

Figure A.2—Batch cycle: Convective dry heat (forced air) with chamber heat continuously maintained (Courtesy SPSmedical)

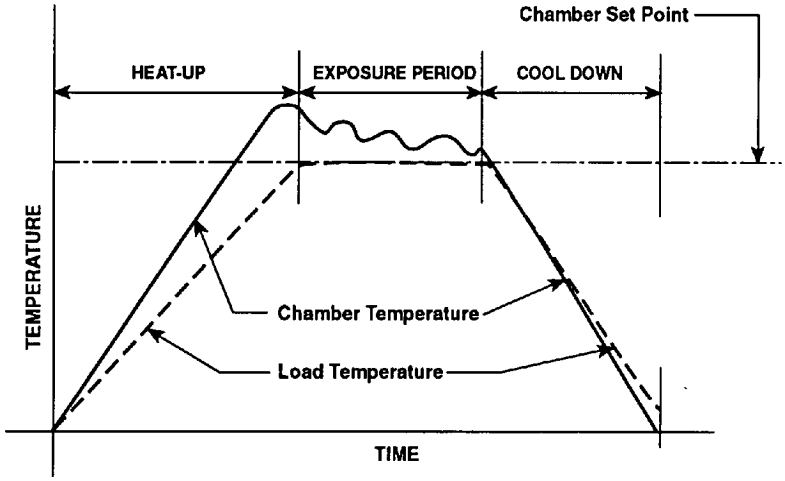

Figure A.3—Batch cycle: Convective dry heat (forced air); load remains in chamber during cool-down (Courtesy SPSmedical)

a) *Temperature:* The most important variable in dry heat sterilization is temperature. It is the measure of 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 also to provide a margin of safety, sterilization engineers use the term "exposure time" to mean the time at which a load has been exposed to a predetermined temperature profile or a specified temperature designed to achieve sterilization;

c) *Air-flow rate and distribution:* Air flow, whether by convection or by 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 via 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 air-flow rate and 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.

A.2.5.1 Indirect measurement

The most common technique 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.

A.2.5.2 Direct measurement

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 if 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 and 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 in 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 assure 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 Food and Drug Administration'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 standard's provisions is provided in section A.4, but, in summary, the standard is based on the following premises: 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 provide reasonable assurance that dry heat sterilizers 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 the standard

A.4.1 Labeling

The requirements of 4.1 are intended to assure that the manufacturer will give users of dry heat sterilizers sufficient information 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 544 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 may 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 air-flow conditions. To ensure that the sterilizer will reliably provide these conditions, requirements are included 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; air-flow 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 all points within the usable chamber are 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 level of sterility assurance. 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 the lethality of the recommended processing parameters.

A.4.7.1 Biological indicator challenge test pack

The test of 4.7 was designed as a manufacturer's qualification test, but it is intended to simulate the most difficult conditions that would normally be encountered in health care facilities. The methods for verifying the attainable sterility assurance level 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 may not be a valid representation of how the equipment will perform in actual use.

A.4.7.2 Simulated-use tests

Effective sterilization of a medical device requires adequate process parameters for biocidal efficacy (a sterility assurance level 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 Certification and recordkeeping

Section 4.8 specifies that a sterilizer manufacturer must 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 changes made in that design do not affect safety and efficacy.

Thorough test reports must be kept by the sterilizer manufacturer 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, the Food and

Drug Administration (FDA) requires sterilizer manufacturers to use biological indicator challenge test packs in the performance validation of their products and to 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 ethylene oxide sterilizers and steam sterilizers in AAMI [1992] and AAMI [1994], 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 packs(s) present a rigorous challenge to the sterilization process, the rationale for the composition of the test pack, and a description of how the test pack itself was validated.

A standard biological indicator challenge test pack has not yet been developed and qualified for the dry heat sterilization process. The AAMI Dry Heat Sterilization Working Group is engaged in developing and round-robin testing such a test pack, but consensus recommendations are not expected to be available for some time. 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 use as a reference in developing and recommending test packs for their equipment.

NOTE—The data discussed in this annex were derived from tests conducted at SPSmedical by Jack Scoville, formerly of SPSmedical.

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

The test pack consists of a 3-in by 3-in pouch fabricated from 3-in nylon tubing, fourteen 2-in by 2-in 8-ply cotton gauze sponges, one dry heat chemical indicator, and one dual-species dry heat biological indicator packaged in a 30# sterilizable blue glassine envelope. The biological indicator and the chemical indicator 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 by 3-in nylon pouch.

B.3 Test objective

The objective of the testing is to define a standard biological indicator challenge test pack, consisting of easily obtainable 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 biological and chemical indicators.

B.4 Methods and materials

Biological indicators must have a D_{180} value that meets the criteria of the *U.S. Pharmacopeia* (USP, 1985).

All temperature-sensing devices must be calibrated to recognized standards, the degree of accuracy and reproducibility to be ±1°C (±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 as 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 biological indicator 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 section B.6 are half-cycle performance data. Sterilization scientists employ the "half-cycle" as part of the "overkill" validation approach (see, for example, AAMI [1988]). The test load is seeded with biological indicators and processed under standard cycle conditions, but the cycle is interrupted at one-half of the normal exposure time, and one-half of the load, with biological indicators, 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 USP (1985). 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} sterility assurance level. 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

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 320°F. Six orthodontic pliers, weighing approximately 3.2 ounces each, were each packaged in a nylon film package, placed three to a shelf in the chamber, and spread evenly. The biological indicator test pack was placed at the center of the lower shelf in front near the door. (See figure B.1.) Temperature profiles for the test pack are shown in tables B.1 and B.2; table B.3 shows biological and chemical indicator results.

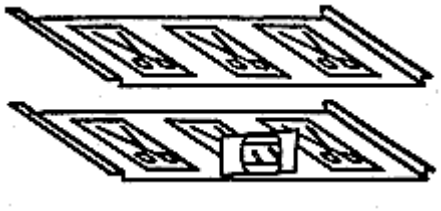

Figure B.1—Load configuration for sterilizer A (Courtesy SPSmedical)

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

Elapsed Time	Test Pack Temperature	Chamber Temperature	Sterilizer Thermometer
17 min	280° F	283° F	320° F
30 min	313° F	301° F	330° F
37 min	320° F	320.4° F	335° F
45 min	325° F	325.4° F	335° F
60 min	327° F	314° F	338° F

Table B.2—Temperature profile for 30-min cycle (sterilizer A)

Elapsed Time	Test Pack Temperature	Chamber Temperature	Sterilizer Thermometer
10 min	240° F	271.5° F	323° F
20 min	283° F	299° F	330° F
25 min	296.1° F	305.9° F	330° F
30 min	303.4° F	304.4° F	330° F

Table B.3—Biological and chemical indicator results (sterilizer A)

Cycle	Spore strip*	Chemical Indicator**	
		Strip	Tape
1 hour	0/1	C	C
30 min	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 challenge test pack was placed in the seventh instrument rack location, facing the drawer handle (front). (See 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-min exposure time) was immediately selected. Figures B.3 and B.4 show the thermal profiles of the biological indicator test pack and instrument rack for a 12-min cycle and a 6-min cycle (half-cycle), respectively. Table B.4 shows the biological and chemical indicator results.

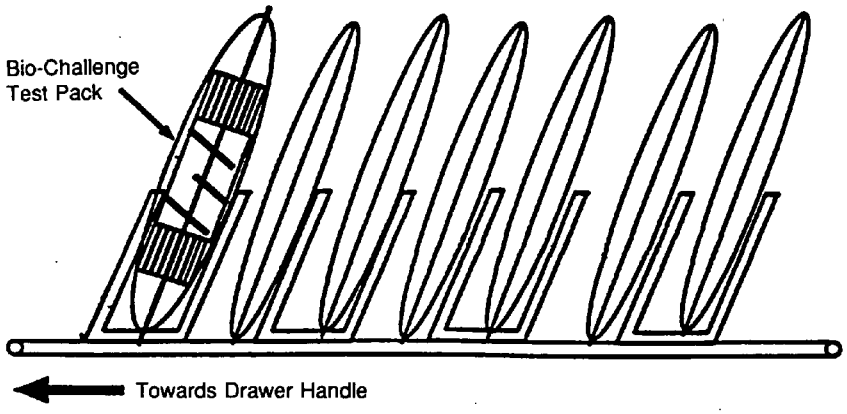

Figure B.2—Load configuration for sterilizer B (Courtesy SPSmedical)

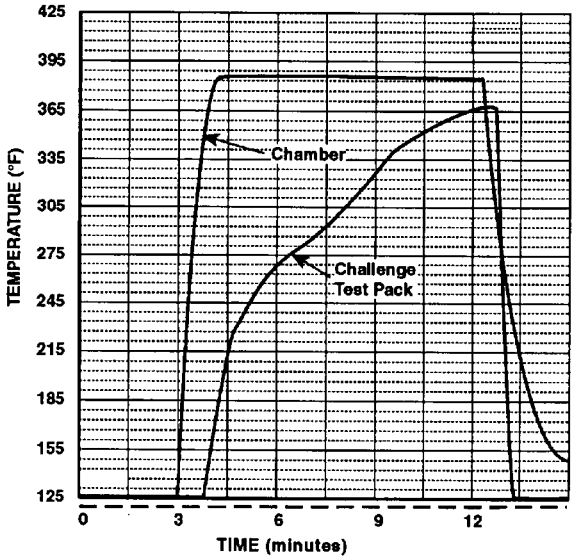

Figure B.3—Temperature profile for biological indicator challenge test pack and instrument rack (sterilizer B, 12-min cycle) (Courtesy SPS medical)

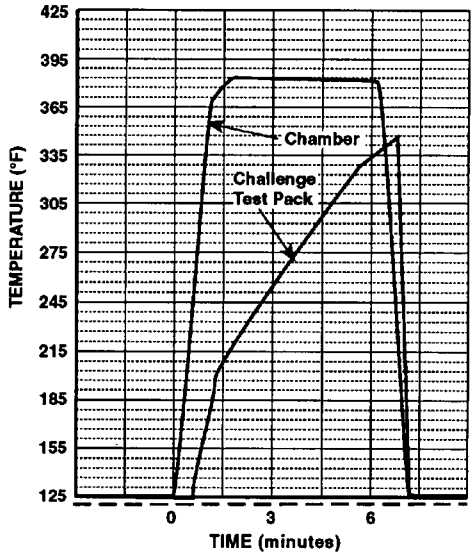

Figure B.4—Temperature profile for biological indicator challenge test pack and instrument rack (sterilizer B, 6-min cycle) (Courtesy SPS medical)

Table B.4—Biological and chemical indicator results (sterilizer B)

Cycle	Spore strip*	Chemical Indicator**	
		Strip	Tape
12 min	0/1	C	C
6 min	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 biological indicator challenge test pack was placed between racks #2 and #3 (numbered from left to right) at the front near the door. (See 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 min, 34 sec

Actual exposure time = 6 min, 2 sec

Pack and chamber temperature at 12 min = 339°F, 397°F, respectively

Time to cooling blower on = 17 min, 36 sec

Total elapsed time, including cool-down = 24 min, 54 sec

Pack and chamber temperature at end of cool-down =
143°F, 87°F, respectively

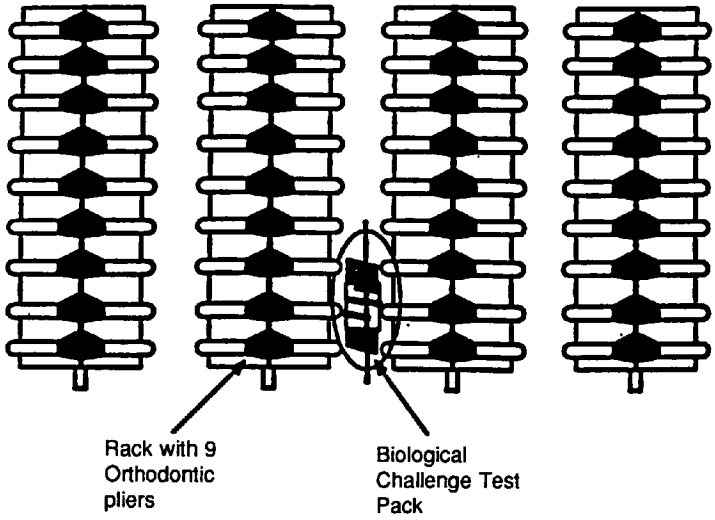

Figure B.5—Load configuration for sterilizer C (Courtesy SPSmedical)

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 biological and chemical indicator results.

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

Elapsed time	Test Pack Temperature	Chamber Temperature
4 min	177° F	208° F
5 min	203° F	339° F
6 min	228° F	269° F
7 min	248° F	293° F
8 min	272° F	321° F
9 min	294° F	344° F
10 min	315° F	365° F
11 min	339° F	388° F
11 min 21 sec	349° F	396° F

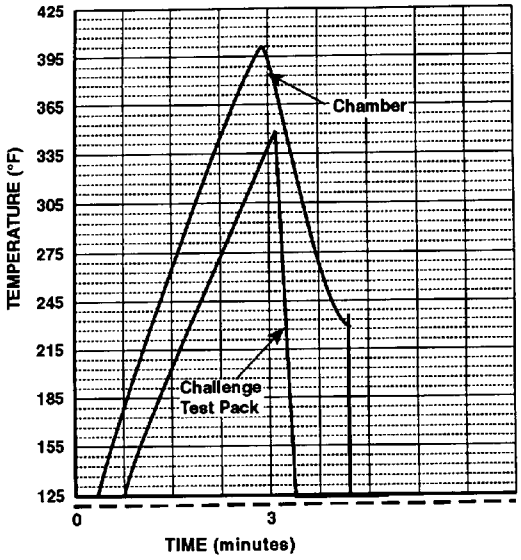

Figure B.6—Temperature profile for sterilizer C (half-cycle)
(Courtesy SPSmedical)

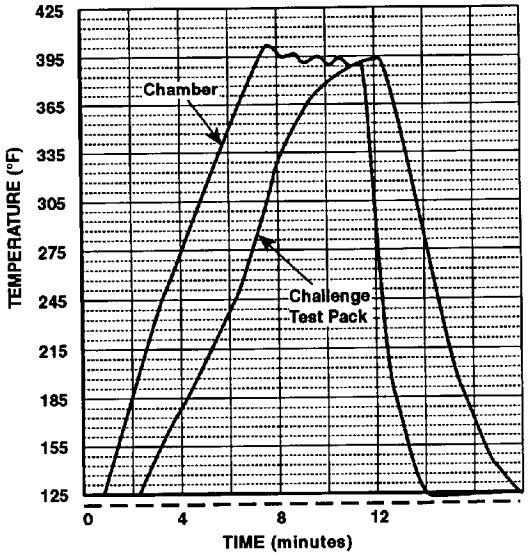

Figure B.7—Temperature profile for sterilizer C (standard-cycle)
(Courtesy SPSmedical)

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, then secured at both ends with dry heat indicator tape. The 18 packaged pliers were then placed on the sterilizer instrument trays, 6 per tray. The biological indicator challenge test pack was placed in the center of the lower tray near the door (front). (See figure B.8.)

Table B.6—Biological and chemical indicator results (sterilizer C)

Cycle	Spore strip*	Chemical Indicator**	
		Strip	Tape
Standard	0/1	C	C
1/2 cycle	1/1	C	C
Control	1/1		

* Number positive/number exposed
** C = complete color change

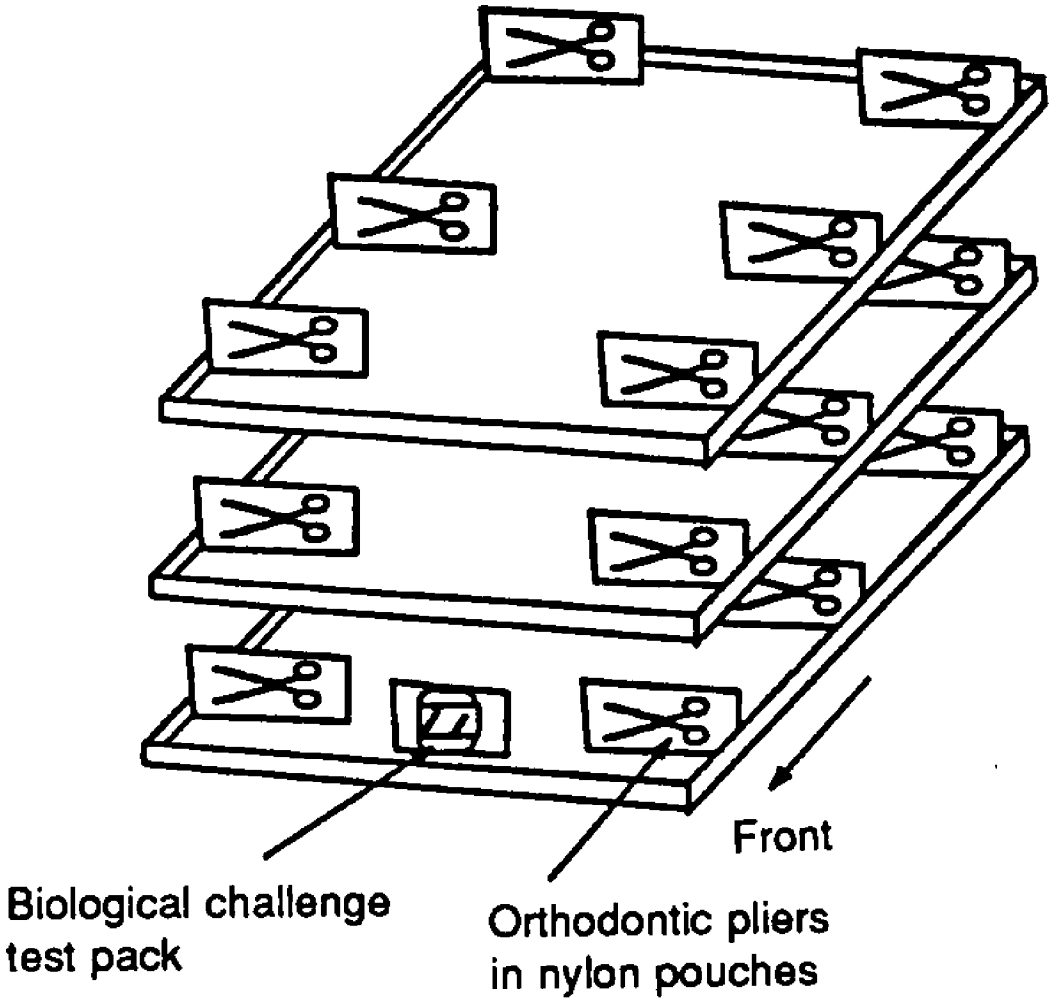

Figure B.8—Load configuration for sterilizer D (test #1) (Courtesy SPSmedical)

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

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

For the standard cycle, the digital exposure timer displayed 46 min. 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 biological and chemical indicator results. Figures B.11, B.12, and B.13 show temperature profiles for a 46-min cycle, an 18-min cycle, and a 16.5-min cycle, respectively.

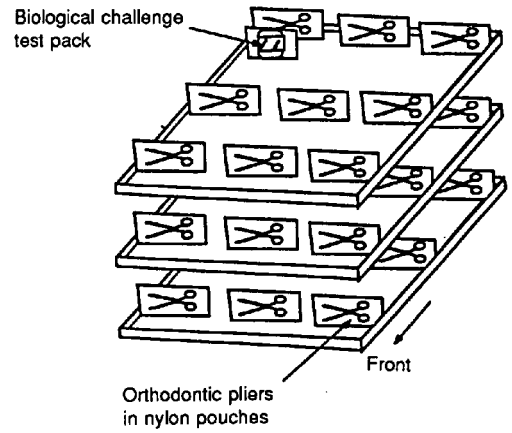

Figure B.9—Load configuration for sterilizer D (test #2) (Courtesy SPSmedical)

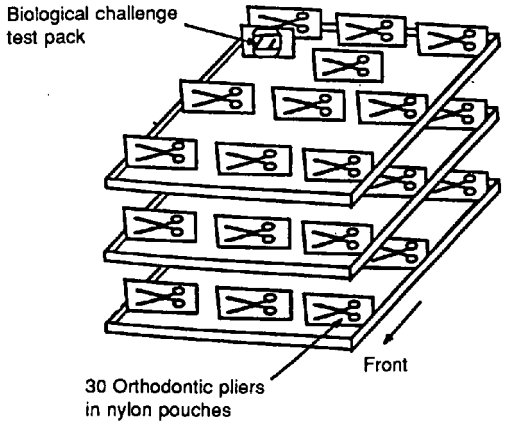

Figure B.10—Load configuration for sterilizer D (test #3) (Courtesy SPSmedical)

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

Elapsed time	Test Pack Temperature	Chamber Temperature
10 min	340° F	374° F
15 min	393° F	401° F

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

Elapsed Time	Test Pack Temperature	Chamber Temperature
5 min	181° F	232° F
10 min	257° F	347° F
15 min	322° F	390° F
18 min	364° F	399° F

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

Elapsed Time	Test Pack Temperature	Chamber Temperature
15 min	361° F	391° F
16 min	370° F	394° F
16 min 30 sec	377° F	369° F

Table B.10—Biological and chemical indicator results (sterilizer D)

Cycle Time	Load Config-uration	Spore strip*	Chemical Indicator**	
			Strip	Tape
46 min	18 pliers	0/1	C	C
18 min	27 pliers	0/1	C	C
16 min 30 sec	30 pliers	1/1	C	C
Control		1/1		

* Number positive/number exposed
** C = complete color change

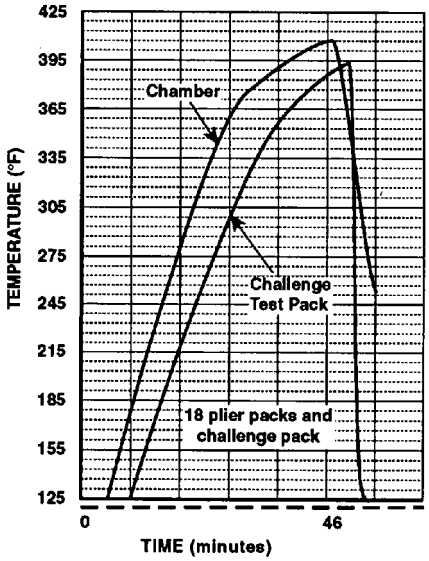

Figure B.11—Temperature profile for sterilizer D (46-min cycle) (Courtesy SPSmedical)

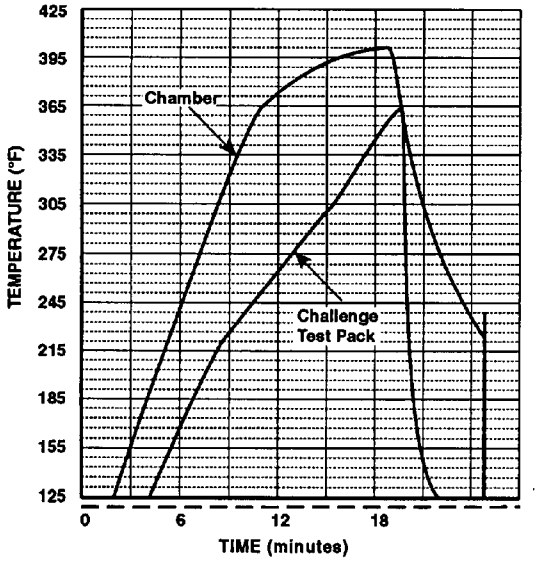

Figure B.12—Temperature profile for sterilizer D (18-min cycle) (Courtesy SPSmedical)

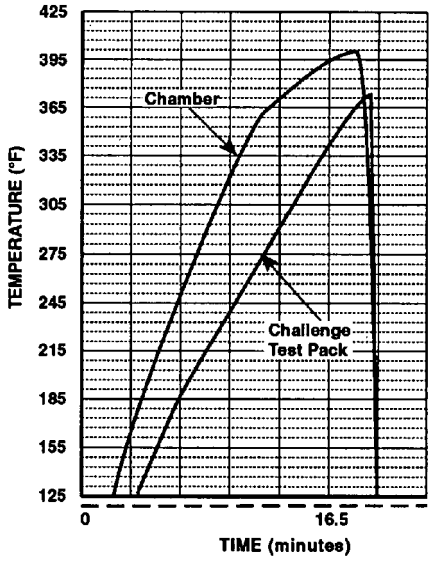

Figure B.13—Temperature profile for sterilizer D (16.5-min cycle) (Courtesy SPSmedical)

Annex C
(informative)
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