List of Titles

American National Standard

ANSI/AAMI ST8:2001

Hospital steam 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.

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

INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the Manager for Technical Development. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News.* The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News.*

List of Titles

American National Standard

ANSI/AAMI ST8:2001
(Revision of ANSI/AAMI ST8:1994)

Hospital steam sterilizers

Developed by
Association for the Advancement of Medical Instrumentation

Approved 11 November 2001 by
American National Standards Institute, Inc.

Abstract: This standard covers minimum construction and performance requirements for hospital sterilizers that use saturated steam as the sterilizing agent and have a volume greater than 2 cubic feet.

Keywords: moist heat sterilization, saturated steam, steam sterilization

List of Titles

AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than 5 years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI.

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Published by

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

Printed in the United States of America

ISBN 1–57020–172–2

List of Titles

Contents

Annexes

Tables

Figures

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Sterilization Standards Committee

This standard was developed by the AAMI Hospital Steam Sterilizer Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the standard does not necessarily imply that all working group members voted for its approval.

At the time this document was published, the **AAMI Sterilization Standards Committee** had the following members:

Cochairs:
Victoria Hitchins, PhD
William E. Young

Members:
Trabue D. Bryans, AppTec Laboratory Services
Virginia C. Chamberlain, PhD, Hendersonville, NC
Anne M. Cofiell, CRST, IAHCSMM
Loretta L. Fauerbach, MS, CIC, Association for Professionals in Infection Control and Epidemiology
Dorothy M. Fogg, RN, BSN, MA, Association of Perioperative Nurses
Lisa Foster, Ion Beam Applications
James M. Gibson, Jr., JM Gibson Associates
Barbara J. Goodman, RN, CNOR, Rising Sun, MD
Joel R. Gorski, PhD, NAMSA
Susan Hadfield, Canadian Standards Association
Deborah A. Havlik, Abbott Laboratories
Victoria Hitchins, PhD, U.S. Food and Drug Administration
Clark W. Houghtling, Cosmed Group, Inc.
Lois A. Jones, Cary, NC
Sue Kuhnert, Sterilization Technical Services
Byron J. Lambert, PhD, Guidant Corporation
Sandra A. Lee, RN, STERIS Corporation
Patrick J. McCormick, PhD, Bausch & Lomb, Inc.
Thomas K. Moore, Getinge/Castle, Inc.
Robert F. Morrisey, PhD, Johnson & Johnson
David Orton, CR Bard Inc.
Barry F.J. Page, Garner, NC
Phil M. Schneider, 3M Healthcare
Michael H. Scholla, PhD, Dupont Tyvek for Sterile Packaging Dupont Nonwovens
Janet K. Schultz, MSN, RN, Roswell, GA
Harry L. Shaffer, Titan Corp.—Titan Scan Technologies
Frank Sizemore, American Society for Healthcare Central Service Professionals
William N. Thompson, Tyco Healthcare
James L. Whitby, MA, MB, FRCP, University of Western Ontario
Thelma Wilcott, Becton Dickinson & Company
Stephen C. Yeadon, Alcon Laboratories, Inc.
William E. Young, Baxter Healthcare Corporation

Alternates:
Bettye Beebe, Alcon Laboratories, Inc.
Louis M. Glasgow, Bausch & Lomb, Inc.
Joyce M. Hansen, Baxter Healthcare Corporation
Susan G. Klacik, ACE, IAHCSMM
Chiu Lin, PhD, U.S. Food and Drug Administration
Lisa N. Macdonald, Becton Dickinson & Company
Ralph Makinen, Guidant Corporation
Janet Prust, 3M Healthcare
James Whitbourne, Sterilization Technical Services
William T. Young, Ion Beam Applications

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

Chair:	Charles O. Hancock
Members:	John Bliley, STERIS Corporation
	Samuel Bowman, Bausch & Lomb Inc.
	Ross A. Caputo, PhD, Pharmaceutical Systems Inc.
	Nancy Chobin, RN, St. Barnabas Health Care System, Lebanon, NJ
	Anne M. Cofiell, CRCST, International Association of Healthcare Central Service Materiel Management
	Alex Farahmand, Defense Personnel Support Center
	Janie Fuller, DDS, MPH, U.S. Food and Drug Administration
	Barbara J. Goodman, RN, Rising Sun, MD
	Charles O. Hancock, Fairport, NY
	Ken Hermsen, Barnstead/Thermolyne
	T.K. “Chip” Moore, Getinge/Castle
	Gregg A. Mosley, Biotest Laboratories
	Charles D. Paige, U.S. Department of Veterans Affairs
	Shaundrea L. Rechsteiner, NAMSA
	Janet K. Schultz, RN, Roswell, GA
	Frank Sizemore, American Society for Healthcare Central Service Professionals
	Linda A. Slone, RN, Sibley Memorial Hospital, Washington, DC
	Gary J. Socola, SPS Medical
	James Whitbourne, STS duoTek
	Martha Young, 3M Health Care
Alternates:	Joel R. Gorski, PhD, NAMSA
	Steve Kirckof, 3M Health Care
	Susan G. Klacik, ACE, International Association of Healthcare Central Service Materiel Management
	Sue Kuhnert, STS duoTek
	Patrick J. McCormick, PhD, Bausch & Lomb Inc.
	Mark N. Smith, Getinge/Castle

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.

Acknowledgment

The AAMI Hospital Steam Sterilizer Working Group gratefully acknowledges the contributions of Zoe Z. Aler, RN, who cochaired the working group from 1986 to 2000, Neal E. Danielson of Wichita, Kansas, and Larry Joslyn of STERIS Corporation. Their expertise, commitment, and diplomacy greatly furthered the working group's accomplishments.

Foreword

This standard was developed by the AAMI Hospital Steam Sterilizer Working Group under the auspices of the AAMI Sterilization Standards Committee. The objective of this standard is to provide minimum labeling, safety, performance, and testing requirements to help ensure a reasonable level of safety and efficacy in steam sterilizers that are intended for use in health care facilities and that have a volume greater than 2 cubic feet.

This standard is the fourth edition of *Hospital steam sterilizers,* which was first published as an American National Standard in February 1983 with the designation ANSI/AAMI ST8:1982. AAMI procedures require that standards be reviewed and, if necessary, revised at least once every 5 years. Accordingly, *Hospital steam sterilizers* was updated and published in revised editions in 1988 and 1994. Compared to the 1994 document, this fourth edition incorporates additional temperature-sensing requirements, expanded air-removal requirements and tests, and new requirements pertaining to cycle documentation and to flash cycles.

Compliance with this standard is voluntary. The existence of the standard does not preclude anyone from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard.

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

This voluntary standard is intended primarily for use by equipment manufacturers in the performance and design qualification of steam sterilizers intended for use in health care facilities. The criteria defined in this standard may be useful to health care personnel and purchasing authorities in the acquisition process. However, the standard is not intended to provide guidelines for hospital receiving inspection testing or for steam sterilization procedures in health care facilities. In addition, any problems with existing equipment should not be judged solely in terms of its conformance to this standard.

As used within the context of this document, “shall” indicates requirements strictly to be followed 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” indicates that a course of action is permissible within the limits of the standard; and “can” is used as a statement of possibility and capability. “Must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

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

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

NOTE—This foreword does not contain provisions of the American National Standard, *Hospital steam sterilizers* (ANSI/AAMI ST8:2001), but it does provide important information about the development and intended use of the document.

American National Standard ANSI/AAMI ST8:2001

Hospital steam sterilizers

1 Scope

1.1 General

This standard applies to steam sterilizers that are intended for use in hospitals and other health care facilities and that have a volume greater than 2 cubic feet (ft^3) (56 liters [L]).

NOTE—For purposes of this standard, "health care facilities" means hospitals, nursing homes, extended-care facilities, freestanding surgical centers, clinics, and medical and dental offices. For convenience, the term "hospital" is sometimes used in this recommended practice; in all instances, this term should be taken to encompass all other health care facilities.

1.2 Inclusions

This standard covers minimum labeling, safety, performance, and testing requirements for steam sterilizers that have a volume greater than 2 ft^3, have automatic controls, generally use an external steam source (but may also have an integral electric boiler), and provide a means for automatically recording time and temperature. Definitions of terms and normative references are also included, as well as an annex explaining the rationale for the provisions of the standard and other informative annexes.

NOTE—This standard is intended primarily for use by manufacturers in the performance and design qualification of steam sterilizers intended for use in health care facilities. The criteria defined in this standard may be useful to health care personnel and purchasing authorities in the acquisition process. However, the standard is not intended to provide guidelines for hospital receiving inspection testing or for steam sterilization procedures in health care facilities.

1.3 Exclusions

Sterilizers that generate steam inside the sterilizing chamber, washer/sterilizers, and all other sterilizers not covered in 1.2 are excluded from this standard. Likewise, this standard does not cover installation acceptance testing, sterilization procedures, machine-operator requirements, or sterility assurance testing in health care facilities. Also, this standard does not address sterilizer performance with reusable rigid sterilization container systems, because the design of container systems varies too widely to permit the establishment of standardized requirements or tests for steam sterilizers.

NOTE—Minimum labeling and performance requirements for small steam sterilizers (those that are 2 ft^3 or less in volume) for dental applications are covered in American Dental Association (1992) and ANSI/AAMI ST55 (AAMI, 1997b); guidelines for the use of such sterilizers are provided in ANSI/AAMI ST42 (AAMI, 1998). For guidelines on in-hospital steam sterilization procedures, see ANSI/AAMI ST46 (AAMI, 1994a) and ANSI/AAMI ST37 (AAMI, 1996b). Guidelines for the selection and use of reusable rigid sterilization container systems are provided in ANSI/AAMI ST33 (AAMI, 1996a).

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, 1986.

2.2 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Biological indicators for saturated steam sterilization processes in health care facilities.* 3rd ed. ANSI/AAMI ST19:1999. Arlington (VA): AAMI, 1999a. American National Standard.

2.3 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Sterilization of health care products—Chemical indicators—Part 2: Class 2 indicators for air removal test.* ANSI/AAMI ST66:1999. Arlington (VA): AAMI, 1999b. American National Standard.

2.4 NATIONAL FIRE PROTECTION ASSOCIATION. *National electrical code.* ANSI/NFPA 70:1996. Quincy (MA): NFPA, 1996. American National Standard.

2.5 UNDERWRITERS LABORATORIES. *Electrical equipment for laboratory use—Part 1: General requirements.* UL 3101-1. Northbrook (IL): UL, 1993.

3 Definitions, symbols, and abbreviations

For the purpose 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 calibrated standards: Standards traceable to national or international standards.

NOTE—The Quality System regulation states that "if national or international standards are not practical or available, the manufacturer shall use an independent reproducible standard. If no applicable standard exists, the manufacturer shall establish and maintain an in-house standard." [21 CFR 820.72(b)(1)]

3.3 certification: Formal report of test results attesting to the satisfactory performance of a sterilizer and accompanied by a statement to that effect signed by the manufacturer's authorized representative.

3.4 chamber: Portion of the sterilizer in which items are processed and which is sealed off from the ambient environment when the door is closed.

3.5 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.

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

3.7 cycle: Defined sequence of operational steps designed to achieve sterilization and carried out in a sealed chamber.

3.8 cycle, steam sterilization, dynamic-air-removal type: Type of sterilization cycle in which air is removed from the chamber and the load by means of pressure and vacuum excursions or by means of steam flushes and pressure pulses.

NOTE 1—In prevacuum steam sterilizers, the dynamic-air-removal cycle depends on one or more pressure and vacuum excursions at the beginning of the cycle to remove air. This method of operation results in shorter cycle times for wrapped items because of the rapid removal of air from the chamber and the load by the vacuum system and because of the usually higher operating temperatures (132 °C to 135 °C [270 °F to 275 °F]). This type of cycle generally provides for shorter exposure times and for accelerated drying of fabric loads by pulling a further vacuum at the end of the sterilizing cycle.

NOTE 2—In steam-flush pressure-pulse steam sterilizers, the dynamic-air-removal cycle depends on a repeated sequence consisting of a steam flush and a pressure pulse to remove air from the sterilizing chamber and processed materials. As is the case with prevacuum sterilizers, the dynamic-air-removal cycle of a steam-flush pressure-pulse sterilizer rapidly removes air from the sterilizing chamber and wrapped items. Air removal is achieved with the sterilizing chamber pressure at above-atmospheric pressure (no vacuum is required to remove air for sterilization). Typical operating temperatures are 121 °C to 123 °C (250 °F to 254 °F) and 132 °C to 135 °C (270 °F to 275 °F).

3.9 cycle, steam sterilization, gravity-displacement type: Type of sterilization cycle in which incoming steam displaces residual air through a port or drain in or near the bottom (usually) of the sterilizer chamber. Typical operating temperatures are 121 °C to 123 °C (250 °F to 254 °F) and 132 °C to 135 °C (270 °F to 275 °F).

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

3.11 D value: Exposure time required under a defined set of conditions to cause a 1-logarithm or 90 % reduction in the population of a particular microorganism.

3.12 exposure time: Period of time during a sterilization process in which items are exposed to the sterilant at the specified sterilization parameters.

NOTE—In a steam sterilization process, exposure time is the period during which items are exposed to saturated steam at the specified temperature.

3.13 F value: Measure of the microbial inactivation capability of a heat sterilization process.

NOTE—The F value is calculated by determining the lethal rate per minute (min) at each process temperature using the z value of the microorganism.

3.14 F_o value: F value calculated at 121.1 °C (250 °F) with a z value of 10 °C (or 18 °F) and a D value of 1 min.

NOTE—The F_o value is a convenient reference value for comparing different sterilization cycles.

3.15 flash sterilization: Process designed for the steam sterilization of patient care items for immediate use. See also ANSI/AAMI ST37.

3.16 handle: As the term is used in this standard, a hand-operated device used to open and close the chamber door or to lock or unlock the chamber. The term may also be applied to devices used to control the flow of steam, water, or power to the sterilizer.

3.17 interlock: Means by which accidental opening of the sterilizer door is prevented when the pressure within the chamber exceeds a defined limit and/or the means by which introduction of steam to the chamber is prevented if the sterilizer door is not locked.

3.18 jacket: Portion of the sterilizer surrounding and affixed to the chamber through which steam is circulated and which functions to help maintain temperature in the chamber.

3.19 pressure gauge: Device that is attached to the chamber or jacket of a steam sterilizer and that is used to indicate, usually in pounds per square inch gauge (psig), the pressure of the steam in the chamber or jacket. See also **psig**.

3.20 pressure vessel: Sealed cavity capable of withstanding internal pressure above atmospheric pressure.

NOTE—All pressure vessels intended for operation at a pressure above 15 psig must be constructed to conform to American Society of Mechanical Engineers (ASME) codes unless they are outside of the scope of these codes.

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

3.22 psig: Pounds per square inch gauge. Other units of saturated pressure are pounds per square inch absolute (psia) and kiloPascals (kPa). Typical values of saturated pressure for steam sterilization are given in Table 1.

Table 1—Conversions of saturated pressure units at sea level

psia	psig	kPa
29.8	15.1	205.8
41.9	27.2	288.6
45.4	30.7	313.2
53.3	38.6	367.6

3.23 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.

3.24 saturated steam: Water vapor in a state of equilibrium between condensation and evaporation.

3.25 steam generator: Device that adds sufficient heat to water to convert it to steam.

3.26 sterility assurance level (SAL): Probability of a viable microorganism being present on a product unit 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 sterility assurance level of 10^{-6} is appropriate for items intended to come into contact with compromised tissue (i.e., tissue that has lost the integrity of the natural body barriers).

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

3.28 sterilizer, steam: Sterilizing apparatus that uses saturated steam under pressure as the sterilizing agent.

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

3.30 z value: Number of degrees of temperature required for a 1-logarithm change in the D value.

NOTE—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, which are permanently fastened and reasonably accessible, that provide the following minimum information:

a) the manufacturer's name;

b) the manufacturer's type and model designation;

c) the serial number;

d) the date of manufacture;

e) the electrical supply requirements;

f) the stamp or label of the inspecting authority;

g) the chamber pressure rating; and

h) the jacket pressure rating (if applicable).

4.1.1.2 Safety

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, where possible, guards shall be provided for operator protection. Adequate written information (see 4.1.2) shall be provided with the sterilizer to alert the operator to areas of potential hazard.

4.1.2 Information manual

At the time of installation or upon request, at any time between the placing of a purchase order and delivery of the equipment, the manufacturer or the manufacturer's agent shall furnish the purchaser with a manual containing the following minimum 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 steam pressure and volume, 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 safety precautions to be taken during routine use and recommended sterilizer settings; and

e) instructions for inspection 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 filters, recorders, steam separators/traps, valves, and safety valves; 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 for purchase by the user or the user's designee a complete service manual that is comprehensive enough to ensure that the safety and effectiveness of the device can be maintained.

NOTE—The depth and detail of the information provided in the service manual may vary with the sophistication and user serviceability of the equipment. The manufacturer and user should negotiate the particulars of the servicing information at the time of purchase. At a minimum, however, information about parts availability should be supplied.

4.2 Sterilizer design, construction, components, and accessories

4.2.1 Pressure requirements

All sterilizers that can be operated at pressures above atmospheric pressure, under normal or "fault" conditions, shall have a pressure-relief device. The design and materials of construction of sterilizers intended to be operated at an internal pressure of 15 psig or more shall conform to the requirements of Section VIII, Division 1, of the ASME *Boiler and pressure vessel code* (see 2.1). The chamber manufacturer shall furnish proof of such conformance. Sterilizers intended to be operated at a pressure below 15 psig shall be designed and tested to withstand a pressure of at least 2.25 times the pressure-relief setting. If steam is produced for the sterilizer by its own dedicated steam generator, the generator shall conform to applicable provisions of the ASME code.

4.2.2 Pressure vessel certification

The manufacturer shall furnish the purchaser with certification demonstrating that each sterilizer complies with the ASME code and other applicable standards.

4.2.3 Electrical components

The sterilizer electrical system shall be designed, manufactured, and tested in accordance with UL 3101-1, *Electrical equipment for laboratory use—Part 1: General requirements* (see 2.5). The sterilizer electrical system shall be designed for installation in conformance to the *National electrical code* (see 2.4).

4.2.4 Corrosion resistance

4.2.4.1 Sterilizer surfaces

The inside surfaces of the sterilizer and the chamber side of the door shall be constructed of materials having corrosion-resistant properties equal to or better than the materials listed in Section II of the ASME *Boiler and pressure vessel code* (see 2.1).

4.2.4.2 Loading accessories

Loading shelves, carts, and other accessories supplied by the sterilizer manufacturer shall be corrosion resistant to the products and materials intended to be processed as well as to the sterilizing agent.

4.2.5 Air filters

At least one bacteria-retentive filter, having a minimum filtration efficiency of 99.97 % for 0.3-micron particles, shall be installed in each chamber vacuum-relief line. Filters shall be readily accessible for routine maintenance.

4.3 Sterilizer safety

4.3.1 Interlock

All sterilizers shall be equipped with an automatic interlock mechanism designed so that, under normal operating conditions, steam cannot enter the chamber when the door is unlocked or unsealed.

NOTE—This requirement is not intended to exclude an automatic sterilizer designed to function during an electrical power failure in order to complete the cycle.

The sterilizer shall be constructed so that the door cannot be opened until chamber pressure has returned to a safe level.

4.3.2 Prevention of thermal hazards

The temperature of all handwheels, handles, or similar devices that the operator will use during normal operation of the sterilizer shall comply with UL 3101-1 (see 2.5).

4.3.3 Sterilizer controls for aborting cycles

A means of safely aborting or terminating a cycle in progress shall be readily accessible to the operator and shall be clearly described in the labeling. A means shall be provided to access the chamber and the load in the event of a power failure.

4.4 Process monitoring and control devices

4.4.1 General

The following process parameters shall be automatically monitored, recorded, and controlled:

a) temperature;

b) time;

c) pressure; and

d) if required for product integrity, rate of change of temperature and pressure.

For temperature, the monitor, recorder, and process control systems shall either be independent or designed in a manner that provides an automatic means for independent verification of temperature control and will cause a warning to occur if specified limits are exceeded.

4.4.2 Chamber temperature

4.4.2.1 Temperature monitoring and recording

The sterilizer shall be equipped with a means of continuously monitoring, recording, and controlling chamber temperature.

4.4.2.2 Positioning of temperature sensors

The temperature sensor(s) shall be positioned to ensure that the actual temperature of the sterilizing medium is at or above the temperature indicated, recorded, and controlled.

4.4.2.3 Accuracy of temperature measurement

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

4.4.2.4 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 sterilization exposure temperature. For example, when recording temperature for a 132 °C (270 °F) cycle, the 1 °C (or 2 °F) resolution requirement shall apply to the 127 °C to 137 °C (260 °F to 280 °F) range. Digital printouts shall be rounded to the nearest whole degree or truncated to whole degrees unless printed in tenths of a degree.

4.4.2.5 Sterilizer temperature control

The control-set temperature shall be selected and the control shall function so that the chamber temperature during the exposure time remains within +3 °C (or +6 °F) and –0 °C (or –0 °F) of the selected sterilization exposure temperature at defined locations within the chamber. Any mechanism provided to the operator to select the sterilization exposure temperature shall be marked in 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 sterilization exposure temperature. The sterilizer control system shall begin the exposure time only when the sterilization exposure temperature has been achieved. If the chamber temperature falls below the sterilization exposure temperature, the sterilizer control system shall reset the timer or abort the cycle and alert the operator whenever this situation occurs.

4.4.3 Thermometric test connection

The sterilizer shall be equipped with a means of connecting an adequate number of temperature-measuring sensors to allow compliance with 4.4.2.5 and to be verified according to 5.4.2.5.

4.4.4 Sterilizer exposure timer

The timer shall have a minimum accuracy of ± 5 % of the set value. See also 4.4.2.5.

4.4.5 Pressure measurement

4.4.5.1 Chamber pressure indicator

The sterilizer shall be equipped with a mechanical gauge, digital indicator, or other device for indicating the vacuum and the pressure within the chamber. Double-door sterilizers shall have a pressure-indicating device at each end, readily visible to and readable by the operator. If a mechanical gauge is used, it shall be accurate to within ± 3 % of the full-scale value. If a digital indicator is used, it shall be accurate to within 1 psi. In the positive-pressure region, the pressure-indicating device shall have graduations of a resolution of 2 psig or less. The scale shall be graduated for a full-scale range of 5 atmospheres absolute.

4.4.5.2 Jacket pressure indicator

Where applicable, the sterilizer shall be equipped with an indicator that displays jacket pressure. This indicator, or another means of indicating that the unit is ready to run a cycle, shall be readily visible to and readable by the operator. If a mechanical gauge is used, it shall be accurate to within ± 3 % of the full-scale value. If a digital indicator is used, it shall be accurate to within 1 psi. Each graduation or increment of resolution shall be 2 psig or less.

4.4.6 Cycle documentation

For each cycle, the following minimum information shall be documented on the sterilizer printout:

a) the cycle parameters selected for that cycle;

b) the date and time the cycle started;

c) the cycle number and assigned sterilizer identification number;

d) the elapsed time at each designated phase change, with temperature and pressure indicated; and

e) the total cycle time.

In addition, space shall be provided for a load control sticker or the recording of the lot number assigned for the cycle; a line shall be provided for the approval signature. Deviations from selected cycle parameters or the functional parameters of the cycle program shall be displayed during their occurrence, and the time of such events shall be recorded on the printout.

See annex B for examples of cycle documentation.

4.5 Biological performance of sterilizers

When the sterilizer is tested according to 5.5, the manufacturer's recommended cycle or cycles shall have a sufficient lethality to reduce a 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 5.5.

4.6 Mechanical air removal

NOTE—The air-removal test (5.6.1) and the leak-rate test (5.6.2) complement each other. A prevacuum sterilizer should meet the requirements of both tests. Neither test applies to gravity-displacement sterilizers. Leak-rate testing does not apply to steam-flush pressure-pulse sterilizers. See also 3.8.

4.6.1 Air removal (dynamic-air-removal sterilizers)

The efficacy of the air-removal system of a dynamic-air-removal sterilizer (prevacuum or steam-flush pressure-pulse) shall be tested according to 5.6.1 and shall meet the acceptance criteria of 5.6.1.4.

4.6.2 Air leaks (prevacuum sterilizers)

When a prevacuum sterilizer is tested according to 5.6.2, it shall exhibit an average leak rate of 1 millimeter of mercury (mmHg) per min or less over the measured time interval.

4.7 Sterilizer performance certification and recordkeeping

The sterilizer manufacturer shall certify reports of tests satisfactorily performed according to this standard and keep them on file for the design life of the sterilizer. The manufacturer shall recertify the equipment design and performance of current production sterilizers every 24 months or upon any change in design that might affect the safety and efficacy of the sterilizer type.

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 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 4.2.3 can be determined by the test method of 5.2.3).

Test apparatus and instruments. Apparatus and instruments used for testing sterilizers must be calibrated in accordance with the federal Quality System regulation (21 CFR 820.72). The quality assurance program establishing the frequency and method of calibration must be documented.

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. If the instructions specify a range of utility supply values (i.e., a range of steam or water pressure), the sterilizer must be tested under the conditions that present the greatest challenge to sterilizer efficacy.

5.1 Labeling

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

5.2 Sterilizer design, construction, components, and accessories

5.2.1 Pressure requirements

Methods by which compliance with 4.2.1 can be verified are provided in 2.1.

5.2.2 Pressure vessel certification

Compliance with 4.2.2 can be verified by inspection.

5.2.3 Electrical components

Methods by which compliance with the electrical safety requirements of 4.2.3 can be verified are provided in 2.4 and 2.5.

5.2.4 Corrosion resistance

5.2.4.1 Sterilizer surfaces

See 2.1.

5.2.4.2 Loading accessories

See 2.1.

5.2.5 Air filters

Inspection can verify that a bacteria-retentive filter of the required filtration efficiency is installed in each chamber vacuum-relief line and that it is readily accessible for routine maintenance. The required performance of the filter can be verified by inspection of the filter manufacturer's certification and documentation that the filter complies with the specified performance criteria and is suitable for the intended conditions of use.

5.3 Sterilizer safety

5.3.1 Interlock

The operation of interlocks can be verified by attempting to perform the interlocked functions under the conditions described. The test to ensure that the door cannot be opened when the chamber is pressurized must be performed at a pressure only slightly above atmospheric pressure, because a hazardous condition could result if the test reveals failure of the interlock. See also 2.1.

5.3.2 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 where the ambient temperature is maintained between 20 °C and 23 °C (68 °F and 73 °F). A normal sterilization cycle is run, and the temperatures are monitored for compliance with 4.3.2.

5.3.3 Sterilizer controls for aborting cycles

Compliance with 4.3.3 can be verified by inspection.

5.4 Process monitoring and control devices

5.4.1 General

Compliance with 4.4.1 can be verified by inspection.

5.4.2 Chamber temperature

5.4.2.1 Temperature monitoring and recording

Compliance with 4.4.2.1 can be verified by inspection.

5.4.2.2 Positioning of temperature sensors

Compliance with 4.4.2.2 can be verified by inspection.

5.4.2.3 Accuracy of temperature measurement

Compliance with 4.4.2.3 can be verified by testing against calibrated standards.

5.4.2.4 Resolution of temperature measurement

Compliance with 4.4.2.4 can be verified by inspection.

5.4.2.5 Sterilizer temperature control

Compliance with 4.4.2.5 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 10 temperature sensors should be used to profile the corner, center, and drain positions in the chamber. Large chambers might require additional sensors to ensure uniformity of measurements. The intent of the temperature-control requirements of 4.4.2.2 and 4.4.2.5 is to ensure that the sterilizer is capable of providing steady-state thermal conditions within the chamber that are consistent with the predicted sterility assurance level (SAL) in the load. Therefore, the manufacturer of the sterilizer must determine and record that, at any place a load could be positioned within the chamber, the temperature parameters of 4.4.2.2 and 4.4.2.5 are satisfied for recommended operating cycles and loads.

5.4.3 Thermometric test connection

Compliance with 4.4.3 can be verified by inspection.

5.4.4 Sterilizer exposure timer

Compliance with 4.4.4 can be verified by inspection and by testing the timer against a calibrated standard.

5.4.5 Pressure indicators

5.4.5.1 Chamber pressure indicator

Compliance with 4.4.5.1 can be verified by inspection and by testing against calibrated standards.

5.4.5.2 Jacket pressure indicator

Compliance with 4.4.5.2 can be verified by inspection and by testing against calibrated standards.

5.4.6 Cycle documentation

Compliance with 4.4.6 can be verified by inspection.

5.5 Biological performance of sterilizers

5.5.1 General testing requirements

The manufacturer shall conduct the tests of 5.5.2, 5.5.3 (if applicable), 5.5.4, and 5.5.5 (if applicable) as part of initial design qualification and periodically thereafter (see 4.7) on production sterilizers. The manufacturer shall maintain records in accordance with 4.7. For each type of load, the porous-load tests (5.5.2, 5.5.4, and 5.5.5) shall produce acceptable results (see 5.5.2.5, 5.5.4.5, 5.5.5.1.5, and 5.5.5.2.5) when performed with separate loads on three consecutive half cycles. For liquid loads (5.5.3), results shall be acceptable (see 5.5.3.5) when the test is performed for three consecutive full cycles. The cycle time reduction value necessary to determine the SAL can be estimated from survival curve data (e.g., Pflug, 1973) or via fraction-negative methods (e.g., Pflug, 1977; Stumbo, 1973).

The BIs used in testing shall contain *Bacillus stearothermophilus* spores and shall comply with the requirements of 2.2. The survival curve shall be established using at least three points in the log reduction area and two replicates in the fraction-negative area. The culturing and incubation conditions shall be in accordance with the instructions supplied by the BI manufacturer.

5.5.2 Biological performance with a fabric test pack

5.5.2.1 Test pack construction

The BI test pack consists of 16 freshly laundered, 100 % cotton towels, in good condition, each approximately 16 inches (in) by 26 in (41 centimeters [cm] by 66 cm). Each towel is folded lengthwise into thirds and then folded widthwise in half. After being folded, the towels are placed one on top of another, with folded ends alternating, to form a stack with the approximate dimensions of 9 in long by 9 in wide by 6 in high (23 cm by 23 cm by 15 cm). One or more BIs are placed between the eighth and ninth towels in the approximate geometric center of the pack. If chemical indicators (CIs) are used, they should be placed adjacent to the BIs. The pack should have a density of approximately 11.3 pounds (lb) per cubic foot. (See Figure 1.)

A temperature sensor with an accuracy of ± 1 °C must be placed in the geometric center of the pack to allow the temperature profile of the load to be determined.

NOTE—The geometric center of the pack may not be the part of the pack that is most difficult to heat, but it will provide a reasonable approximation for purposes of the temperature profile.

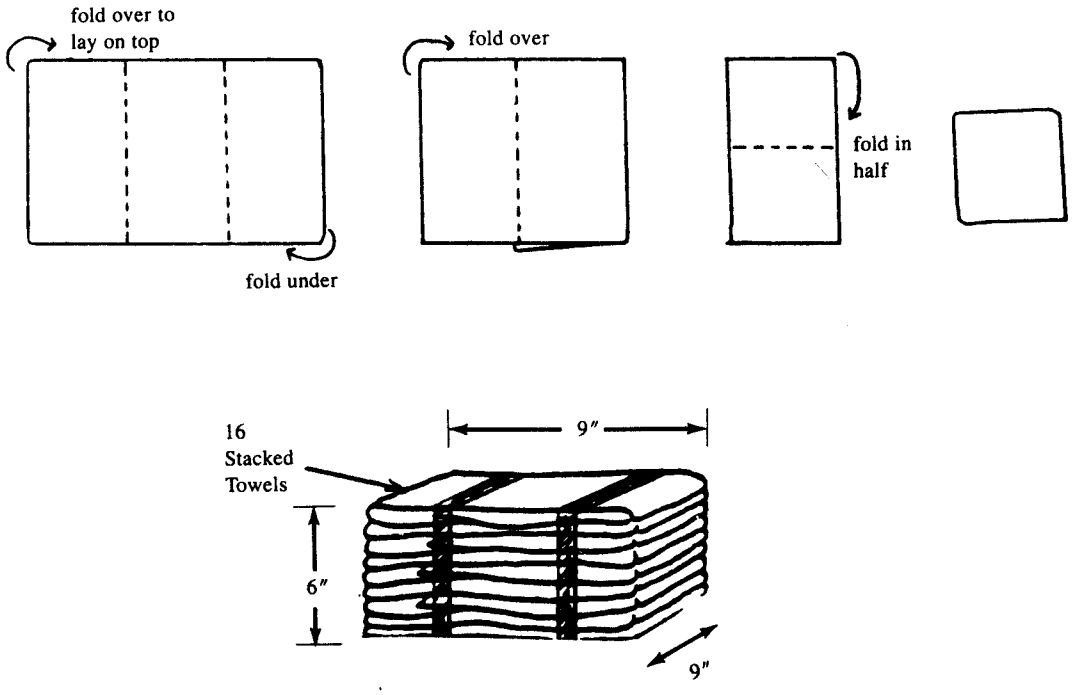


Figure 1—Preparation of the 16-towel BI test pack

5.5.2.2 Test pack placement

The test pack is placed flat (layers of towels horizontal) on a rack in the area of the sterilizer chamber that is least favorable to sterilization. This area (the “cold point”) varies with the design of the sterilizer. The cold point must be determined before the location for test pack placement is selected (see 5.4.2.5); it is often found in the bottom of the chamber near the door(s). For gravity-displacement sterilizers, the test is run in a chamber fully loaded with test packs (without BIs) (see Figure 2); the actual number of packs needed to make a full load will vary with chamber dimensions and loading equipment. For dynamic-air-removal sterilizers, the test is run in an otherwise empty chamber.

NOTE—The test loads for gravity-displacement sterilizers differ from those for dynamic-air-removal sterilizers because of the different effects of chamber air content on steam penetration. Dynamic-air-removal cycles are subject to the “small-load effect,” whereas gravity-displacement cycles are more challenged by a large load that inhibits the air-displacement process.

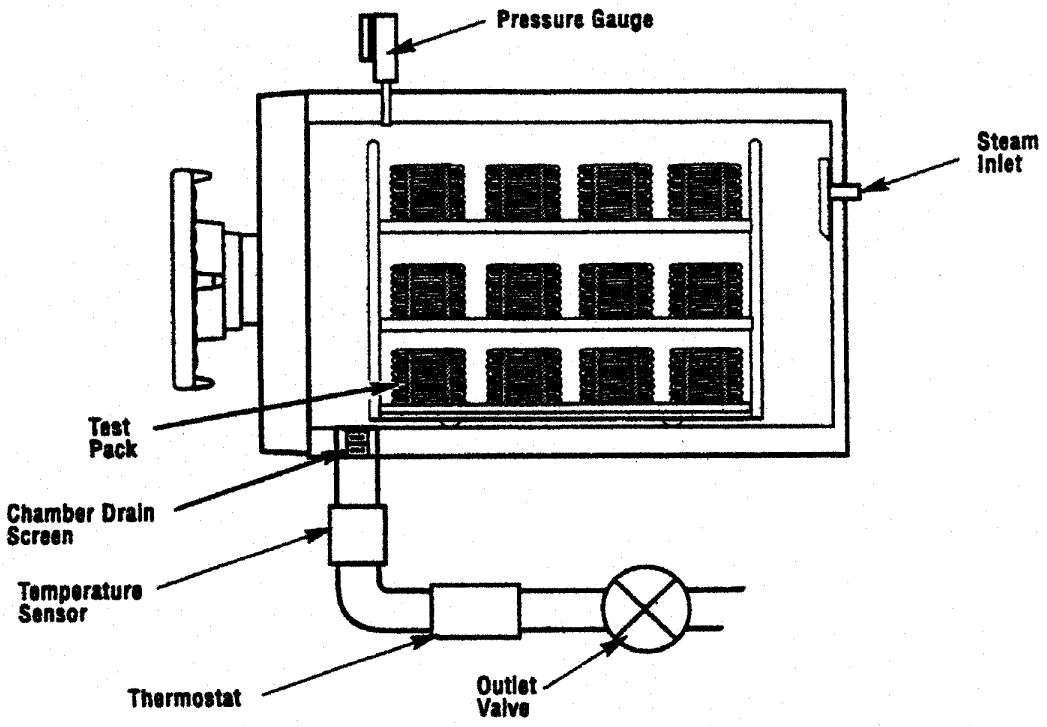


Figure 2—Placement of a BI test pack for qualification testing of gravity-displacement steam sterilizers

5.5.2.3 Cycle operation

A normal sterilization cycle, including drying time, 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 4.5 and the acceptance criteria of 5.5.2.5.

5.5.2.4 Incubation of biological indicators

See 5.5.1.

5.5.2.5 Acceptance criteria

a) *Sterility assurance level.* The manufacturer shall demonstrate that the recommended cycle has a SAL of at least 10^{-6} when the challenge test pack is used. This SAL represents the inactivation of 12 logarithms of a microorganism with a $D_{121\,°C}$ of approximately 1.0 min and results in a minimum product F_o value of ≥ 12 (based on a reference z value of 10 °C) (see AAMI TIR13 and ANSI/AAMI/ISO 14161, annex A). The temperature sensor readings will confirm the achievement of a time-at-temperature sufficient to produce an F_o of at least 12.

b) *Moisture retention.* Moisture retained by the fabric test pack shall cause no more than a 3 % increase in presterilization test pack weight, and the pack shall exhibit no wet spots.

5.5.3 Biological performance with liquid loads (if applicable)

NOTE—Because the evaluation of liquid load cycle performance is more difficult to standardize than that of other load types, this test provides limited information. Manufacturers of sterilizers with liquid load cycles that use this test for validation/qualification should inform their customers of these limitations and advise them that the cycle is not intended for sterilization of materials that come into direct contact with patients.

5.5.3.1 Test flasks

Three 1,000-milliliter (mL) flasks are used in the liquid cycle test. The flasks shall be Type 1 borosilicate (e.g., Pyrex® glass).

CAUTION—Screw caps or rubber stoppers with crimped seals must not be used. Serious injury can occur if flask seals are not designed to prevent explosive decompression.

Each flask is filled with 1,050 mL of water. A BI containing *B. stearothermophilus* spores and media in a hermetically sealed vial is suspended in the center of the first flask. The second water-filled flask is fitted with a thermocouple or other appropriate temperature-sensing device so that the temperature at the center of the liquid can be sensed and a permanent temperature record of variations throughout the cycle can be made. The third water-filled flask is used to test liquid loss. An appropriate self-sealing vented closure is placed on each flask.

An alternative biological test is to fill the first flask with 1,050 mL of soybean casein digest media or its equivalent, rather than water. A spore strip meeting the requirements of 5.5.1 is placed in the flask with the media. The spore strip should be suspended within the flask at a point approximately one-third up from the bottom. The flask shall be run in the sterilization cycle immediately after the spore strip has been added.

5.5.3.2 Placement of test flasks

The three flasks are placed in the center of an otherwise empty sterilizer chamber.

5.5.3.3 Cycle operation

A normal liquid cycle is run at 121 °C (250 °F) according to the instructions that the manufacturer provides to health care facilities.

5.5.3.4 Incubation of biological indicators

The BIs are retrieved and incubated according to the instructions of the BI manufacturer. If the alternate test described in 5.5.3.1 is used, the flask containing the spore strip is removed from the chamber after the sterilization cycle is complete and the load has cooled. The flask is then placed in an incubator and incubated at the BI manufacturer's recommended temperature for the recommended amount of time (usually 7 days or less).

5.5.3.5 Acceptance criteria

Sterility of the load shall be demonstrated by the killing of all spores on the BIs. For acceptable test results, closures on the flasks shall automatically seal, and water loss from the third water-filled flask shall not exceed 50 mL. The temperature profile obtained by the temperature sensor shall demonstrate that 121 °C (250 °F) was achieved and maintained in the center of the liquid load for at least 12 min. This equates to an F_o of 12, thus providing the required SAL of at least 10^{-6}.

5.5.4 Biological performance with wrapped instrument test pack

5.5.4.1 Test pack construction

The total weight of the test pack shall be at least 16 lb (7.2 kilograms [kg]). The wrapped instrument pack consists of a) miscellaneous metal surgical instruments, b) a perforated or wire-mesh-bottom tray approximately 20 in (51 cm) in length and 10 in (25 cm) in width and lined with a 100 % cotton surgical towel, c) two BIs, and d) two wrappers measuring 54 in by 54 in (137 cm by 137 cm). Wrappers shall be made of 100 % cotton, 140-thread-count, two-ply fabric and shall be freshly laundered. The cotton surgical towel is placed in the bottom of the tray and the surgical instruments are spread out evenly on the towel (see Figure 3). The BIs are placed among the instruments. The tray and its contents are sequentially wrapped with the two wrappers and secured with autoclave tape (see Figure 4).

5.5.4.2 Test pack placement

The wrapped instrument test pack is placed horizontally in the lower portion of the sterilizer near the drain. The test is run in a fully loaded sterilizer; the number of packs needed for a full load will vary depending on chamber dimensions and loading equipment. Simulated instrument test packs may be used to achieve a fully loaded chamber; these simulated test packs are identical to the wrapped instrument test pack except that they do not contain BIs, and similar metal materials can be substituted for surgical instruments.

5.5.4.3 Cycle operation

A normal sterilization cycle, including drying time, 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 4.5 and the acceptance criteria of 5.5.4.5.

5.5.4.4 Incubation of biological indicators

See 5.5.1.

5.5.4.5 Acceptance criteria

a) *Sterility assurance level.* The manufacturer shall demonstrate that the recommended cycle has a SAL of at least 10^{-6} when the wrapped instrument pack is used.

b) *Moisture retention.* When measured immediately after completion of the cycle, the wrapped instrument packs shall have no wet spots on the outer wrappers. Moisture retained by the 100 % cotton towel shall cause no more than a 20 % increase in the presterilization weight of the towel.

NOTE—The 20 % weight gain in the towel represents roughly 0.5 ounces (oz) of water out of the 5.0 to 5.5 ounces of condensate formed in the process of heating the instruments. This amount of water remaining in the towel immediately after the completion of the cycle has been found to be normal and reasonable. However, by the time the pack has been allowed to cool to room temperature, the weight gain of the towel will probably be much lower (less than 5 %).

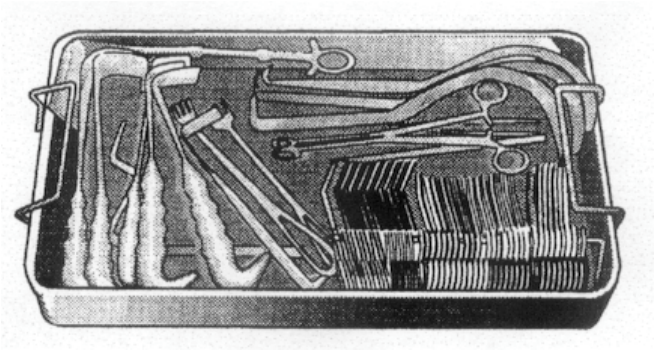


Figure 3—Example of a surgical instrument tray to be used in the wrapped instrument test

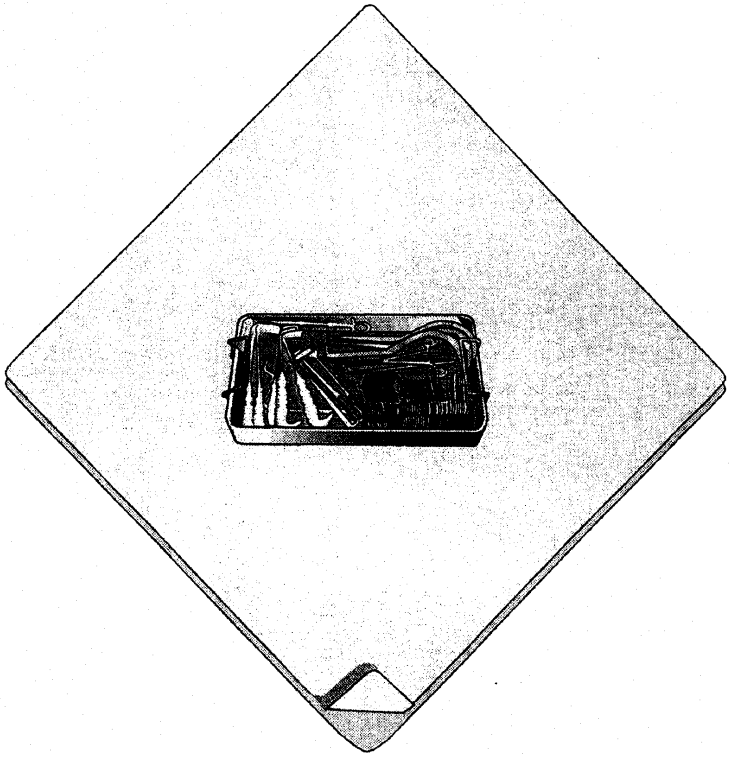


Figure 4—Surgical instrument tray (20 in by 10 in) and wrapper (54 in by 54 in) for use in the wrapped instrument test pack

5.5.5 Biological performance of abbreviated (flash/emergency) cycles for porous and nonporous items, either unwrapped or in a single wrapper

5.5.5.1 Gravity cycles for unwrapped nonporous items

5.5.5.1.1 General

If the sterilizer provides abbreviated (flash/emergency) cycles for the processing of unwrapped nonporous items, two separate sets of tests shall be conducted: a minimum-load test and a maximum-load test. The sterilizer manufacturer shall specify the exposure temperature to be used.

5.5.5.1.2 Test pack construction

For both tests, a metal perforated or wire-mesh-bottom tray, which is typically approximately 20 in (41 cm) in length and 10 in (25 cm) in width, shall be used. For the minimum-load set of test cycles, a single, nonporous instrument weighing no more than 100 grams (g) shall be placed in an otherwise empty instrument tray. For the maximum-load set of test cycles, the instrument tray shall contain at least 16 lb of simulated metal surgical instruments spread evenly in the tray. At least two BIs shall be placed in the test pack to be positioned over the chamber drain. At least one BI shall be placed in each additional test pack used.

5.5.5.1.3 Test pack placement

For the minimum-load test, the test pack containing a single instrument shall be placed on the lower shelf of the sterilizer, above the drain, in an otherwise empty chamber. For the maximum-load test, the test pack containing two BIs shall be placed on the lower shelf of the sterilizer, above the drain; the remainder of the chamber volume shall be filled with the maximum number of test packs possible, each filled with instruments and each containing one BI. The manufacturer shall define what constitutes a maximum load.

5.5.5.1.4 Cycle operation

A sterilization cycle shall be run according to the manufacturer's instructions, with exposure times appropriate for establishing compliance with the sterility assurance requirements of 4.5 and the acceptance criteria of 5.5.5.1.5.

5.5.5.1.5 Acceptance criteria

The manufacturer shall demonstrate that the recommended cycle has a SAL of at least 10^{-6}.

NOTE—There is no acceptance criterion for moisture retention because visible moisture is to be expected for this type of cycle.

5.5.5.2 Dynamic-air-removal cycles for single-wrapped or unwrapped nonporous items

5.5.5.2.1 General

When dynamic-air-removal techniques are employed for processing single-wrapped or unwrapped nonporous items, the sterilizer manufacturer shall define maximum load conditions and the exposure temperature. If a single wrap (one layer) is recommended by the manufacturer, it shall meet the wrapper specifications defined in 5.5.4.1. Two separate sets of tests shall be conducted: a minimum-load test and a maximum-load test.

5.5.5.2.2 Test pack construction

For both tests, a metal perforated or wire-mesh-bottom tray, which is typically approximately 20 in (41 cm) in length and 10 in (25 cm) in width, shall be used. For the minimum-load set of test cycles, a single instrument weighing no more than 100 g shall be placed in an otherwise empty instrument tray. For the maximum-load set of test cycles, the instrument tray shall contain at least 16 lb of simulated metal surgical instruments spread evenly in the tray. At least two BIs shall be placed in the test pack to be positioned over the chamber drain. At least one BI shall be placed in each additional test pack used. If a single wrapper is recommended by the manufacturer, each test pack shall be wrapped in a single thickness of wrapping material that is taped closed but not sealed.

5.5.5.2.3 Test pack placement

For the minimum-load test, the test tray containing a single instrument shall be placed on the lower shelf of the sterilizer, above the drain, in an otherwise empty chamber. For the maximum-load test, the test pack containing two BIs shall be placed on the lower shelf of the sterilizer, above the drain; the remainder of the chamber volume shall be filled with the maximum number of test packs possible, each filled with instruments and each containing one BI. The manufacturer shall define what constitutes a maximum load.

5.5.5.2.4 Cycle operation

A sterilization cycle shall be run according to the manufacturer's instructions, with exposure times appropriate for establishing compliance with the sterility assurance requirements of 4.5 and the acceptance criteria of 5.5.5.2.5.

5.5.5.2.5 Acceptance criteria

The manufacturer shall demonstrate that the recommended cycle has a SAL of at least 10^{-6}.

NOTE—There is no acceptance criterion for moisture retention because visible moisture is to be expected for this type of cycle.

5.6 Mechanical air removal

5.6.1 Air removal (dynamic-air-removal sterilizers)

5.6.1.1 Test pack construction

The Bowie-Dick test pack consists of folded, 100 % cotton surgical towels that are clean and preconditioned. The towels shall be folded to a size not smaller than 9 in (250 mm ± 20 mm) in one direction and 12 in (300 mm ± 20 mm) in the other direction, and then placed one above the other. The height of the test pack shall be 10 to 11 in (250 to 280 mm). The weight of the test pack shall be 8.8 lbs ± 5 % (4 kg ± 5 %).

NOTE—The total number of towels may vary from test to test, depending on towel thickness and wear.

A commercially available Bowie-Dick test indicator sheet conforming to 2.3 shall be placed across the center layer of the pack. Three temperature-sensing devices, placed 1.5 inches apart, shall be positioned diagonally from opposing corners of the cubic volume through the geometric center of the test pack. Care should be taken to prevent the sensor leads from providing a channel for air entry into the test pack. A single, two-ply fabric wrap, made of 100 % cotton with a thread count both warp and weft of 5.5/mm, shall be loosely applied (see Figure 5). The pack should be secured with tape not exceeding 1 in (25 mm) in width.

5.6.1.2 Test pack placement

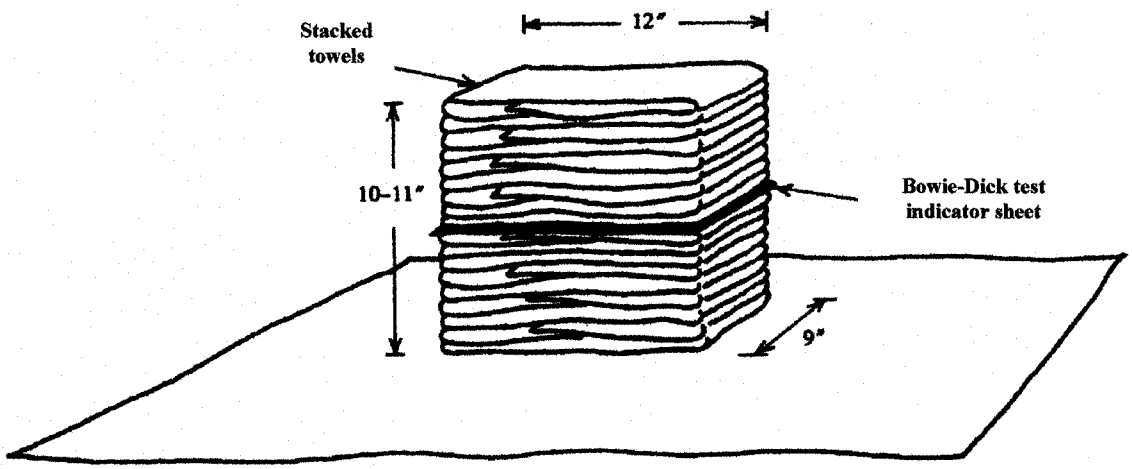
The test pack shall be placed horizontally on the bottom front of the loading rack, near the door and over the chamber drain, in an otherwise empty chamber (see Figure 6). The temperature-sensing devices in the test pack shall be connected to a temperature recorder. An additional temperature-sensing device shall be placed in the chamber drain at a minimum depth of 100 mm. Care should be taken not to allow the temperature-sensing device to come into contact with any surface in the drain.

5.6.1.3 Cycle operation

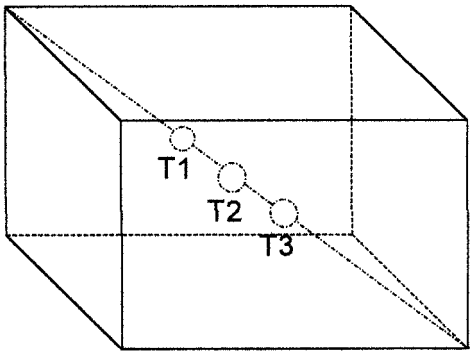
A sterilization cycle is run according to the instructions that the sterilizer manufacturer will provide to health care facilities. The test pack shall be exposed to saturated steam at 134 °C (273 °F) for 3.5 min ± 5 sec and/or 121 °C (250 °F) for 15 min ± 5 sec or such combinations for time and temperature as the manufacturer shall specify for the intended use of the sterilizer. In all cases, the permitted tolerance of the test temperature shall be +1.5/–0 °C (+2.7/–0 °F), and the time given shall be the time within which the color change of the indicator sheet shall occur. Drying time may be omitted in the interest of saving time; it has no effect on the outcome of the test. Upon removal from the sterilizer, the test pack is opened, care being taken to avoid thermal injury to the hands or face from the still-hot test pack. The Bowie-Dick test indicator sheet is removed from the pack and examined by a person trained in its interpretation.

NOTE 1—If an exposure time longer than 4 min is used at 134 °C (273 °F), the test results will be invalid.

NOTE 2—A sterilizer tested from a "cold start" (after the sterilizer has been turned on and before a load is processed) could produce false failures; it is necessary to preheat the sterilizer to operating temperature by running at least one cycle in an empty chamber.



(a) Dimensions and components



(b) Placement of temperature sensors within the pack

Figure 5—Composition of the Bowie-Dick test pack

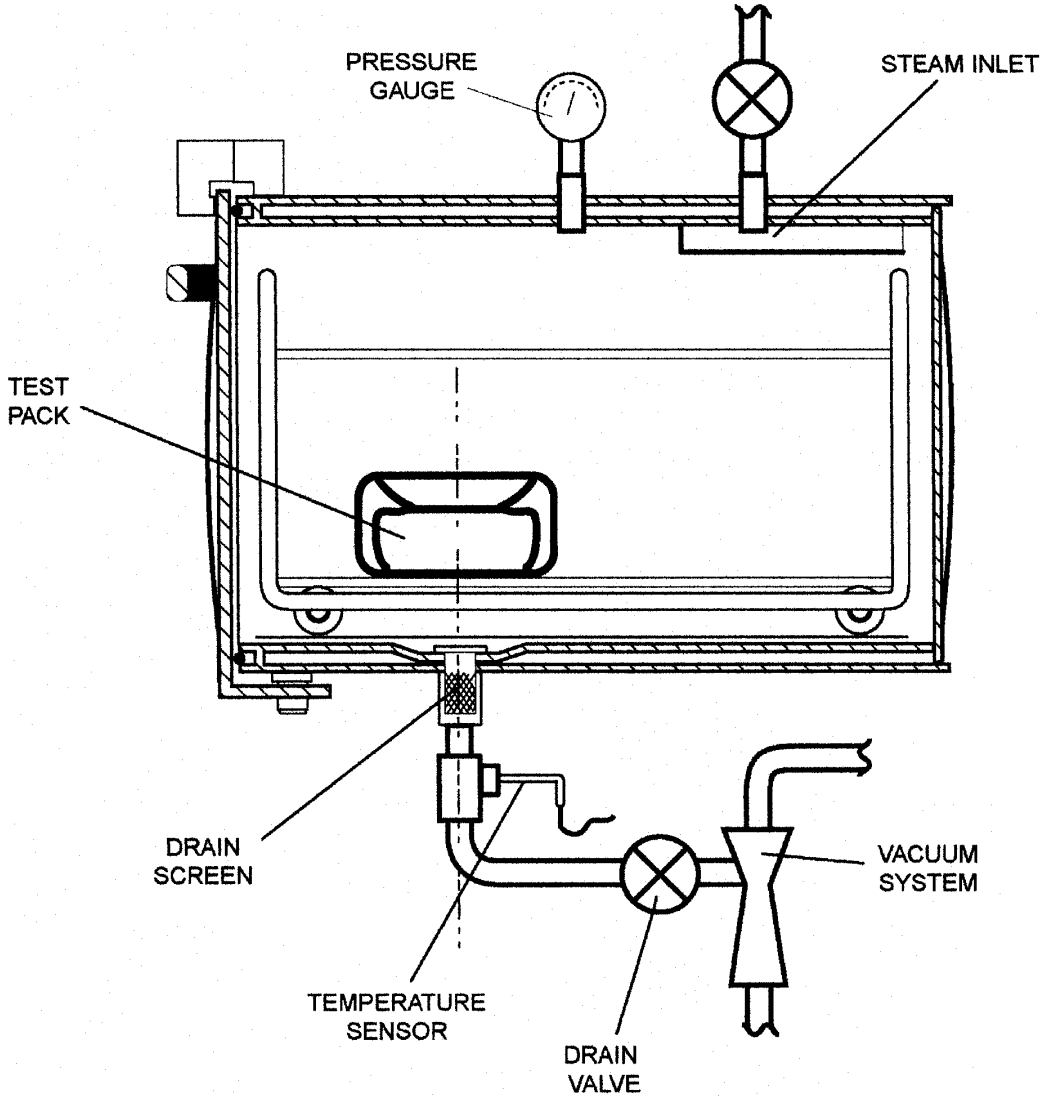


Figure 6—Placement of the Bowie-Dick test pack

5.6.1.4 Acceptance criteria

Following the air-removal phase of the sterilization cycle and upon pressurization to the sterilizing temperature selected for the exposure phase, the temperature indicated by the test pack temperature-indicating devices shall converge with the temperature measured in the chamber drain. The load temperature-indicating devices shall attain the exposure temperature within 10 sec of progressing into the exposure phase (see Figure 7). In addition, the Bowie-Dick test indicator sheet (read at the completion of the cycle after the test pack is removed from the sterilizer) shall show a uniform color change; that is, the color in the center should be the same as that at the edges. The exact color change of the sheet might depend on the brand or the storage conditions. What is important is whether the same color occurs at the center and the edges. The temperature at the edges will be greater than at the center.

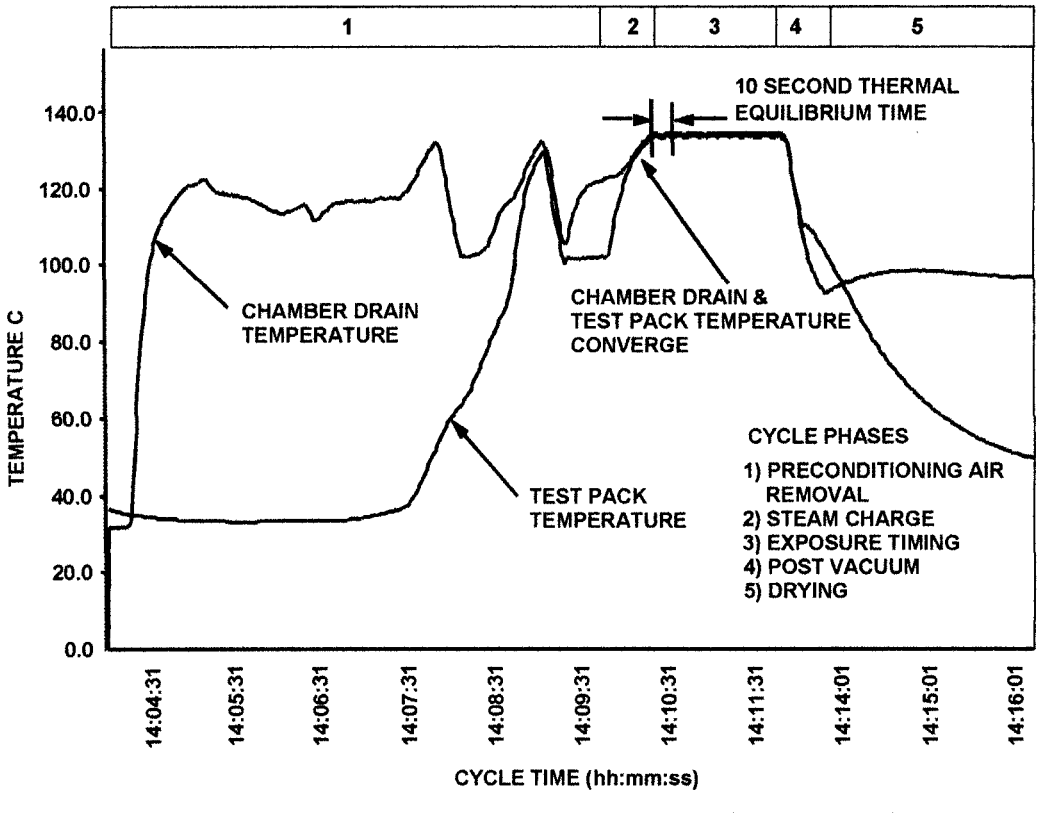


Figure 7—Time/temperature profile of temperature sensor T1

NOTE—The preconditioning phase (Phase 1) above is shown for illustration purposes only and is not intended to specify any particular type of cycle.

5.6.2 Air leaks

5.6.2.1 General

In the leak-rate test, a vacuum is drawn in the chamber. Then, all valves leading to the chamber are closed, the means of drawing a vacuum is stopped, and the chamber pressure is observed for a timed period. The leak-rate test should be carried out when the sterilizer is at normal working temperature.

5.6.2.2 Test procedure

a) Connect to the sterilizer chamber an absolute pressure gauge suitable for operation over the total pressure range of the test cycle.

b) For a sterilizer with a heated jacket, stabilize the temperature of the chamber by running a normal operating cycle. For a sterilizer without a heated jacket, stabilize the chamber temperature by ensuring that the temperature of the sterilizer is not more than 20 °C (36 °F) from ambient temperature.

NOTE—In a closed vessel at 30 mmHg, the pressure changes by approximately 0.75 mmHg for each 10 °C change in temperature over the range of 20 °C to 140 °C (68 °F to 284 °F); at 50 mmHg, the change is approximately 1.5 mmHg. The test could be compromised if the temperature changes by more than 10 °C during the period in which the chamber pressure is monitored.

c) With the temperature stabilized and the sterilizer chamber empty except for fixed racks or interior equipment and the necessary monitoring sensors, start the test cycle. When the pressure in the sterilizer chamber is approximately 50 mmHg or less, close all valves connected to the chamber and stop the vacuum system. Observe and record the time (T1) and the absolute pressure (P1). Wait 5 min ± 10 sec, and then observe and record the chamber absolute pressure (P2). After an additional 15 min ± 10 sec, again observe and record the chamber absolute pressure (P3).

NOTE—The sterilizer may be fitted with a selectable cycle that will carry out this procedure (or a similar cycle determined by the manufacturer to yield equivalent results) automatically and display the air-leakage-rate test results.

d) At the end of the test, calculate the rate of pressure rise for the P3–P2 period ([P3–P2]/15), and check for compliance with the acceptance criteria of 5.6.2.3.

NOTE—A value of (P2–P1) greater than 1.5 mmHg could be the result of the initial presence of condensate in the chamber or plumbing.

5.6.2.3 Acceptance criteria

The leak rate shall be deemed acceptable if an average leak rate of 1 mmHg per min or less is demonstrated over the measured time interval.

5.7 Sterilizer performance certification and recordkeeping

Compliance with 4.7 can be verified by inspection.

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 steam sterilizers intended for use in health care facilities. This annex also provides the rationale for each of the provisions of the standard.

A.1.1 Historical background and scope of the standard

In 1978, the AAMI Sterilization Standards Committee established a Steam Sterilization Subcommittee to supervise the development of voluntary performance standards for both industrial steam sterilizers and sterilizers intended for use in health care facilities. The subcommittee, in turn, established a Sterilizer Standards Working Group to assess the need for device performance standards and to develop the standards.

The working group decided to confine the scope of this standard to those steam sterilizers intended for use in health care facilities that have a volume greater than 2 ft^3, thereby excluding the so-called table-top steam sterilizers, industrial steam sterilizers, and washer/sterilizers. Table-top steam sterilizers were excluded because the mechanical and electrical features of these devices differ significantly from the features of floor-mounted units. The working group felt that the large number of variances and exceptions necessary to cover both table-top and floor-mounted sterilizers might ultimately compromise the value of the standard or result in a document difficult to interpret. (A standard for table-top steam sterilizers for dental applications was ultimately developed by the American Dental Association [ADA, 1992], and AAMI later developed a recommended practice for the use of table-top steam sterilizers, the latest edition of which is AAMI [1998]. An AAMI standard for table-top steam sterilizers was also developed [AAMI, 1997b].)

Industrial steam sterilizers are often custom designed to handle only one specific product type or one specialized process. The diversity of construction and performance differences arising out of this specialization convinced the working group that these types of sterilizers could not be readily addressed in a standard covering hospital steam sterilizers. AAMI subsequently developed a standard to address the minimum performance requirements of industrial moist heat sterilizers and the process design, validation, and routine monitoring of industrial moist heat sterilization cycles. A later edition of this standard (AAMI, 1994b) reflected AAMI's adoption of an international standard on industrial moist heat sterilization. Subsequently, AAMI TIR13 was developed to supplement the standard.

The working group ultimately decided to develop a standard specifically for floor-mounted steam sterilizers intended for use in health care facilities. Concurrently, the development of a recommended practice for hospital steam sterilization processing was begun; AAMI's *Good hospital practice: Steam sterilization and sterility assurance* was first published in 1980, and revised versions were published in 1988 and 1994.

The American National Standard, *Hospital steam sterilizers,* was first approved and published in February 1983. In accordance with AAMI procedures, the Hospital Steam Sterilizer Working Group began the review and revision of the standard in 1987, and a second edition was published in 1988. The major change reflected in the 1988 edition concerned the construction and placement of the BI test pack. The format of the third (1994) edition was revised for consistency with International Organization for Standardization (ISO) standards. In addition, the scope was expanded to include steam-flush, pressure-pulse sterilizers; the normative references and bibliography were updated; the definitions section was expanded; and the provisions concerning sterilizer temperature control and vacuum leak testing were clarified. The present (fourth) edition of the standard incorporates additional temperature-sensing requirements, expanded air-removal requirements and tests, and a new requirement for cycle documentation.

A.1.2 Need for the standard

Steam sterilizers are intended to render products and materials sterile. Because many of the materials processed with steam in health care facilities are intended for use in surgical procedures, the failure or inadequate performance of the sterilizer could result in serious, even life-threatening, patient infections. In addition, steam sterilizers use steam at high pressures and temperatures as the sterilizing agent, thereby presenting potential risks to the safety of the sterilizer operator.

At the outset of the standards-development effort, three areas of concern were identified: the safety of sterilizer operators, the effectiveness of sterilization parameter measurement and control by the sterilizer, and the adequacy

of validation of sterilizer performance and cycle parameters. The committee judged that these potential problem areas could best be addressed by defining safety and performance criteria that could be used by manufacturers in qualifying equipment design. It was recognized that user education was also an important element of sterility assurance, and, as noted in A.1.1, a separate effort was initiated to develop appropriate guidelines for hospital steam sterilization processing.

The committee's determination that a voluntary performance standard for steam sterilizers was needed was subsequently supported by the Food and Drug Administration's (FDA's) classification of steam sterilizers as class II (performance standards). The FDA's 24 August 1979 *Federal Register* notice proposing the classification of steam sterilizers identified patient infection and steam burns to operating personnel as potential health risks that could result from the improper performance or design of steam sterilizers.

The above recommendations largely coincided with the initial scope defined for this standard in 1978. The specific rationale for each of the provisions of the standard is provided in section A.4 of this annex, but, in summary, the standard is based on the following premises: Minimizing the risk of patient infection requires adequate control of sterilizing time, temperature, and steam saturation. Assurance of this control is best provided by defining criteria for use in the qualification of the equipment by the manufacturer; therefore, this standard addresses the performance characteristics and instrumentation needed to provide adequate process control. With respect to potential safety hazards, the standard defines device 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 steam sterilizers intended for use in health care facilities will adequately sterilize medical products and materials through control of the necessary variables for steam sterilization, and that steam sterilizers can be used safely by health care personnel.

A.2 Normative references

No additional guidance is provided for section 2 of this standard.

A.3 Definitions, symbols, and abbreviations

No additional guidance is provided for section 3 of this standard.

A.4 Rationale for the specific provisions of the standard

A.4.1 Labeling

The requirements of 4.1 are intended to help ensure that manufacturers of steam sterilizers give sufficient information to users 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 steam sterilizers.

A.4.2 Sterilizer design, construction, components, and accessories

A.4.2.1 Pressure requirements

The standard incorporates by reference the requirements of the ASME *Boiler and pressure vessel code* (normative reference 2.1) to help ensure that the sterilizer will be able to withstand ordinary chamber pressures, with a generous safety margin built in to protect the operator.

A.4.2.2 Pressure vessel certification

The ASME *Boiler and pressure vessel code* (normative reference 2.1) requires that the manufacturer provide the purchaser with certified documentation attesting to compliance with 4.2.1.

A.4.2.3 Electrical components

Compliance with UL 3101-1 (normative reference 2.5) and the *National electrical code* (normative reference 2.4) helps protect sterilizer operators from electrical hazards.

A.4.2.4 Corrosion resistance

The interior surfaces of steam sterilizers are routinely subjected to moisture and, therefore, must be corrosion resistant in order to prolong the useful life of the equipment and to prevent the contamination of loads. It is also the

intent of 4.2.4 to help ensure that the materials used will present a clean appearance that can be easily maintained over time.

A.4.2.5 Air filters

Air-break filters help prevent recontamination of products and materials before they are removed from the sterilizer.

A.4.3 Sterilizer safety

The safe use of steam at high temperatures and pressures necessitates that sterilizers be designed with features for operator protection.

A.4.3.1 Interlock

The interlock provisions of 4.3.1 were developed to ensure that steam cannot enter the sterilizer until all doors are locked and, further, that doors cannot be opened until the pressure has been reduced to a safe level.

A.4.3.2 Prevention of thermal hazards

The requirements of 4.3.2 are intended to ensure that surfaces touched by the operator during normal sterilizer operation cannot exceed a safe temperature.

A.4.3.3 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.4.4 Process monitoring and control devices

The efficacy of steam sterilization processes depends on the effectiveness of air removal and the attainment of saturated steam conditions at a specific temperature for a specified time. To ensure that the sterilizer will reliably provide these conditions, this standard includes requirements in 4.4.2, 4.4.4, and 4.4.5 for the location, accuracy, and readability of the sterilization-parameter indicating and recording system. Regarding temperature control in particular (4.4.2), the objective of the requirements is to ensure that at all points within the usable chamber, the temperature is within the control band of 4.4.2.5. The test of 5.4.2.5 provides proof that the temperature of the sterilizing medium will conform to 4.4.2.5. The requirement of 4.4.3 is intended to facilitate compliance with 4.4.2.5.

Accuracy requirements should ensure uniform temperature control, exposure time, and pressure readings. In addition, several control features are required for safe operation during unusual circumstances, such as an electrical power failure or loss of steam pressure. The accuracy requirements are considered realistic and consistent with an acceptable level of sterility assurance.

By providing for minimum cycle documentation and a consistent format of the printout, the requirements of 4.4.6 help sterilizer operators verify correct equipment performance and more readily detect deviations from the specified cycle.

A.4.5 Biological performance of sterilizers

Steam sterilizers must be biologically challenged to ensure the efficacy of the equipment and the lethality of the recommended processing parameters. The tests of 5.5 were designed as manufacturers' qualification tests, but they are intended to simulate the most difficult conditions that would normally be encountered in health care facilities. This standard requires that tests be performed to qualify the most generic types of cycles that may be encountered in health care facilities. They include provisions satisfying the requirements mandated by the Veterans Administration for steam sterilizers intended for use in military hospitals.

To demonstrate that the sterilizer functions in a reproducible manner, this standard requires three consecutive runs of each test for certification. Such studies must be repeated at least every 24 months or whenever a design change occurs that could affect performance. Because BIs of known resistance are accepted as the best monitors of sterilization processes, the test protocols require the demonstration of sterility by means of these monitors.

It is recognized that placement of the BI/fabric test pack horizontally, rather than on edge, is contrary to recommended loading practices, but the test pack is placed in this manner to accentuate the biological challenge. Placement near the drain generally ensures that the pack is in the coolest portion of the chamber.

A.4.6 Mechanical air removal

A.4.6.1 Air removal (dynamic-air-removal sterilizers)

Dynamic-air-removal sterilizers use preconditioning techniques to remove air from both the sterilizing chamber and the load before the chamber is pressurized with steam to a sterilizing exposure temperature. Effective removal of air

is critical to predictable steam penetration and, therefore, to sterilization. Numerous preconditioning methods are used to remove air, including variations of prevacuum air removal and above-atmospheric-pressure processes such as the steam-flush pressure-pulse process.

The Bowie-Dick test was originally developed to evaluate the ability of high-vacuum steam sterilizers to effectively reduce air residuals from the chamber space and detect the presence of air leaks. It was later found that the same test could provide evidence of both air leaks and ineffective air removal for other air-removal techniques that do not use a deep vacuum. Health care facilities use the Bowie-Dick test as a simple method of assessing air removal and detecting leaks. However, the color change on an indicator sheet is not adequately quantitative for purposes of a sterilizer manufacturer's verification of effective air removal. Figure 7 shows that the pack temperature converges with the chamber drain temperature in a temperature-instrumented test pack when air is adequately removed from the load and the sterilizing chamber. This temperature measurement evaluation provides quantitative assurance that a dynamic-air-removal conditioning sequence is effective.

The instrumented Bowie-Dick test pack is placed in an otherwise empty chamber to maximum the potential (small-load effect) for detecting air that enters by means of a leak or as a result of an ineffective air-removal process.

A.4.6.2 Air leaks (prevacuum sterilizers)

An air-leak-rate test is used to provide an indication of the relative "tightness" of the chamber. Air-leak-rate test results provide an indication of the integrity of the vessel and plumbing system.

Annex B
(informative)

Examples of cycle documentation

A sterilization cycle is commonly shown graphically as a sequence of phases and steps plotted against one or more variables relevant to operation of the cycle. This format enables the user to visualize the mechanics of the cycle. Phases are parts of a cycle that can be uniquely described (e.g., prevacuum, preconditioning, steam charge, exposure, post-vacuum, air vent). Steps are parts of a phase and also have uniquely described functions that may be repeated as a sequence within a phase a selected number of times (e.g., 1 [steam pulse, vacuum], 2 [steam pulse, vacuum], *n* [steam pulse, vacuum]). Cycle documentation verifies that the events making up a cycle have occurred. Figure B.1 is a schematic of a cycle. Figures B.2, B.3, and B.4 are examples of cycle documentation.

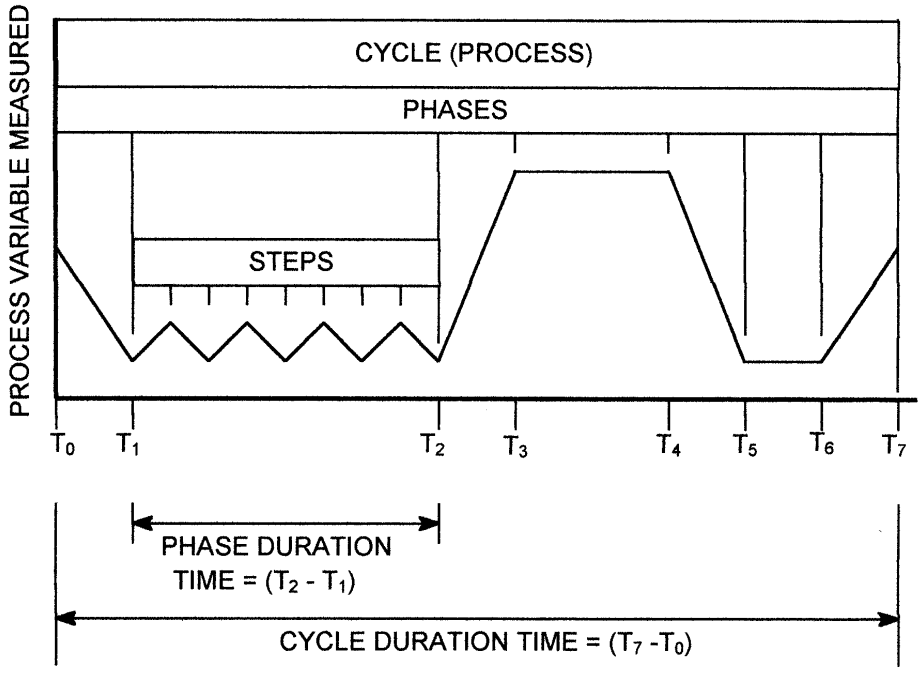


Figure B.1—Schematic of a cycle

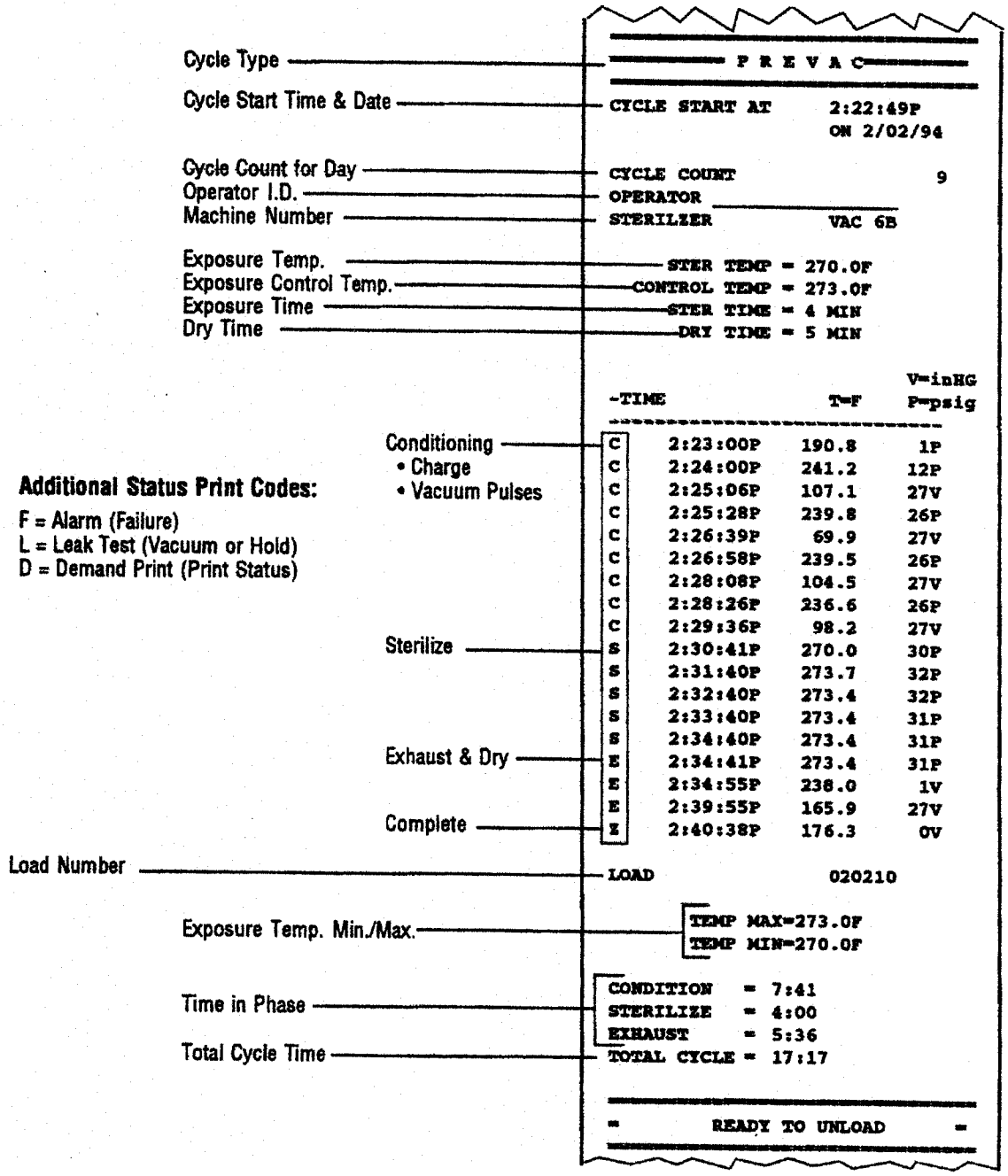


Figure B.2—Example of a cycle printout

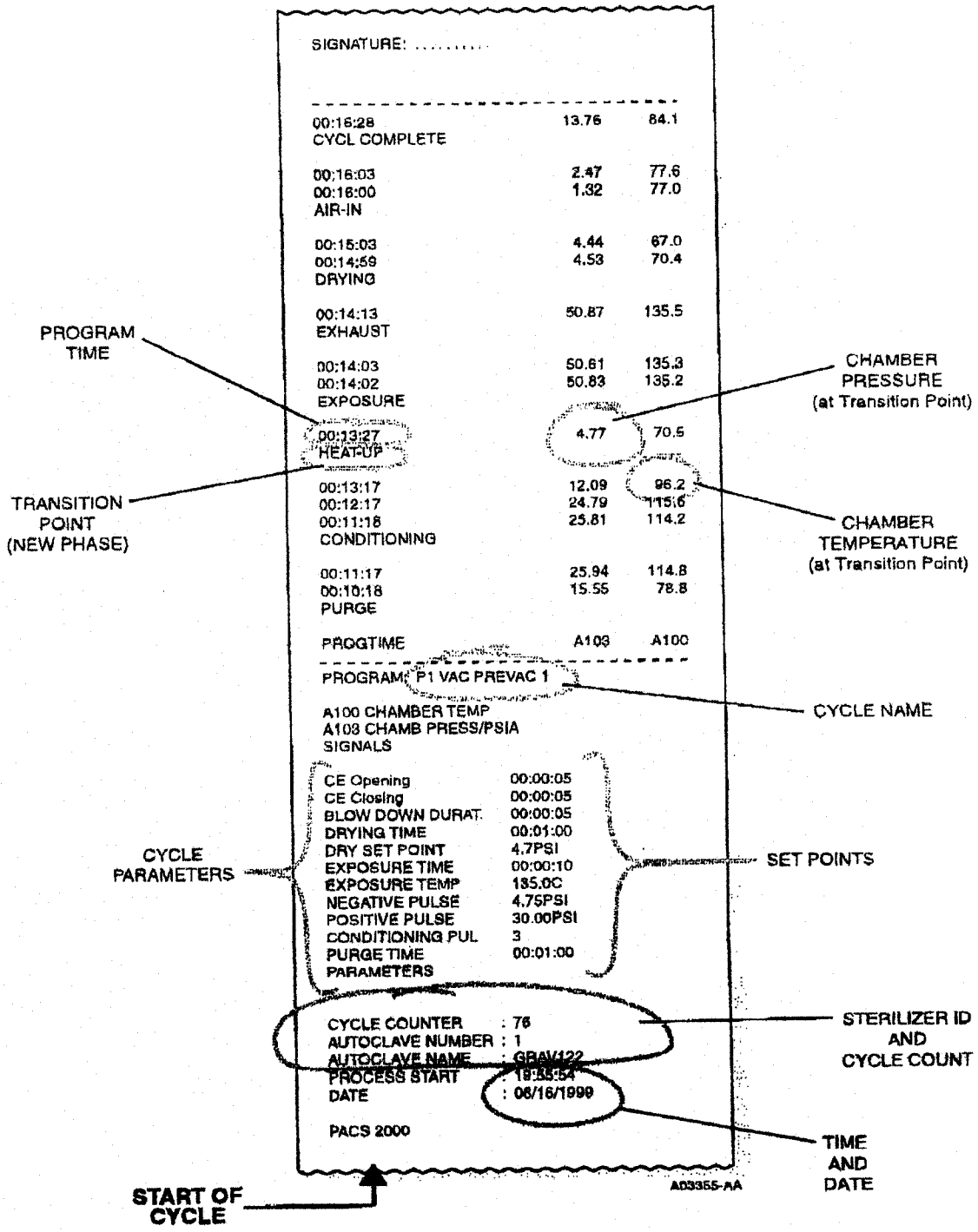


Figure B.3—Example of a cycle printout

Operator identification: _____
Equipment identification: _____
Run Number: _____
Date: mm/dd/yy
Time: hh:mm:ss
Software Version: aaa-bbb

Cycle Name: XYZ
Set Points:
Preconditioning pulses: 3
Exposure temperature: xxx.x °C
Exposure time: hh:mm:ss
Drying time: hh:mm:ss

Phase	Time (hh:mm:ss)	Chamber pressure (psia)	Chamber temperature (°C)	Duration (hh:mm:ss)
Air displace	09:11:43	38.8	131.0	
	09:13:13	22.2	129.2	00:01:30
Preconditioning				
Steam pulse	09:13:13	22.2	129.2	
	09:14:05	41.6	132.0	00:00:52
Vent	09:14:05	41.6	132.0	
	09:14:16	14.9	114.2	00:00:11
Steam flush	09:14:16	14.9	114.2	
	09:15:01	15.67	115.8	00:00:45
Steam pulse	09:15:01	15.67	115.8	
	09:15:50	41.6	132.0	00:00:49
Vent	09:15:50	41.6	132.0	
	09:16:03	14.9	112.4	00:00:13
Steam flush	09:16:03	14.9	112.4	
	09:16:48	15.5	126.9	00:00:45
Steam pulse	09:16:48	15.6	115.8	
	09:17:37	41.6	132.0	00:00:49
Vent	09:17:37	41.6	132.0	
	09:17:51	14.9	109.9	00:00:14
Steam flush	09:17:51	14.9	109.9	
	09:18:36	15.3	126.2	00:00:45
	Phase duration time:			00:05:23
	Sequence repeats:			3
Steam charge	09:18:36	15.3	126.2	
	09:19:31	42.5	134.1	00:00:55
Exposure	09:19:31	42.5	134.1	
	09:22:31	42.5	134.7	00:03:00
	Maximum	45.4	135.1	
	Minimum	43.9	134.0	
Exhaust	09:22:31	42.5	102.7	
	09:22:48	14.1	103.0	00:00:17
Cycle complete		Total cycle time		00:11:05

Alarm condition: Time
Low temperature: hh:mm:ss
Over temperature: hh:mm:ss
Steam charge slow: hh:mm:ss
(Note: Typical alarms)

Cycle Approved: Y/N Reviewed by: _____ Date: _____

Figure B.4—Example of cycle printout information

NOTE—This information is shown in expanded format using full words. Actual printouts may use symbols and abbreviations to condense the size of the cycle documentation.

Annex C
(informative)

Bibliography

AMERICAN DENTAL ASSOCIATION. Portable steam autoclave sterilizers for health care use. ANSI/ADA Specification No. 59. Chicago: ADA, 1992. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Good hospital practice: Steam sterility and sterility assurance.* 2nd ed. ANSI/AAMI ST46:1993. Arlington (VA): AAMI, 1994a. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Sterilization of health care products—Requirements for validation and routine control—Industrial moist heat sterilization.* ANSI/AAMI/ISO 11134:1993. Arlington (VA): AAMI, 1994b. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Guidelines for the selection and use of reusable rigid sterilization container systems for ethylene oxide sterilization and steam sterilization in health care facilities.* 2nd ed. ANSI/AAMI ST33:1996. Arlington (VA): AAMI, 1996a. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Flash sterilization: Steam sterilization of patient care items for immediate use.* 2nd ed. ANSI/AAMI ST37:1996. Arlington (VA): AAMI, 1996b. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Principles of industrial moist heat sterilization.* AAMI TIR13:1997. Arlington (VA): AAMI, 1997a.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Table-top steam sterilizers.* ANSI/AAMI ST55:1997. Arlington (VA): AAMI, 1997b. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Steam sterilization and sterility assurance in office-based, ambulatory-care, medical and dental facilities.* ANSI/AAMI ST42:1998. Arlington (VA): AAMI, 1998. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Sterilization of health care products—Chemical indicators—Part 2: Class 2 indicators for air removal test sheets and packs.* ANSI/AAMI ST66:1999. Arlington (VA): AAMI, 1999. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Sterilization of health care products—Biological indicators—Guidance for the selection, use, and interpretation of results.* ANSI/AAMI/ISO 14161:2000. Arlington (VA): AAMI, 2000. American National Standard.

PFLUG, IJ. Heat sterilization. In: PHILLIPS, CG and MILLER, WS (eds). *Industrial sterilization.* Durham (NC): Duke University Press, 1973.

PFLUG, IJ. *Microbiology and engineering of sterilization processes.* Philadelphia: Parenteral Drug Association, 1977.

STUMBO, CR. *Thermobacteriology in food processing.* 2nd ed. New York: Academic Press, 1973.

UNDERWRITERS LABORATORIES. *Electrical equipment for laboratory use—Part 1: General requirements.* UL 3101-1. Northbrook (IL): UL, 1993.

