List of Titles

American National Standard

ANSI/AAMI ST:55:1997

Table-top steam sterilizers

AAMI Association for the Advancement of Medical Instrumentation

American National Standard ANSI/AAMI ST55—1997

Table-top steam sterilizers

Approved 24 February 1997
Association for the Advancement of Medical Instrumentation

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American National Standards Institute, Inc.

Abstract: This standard establishes minimum construction and performance requirements for small table-top steam sterilizers that use saturated steam as the sterilizing agent and have a volume less than or equal to 2 cubic feet.

Keywords: design, labeling, process monitoring, testing, air removal

List of Titles

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List of Titles

Contents

Figures

Annexes

Committee representation

Association for the Advancement of Medical Instrumentation

Sterilization Standards Committee

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

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NOTE—Participation by federal agency representatives in the development of this recommended practice does not constitute endorsement by the federal government or any of its agencies.

[1] Retired

Acknowlegment

The committee wishes to acknowledge the late Ruth A. Brooks, International Association of Central Service Materiels Management, for her contributions to the preparation of this standard.

Foreword

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

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

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.

This voluntary standard is intended primarily for use in the performance and design qualification of table-top 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 health care facilities. In addition, any problems with existing equipment should not be judged solely in terms of its conformance to this standard.

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

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

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

NOTE—This foreword does not contain provisions of the draft AAMI standard, *Table-top steam sterilizers* (ANSI/AAMI ST55), but it does provide important information about the development and intended use of the document.

List of Titles

Table-top steam sterilizers

1 Scope

1.1 General

This standard applies to steam sterilizers that are intended for use in health care facilities and that have a volume less than or equal to 2 cubic feet (56 liters).

NOTE—For the purposes of this standard, *health care facilities* means hospitals, nursing homes, extended-care facilities, free-standing surgical centers, clinics, and medical and dental offices.

1.2 Inclusions

This standard covers minimum labeling, safety, performance, and testing requirements for small steam sterilizers that have a volume less than or equal to 2 cubic feet, that have automatic controls, that generate steam from water within the sterilization chamber or from an integral steam generator, and that provide means of controlling time and temperature. Definitions of terms and normative references are also included.

NOTE—This standard is intended primarily for use by manufacturers in the performance and design qualification of table-top 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 a health care facility receiving inspection testing or for steam sterilization procedures in health care facilities.

1.3 Exclusions

Cassette sterilizers, sterilizers that use external steam sources, washer/sterilizers, and all other sterilizers not covered in 1.2 are excluded from the scope of this standard.

NOTE—Minimum labeling and performance requirements for large steam sterilizers (those having a volume greater than 2 cubic feet) are covered in AAMI (1994). Guidelines for steam sterilization procedures are provided in AAMI (1993a) and AAMI (1992).

2 Normative references

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

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

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Steam sterilization and sterility assurance in office-based, ambulatory-care medical and dental facilities.* ANSI/AAMI ST42-1992. Arlington (Vir.): AAMI, 1992

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Sterilization of health care products—Biological indicators—Part 1: General requirements.* ANSI/AAMI ST59. Arlington (Vir.): AAMI, (in preparation).

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization.* ANSI/AAMI ST19. Arlington (Vir.): AAMI, (in preparation).

ASSOCIATION FOR *THE* ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Sterilization of health care products—Requirements for validation and routine control—Industrial moist heat sterilization, 2nd edition.* ANSI/AAMI/ISO 11134. Arlington (Vir.): AAMI, 1993.

INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Safety requirements for electrical equipment for measurement, control, and laboratory use—Part 1: General requirements.* IEC 1010-1 IEC, 1990. *

INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Safety requirements for electrical equipment for measurement, control, and laboratory use—Part 2-041: Particular requirements for autoclaves and sterilizers using*

* or equaivalent adoption as an American National Standard.

steam for the treatment of medical materials, and for laboratory processes. IEC 1010-2-041 Geneva, Switzerland: IEC 1995.

NATIONAL FIRE PROTECTION ASSOCIATION. *National Electrical Code.* ANSI/NFPA 70-1996. NFPA, 1996. American National Standard.

3 Definitions

For the purposes of this American National 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 cassette sterilizer: Sterilizer that utilizes a removable cassette as both the container to hold the goods to be sterilized and the vessel that contains the sterilant (steam) for processing.

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

3.4 certified laboratory standards: Standards traceable to the National Institute for Standards and Technology or other recognized industry or government standards.

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

3.6 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.

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

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

3.9 handle: 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.

3.10 holding time: Period at which the temperature at all parts of the load is held within the sterilization temperature band.

NOTE—It follows immediately after the equilibration time. The extent of the holding time is related to the sterilization temperature.

3.11 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.

3.12 jacket: Portion of the sterilizer (where applicable), surrounding and affixed to the chamber, through which steam is circulated and which functions to help maintain temperature in the chamber.

3.13 nonhygroscopic: Unable to absorb or retain moisture.

3.14 pressure gauge: Device attached to the chamber or jacket of a steam sterilizer, which is used to indicate, usually in pounds per square inch (psig), the pressure of the steam in the chamber or jacket.

3.15 pressure vessel: Sealed cavity capable of withstanding internal pressure above atmospheric pressure. 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 the scope of these codes.

3.16 probability of survival: See sterility assurance level.

3.17 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.

3.18 saturated steam: Moist heat at a temperature related to water-saturated steam pressure, as defined in the *ASME Steam Tables.*

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

3.20 sterility assurance level (SAL): Probability of a viable microorganism being present on a product unit after sterilization.

NOTE—(SAL) is normally expressed as 10^{-n}. A SAL of 10^{-6} means that there is a chance, no greater than one in a million, that an individual sterilized item will be contaminated (with a single viable microbe). A SAL of 10^{-6} is generally accepted as appropriate for sterilized items intended to come into contact with compromised tissues (that is tissues that have lost the integrity of natural body barriers). A SAL of 10^{-3} is considered appropriate for items not intended to come in contact with compromised tissue.

3.21 sterilization temperature: Minimum temperature achieved and maintained during the holding time.

NOTE—The temperature should be selected to achieve the desired SAL.

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

3.23 sterilizer, gravity-displacement type: Sterilizer in which the incoming steam displaces residual air through a port or drain that is usually sited at or near the low point of the sterilization chamber.

NOTE—Typical operating temperatures are 121° C to 123° C (250° Fto 254° F) and 132° C to 135° C (270° F to 275° F).

3.24 sterilizer, steam, dynamic-air-removal type: Type of steam sterilizer in which air is removed from the chamber and the load by means of pressure and vaccuum excursions or by means of steam flushes and pressure pulses.

NOTE—Dynamic-air-removal sterilizers require shorter times for the sterilization of wrapped items because of the rapid removal of air from the chamber and its load by the vacuum system, because higher operating temperatures are employed (132° C to 134° C {270° F to 275° F}) or 141° C to 144° C (285° F to 291° F). Drying can be accelerated by pulling an additional vacuum at the end of the sterilizing cycle to assist in the removal of the steam.

3.25 sterilizer, steam: Sterilizing apparatus that uses saturated steam under pressure as the sterilant.

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

3.27 z value: Number of degrees of temperature required to obtain a tenfold change in the D value.

NOTE—The z value can be obtained by calculation from determinations of death time at a minimum of three different temperatures or by plotting log (death time) against temperature, where the reciprocal of the slope will be the z value.

4 Requirements

4.1 Labeling

4.1.1 Device markings

NOTE—See also IEC 1010-1, *Safety requirements for electrical equipment for measurement, control, and laboratory use, Part 1:General requirements*, clause 5.3.

4.1.1.1 Identification

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

a) the manufacturer's name and address;

b) the manufacturer's type and model designation;

c) the serial number;

d) the electrical supply requirements;

e) the stamp or label of the inspecting authority;

f) the chamber pressure rating;

g) 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 fastened to the sterilizer to alert the operator of high-temperature surfaces. Where possible, guards shall be provided for operator protection. Adequate written information (see 4.1.2) shall be provided in the operator's manual to alert the operator of potential high-temperature areas on and around the sterilizer during operation.

4.1.2 Operator's manual

The manufacturer or the manufacturer's agent shall furnish the purchaser with a manual containing the following minimum information:

a) the name, address, and phone number of the manufacturer;

b) the manufacturer's type and model designation of the sterilizer;

c) instructions for the installation of the sterilizer, complete and comprehensive enough to ensure the safe and effective operation of the equipment, including such information as the required building system utilities and water quality;

d) instructions for the safe and effective operation and routine monitoring of the sterilizer, including normal safety precautions to be taken during routine use as well as recommended sterilizer cycle settings for sterilization and drying, load size and type of materials, and load configuration;

e) a statement directing the user to refer to the instrument or medical device manufacturer's written instructions for specific cleaning and sterilization recommendations;

f) 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 an insert or a sticker affixed to the manual.

4.1.3 Service manual

The manufacturer shall make available to the user or the user's designee a complete service manual, sufficiently comprehensive 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. As 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 clause 2). 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, if applicable.

4.2.3 Electrical components

The sterilizer electrical system shall be designed, manufactured, and tested in accordance with IEC 1010-1, *Safety requirements for electrical equipment for measurement, control, and laboratory use—Part 1: General requirements* (see clause 2). The sterilizer electrical system shall be designed for installation in conformance to the *National Electrical Code* (see clause 2).

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-resistance properties equal to or better than the materials listed in Section II of the ASME *Boiler and Pressure Vessel Code* (see clause 2).

4.2.4.2 Loading accessories

Loading shelves 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 steam.

4.2.5 Air filters

At least one bacteria-retentive filter, having a minimum filtration efficiency of 99.97 percent for 0.3-micron particles, shall be installed in each chamber vacuum-relief line if the sterilizer requires breaking the vacuum or relieving chamber pressure with outside air. 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.

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 doors cannot be opened until chamber pressure has been released.

4.3.2 Prevention of thermal hazards

The temperature of all handwheels, handles, or similar devices that will be used by the operator during normal operation of the sterilizer shall comply with IEC 1010-1 and IEC 1010-2-41 (see clause 2).

4.3.3 Sterilizer controls for aborting cycles

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

4.4 Process monitoring and control devices

4.4.1 Chamber temperature

4.4.1.1 Temperature monitoring and recording

The sterilizer shall be equipped with a means of indicating chamber temperature throughout the cycle. There shall be a means, or the provision to connect a means, to produce a digital or analog recording of the chamber temperature. The indicating and recording means may be one and the same.

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

4.4.1.2 Positioning of temperature sensors

The sensor(s) for the indicators(s) shall be positioned so as to measure the temperature of the steam at the coldest point within the chamber.

4.4.1.3 Accuracy of temperature measurement

When tested against certified laboratory standards, the temperature indicator(s) shall be accurate to within $\pm$ 1° C ($\pm$2° F) over the sterilizer's designated operating range.

4.4.1.4 Resolution of temperature measurement

Temperature graduations on a recorder chart, if provided, shall not exceed 1° C (2° F) within a range of $\pm$ 5° C ($\pm$ 10° F) of the manufacturer's recommended sterilization temperature. Digital printouts shall be rounded to the nearest whole degree or truncated to whole degrees unless printed in tenths of a degree (see annex B).

4.4.2 Sterilizer temperature control

The control set temperature shall be selected and the control shall function so that the chamber temperature is within + 3° C (+ 6° F) and - 0° C (-0° F) of the selected sterilization exposure temperature. The mechanism used by the operator to select the sterilization exposure temperature shall be marked in, or adjustable to, increments no larger than 1° C (2° F) within a range of ± 5° C (± 10° F) of the manufacturer's recommended sterilization exposure temperature. The temperature control system shall initiate sterilization exposure timing when the selected sterilization exposure temperature is achieved and shall reset the timer when the chamber temperature falls 1° C (2° F) below the control set temperature and alert the operator to the occurrence of the under-temperature condition (see annex B).

4.4.3 Sterilizer holding timer

Each sterilizer shall be equipped with a reset timer for timing sterilization exposure. The timer shall automatically reset in the event of an electrical power failure unless the controls are capable of determining that the temperature has not dropped below the limit established in 4.4.2. The timer shall have a minimum accuracy of ± 5 percent of the set value (see annex B).

4.4.4 Pressure indicators

4.4.4.1 Chamber pressure indicator

The sterilizer shall be equipped with a mechanical gauge, digital indicator, or other device for indicating the pressure within the chamber. The means of indicating pressure shall be accurate to within ± 3 percent of the full-scale value. In the positive-pressure region, the indicator shall have graduations or a resolution of 2 psig (13.5 kilopascals [kPa]) or less. The scale shall be graduated for a full-scale range of 5 atmospheres absolute.

4.4.4.2 Jacket pressure indicator

Where applicable, the sterilizer shall be equipped with an indicator that displays jacket pressure. This indicator shall be readily visible to and readable by the operator. The accuracy of the means of indicating pressure shall be within ± 3 percent of full-scale value, and each graduation or increment of resolution shall be 2 psig (13.5 kPa) or less. The scale shall be graduated for a full-scale range of 5 atmospheres absolute.

4.5 Biological performance of sterilizers

When tested according to 5.5, biological indicators processed in half cycles should result in no growth of the test spores. The recommended exposure should result in no growth of the test spores. The recommended exposure time shall have a sufficient lethality to reduce a microbial population having a D_{121} value of 1 minute to a 10^{-6} probability of a surviving organism, i.e., an overkill method shall be used (see ANSI/AAMI/ISO 11134:1993), and the test results shall otherwise meet the acceptance criteria defined in 5.5.

NOTE—*Bacillus stearothermophillus* spores with a $D_{121° C}$ value greater than 1.0 min may be used to validate the biological performance of a steam sterilizer. When these are used, it is necessary to validate using an appropriate fraction of the full sterilization process. The lethality of the full cycle will be at least the equivalent of that required to acheive a 12-log reduction of a spore suspension with a $D_{121° C}$ value of 1 min.

4.6 Air removal

4.6.1 Dynamic-air-removal efficacy

The efficacy of the vacuum (air removal) system of the sterilizer shall be tested according to 5.6.1 (the Bowie-Dick test). The indicator tape or printed test sheet shall show a uniform color change, i.e., the color in the center should be the same as that at the edges (see also 5.6.1.1).

4.6.2 Dynamic-air-removal sterilizer vacuum leaks

When tested according to 5.6.2, the sterilizer shall exhibit a maximum average leak rate of 1 millimeter mercury (mmHg) per minute over the measured time interval.

NOTE—The Bowie-Dick test and the leak-rate test are complementary to each other. A prevacuum sterilizer should meet the requirements of both tests. Neither Bowie-Dick testing nor vacuum leak testing is applicable to gravity-displacement sterilizers.

4.6.3 Air removal from gravity-displacement sterilizers

When tested according to 5.6.3, all temperatures measured within the chamber and load during the timed exposure phase of the cycle, as well as the theoretical steam temperature (which is calculated from the measured pressure), shall not be lower than the sterilization temperature and not higher than 3° C (6° F) above the sterilization temperature (see figure 1). In addition, all measured temperatures and the theoretical temperature shall not fluctuate by more than ± 1.5° C, and they shall not differ from one another by more than 2° C (4° F).

4.7 Moisture retention

For packaged items claimed to be compatible by the sterilizer manufacturer, no visible moisture should be present.

4.8 Sterilizer performance certification and record-keeping

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

[FOR FIGURE 1]

Conversion factor

For discrete temperatures: $°F = (°C \times 1.8) + 32$

For temperature differences: $°F = (°C \times 1.8)$

Gauge Pressure in Hg Vao	Absolute Pressure pcia	Temperature °F	Sensible (hf) BTU/lb	Heat Content		Specific Volume Steam (Vg) ft^3/lb
				Latent (hfg) BTU/lb	Total (hg) BTU/lb	
27.96	1	101.7	69.5	1,032.9	1.102.4	333.0
25.91	2	126.1	93.9	1,019.7	1,113.6	173.5
23.87	3	141.5	109.3	1,011.3	1,120.6	118.6
21.83	4	153.0	120.8	1,004.9	1,125.7	90.52
19.79	5	162.3	130.1	999.7	1,129.8	73.42
17.75	6	170.1	137.8	995.4	1,133.2	61.89
15.70	7	176.9	144.6	991.5	1,136.1	53.57
13.66	8	182.9	150.7	987.9	1,138.6	47.26
11.62	9	188.3	156.2	984.7	1,140.9	42.32
9.58	10	193.2	161.1	981.9	1,143.0	38.37
7.54	11	197.8	165.7	979.2	1,144.9	35.09
5.49	12	202.0	169.9	976.7	1,146.6	32.35
3.45	13	205.9	173.9	974.3	1,148.2	30.01
1.41	14	209.6	177.6	972.2	1,149.8	28.00
Gauge Press psig						
0	14.7	212.0	180.2	970.6	1,150.8	26.80
1	15.7	215.4	183.6	968.4	1,152.0	25.20
2	16.7	218.5	186.8	966.4	1,153.2	23.80
3	17.7	221.5	189.8	964.5	1,154.3	22.50
4	18.7	224.5	192.7	962.6	1,155.3	21.40
5	19.7	227.4	195.5	960.8	1156.3	20.40
6	20.7	230.0	198.1	959.2	1,157.3	19.40
7	21.7	232.4	200.6	957.6	1,158.2	18.60
8	22.7	234.8	203.1	956.0	1,159.1	17.90
9	23.7	237.1	205.5	954.5	1,160.0	17.20
10	24.7	239.4	207.9	952.9	1,160.8	16.50
11	25.7	241.6	210.1	951.5	1,161.6	15.90
12	26.7	243.7	212.3	950.1	1,162.3	15.30
13	27.7	245.8	214.4	948.6	1,163.0	14.80
14	28.7	247,9	216.4	947.3	1,163.7	14.30
15	29.7	249.8	218.4	946.0	1,164.4	13.90
16	30.7	251.7	220.3	944.8	1,165.1	13.40
17	31.7	253.6	222.2	943.5	1,165.7	13.00
18	32.7	255.4	224.0	942.4	1,166.4	12.70
19	33.7-	257.2	226.8	941.2	1,167.0	12.30
20	34.7	258.8	227.6	940.1	1,167.6	12.00
22	36.7	262.3	230.9	937.8	1,168.7	11.40
24	38.7	265.3	234.2	935.8	1,170.0	10.80
26	40.7	268.3	237.3	933.5	1,170.8	10.30
28	42.7	271.4	240.2	931.6	1,171.8	9.87
30	44.7	274.0	243.0	929.7	1,172.7	9.46
32	46.7	276.7	245.9	927.6	1,173.5	9.08
34	48.7	279.4	248.5	925.8	1,174.3	8.73
36	50.7	281.9	251.1	924.0	1,175.1	8.40
38	52.7	284.4	253.7	922.1	1,175.8	8.11
40	54.7	286.7	256.1	920.4	1,176.5	7.83
42	56.7	289.0	258.5	918.6	1,177.1	7.57
44	58.7	291.3	260.8	917.0	1,177.8	7.33
46	60.7	293.5	263.0	915.4	1,178.4	7.10
48	62.7	295.6	265.2	913.8	1,179.0	6.89
50	64.7	297.7	267.4	912.2	1,179.6	6.68

Figure 1—Properties of saturated steam table (courtesy of Spirax Sarco, Inc.)

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 in-health care facility installation, acceptance, or preventive maintenance testing. The paragraph numbers below correspond to those of section 4 except for the first digit (e.g., conformance with the requirement of 4.2.3 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 for accuracy. The quality assurance program establishing the frequency and method of calibration shall be documented. The calibration of all test instruments shall be traceable to primary standards, as specified in federal regulations for good manufacturing practices (GMPs) (21 CFR Part 820).

Installation and Operation of Sterilizers. The sterilizers used in testing compliance with the requirements of section 4 shall be identical to and installed and operated in the same way as those that will be provided by the manufacturer to health care facilities. If a range of utility supply values is specified (that is, a range of steam or water pressure), the sterilizer shall 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 the ASME *Boiler and pressure vessel code* (see clause 2).

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 IEC 1010-1 and IEC 1010-2-41 (see clause 2).

5.2.4 Corrosion resistance

5.2.4.1 Sterilizer surfaces

See ASME Boiler and pressure vessel code (see clause 2).

5.2.4.2 Loading accessories

See ASME Boiler and pressure vessel code (see clause 2).

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.

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 may not be opened when the chamber is pressurized must be performed at only slightly above atmospheric pressure, as a hazardous condition may result if the test reveals a failure of the interlock. See ASME *Boiler and pressure vessel code* (see clause 2).

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 in which the ambient temperature is maintained between 18° C and 24° C (64° F and 75° F). A normal sterilization cycle is run, and the temperatures monitored for compliance with the NFPA *National Electrical Code* (see clause 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 Chamber temperature

5.4.1.1 Temperature monitoring and recording

Compliance with 4.4.1.1 can be verified by inspection.

5.4.1.2 Positioning of temperature sensors

Compliance with 4.4.1.2 can be verified by inspection.

5.4.1.3 Accuracy of temperature measurement

Compliance with 4.4.1.3 can be verified by testing against certified standards.

5.4.1.4 Resolution of temperature measurement

Compliance with 4.4.1.4 can be verified by inspection.

5.4.2 Sterilizer temperature control

Compliance with 4.4.2 can be verified by placing calibrated temperature-measuring sensors with continuous readout in the sterilizer chamber. The number of sensors may vary with the chamber size and configuration, but a minimum of five temperature sensors is required. A sensor should be placed in each of the following locations: the lower front, upper front, center, lower rear, and upper rear of the rack, tray, or shelf containing the load in the chamber. The intent of this temperature control is to assure that the sterilizer is capable of providing steady state thermal conditions within the chamber that are consistent with the desired sterility assurance level. The manufacturer of the sterilizer shall verify and document that at any place an item may be positioned within the chamber, the minimum temperature parameters of 4.4.1.2 and 4.4.2 are satisfied for the recommended operating cycles and loads.

5.4.3 Sterilizer holding timer

Compliance with 4.4.3 can be verified by inspection and by testing the timer against a certified laboratory standard traceable to the National Institute of Standards and Technology.

5.4.4 Pressure indicators

5.4.4.1 Chamber pressure indicator

Compliance with 4.4.4.1 can be verified by inspection and by testing against certified standards.

5.4.4.2 Jacket pressure indicator

Compliance with 4.4.4.2 can be verified by inspection and by testing against certified standards.

5.5 Biological performance of sterilizers

The tests of 5.5.1, 5.5.2 (if applicable), and 5.5.3 shall be conducted by the manufacturer as part of the initial design qualification and periodically thereafter (see 4.8) on production sterilizers; records shall be maintained in accordance with 4.8. The tests must be performed with separate loads on at least three consecutive cycles run at one-half the manufacturer's recommended holding time and on at least three consecutive cycles run at the manufacturer's recommended holding time. The biological indicators used in testing shall contain *Bacillus stearothermophilus* spores and shall comply with the requirements of ANSI/AAMI ST59 and ANSI/AAMI ST19 (in preparation) (see clause 2). The culturing and incubation conditions shall be in accordance with the instructions supplied by the manufacturer of the biological indicator.

5.5.1 Biological performance with a test pack

NOTE—Alternative test packs are acceptable if equivalence with the reference test pack has been demonstrated.

5.5.1.1 Test pack construction

The biological-indicator test pack (figure 2) for table-top steam sterilizers consists of three 100 percent cotton towels, freshly laundered (but not ironed) and in good condition, each approximately 16" x 26" in size, and stored so as to stabilize the pack. Each towel is folded, as illustrated in figure 3, lengthwise three times, then widthwise once, and set aside. A 24" x 24" 140 thread count 100% cotton muslin wrap (two-ply) or 50% polyester/50% cotton blend

Type 180 percale material is placed on a flat surface with a stainless steel emesis basin on top. In the basin are placed one 4” x 4” gauze pad and one 2” x 2” gauze pad. A biological indicating strip (BI) or equivalent (see ANSI/AAMI ST59 and ANSI/AAMI ST19, in preparation) is placed on the two pads. Then an 8.5” x 24” fan-fold paper towel is placed in the basin. The folded towels are then added placing a BI between each towel as indicated, for a minimum of three BIs. A temperature sensor, with an accuracy of ± l° C, must be placed in the geometric center of the pack to measure the temperature of the pack. The entire package is then wrapped and sealed with sterilization tape as shown in figure 4.

Alternatively:

The biological indicator test pack may be prepared using freshly laundered 100% cotton muslin sheets or 50% polyester/50% cotton blend Type 180 percale material measuring approximately 90 cm x 120 cm (36” x 48”) each. Sheets shall be dry, but not ironed, and shall be stored so as to stabilize for at least 1 hour in an environment between 18° C and 22° C (64° F and 72° F) and a relative humidity controlled between 35% and 70%. As in the above test pack, one 4” x 4” and one 2” x 2” gauze pad are placed in a stainless steel emesis basin. A BI is placed on the two pads. The folded towels are then added, placing a BI between each towel. A temperature sensor, with an accuracy of ±1° C, must be placed in the geometric center of the pack to measure the temperature of the pack.

NOTE—Fabric conditioning agents may affect the characteristics of the fabric and contain volatiles that will contribute noncondensable gases to the chamber.

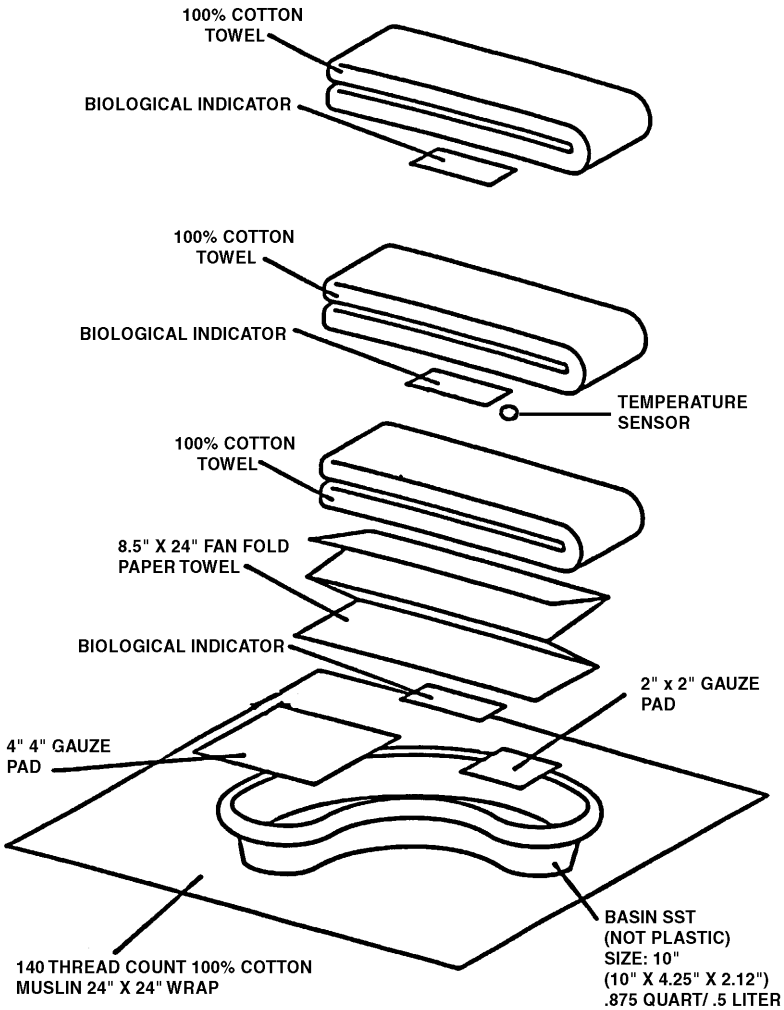


Figure 2—Three-towel linen load

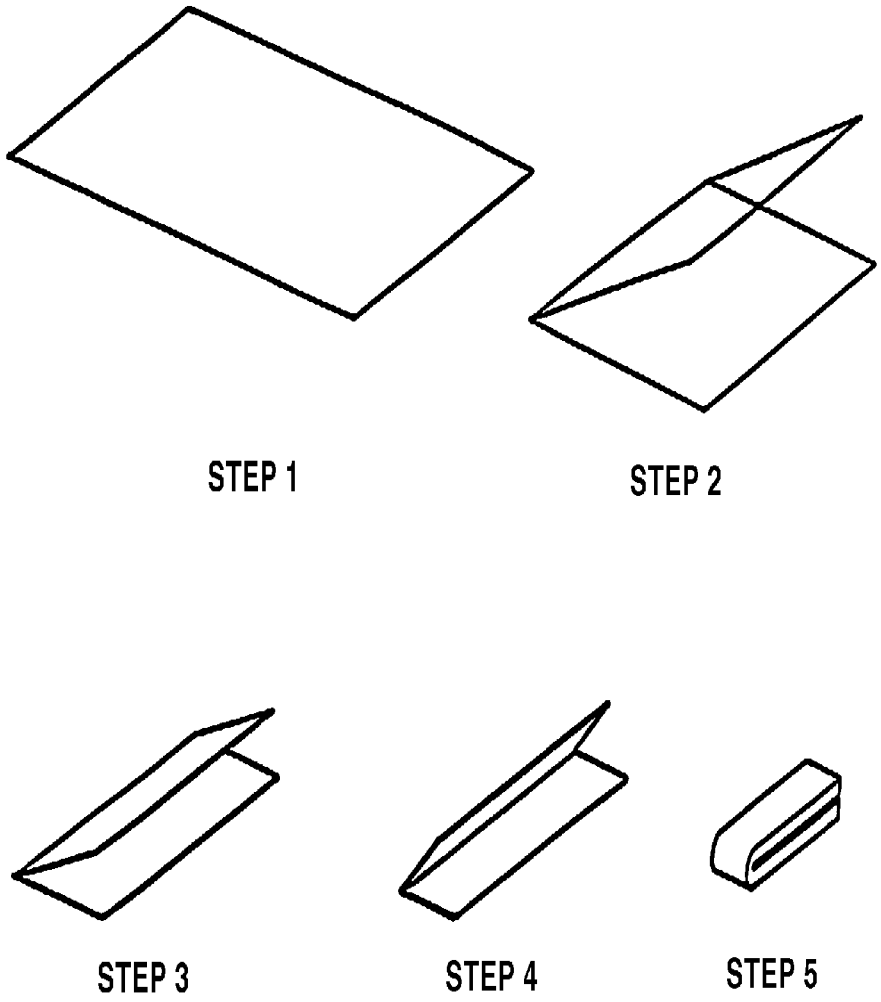


Figure 3—Towel folding procedure

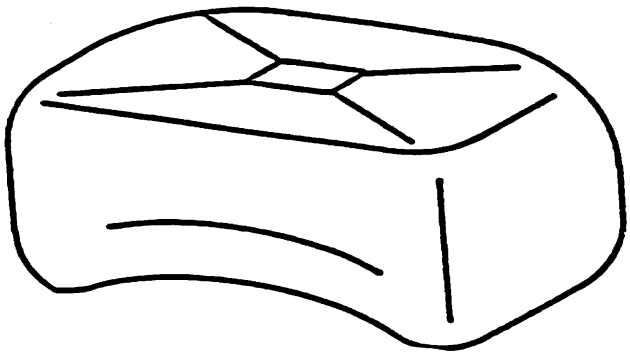


Figure 4—Completed wrapped pack (3 Towel-linen load)

The test pack is composed of three sheets of textile folded to cover the total horizontal surface area of the usable space of the sterilizer chamber as defined by the manufacturer, and wrapped with a fourth sheet folded to form at least a double thickness of material as an outer cover. The pack is then sealed with sterilization tape. The pack as described above should fill approximately 80% (±5 percent*)* of the usable chamber volume as defined by the manufacturer.

Alternatively, multiple test packs may be used in larger chambers to create a full load where approximately 80% of the usable chamber volume is filled. Such packs should be constructed as described above, including BI and temperature sensors with three sheets of textile folded to 20 x 15 cm (8" x 6") and wrapped with a fourth sheet folded to form at least a double thickness of material as an outer cover.

5.5.1.2 Test pack placement

The test pack is placed flat (as arranged for wrapping) in the sterilizer chamber area that is least favorable to sterilization, as evidenced by temperature profile measurements by the manufacturer. This area (cold part) varies with the design of the sterilizer but is normally in the front of the sterilizer, near the door. This test should be run with the chamber loaded with the maximum number of such packs to fill usable chamber space, where approximately 80% of the usable chamber volume is filled.

NOTES—

1) See also clause 5.5.1.2 of ANSI/AAMI ST8-1994, *Hospital steam sterilizers.*

2) The biological test pack requirements cover only horizontal sterilizers.

5.5.1.3 Cycle operation

A normal sterilization cycle, including drying time, is run according to the instructions the manufacturer provides health care facilities, but with holding time appropriate for establishing compliance with the sterility assurance requirements of 4.5 and the acceptance criteria of 5.5.1.5.

5.5.1.4 Incubation of biological indicators

See 5.5.

5.5.1.5 Acceptance criteria

5.5.1.5.1 *Sterility assurance level*: The manufacturer shall demonstrate that the recommended cycle has a sterility assurance level of at least $10^{-6}$when the test pack is used. In theory, this sterility assurance level represents the inactivation of 12 logarithms of a microorganism based on a $D_{121° C}$ of 1.0.

5.5.1.5.2 *Moisture retention:* The pack shall exhibit no visible moisture (see 4.7).

5.5.2 Biological performance with liquid loads (if applicable)

5.5.2.1 Test flasks

Three flasks of a size compatible with the chamber configuration are used in the liquid cycle test. The flasks must be Type borosilicate (for example, Pyrex glass).

CAUTION—Screw caps or rubber stoppers with crimped seals must not be used!

Each flask is filled with a measured quantity of water. A biological indicator containing *B. stearothermophilus* spores and media in a hermetically sealed vial is suspended with a temperature sensor in the center of each flask, a third of the distance from the height of the fluid (from the bottom). Liquid loss shall be monitored from all sample fluids. An appropriate vented closure is placed on each flask.

NOTE—An alternative biological test is to fill three flasks with soybean casein digest media or its equivalent. A spore strip meeting the requirements of 5.5 is placed in each flask with the media, along with a temperature sensor. The flasks must be run in the sterilization cycle immediately after the spore strip has been added.

5.5.2.2 Placement of test flasks

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

5.5.2.3 Cycle operation

A normal liquid cycle is run at 121° C (250° F) according to the written instructions that the manufacturer provides with the equipment.

5.5.2.4 Incubation of biological indicators

The biological indicators are retrieved and incubated according to the instructions of the biological indicator manufacturer. If the alternative test noted in 5.5.2.1 is used, the hermetically sealed vial should be suspended at the zone of the flask that is slowest to heat (in the geometric center, approximately one-third up from the bottom). After the sterilization cycle is complete and the load has cooled, the flask containing the spore strip is placed in an incubator and incubated for at least 7 days at the temperature recommended by the manufacturer of the biological indicator.

5.5.2.5 Acceptance criteria

Sterility of the load shall be demonstrated by the killing of all spores on the biological indicators. For acceptable test results, closures on the flasks must automatically seal, and water loss from the third water-filled flask must not exceed 50 milliliters (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 sterility assurance level of at least 10^{-6}.

5.5.3 Biological performance with wrapped instrument test pack

5.5.3.1 Test pack construction

The wrapped instrument pack of 5.7.2.1 should be used. At least three biological indicator strips (or equivalent) are placed among the instruments before the pack is wrapped and sealed.

5.5.3.2 Test pack placement

The wrapped instrument test pack shall be placed horizontally in the coolest part of the sterilizer, typically at the front near the door, or as determined by the manufacturer. The test shall be run in a fully loaded sterilizer. 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 biological indicators, and similar metal materials can be substituted for surgical instruments. While the actual number of packs needed for a full load will vary depending on the chamber dimensions and loading equipment, the number and arrangement of the packs shall always be consistent with good sterilization techniques.

5.5.3.3 Cycle operation

A sterilization cycle, including drying time, is run according to the instructions provided by the manufacturer.

5.5.3.4 Incubation of biological indicators

See 5.5.

5.5.3.5 Acceptance criteria

Sterility assurance level. The manufacturer shall demonstrate that the recommended cycle has a sterility assurance level of at least 10^{-6} when the test pack is used. In theory, this sterility assurance level represents the inactivation of 12 logarithms of a microorganism based on a $D_{121° C}$ of 1.0.

5.6 Air removal

5.6.1 Dynamic-air-removal efficacy

5.6.1.1 Test pack

A commercially available Bowie-Dick-type test pack equivalent to the Bowie-Dick test pack recommended in AAMI (1994) must be used.

5.6.1.2 Test pack placement

The test pack shall be placed horizontally on the bottom and in the front of the sterilizer rack, near the door, in the coolest part of the sterilizer as determined by the manufacturer, in an otherwise empty chamber.

5.6.1.3 Cycle operation

A prevacuum cycle is run according to the instructions that the sterilizer manufacturer will provide to health care facilities. The recommended holding time is 3½ min, but if ½ min exposures cannot be selected on the sterilizer, a 4 min holding time may be used. The holding time shall never exceed 4 min at 132° C (270° F). Drying 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 test sheet is removed from the pack and examined by a person trained in its interpretation.

NOTE—If holding times longer than 4 min are used, the test should be considered invalid and the results meaningless; even an extra minute may affect the results. A sterilizer tested from a "cold start" (after the sterilizer has been turned on and before a load is processed) may produce false failures; the sterilizer must be preheated to operating temperature by running at least one cycle in an empty chamber.

5.6.1.4 Acceptance criteria

Refer to manufacturer's instructions.

After a satisfactory test run, the tape or printed test sheet should show a uniform color change, i.e., the color in the center should be the same as that at the edges. The exact color change of the tape or sheet may depend on brand or storage conditions; of importance is whether or not the same color occurs at the center and the edges. The temperature at the edges will be greater than at the center.

5.6.1.5 Unsatisfactory test results

Any unexpected color change, such as the center of the test sheet or crossed indicator tape being paler than the edges, indicates that there was an air pocket present during the cycle due to sterilizer malfunction.

5.6.2 Dynamic-air-removal sterilizer vacuum leaks

5.6.2.1 General

The leak rate test involves the drawing of a vacuum in the chamber followed by closing all valves leading to the chamber, stopping the means of drawing the vacuum, and observing the chamber pressure 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

5.6.2.2.1 Connect to the sterilizer chamber an absolute pressure gauge (with at least the accuracy of the gauge specified in 4.4.4.1) suitable for operation over the total pressure range of the test cycle.

5.6.2.2.2 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 (18° F) 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 (18° F) during the period in which the chamber pressure is monitored.

5.6.2.2.3 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 time (T1) and the absolute pressure (P1). Wait 5 min plus or minus 10 sec, then observe and record the chamber absolute pressure (P2). After an additional 15 min plus or minus 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.

5.6.2.2.4 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 requirements of 5.6.2.3.

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

5.6.2.3 Acceptance criteria

A vacuum 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.

5.6.3 Air removal from gravity-displacement sterilizers

5.6.3.1 General

Air within the chamber must be removed so as to establish the saturated steam conditions necessary for effective moist heat sterilization. The air removal means vary for the accomplishment of this requirement. The manufacturer shall demonstrate that the method of air removal is adequate to establish the required conditions for a "worst case" load. In this instance the "worst case" load is the most absorbent test pack load that fully occupies the available use chamber volume.

5.6.3.2 Test

The manufacturer should conduct a series of tests using the test pack for the biological evaluation as an indirect measure of effective air removal. Further, the manufacturer should simultaneously monitor the temperature at various points in and around the various test pack(s) to ensure that those points are at or above the predetermined exposure temperature for a time sufficient to satisfy the sterility assurance level intended for the cycle. These temperatures should correlate with the temperature/pressure relationships defined in figure 1 for the intended use.

5.7 Test methods for measurement of moisture retention

5.7.1 Textile test packs

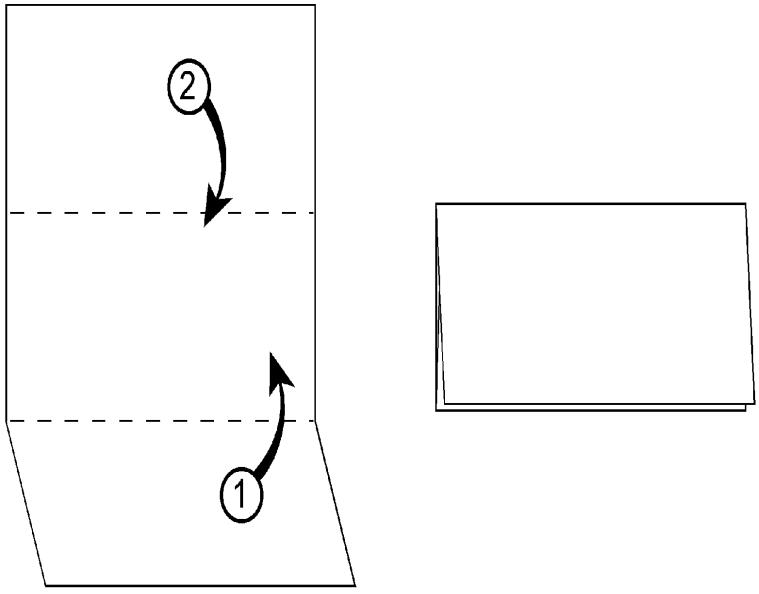
5.7.1.1 Pack configuration

Prepare the test packs using freshly laundered textiles. Textiles should be dry but not ironed and stored so as to stabilize for at least one hour in an environment between 18° C and 22° C (64° F and 72° F) and a relative humidity controlled between 35 and 70 percent. Weigh and record test pack(s) prior to sterilization so that it can be compared to poststerilization weight as called for in 5.7.1.5.

NOTE—Fabric conditioning agents may affect the characteristics of the fabric and contain volatiles that will contribute noncondensable gases to the chamber.

a) Nine reusable, 100% cotton, surgical towels should be each folded to yield nine plies. (See figure 5.) Each folded towel should measure approximately 9” x 6” (23 cm x 15 cm). Stack these towels one upon the other and sequentially double wrap them in 24” x 24” (61 cm x 61 cm) 100% cotton, 140-thread count, two-ply wrappers.

Steps 1 and 2: Fold the towel lengthwise into thirds to produce three plies.



Steps 3 and 4: Take the folded towel and fold lengthwise again into thirds to produce nine plies.

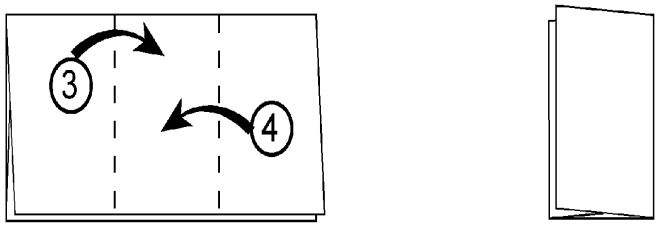


Figure 5—Folding a surgical towel to yield nine plies (See 5.7.1.1, item 1)

b) An alternative test pack for consideration is composed of three 100% cotton muslin sheets of textile measuring approximately 36” x 48” (90 cm x 120 cm) each. The sheets are folded to cover the total horizontal surface area of the chamber usable space as defined by the manufacturer. The sheet pack is wrapped with a fourth sheet folded to form at least a double thickness of material as an outer cover. The pack formed as described above should fill approximately 80% (+1%/- 5%) of the usable chamber volume as defined by the manufacturer.

c) Alternatively, multiple test packs may be used in larger chambers to create a full load where approximately 80% of the usable chamber volume is filled. Such packs should be constructed of three sheets of textile folded to 8” x 6” (20 cm x 15 cm) and wrapped with a fourth sheet folded to at least a double thickness of material as an outer cover.

5.7.1.2 Pack placement

Place each pack so that the layers of textile within are vertical to the surface of the loading tray. Do not load tightly. Leave sufficient space between each pack for ease in air displacement, steam evacuation, and drying. Use as many packs as can be properly placed in the size of chamber being tested.

5.7.1.3 Cycle operation

Utilize the sterilization cycle and in-chamber drying time that is specified in the equipment’s operating instructions.

5.7.1.4 Out-of chamber cooling

Remove the loading tray of packs from the chamber and do a visual exam for external moisture on the packs or tray. Place the tray on a rack to avoid flush contact of the tray of hot packs with a cool surface. Allow the tray of packs to thoroughly cool in an area away from air-conditioning turbulence. The cooling environment should be approximately 18–22° C (64–72° F) with a relative humidity of 35–70%.

5.7.1.5 Evaluation of pack for moisture retention

NOTE—It is always appropriate to examine for moisture residual after the packs have thoroughly cooled because a warm pack often has some residual hot vapor that will evaporate as the packs cool. Prematurely checking the packs (e.g., just as they come out of the sterilizer) will often reveal pack moisture by weight and by touch that may not be there after cooling to room temperature.

Visually inspect the outside of the pack(s) and the loading tray for any evidence of moisture. Reject packs with visible external moisture. Weigh each pack that appears to be dry on the outside and compare it to the presterilization weight. Inspect components of pack individually for dryness. Inspect for compliance with 4.7.

Moisture retained by the test pack must cause no more that a 3% increase in the presterilization test pack weight, and the pack must exhibit no wet spots.

NOTE—It is advisable to perform this same test with a pack wrapped in nonwoven disposable wrappers used in the same manner as they are most commonly used in this type of sterilizer.

5.7.2 Wrapped instrument test trays

5.7.2.1 Test tray composition

Line a perforated metal instrument tray(s) with a freshly laundered 100% cotton surgical towel. Instruments representing a maximum load configuration should be placed in the tray(s). The tray(s) should be sequentially wrapped in a 100 % cotton two-ply wrapper or equivalent (see 5.7.1.1).

NOTE—The maximum load configuration should be in alignment with the recommended preparation practice as described in ANSI/AAMI ST42-1992.

5.7.2.2 Tray placement

If more than one tray may be sterilized at a time, place each tray in accordance with the manufacturer’s written instructions.

5.7.2.3 Cycle operation

As in 5.7.1.3.

5.7.2.4 Out-of-chamber cooling

As in 5.7.1.4.

5.7.2.5 Evaluation of tray for moisture retention

As in 5.7.1.5. Also see NOTE following 5.7.1.5.

5.7.3 Paper-plastic peel pouch test

5.7.3.1 Pouch preparation

Prepare a number of sealed pouches, each containing a metal instrument, sufficient to constitute a full load as defined by the manufacturer.

5.7.3.2 Pouch placement

Place pouches in the chamber according to the manufacturer's written instructions.

NOTE—Standing pouches on edge with the paper side of one pouch adjacent to the plastic side of another during sterilization often improves drying.

5.7.3.3 Cycle operation

As in 5.7.1.3.

5.7.3.4 Out-of-chamber cooling

As in 5.7.1.4.

5.7.3.5 Evaluation of pack for moisture

As in 5.7.1.5 except that weighing should not be necessary.

NOTE—Tests using double pouches may be advisable as this is sometimes practiced.

5.8 Sterilizer performance certification and record-keeping

Compliance with 4.8 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 table top steam sterilizers intended for use in health care facilities. This annex also provides the rationale for each of the provisions of the standard.

A.2 Historical background

In 1976, 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 and to develop device performance standards.

The working group decided to confine the scope of this standard to those steam sterilizers that have a volume greater than 2 cubic ft and intended for use in health care facilities, 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].

The Sterilization Standards Committee, recognizing the need to provide guidance in the practice of sterilization using table-top steam sterilizers in a variety of health care facilities established the Ambulatory Care and Office-Based Steam Sterilization Working Group to undertake the development of a general table-top sterilizer standard that would address the need for guidelines for steam sterilization, by either the wrapped or unwrapped method, in all such applications. The resulting ANSI/AAMI ST42-1992 *Steam sterilization and sterility assurance in office-based ambulatory care medical and dental facilities* has provided much needed user guidance to ambulatory care clinics, office-based surgical practices, dental offices, and similar health care facilities.

The American Dental Association standard ANSI/ADA No.59 (1991) for *Portable steam sterilizers for use in dentistry*, however, is so limited in scope as to be of little value in providing guidance to sterilizer manufacturers concerning the performance qualification of table-top sterilizers for general health care use. Consequently, the Hospital Steam Sterilizer Working Group was charged with the responsibility of developing a sterilizer manufacturers standard for table-top steam sterilizers intended for general health care use.

A.3 Need for the standard

Steam sterilizers are intended to render products and materials sterile. Since 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 the sterilizer operator, the effectiveness of sterilization parameter measurement and control by the sterilizer, and the adequacy of validation of sterilizer performance and cycle parameters. In the judgment of the AAMI committee, these potential problem areas could be addressed by defining safety and performance criteria that could be used by the manufacturer in qualifying equipment design. It was recognized that user education was also an important element of sterility assurance, and, as noted in A.2, a separate effort was initiated to develop appropriate guidelines for hospital steam sterilization processing.

The need for a performance standard for steam sterilizers was subsequently supported by the Food and Drug Administration’s (FDA’s) classification of steam sterilizers into Class II (performance standards). Based on the recommendations of three advisory panels, the FDA deemed a performance standard necessary for reasonable assurance of device safety and effectiveness. 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.

As a gap existed in standards for the construction and performance of sterilizers of less than 2 cubic feet in chamber volume, the Hospital Steam Sterilizer Working Group undertook the development of such a general standard. 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: To minimize the risk of patient infection, adequate control of sterilizing time, temperature, and steam saturation is needed. 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 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.4 Rationale for the specific provisions of the standard

A.4.1 Labeling

The requirements of 4.1 are intended to assure that the manufacturer will give users of steam sterilizers sufficient information to enable them to correctly install, safely and effectively operate, and adequately maintain the equipment. In view of the relatively long life of a sterilizer, a permanently fastened identification plate (4.1.1.1) is required in order to permit the identification of essential characteristics if operating manuals have been lost. The labeling and markings required in 4.1.1.2 are intended to reduce the risk of operator burns from high-temperature surfaces. The operator 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, accessories

A.4.2.1 Pressure requirements

The standard incorporates by reference the requirements of the ASME *Boiler and pressure vessel code* in order 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

As required by ASME (1986), the manufacturer shall provide the purchaser with certified documentation attesting to compliance with 4.2.1.

A.4.2.3 Electrical components

Compliance with IEC 1010-1, IEC 1010-2-41 and the *National Electrical Code* 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 shall be corrosion-resistant in order to prolong the useful life of the equipment and prevent loads from being contaminated. 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 may be necessary to abort or terminate a cycle in progress. For their own safety, operators should clearly understand how to accomplish this procedure.

A.4.4 Process monitoring and control devices

The efficacy of steam sterilization processes depends upon the effectiveness of air removal and the attainment of saturated steam conditions at a specified temperature for a specified time. To ensure that the sterilizer will reliably provide these conditions, requirements are included in 4.4.1, 4.4.2, 4.4.3, and 4.4.4 for the location, accuracy, and readability of the sterilization-parameter indicating and recording system. Regarding temperature control in particular (4.4.1 and 4.4.2), the objective of the requirements is to ensure that all points within the usable chamber are within the control band of 4.4.2, so that the actual chamber temperature does not fall below the selected sterilization exposure temperature. The test of 5.4.2 provides proof that the temperature of the sterilizing medium will conform to 4.4.2.

Accuracy requirements should ensure uniform temperature control, holding 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.

A.4.5 Biological performance of sterilizers

Steam sterilizers shall 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. The biological challenge test pack itself was developed at the Eastman Dental School in 1966. Tests are required for the three most commonly run cycles: fabric cycles, liquid loads, and wrapped instruments.

To demonstrate that the sterilizer functions in a reproducible manner, three consecutive runs of each test are required for certification. Such studies shall be repeated at least every 24 months or whenever a design change occurs that could affect performance. Since biological indicators 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.

Placement of the biological indicator/fabric test pack horizontally, rather than on edge, more fully challenges the sterilizer, but is not an excessive challenge. It is recognized that the horizontal configuration is contrary to recommended loading practices, but this is done to accentuate the biological challenge.

Although it is acknowledged that there are new generations of materials, woven and nonwoven, with various fiber compositions, weights, and thread counts, which are being used extensively by many health care facilities as both pack components and wrappers, the provisions of this standard call for these items to comply with 5.5.1.1.

A.4.6 Air removal

A.4.6.1 Dynamic-air-removal efficacy

Dynamic-air-removal sterilizers are used to minimize the amount of air present in the sterilizer chamber, thereby enhancing the penetration of steam into porous loads. A dynamic-air-removal sterilizer residual air test, generally referred to as the Bowie-Dick test, is used to determine the efficacy of the vacuum (air removal) system of a dynamic-air-removal sterilizer. It is NOT a sterility assurance test.

The Bowie-Dick test was developed to evaluate the ability of dynamic-air-removal sterilizers to effectively reduce air residuals from the chamber space and detect the presence of air leaks. The final level of residuals should prevent compaction of air by reentrainment into a load (the small-load effect) as steam is introduced after evacuation. If air has not been sufficiently removed because the vacuum pump is malfunctioning, the control switch cuts off evacuation too soon, or chamber air leaks exist, steam will subsequently drive the available air back into the load. Air pockets will therefore occur, and sterilizing conditions will not be attained.

The test is conducted in an otherwise empty chamber to maximize the potential for detecting any air that enters by means of a leak or is not removed despite the appropriate level of vacuum being achieved. Other packs in the chamber would entrain a percentage of the air and reduce the sensitivity of the test.

A.4.6.2 Dynamic-air-removal sterilizer vacuum leaks

Air leaking into the sterilizer chamber that has not passed through a bacteria-retentive filter may present the risk of recontaminating the goods. A vacuum leak rate test is used to provide an indication of the relative "tightness" of the chamber. Leak rate test results provide an indication of the integrity of the vessel and plumbing system.

A.4.7 Moisture retention

Visible moisture may provide a path for microorganisms to contaminate the package. This is unacceptable and is a breach of sterility assurance practice.

A.4.8 Sterilizer performance certification and record-keeping

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

Thorough test reports must be kept by the sterilizer manufacturer as proof and documentation that the sterilizer conforms to this standard. It is the purchaser's right to receive, upon request, a copy of these test reports from the manufacturer.

Annex B
(informative)

Examples of temperature during the holding time

B.1 Introduction

This annex provides examples of possible prevailing temperatures during the holding time and is to be read as a clarification of the requirements in clauses 4.4.1, 4.4.2, and 4.4.3.

B.2 Legend

SET=Control Set Temperature or Sterilization Exposure Temperature

_____=Temperature

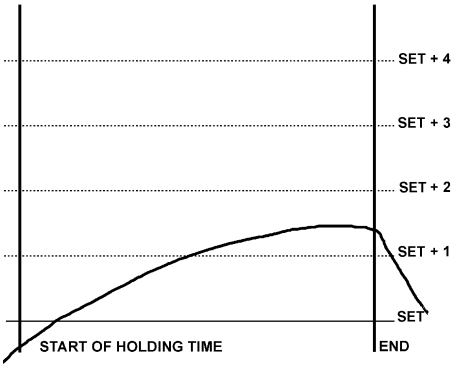


Figure B.1—Not acceptable process
During the holding time:
–the temperature is lower than SET

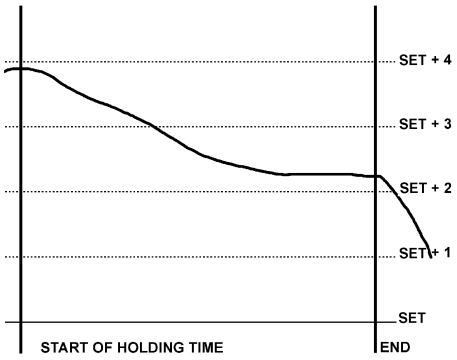


Figure B.2—Not acceptable process
During the holding time:
–measured temperature more than 3K above SET

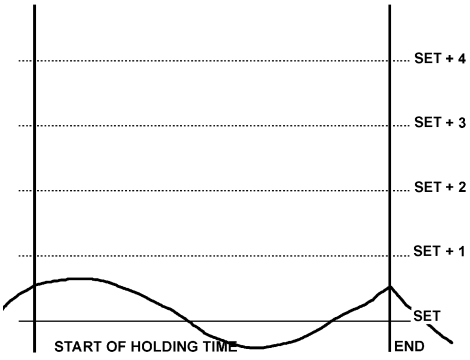


Figure B.3—Not acceptable process
During the holding time:
–the temperature is lower than SET

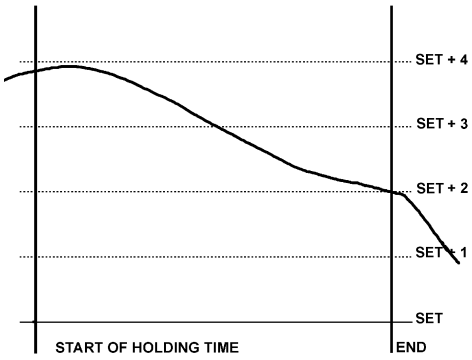


Figure B.4—Not acceptable process
During the holding time:
–the high temperature is more than 3K above SET

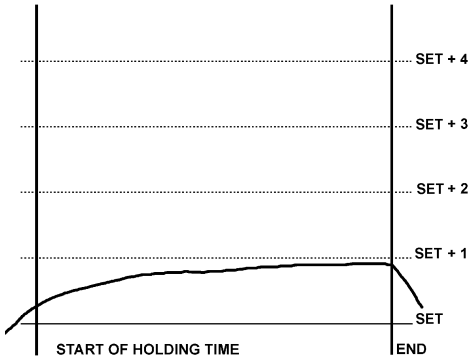


Figure B.5—Acceptable process

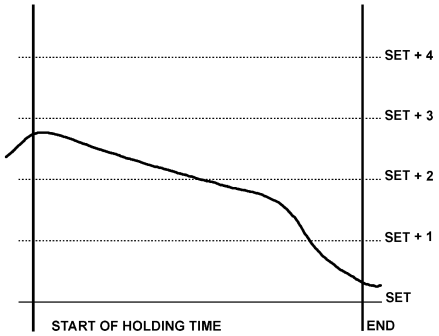


Figure B.6—Acceptable process

Annex C
(informative)

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