List of Titles

American National Standard

ANSI/AAMI ST45:1992

BIER/steam vessels

AAMI Association for the Advancement of Medical Instrumentation

List of Titles

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

© 2000 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

Copyright and Permissions

Publication, reproduction, photocopying, storage, or transmission, electronically or otherwise, of all or any part of these documents without the prior written permission of the Association for the Advancement of Medical Instrumentation or the copyright holder (if not AAMI) is prohibited by law. It is illegal under federal law (17 U.S.C. § 101, *et seq*.) to make copies of all or any part of these documents (whether internally or externally) without the prior written permission of the copyright holder. Violators risk legal action, including civil and criminal penalties, and damages of $100,000 per offense. For permission regarding the use of all or any part of these documents, contact AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795. Phone: (703) 525-4890; Fax: (703) 525-1067.

Violators of this copyright policy should be reported to AAMI's legal counsel:

McKenna & Cuneo, L.L.P.
1900 K Street, N.W.
Washington, DC 20006
Attn: Jacqueline A. Henson, Esq.
Phone: (202) 496-7500

ST45 BIER/Steam Vessels

American National Standard

ANSI/AAMI ST45-1992
(Revision of AAMI BSV-3/81)

BIER/Steam vessels

Developed by
Association for the Advancement of Medical Instrumentation

Approved 29 June 1992 by
American National Standards Institute

ABSTRACT:

This standard contains construction guidelines, performance requirements, and the terminology for a test apparatus that measures the resistance performance pattern of biological indicators exposed to saturated steam. The test apparatus contains a pressure vessel and is designated a biological indicator-evaluator resistometer with saturated steam (BIER/steam vessel).

Committee representation

Association for the Advancement of Medical Instrumentation

Sterilization Standards Committee

This standard was developed by the Biological Indicators Working Group of the AAMI Sterilization Standards Committee. Committee approval of the standard does not necessarily imply that all committee and subcommittee members voted for its approval.

The AAMI Sterilization Standards Committee has the following members:

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

Members:
Carl W. Bruch, PhD, Consultant, Dellwood, MN
Virginia C. Chamberlain, PhD, Center for Devices and Radiological Health, Food and Drug Administration
Neal E. Danielson, HCA Wesley Medical Center, Wichita, KS
Judith Dowler, Radiation and Medical Devices, Health and Welfare Canada
Frank B. Engley, Jr., PhD, University of Missouri School of Medicine, Columbia, Missouri
Collette Keyser, RN, Alexandria, VA (Colonel, U.S. Army, Retired)
Robert F. Morrissey, PhD, Johnson & Johnson
Barry F.J. Page, Health Industry Manufacturers Association
Marimargaret Reichert, RN, Reichert and Associates
Janet K. Schultz, RN, American Sterilizer Company
James Whitbourne, Sterilization Technical Services
James L. Whitby, MB, PhD, University of Western Ontario, London, Ontario

Biological Indicators Working Group

© *2000 Association for the Advancement of Medical Instrumentation*

Cochairpersons: Gary S. Graham
Gordon S. Oxborrow

Members: Thomas A. Augurt, PhD, Propper Manufacturing Company, Inc.
David F. Bekus, Ethicon, Inc.
Trabue D. Bryans, North American Science Associates, Inc.
Virginia C. Chamberlain, PhD, Center for Devices and Radiological Health, Food and Drug Administration
Gary S. Graham, PhD, American Sterilizer Company
Thomas L. Hansen, Sherwood Medical
Lois A. Jones, Becton Dickinson & Company
Michael S. Korczynski, PhD, Abbott Labs Hospital Product Division
Larry Joslyn, Joslyn Sterilizer Company
Patrick J. McCormick, PhD, MDT Corporation
Gregg A. Mosely, J.R. Gillis & Associates
Gordon S. Oxborrow, 3M Company
Jack Scoville, Cottrell Ltd.
Zenius Seliokas, Davis and Geck
James Whitbourne, Sterilization Technical Services
William E. Young, Baxter Healthcare Corporation

Alternates: Christopher Demitrius, Food and Drug Administration
James Gibson, Johnson & Johnson Medical Inc.
Daniel W. Janssen, 3M Medical Surgical Division
Carolyn Kinsley, Becton Dickinson & Company
Anna McLernon, PhD, Ethicon, Inc.

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.

Foreword

This standard was developed by the Biological Indicators Working Group of the AAMI Sterilization Standards Committee. The objective of this standard is to provide performance requirements and terminology for equipment used to determine the resistance performance of biological indicators exposed to saturated steam, i.e., a biological indicator-evaluator resistometer vessel using saturated steam (BIER/steam vessel). *BIER/Steam Vessels* (ANSI/AAMI ST45-1992) is a revision of an AAMI standard first approved in 1981, and includes a new section on software quality assurance.

The concepts incorporated in this document should not be considered inflexible or static. To remain relevant, this standard must be reviewed and updated periodically to assimilate progressive technological developments. This standard reflects the conscientious efforts of those individuals and organizations substantially concerned with its scope and provisions to develop a standard for those performance levels that can reasonably be achieved at this time.

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

© *2000 Association for the Advancement of Medical Instrumentation*

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 is not part of the American National Standard, *BIER/Steam vessels* (ANSI/AAMI ST45-1992).

BIER/Steam vessels

1 Scope

1.1 General

This standard establishes requirements for saturated steam vessels intended for use in evaluating the resistance performance of biological indicators.

1.2 Inclusions

This standard includes minimum construction and performance requirements intended to:

a) help assure that the exposure chamber is effective in determining the resistance performance of biological indicators;

b) help assure the safety of trained personnel using the equipment.

1.3 Exclusions

This standard does not provide either presterilization or poststerilization procedures. It does not cover machine operator requirements, nor does it specify the tests that should be performed to demonstrate the predictability, reliability, and reproducibility of biological indicator resistance performance, nor does it indicate how this information can be related to quantitated production-sterilization processes.

2 Normative references

The following standards contain provisions that, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below.

2.1 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Safe current limits for electromedical apparatus*. ANSI/AAMI ES1—1985. Arlington (Vir.): AAMI, 1985. American National Standard. ISBN: 0-910275-50-5

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

2.3 AMERICAN SOCIETY OF MECHANICAL ENGINEERS. *ASME steam tables*. New York: ASME, 1983.

2.4 NATIONAL FIRE PROTECTION ASSOCIATION. *National electrical code*. ANSI/NFPA No. 70-1990. Boston: NFPA, 1990. American National Standard.

3 Definitions

For the purposes of this American National Standard, the following definitions apply.

3.1 absolute pressure: Pressure that is measured when the reference baseline is 0 kPa (0 psia) and not atmospheric pressure.

3.2 accuracy: Agreement between an experimentally-determined value and the accepted reference value.

© *2000 Association for the Advancement of Medical Instrumentation*

3.3 BIER/steam vessel: Abbreviation for biological indicator-evaluator resistometer that uses saturated steam in a pressure vessel.

3.4 biological indicator: Sterilization process monitoring device consisting of a standardized, viable population of microorganisms (usually bacterial spores) known to be resistant to the mode of sterilization being monitored.

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

3.5 calibration: Comparison of a measurement standard or instrument of known accuracy with another standard or instrument to detect, correlate, report, or eliminate by adjustment any variation in the accuracy of the measurement being compared.

3.6 gauge: Instrument or means of measuring or testing.

3.7 interim standard: Instrument used as a standard unit until an authorized standard is established.

3.8 precision: Relative tightness of the distribution of measurements of a quantity about their mean value, expressed in terms of standard deviation.

3.9 readout unit: Apparatus employed to provide indications and/or recordings of a transducer output.

3.10 reference standard: Standard of the highest order of accuracy in a calibration system that establishes the basic accuracy values for that system.

3.11 saturated steam: Maximum partial pressure of steam as a gas which can be admitted to an environment at a given temperature before the steam changes state from a gas to a liquid.

NOTE — This pressure/temperature relationship is published in many references such as the *ASME steam tables* (see 2.3).

3.12 saturated steam sterilization: Process that uses saturated steam at a temperature for a sufficient time to destroy all organisms.

NOTE — The sterilization process is generally expressed as a probability function of the survival of a microorganism.

3.13 software quality assurance (SQA): Program which includes a protocol for formal review and validation of device software to ensure overall functional reliability.

NOTE — The major goals of an SQA program are correctness, reliability, testability, and maintainability.

3.14 sterilization: Process by which all viable forms of microorganisms are destroyed.

NOTE — This process is generally expressed as a probability function.

3.15 transfer standard: Designated measuring equipment used in a calibration system as a medium for transferring the basic value of reference standards to lower echelon transfer standards or measuring and test equipment.

3.16 validation: Verification that a process, system, or test method has been demonstrated to reliably perform the function for which it is intended.

NOTE — Such demonstrations need to be documented with data, experiments, process capability studies, or by other appropriate means.

4 Requirements

© *2000 Association for the Advancement of Medical Instrumentation*

4.1 Pressure vessel labeling

4.1.1 Commercially-produced BIER/steam vessels

Each commercially available BIER/steam vessel that will be used to evaluate the performance of biological indicators shall have at least one nameplate, permanently fastened and reasonably accessible, which includes the following information and certification:

a) name of manufacturer;

b) manufacturer's type and model designation;

c) chamber pressure rating;

d) jacket pressure rating (if applicable);

e) stamp of inspecting authority;

f) serial number;

g) electrical characteristics.

4.1.2 Custom-assembled BIER/steam vessels

BIER/steam vessels that are custom-assembled as prototype units shall meet appropriate safety standards for pressure vessels and shall be appropriately labeled and/or certified.

4.2 Documentation

At the time of installation of a BIER/steam vessel the user shall have or shall develop the following information:

a) instructions for the installation of the BIER/steam vessel;

b) recommendations for maintenance and inspection of the BIER/steam vessel;

c) a protocol for safe operation of the BIER/steam vessel;

d) equipment performance data for the BIER/steam vessel.

4.2.1 Installation instructions

These instructions shall include those installation procedures that will facilitate the safe, efficient operation of the unit.

4.2.2 Maintenance and inspection recommendations

At least the following information shall be provided:

a) an inspection schedule to ensure efficient operation;

b) a maintenance schedule;

c) a statement concerning the need to fulfill the requirements of 4.2.2.a and 4.2.2.b, either by means of an in-house program or outside service contract, or both;

d) the name and address of the manufacturer;

e) the name, address, and telephone number of the authorized service agent.

4.2.3 Operations manual

The operations manual shall include the following:

© *2000 Association for the Advancement of Medical Instrumentation*

a) instructions for the safe and effective operation of the BIER/steam vessel;

b) the name and address of the manufacturer;

c) the manufacturer's type and model designation;

d) the name, address, and telephone number of the authorized service agent.

4.2.4 Equipment performance documentation

The documentation of the equipment shall include data to support that the specified parametric conditions (of steam pressure and temperature) are met.

4.2.4.1 The time to achieve target temperature and corresponding saturated steam pressure shall be reproducible at the site monitored.

NOTE — The preferred site for monitoring temperature is at the site of placement of the biological indicators.

4.2.4.2 The time required for gravity displacement systems to achieve target temperature and corresponding pressure (e.g., 121°C ± 0.5°C, 204.8 kPa [29.7 psia]) shall not exceed 10 seconds from 100°C or atmospheric pressure. The time required for test systems employing prevacuum when the chamber is empty to achieve target temperature and corresponding pressure shall not exceed 15 seconds.

4.2.4.3 The time to exhaust to atmospheric pressure shall be reproducible and shall not exceed 10 seconds.

NOTE — Post-vacuums may be employed to cool the biological indicator load.

4.3 Equipment construction

4.3.1 Design

The design, material, and testing of BIER/steam vessels shall conform to all applicable ASME requirements (see section 2).

4.3.2 Electrical components

4.3.2.1 The BIER/steam vessel shall conform to applicable requirements of the *National electrical code* (see 2.4).

4.3.2.2 The BIER/steam vessel shall conform to applicable requirements of *Safe current limits for electromedical apparatus* (see 2.1).

4.3.3 Steam supply

Steam generators used exclusively for heating and charging BIER/steam vessels are recommended; generators shall be constructed to conform to applicable provisions of the ASME *Boiler and pressure vessel code* (see 2.2).

4.3.3.1 The boiler capacity shall be sufficient to provide an adequate quantity of saturated steam at all times.

4.3.3.2 The steam supply to the vessel shall be controlled to give the desired saturated steam pressure.

4.3.3.3 The saturated steam supply to the vessel shall be controlled to give the required reproducibility in physical test conditions.

4.3.3.4 The supply lines shall be large and well insulated and shall have a minimum of bends so that adequate steam without excess condensate is supplied to the BIER/steam vessel.

NOTE — Steam traps should be used to minimize condensate.

© *2000 Association for the Advancement of Medical Instrumentation*

4.3.4 Safety considerations

Hazards that can be associated with the use of BIER/steam vessels warrant special consideration due to the unique features of equipment design and operation.

4.3.4.1 Door (lid) interlocks

Doors (lids) that allow the total relief of pressure in the vessel shall have a safety locking mechanism. Under normal operating conditions, the automatic locking mechanism shall prevent the admission of steam to the chamber while the door (lid) is unlocked. Injection mechanisms providing for the insertion into, and/or withdrawal of test materials from, a pressurized vessel shall be designed to ensure mechanical and operator safety. Under normal operating conditions, the automatic locking mechanism shall prevent the opening of the doors (lids) while there is a pressure differential of more than 27 kPa (3.915 psia) in the vessel.

4.3.4.2 Handles

All devices used to position, tighten, or loosen the door (lid), and all devices (valves) used to manually control the flow of steam shall be of low thermal conductivity material. Steam and water supply lines and, if applicable, air lines shall be equipped with manual shut-off valves.

4.3.4.3 Main power switch

A power disconnect switch shall be located within easy reach of the operator.

4.3.4.4 Safety valve(s) and rupture disc(s)

A safety valve and/or rupture disc shall be provided for each pressurized chamber. The safety valve and/or rupture disc shall comply in capacity with local safety codes and the ASME code for unfired pressure vessels (see 2.2).

4.3.4.5 Strainers

Strainers shall be located in the vacuum and effluent openings of BIER/steam vessels.

NOTE — Bleeder valves do not require strainers.

4.3.4.6 Thermal insulation

All heat-emitting surfaces (such as steam lines, jacket walls of steam-jacketed vessels, and walls of steam-under-pressure chambers) shall be lagged with thermal insulation (except where lagging will adversely affect the function of the sterilizer) in order to minimize heat loss, maximize thermal stability, and protect the operator from burns.

5 Control and readout instrumentation

5.1 System control

5.1.1 Pressure and temperature control

Operation of the saturated steam vessel requires that the pressure and temperature of the saturated steam be closely controlled, since these parameters are interrelated; this relationship shall be known (from 2.3) for the specific process and shall be shown to be in proper agreement.

5.1.2 Calibration of monitoring equipment

Apparatus and instruments used for monitoring the BIER/steam vessel and its components shall be recalibrated on a scheduled basis to assure laboratory accuracy.

© *2000 Association for the Advancement of Medical Instrumentation*

NOTE — Calibration of pressure and temperature measuring devices shall be traceable to the National Institute of Standards and Technology.

5.1.3 Adjustments

When adjustments are required, the instructions of the manufacturer shall be followed.

5.1.4 Calibration system requirements

Measuring and test equipment and measurement standards shall be calibrated at periodic intervals established on the basis of stability, purpose, and degree of usage. Intervals shall be shortened as required to assure continued accuracy as evidenced by the results of preceding calibrations and may be lengthened only when the results of previous calibrations provide definite indications that such action will not adversely affect the system accuracy.

5.1.4.1 Calibration standards

Apparatus and instruments used for monitoring the BIER/steam vessel and its components shall be calibrated, utilizing reference standards (or interim standards) whose calibration is certified as being traceable to the National Institute of Standards and Technology, has been derived from accepted values of natural physical constants, or has been derived by the ratio type of self-calibration techniques. Reference standards requiring calibration by a higher level standards laboratory shall be calibrated by a facility capable of providing the required service.

All reference standards used in the calibration shall be supported by certificates, reports, or data sheets attesting to the date, accuracy, and conditions under which the furnished results were obtained. All subordinate standards and measuring and test equipment shall be supported by like data when such information is essential to achieving the accuracy and control required by this document.

5.1.4.2 Calibration records

The application of these requirements shall be supported by records designed to assure that established schedules and procedures are followed to maintain the accuracy of all apparatus, instruments, and components. The records shall include a suitably-identified record of calibration or other means of control for each item, providing calibration interval and date of certification of last calibration. In addition, the individual record of any item whose accuracy must be reported via a calibration report or certificate shall quote the report or certificate number for ready reference.

5.2 Pressure control and monitoring

5.2.1 Pressure control devices

Pressure control devices are devices that permit regulation of saturated steam pressure. Major types of pressure control devices are:

a) absolute pressure switches;

b) pressure regulators;

c) manual controllers.

5.2.2 Pressure monitoring devices

Pressure monitoring devices are devices that measure saturated steam pressure. Major types of pressure monitoring devices include:

a) transducers with recorder or electronic gauge;

b) mechanical gauges.

© *2000 Association for the Advancement of Medical Instrumentation*

Pressure monitoring devices shall show that vessel pressure is within 3.45 kPa (0.5 psia) of the saturated steam pressure.

5.3 Temperature control and monitoring

5.3.1 Temperature control devices

Temperature control devices permit the control of the temperature of saturated steam. Major types of temperature control devices include:

a) thermocouples with appropriate controllers;

b) resistance temperature detectors with appropriate controllers;

c) manual controllers.

Temperature control devices shall control the temperature of saturated steam to within 0.5°C of the process controller set point.

5.3.2 Temperature monitoring devices

Temperature monitoring devices measure the temperature of saturated steam at specific sites. Major types of temperature monitoring devices are:

a) thermocouples and resistance temperature detectors with appropriate readout units;

b) gas-, liquid-, or vapor-filled bulbs with appropriate readout units;

c) mercury-in-glass thermometers.

Temperature monitoring devices shall be capable of determining saturated steam temperature to within 0.5°C.

5.4 Exposure monitoring

Each sterilizer shall be equipped with a timing device. The timer shall be graduated so that fractions of a minute can be read with a precision of 1 second. Timers shall have a repeatability of 1 percent.

6 Software quality assurance (SQA)

6.1 Software developed in-house

When a BIER unit manufacturer incorporates software developed in-house, an SQA program that outlines a systematic approach to development should be in place. The major goals of this program are:

a) measuring the development process phase;

b) validating that the output of each phase satisfies requirements;

c) documenting and controlling any changes made;

d) revalidating.

6.2 Custom-developed software

When a BIER unit manufacturer incorporates custom software purchased from contractors, the contractors shall have an SQA program that ensures that the major goals listed in clause 6.1 have been adequately achieved.

6.3 Off-the-shelf software

When a BIER unit manufacturer incorporates software from vendors or subcontractors, the SQA program

© *2000 Association for the Advancement of Medical Instrumentation*

should ensure, through appropriate testing prior to use in production, that the software is adequate for its intended application.

NOTE — For more in-depth information concerning software validation see the following:

a) ANSI/IEEE Standard 730.1-1989, *Standard for Software Quality Assurance Plans*, 1984.

b) NBS Special Publication 500-98, *Planning for Software Validation, Verification and Testing*, November 1982.

c) NBS Special Publication 500-75, *Validation, Verification, and Testing of Computer Software*, February 1981.

Annex A
(informative)

Rationale for the development and provisions of this standard

A.1 General

This standard describes test equipment used to evaluate the performance of biological indicators exposed to saturated steam. Resistance values determined using this standard may vary due to factors other than the performance of the BIER/steam vessel (Oxborrow et al., 1990).

A.2 Need for the standard

The performance of biological indicators is critical to their acceptance as a means of monitoring the efficacy of steam sterilization processes. In order to evaluate the performance of biological indicators, it is necessary to define test equipment that will safely provide an acceptable set of reproducible physical test conditions. This reference set of test conditions can be used to certify the performance of biological indicators for steam sterilization.

The need for a reference set of test conditions is supported by the round-robin testing conducted by a U.S. Pharmacopeia (Mayernic, 1972; Macek, 1972) advisory panel on biological indicators. These studies show that a standard set of test conditions is required to meaningfully evaluate the performance of biological indicator lots.

Additional general information on biological indicators is shown in Chapter 1035, *Biological indicators,* of USP, 1990 (p. 1625). Specific requirements are detailed in the USP monograph *Biological indicator for steam sterilization, paper strip* (USP 1990, p. 171) and in the American National Standards, *Biological indicators for saturated steam sterilization processes in health care facilities* (AAMI, 1986) and *Guideline for the use of ethylene oxide and steam biological indicators in industrial sterilization processes* (AAMI, 1991).

Other factors, such as the synergistic effects of air and steam in air-steam mixtures, could influence biological indicator performance. Additional tests to determine the effects of such factors can be found in Joslyn, 1991.

Annex B
(informative)

Bibliography

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Biological indicators for saturated steam sterilization processes in health care facilities.* ANSI/AAMI ST19-1986. Arlington (Vir.): AAMI, 1986. American National Standard. ISBN 0-910275-58-0.

© *2000 Association for the Advancement of Medical Instrumentation*

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Guideline for the use of ethylene oxide and steam biological indicators in industrial sterilization processes.* ANSI/AAMI ST34-1991. Arlington (Vir.): AAMI, 1991. American National Standard. ISBN 0-910275-57-2.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE, FOOD AND DRUG ADMINISTRATION, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, OFFICE OF COMPLIANCE. DIVISION OF COMPLIANCE PROGRAMS. *Preproduction quality assurance planning: recommendations for medical device manufacturers*. Rockville (Md.): FDA/CDRH, 1987.

JOSLYN, LJ. Sterilization by heat. In BLOCK, SS. *Disinfection, sterilization and preservation*. 4th ed., Philadelphia: Lea and Febiger, 1991, p. 515-523.

MACEK, TJ. Biological indicators — a U.S.P. review. *Bull. Parent. Drug Assn*, 1972, vol. 26, no. 1, p. 18-25.

MAYERNICK, J.J. Biological indicators for steam sterilization — a U.S.P. collaborative study. *Bull. Parent. Drug Assn*, 1972, vol. 26, no. 5, p. 205-211.

OXBORROW, GS., TWOHY, CW., and DEMITRIUS, C. Determining the variability of BIER vessels for EtO and steam. *Medical Device and Diagnostic Industry,* May 1990, vol 12, no. 5, p. 78-83.

UNITED STATES PHARMACOPEIAL CONVENTION INC. *United States Pharmacopeia, XXII Revision*. Rockville (Md.): USP, 1990.

© ***2000 Association for the Advancement of Medical Instrumentation***