

**American
National
Standard**

ANSI/AAMI ST44:2002

**Resistometers used for
characterizing the performance
of biological and
chemical indicators**

AAMI

Association for the
Advancement of Medical
Instrumentation



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A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

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Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

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American National Standard

ANSI/AAMI ST44:2002
(Combined revision of ANSI/AAMI ST44:1992
and ANSI/AAMI ST45:1992)

Resistometers used for characterizing the performance of biological and chemical indicators

Developed by
Association for the Advancement of Medical Instrumentation

Approved 12 September 2002 by
American National Standards Institute, Inc.

Abstract: This standard establishes minimum safety and performance requirements for biological indicator-evaluator resistometer (BIER) and chemical indicator-evaluator resistometer (CIER) vessels.

Keywords: dry heat, EO, ethylene oxide, steam, sterilization equipment, thermal

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Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Sterilization Standards Committee

This standard was developed by the AAMI Indicator-Evaluator Resistometer Working Group under the auspices of the Sterilization Standards Committee of the Association for the Advancement of Medical Instrumentation. Working group approval of the standard does not necessarily imply that all working group members voted for its approval.

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

Cochairs: Victoria Hitchins, PhD

William E. Young

Members:

Trabue D. Bryans, AppTec Laboratory Services

Virginia C. Chamberlain, PhD, Hendersonville, NC

Anne Cofiell, CRCST, International Association of Healthcare Central Service Materiel Management

Lorretta L. Fauerbach, MS, CIC, Association for Professionals in Infection Control and Epidemiology

Dorothy M. Fogg, RN, BSN, MA, Association of Perioperative Registered Nurses

Lisa Foster, Ion Beam Applications

James M. Gibson, Jr., JM Gibson Associates

Barbara J. Goodman, RN, CNOR, Rising Sun, MD

Joel R. Gorski, PhD, NAMSA

Susan Hadfield, Canadian Standards Association

Deborah A. Havlik, Abbott Laboratories

Victoria Hitchins, PhD, U.S. Food and Drug Administration

Clark W. Houghtling, Cosmed Group Inc.

Lois A. Jones, Becton Dickinson & Company

Sue Kuhnert, STSduoTek

Byron J. Lambert, PhD, Guidant Corporation

Sandra A. Lee, RN, STERIS Corporation

Patrick J. McCormick, PhD, Bausch & Lomb, Inc.

Thomas K. Moore, Getinge/Castle Inc.

Robert F. Morrissey, PhD, Johnson & Johnson

David Orton, CR Bard

Barry F.J. Page, Garner, NC

Phil M. Schneider, 3M Healthcare

Michael H. Scholla, MS, PhD, Dupont Medical Packaging Systems

Janet K. Schultz, MSN, RN, Roswell, GA

Harry L. Shaffer, Titan Corporation

Robert J. Sharbaugh, PhD, CIC, Hill-Rom Company

Frank Sizemore, American Society for Healthcare Central Service Professionals

William N. Thompson, TYCO Healthcare

James L. Whitby, MA, MB, FRCP, London, ON

Thelma Wilcott, Becton Dickinson & Company

Steve C. Yeadon, Alcon Labs

William E. Young, Baxter Healthcare Corporation

Alternates:

Bettye Beebe, Alcon Labs

Louis M. Glasgow, Bausch & Lomb, Inc.

Joyce M. Hansen, Baxter Healthcare Corporation

Susan G. Klacik, AS, International Association of Healthcare Central Service Materiel Management

Chiu Lin, PhD, U.S. Food and Drug Administration

Lisa Macdonald, Becton Dickinson & Company

Ralph Makinen, Guidant Corporation

Janet Prust, 3M Healthcare

James Whitbourne, STSduoTek

William T. Young, Ion Beam Applications

At the time this document was published, the **AAMI Indicator-Evaluator Resistometer Working Group** had the following members:

<i>Cochairs:</i>	Joel R. Gorski, PhD Larry Joslyn
<i>Members:</i>	Richard B. Barrett, PhD, Tempil Inc. Kevin Corrigan, Johnson & Johnson Christopher Demitrius, FDA/CDRH Shawn A. Doyle, Sterilator Company Inc. Catherine J. Finocchario, Bausch & Lomb Inc. Dan B. Floyd, Nelson Laboratories Inc. John R. Gillis, PhD, SGM Biotech Inc. Zory R. Glaser, PhD, MPH, CSPDM Joel R. Gorski, PhD, NAMSA Charles O. Hancock, H&W Technology LLC Marvin L. Hart, Marvin L. Hart & Associates Lois A. Jones, MS, Becton Dickinson & Company Larry Joslyn, STERIS Corporation Jim Kaiser, Getinge/Castle Inc. Steve Kirckof, 3M Healthcare Sue Kuhnert, STSduoTek Gregg A. Mosley, Biotest Laboratories William T. Young, Ion Beam Applications
<i>Alternates:</i>	Jude Kral, STERIS Corporation Elaine Mayhall, PhD, U.S. Food and Drug Administration/CDRH Patrick J. McCormick, PhD, Bausch & Lomb Inc. Shaundrea L. Rechsteiner, NAMSA Phil M. Schneider, 3M Healthcare James Whitbourne, STSduoTek Jonathan A. Wilder, PhD, MBA, H&W Technology LLC

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

Foreword

This American National Standard was developed by the Association for the Advancement of Medical Instrumentation (AAMI) Indicator-Evaluator Resistometer Working Group under the auspices of the AAMI Sterilization Standards Committee. The objective of this standard is to provide performance requirements, terminology, equipment specifications, and guidance on resistometers that characterize the performance of biological and chemical indicators intended for use with sterilization processes using steam, ethylene oxide (EO), and dry heat.

This standard is a combined revision of ANSI/AAMI ST44:1992, *BIER/EO gas vessels*, and ANSI/AAMI ST45:1992, *BIER/steam vessels*, and is based in part on these two documents as well as ISO 11140-2:1998, *Sterilization of health care products—Chemical indicators—Part 2: Test equipment and methods*.

Recognizing that a resistometer vessel can be used for characterization of either biological or chemical indicators, this standard has taken this commonality into consideration. This standard combines the previously separate standards for ethylene oxide (ST44) and steam (ST45) resistometers, and also includes specifications for dry heat resistometers. This standard was written with the knowledge and understanding of the advancement in available technology necessary to create resistometers capable of accurately and consistently characterizing biological and chemical indicators. One significant change to this standard as compared to the ST44 and ST45 standards is that specific resistometer exposure parameters for characterizing indicators have been taken out of this standard and can be found in the respective standards for biological and chemical indicators.

The concepts incorporated into 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 to conform to the recommended practice. “Should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the standard. “Can” is used as a statement of possibility and capability. Finally, “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 Technical Programs, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—This foreword is not part of the American National Standard *Resistometers used for characterizing the performance of biological and chemical indicators* (ANSI/AAMI ST44:2002), but it does provide important information about the development and intended use of the document.

Introduction

Resistometers are test instruments designed to evaluate the effects of sterilizing environments on biological inactivation kinetics, chemical reactions, material degradation, and product bioburden. The laboratory resistometer test systems allow precise variation of the environmental conditions and cycle sequences in order to produce controlled physical studies. The results of those studies are used in research and quality control programs to establish appropriateness of biological and chemical indicators for applications.

Resistometer test systems differ from conventional sterilizers. Instrumentation selection and control requirements for resistometers are based on mathematical models in which rates of reaction, measurement accuracy, and process control requirements are evaluated to quantify the effects induced by test equipment controlled variables. The requirements for accurate measurement, precise control, and rapid rates of change approach limits of commercially available process control and calibration instrumentation accuracy. The measurement and control requirements often prohibit practical validation of a resistometer laboratory test system by using procedures that might be employed in a conventional heat or chemical sterilization system. Resistometer systems are test instruments rather than sterilizers; thus, an understanding of instrumentation and process design is critical in clarifying requirements for precision and accuracy. Practical design has to consider:

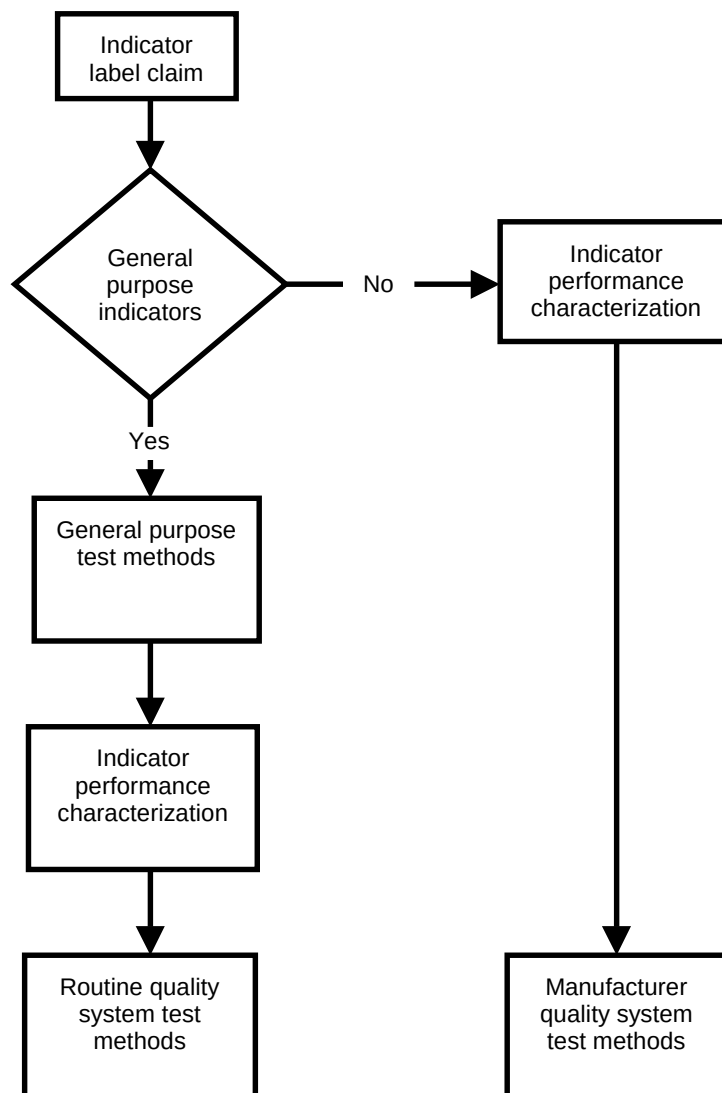
- Achievable measurement and control,
- Acceptable equipment induced variation in test results,
- Economic design (using tight process controls only where required),
- Test method correlation with intended use,
- Historical knowledge applied to test procedures and an understanding of micro-environmental physical phenomenon, and
- Testing and analysis alternatives when accurate quantitative determinations exceed physical measurement and control limits.

Diverse requirements for biological and chemical indicators are used for evaluating sterilization processes. Chemical indicators are evolving that are intended to emulate the capabilities of biological evaluation methods for verifying efficacy. This requires characterization of biological inactivation characteristics as well as substantiation of chemical indicator characteristics. Additionally, numerous variations in cycles may affect applicability of indicators for the intended use. Testing the performance of biological and chemical indicators requires specific equipment. This ANSI/AAMI standard specifies the performance requirements and test capabilities for test equipment able to:

- Characterize the response of biological and chemical indicators to the critical physical parameters encountered during exposure to steam, ethylene oxide, and dry heat sterilization processes;
- Evaluate applicability of the biological and chemical indicators for the intended use; and
- Perform quality control testing on biological and chemical indicators used to monitor processes.

Figure 1 shows a typical sequence for evaluating biological and chemical indicators used in monitoring sterilization processes.

Figure 1—Typical sequence for evaluating biological and chemical indicators used in monitoring sterilization processes



Explanation of Figure 1

Routine quality system test methods are based on testing required in the applicable provisions of the normative references for biological and chemical indicators (Section 2—Normative references). Indicator performance characterization relates to information that may be needed to apply an indicator at points other than the test points required in the normative references. The following definitions apply to Figure 1.

Indicator label claim: Commercial performance declarations about indicators distributed by device manufacturers.

General purpose indicators: Indicator intended for use in multiple types of processes, where the type of process does not substantially change the ability of the indicator to quantify delivered lethality for the sterilization medium within defined limits. An indicator is not considered to be a general purpose indicator if the indicator label claim specifically limits its application to one type of process relative to the variety of processes for a sterilization medium. For example, an indicator is not a general purpose indicator if it applies only to gravity sterilization versus all steam sterilization processes (e.g., vacuum-assisted), because using it for such processes will result in significant changes in performance or damage the indicator.

Indicator performance characterization: Qualitative and quantitative attributes that qualify the device as an indicator.

General purpose test methods: Series of tests performed to emulate conditions that might change an indicator's native expected performance characteristics when the indicator is intended for use in multiple types of processes using a given sterilization medium. The tests selected are used to quantify whether a variation in a sterilization process is likely to substantially change the ability of the indicator to quantify delivered lethality relative to defined performance limits. The tests selected may be used to verify that indicators are not physically damaged or adversely affected by unrecognized anomalies when they are applied in accordance with recommendations for intended use. For example, different air removal techniques, such as gravity displacement, or prevacuum or steam-flush pressure-pulsing, may shift the indicator's performance characteristics outside the required minimum process lethality limits. An indicator appropriate for a gravity sterilization process may not work properly in a prevacuum or steam-flush pressure-pulsing process. An indicator may be physically damaged with deep vacuums or multiple pulse pressure excursions.

Routine quality system test methods: Tests performed in accordance with consensus standard requirements or agency-approved methods that are designed to standardize safety, efficacy, and quality systems on the basis of the best available knowledge. The number of tests required for routine release testing may depend on the support information derived during performance characterization and general purpose performance testing. For example, an indicator that exhibits minimal performance-shift characteristics when tested under several process variation conditions and that exhibits predictable characteristics within defined limits over the intended-use range may only require testing at one test condition for routine release, with periodic testing at other test conditions within the intended-use range.

Manufacturer quality system test methods: Test methods specifically designed and approved to meet quality system requirements for indicators that have limited, specific, or new application claims. Indicators may not comply, or consensus standards may not exist for the indicator application.

Resistometers used for characterizing the performance of biological and chemical indicators

1 Scope

1.1 Inclusions

This standard specifies the requirements for resistometers that characterize the performance of biological and chemical indicators used in steam, ethylene oxide (EO), and dry heat processes. This standard also provides informative methods that help characterize the performance of biological and chemical indicators for their intended use and routine quality control testing.

1.2 Exclusions

This standard does not consider equipment and methods used to characterize biological or chemical indicators exposed to γ and β irradiation, steam-formaldehyde or sterilization processes, or combination processes such as washer disinfectors.

This standard does not specify testing, performance, or acceptance requirements that are specifically covered in the normative references.

This standard does not address safety aspects of the test equipment because specific federal, state, or local regulations govern such requirements.

2 Normative references

The following publications 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 publications indicated below. The American National Standards Institute maintains a register of currently valid American National Standards.

2.1 ISO/TR 10013:2001, *Guidelines for quality management system documentation*.

2.2 ANSI/AAMI/ISO 11134:1993, *Sterilization of health care products—Requirements for validation and routine control—Industrial moist heat sterilization*.

2.3 KEMPER CA and PFLUG IJ. *Microbiology and engineering of sterilization processes*, 10ed., 1999. Chapter 12, "Temperature measurement in the gathering of design data or during validation of equipment and processes."

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 is not atmospheric pressure.

3.2 accuracy: Degree to which a measurement, or an estimate based on measurements, represents the true value of the attribute that is being measured.

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

3.4 calibration: Set of operations that establish, under specified conditions, the relationship between values indicated by a measuring system, or values represented by a material measure or reference material, and the corresponding values of that quantity obtained from a reference standard.

3.5 carrier: Supporting material on which test organisms are deposited.