

American National Standard



ANSI/AAMI/ ISO 18472: 2022

Sterilization of health care
products—Biological and
chemical indicators—Test
equipment



Sterilization of health care products—Biological and chemical indicators—Test equipment

Approved 13 December 2021 by
AAMI

Approved 24 August 2022 by
American National Standards Institute

Abstract: Specifies requirements for test equipment to be used to test biological indicators for steam, ethylene oxide gas and dry heat sterilization processes for conformity to the requirements given in ISO 11138 series and test chemical indicators for steam, ethylene oxide gas, dry heat and vaporized hydrogen peroxide sterilization processes for conformity to the requirements given in ISO 11140-1:2014.

Keywords: test equipment, biological indicators, chemical indicators

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Published by

AAMI
901 N. Glebe Road, Suite 300
Arlington, VA 22203
www.aami.org

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Printed in the United States of America

ISBN 978-1-57020-860-7

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Committee representation

Association for the Advancement of Medical Instrumentation

Resistometer Working Group

The adoption of ISO 18472 as an American National Standard was initiated by the **AAMI Resistometer Working Group**. **AAMI ST-WG91** provides input to the **AAMI Sterilization Standards Committee (U.S. TAG to ISO/TC 198)** which is the responsible group for providing the U.S. input to the relevant group in ISO/TC 198. U.S. representatives from **AAMI Resistometer Working Group** and the U.S. TAG played an active part in developing the ISO document.

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

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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.

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Background of ANSI/AAMI adoption of ISO 18472:2018

As indicated in the foreword to the main body of this document (page ix), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard, which was developed by ISO/TC 198 to provide guidance to manufacturers on test equipment for biological indicators and chemical indicators.

U.S. participation in ISO/TC 198 is organized through the U.S. Technical Advisory Group, AAMI Sterilization Standards Committee, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.

AAMI encourages its committees to harmonize their work with International Standards in the area of sterilization of health care products. Upon review of ISO 18472, the US TAG to ISO/TC 198 and the AAMI Resistometer Working Group decided to adopt it verbatim, as a first edition of ANSI/AAMI/ISO 18472:2022.

AAMI and ANSI procedures require that standards be reviewed and, if necessary, revised every five years to reflect technological advances that may have occurred since publication.

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.

NOTE Users of this standard are advised that this document is an AAMI identical adoption of an ISO document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g. colour instead of color);
- Use of SI units (e.g. metres instead of feet, Celsius instead of Fahrenheit, etc.);
- Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15).

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE Beginning with the ISO foreword on page ix, this American National Standard is identical to ISO 18472:2018.

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 18472:2006), which has been technically revised.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

To test the performance of biological and chemical indicators, specific test equipment is required. This document specifies the performance requirements for the test equipment to be used to establish the response of biological and chemical indicators to critical process variables. This document does not apply to test equipment for indicators used in irradiation, isolator/room biodecontamination (at atmospheric pressure), or low temperature steam and formaldehyde processes.

Resistometers constitute test equipment designed to create precise and repeatable sterilizing environments, allowing the evaluation of their effect on biological inactivation kinetics, chemical reactions, material degradation and product bioburden. Resistometers allow precise variation of the environmental conditions and cycle sequences in order to produce controlled physical studies. When used with the defined test methods given in the appropriate parts of ISO 11138 for biological indicators and ISO 11140 for chemical indicators, the results of these studies can be used to demonstrate conformance of biological indicators and chemical indicators to these standards.

Resistometers differ from conventional sterilizers. Instrumentation selection and control requirements for resistometers are based upon 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 measurement accuracy. The measurement and control requirements often prohibit practical validation of a resistometer using procedures that might be employed in a conventional heat or chemical sterilization system. Resistometers are considered test equipment rather than sterilizers; therefore, an understanding of instrumentation and process design is critical in clarifying requirements on precision and measurement accuracy. Practical design takes the following into consideration:

- achievable measurement and control;
- acceptable equipment induced variation in test results;
- economic design (utilizing 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 phenomena;
- testing and analysis alternatives, when accurate quantitative determinations exceed physical measurement/control limits.

Sterilization of health care products—Biological and chemical indicators—Test equipment

1 Scope

This document specifies the requirements for test equipment to be used to:

- test biological indicators for steam, ethylene oxide gas and dry heat sterilization processes for conformity to the requirements given in ISO 11138 series;
- test chemical indicators for steam, ethylene oxide gas, dry heat and vaporized hydrogen peroxide sterilization processes for conformity to the requirements given in ISO 11140-1:2014.

This document also provides informative methods useful in characterizing the performance of biological and chemical indicators for intended use and for routine quality control testing.

This document does not specify requirements for test equipment for processes specifically for testing chemical and biological indicators intended to monitor isolator and room biodecontamination processes at atmospheric pressure.

ISO 11138-2:2017, ISO 11138-3:2017, ISO 11138-4:2017 and ISO 11140-1:2014 require the use of resistometers specified in this document, and these resistometers are used in conjunction with the test methods specified in the appropriate parts of ISO 11138 series and ISO 11140 series.

Resistometers for low temperature steam and formaldehyde indicators are not included in this document. Test methods using laboratory apparatus for low temperature steam and formaldehyde are included in ISO 11138-5:2017.

Test equipment for testing Type 2 (e.g. Bowie Dick) chemical indicators are specified in ISO 11140-3:2007, ISO 11140-4:2007, and ISO 11140-5:2007.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11138-1:2017, *Sterilization of health care products—Biological indicators—Part 1: General requirements*

ISO 11138-2:2017, *Sterilization of health care products—Biological indicators—Part 2: Biological indicators for ethylene oxide sterilization processes*

ISO 11138-3:2017, *Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization processes*

ISO 11138-4:2017, *Sterilization of health care products—Biological indicators—Part 4: Biological indicators for dry heat sterilization processes*

ISO 11138-5:2017, *Sterilization of health care products—Biological indicators—Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes*

ISO 11140-1:2014, *Sterilization of health care products—Chemical indicators—Part 1: General requirements*