American National Standard

ANSI/AAMI/ISO 11140-6:2024

Sterilization of health care products—Chemical indicators—Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers

AAMI
Advancing Safety in Health Technology

Sterilization of health care products—Chemical indicators—Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers

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AAMI

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Abstract: This document specifies the performance requirements and test methods for hollow devices and porous devices as well as the chemical indicators and biological indicators that are utilized within these devices for testing a specific steam penetration performance of type B cycles and some type S cycles of small steam sterilizers according to EN 13060.

Keywords: chemical indicators, process challenge devices, small steam sterilizers

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Committee representation

Association for the Advancement of Medical Instrumentation

Chemical Indicators Working Group

The adoption of ISO 11140-6:2022 as an American National Standard was initiated by the AAMI Chemical Indicators Working Group (AAMI ST-WG06). AAMI ST-WG06 provides input to the Sterilization Standards Committee (AAMI ST), which is the responsible group for providing the U.S. input to the relevant group in ISO/TC 198. U.S. representatives from AAMI ST-WG06 and the Technical Advisory Group (TAG) played an active part in developing the ISO document.

At the time this document was published, the **AAMI Chemical Indicators Working Group** has the following members:

Cochairs:
Jaime Terran
Anthony Piotrkowski

Members:
Anas Aljabo, SteriLabs Canada Inc.
Richard Bancroft, STERIS Corporation | Healthcare
Jennifer Bangle, 3M Health Care
Gillian Cairns, BSI Healthcare
Kenneth Campbell, Kenneth Campbell Person
Nancy Chobin, Nancy Chobin (Individual)
Michael Christensen, Abbott Laboratories
Dorin Cioraca, SciCan Ltd
Fiona Collins, American Dental Association (ADA)
Jacqueline A. Daley, Providence St Joseph Health System
Kimbrell Darnell, Becton Dickinson & Company
Kris Fischbach, Medtronic Inc Campus
Gloria H. Frost, Cardinal Health
Benjamin Fryer, Advanced Sterilization Products (ASP)
Susan G. Klacik, HSPA
Ann M. Kobayashi, Ann M. Kobayashi (Individual)
Rhashamekia Law, Rhashamekia Law (Individual)
Viktoriya Lusignan, Getinge USA
Albert (Ted) E. May, Andersen Products Inc
John L. Mazzilli, Saddleback Memorial Medical Center
Josha McCarthy, Sierra Nevada Memorial Hospital
Clarence Murray III, FDA/CDRH
Frank E. Myers, UC San Diego Health, Hillcrest
Susumu Nozawa, Siemens Healthineers
Kimberly Patton, Performance Review Institute MedAccred
Jason Pope, Sotera Health LLC
Scott Prochaska, LA-CO Industries Inc
Hannah Robinson, Mesa Laboratories Biological Indicator Division- Bozeman Facility
Matthew Roybal, Johnson & Johnson
Angela Salmen, Angela Salmen (Individual)
Jade Roger Schiesser, Boston Scientific Corporation
Andrew Sharavara, Propper Manufacturing Co Inc
Gary J. Socola, HIGHPOWER Validation Testing & Lab Services Inc
Julie TerWee, Pfizer Parenteral Center of Excellence
Jania Torreblanca, Michigan Medicine (University of Michigan Health System)
Melissa Vargas, Christiana Care Health Services
Deanna Webster, Bausch & Lomb Inc

Dean Wellman, Midmark Corporation
Nicole Williams, Sterilucent Inc
Robin Woodland, Robin Woodland (Individual)
Jarl Yeager, Powder River Medical Resources
Roberto Zumbado, Philips

Alternates:
Myrelis Aguilar, Johnson & Johnson
Kristy L. Azzolin, American Dental Association (ADA)
Amanda Bertalotto, Amanda Bertalotto (Individual)
Tonia J. Bevers, Abbott Laboratories
Angela Helene Brightwell, Medtronic Inc Campus
Dania Cortes, Sotera Health LLC
Christophe Deneux, Becton Dickinson & Company
Sreekanth Gutala, FDA/CDRH
Kelly Holt, Getinge USA
Jim Latham, LexaMed Ltd
Kelly Makimoto, SciCan Ltd
Kurt McCauley, Mesa Laboratories Biological Indicator Division- Bozeman Facility
Uyen Nguyen, Advanced Sterilization Products (ASP)
Katia Petrov, Cardinal Health
Anthony M. Piotrkowski, STERIS Corporation | Healthcare
Michael J. Schoene, Bausch & Lomb Inc
Robert Snirch, BSI Healthcare
Jamie S. Terran, Propper Manufacturing Co Inc
Ileana M. Toro-Lozada, Avanos Medical
Janelle Trboyevich, Boston Scientific Corporation
Donald P. Tumminelli, HIGHPOWER Validation Testing & Lab Services Inc
Craig A. Wallace, 3M Health Care
Jill A. Warren, Siemens Healthineers
Jon Wood, HSPA
Daryl Woodman, Andersen Products 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.

Background of ANSI/AAMI adoption of ISO 11140-6:2022

As indicated in the foreword to the main body of this document (page vii), 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 specify the performance requirements and test methods for hollow devices and porous devices as well as the chemical indicators and biological indicators that are utilized within these devices for testing a specific steam penetration performance of type B cycles and some type S cycles of small steam sterilizers according to EN 13060.

U.S. participation in ISO/TC 198 is organized through the U.S. Technical Advisory Group, AAMI ST, 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 chemical indicators. Upon review of ISO 11140-6:2018, the U.S. TAG to ISO/TC 198 and the AAMI Chemical Indicators Working Group decided to adopt it verbatim, as a first edition of ANSI/AAMI/ISO 11140-6:2024.

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 vii, this American National Standard is identical to ISO 11140-6:2022.

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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers and associated equipment for processing of medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 11140 series can be found on the ISO website.

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

This document includes a description of both hollow and porous process challenge devices (PCDs) and their performance requirements, along with methods by which an alternative PCD can be shown to have equivalent performance to that of the reference PCD. Small sterilizers unable to accommodate a sterilization module [rectangular parallelepiped of dimensions 300 mm (height) × 600 mm (length) × 300 mm (width)] cannot be tested using the tests described in EN 285 for large sterilizers for wrapped goods and porous loads because

— the chamber size of a small steam sterilizer according to EN 13060 is unable to accommodate the standard test pack from EN 285, and

— the efficacy of the tests is impaired when the test pack occupies a large proportion of the chamber volume (>20 % chamber volume).

Indicators described in this document are intended to be used in conjunction with appropriate PCDs to show penetration of steam into the PCD. The reference indicator systems and alternative indicator systems pose specified challenges to air removal and steam penetration.

The devices described in this document are intended for use only in small steam sterilizers conforming to EN 13060 to monitor steam penetration in type B cycles and some type S cycles.

NOTE Even though the hollow load was originally designed as a type test in EN 867-5 (withdrawn standard replaced by this document) to test the performance of small steam sterilizers conforming with EN 13060, the same test is also used in other standards, for example, EN 285.

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WARNING — The use of this document can involve hazardous materials, operations and equipment. It is the responsibility of the user of this document to establish appropriate safety and health practices and determine the applicability of any other restrictions prior to use.

1 Scope

This document specifies the performance requirements and test methods for hollow devices and porous devices as well as the chemical indicators and biological indicators that are utilized within these devices for testing a specific steam penetration performance of type B cycles and some type S cycles of small steam sterilizers according to EN 13060.

NOTE The hollow and porous devices described in this document are not intended for use as surrogate devices for hollow and porous medical devices used in health care facilities.

a) Chemical indicators used with a porous device specified in this document are designed to demonstrate the adequacy of steam penetration into a porous device in small steam sterilizers (see EN 13060).

   This document specifies the requirements for:

   — a reference porous device (RPD) as a reference device by which alternative porous indicator systems (APISs) can be shown to be equivalent in performance according to this document, i.e. a textile test pack in which steam penetration is judged by thermometric means;

   — an alternative porous chemical indicator system equivalent in performance to the RPD, i.e. an APIS, usually commercially manufactured, of any design.

b) Chemical indicators used with a hollow load device specified in this document are designed to demonstrate the adequacy of steam penetration into a narrow lumen (previously known as hollow load A) in small steam sterilizers (see EN 13060).

   This document specifies the requirements for:

   — a reference hollow device (RHD) used as a reference device in this document, i.e. a lumened device with attached capsule in which steam penetration is judged by inactivation or survival of a specified biological indicator;

   — an alternative hollow device:

      — employing the same specific test load as defined for the RHD and a chemical indicator designed specifically for use in the reference hollow test load, i.e. a lumened device with an attached capsule in which steam penetration is judged by visual examination of a chemical indicator;