American National Standard

# ANSI/AAMI/ ISO 11140-3: 2007/(R)2015

Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test

AAMI
Advancing Safety in Healthcare Technology

# The Objectives and Uses of AAMI Standards and Recommended Practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

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.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards health care professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

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All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

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.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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# Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test

Approved 20 March 2007 by
**Association for the Advancement of Medical Instrumentation**

Approved 12 April 2007 and reaffirmed 7 August 2012 and 10 November 2015 by
**American National Standards Institute, Inc.**

**Abstract:** Specifies the requirements for chemical indicators to be used in the steam penetration test for steam sterilizers for wrapped goods, e.g. instruments and porous materials. The indicator for this purpose is a Class 2 indicator as described in ISO 11140-1.

**Keywords:** apparatus, indicator, labeling, packaging, performance, system, quality

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## Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

| International designation | U.S. designation | Equivalency |
|---|---|---|
| IEC 60601-1:2005 | ANSI/AAMI ES60601-1:2005 | Major technical variations |
| IEC 60601-1-2:2007 | ANSI/AAMI/IEC 60601-1-2:2007 | Identical |
| IEC 60601-2-2:2006 | ANSI/AAMI/IEC 60601-2-2:2006 | Identical |
| IEC 60601-2-4:2002 | ANSI/AAMI DF80:2003 | Major technical variations |
| IEC 60601-2-19:1990 and Amendment 1:1996 | ANSI/AAMI II36:2004 | Major technical variations |
| IEC 60601-2-20:1990 and Amendment 1:1996 | ANSI/AAMI II51:2004 | Major technical variations |
| IEC 60601-2-21:1994 and Amendment 1:1996 | ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts) | Identical |
| IEC 60601-2-24:1998 | ANSI/AAMI ID26:2004 | Major technical variations |
| IEC 60601-2-50:2001 | ANSI/AAMI/IEC 60601-2-50:2006 | Identical |
| IEC/TR 60878:2003 | ANSI/AAMI/IEC TIR60878:2003 | Identical |
| IEC/TR 62296:2003 | ANSI/AAMI/IEC TIR62296:2003 | Identical |
| IEC 62304:2006 | ANSI/AAMI/IEC 62304:2006 | Identical |
| IEC/TR 62348:2006 | ANSI/AAMI/IEC TIR62348:2006 | Identical |
| ISO 5840:2005 | ANSI/AAMI/ISO 5840:2005 | Identical |
| ISO 7198:1998 | ANSI/AAMI/ISO 7198:1998/2001/(R)2004 | Identical |
| ISO 7199:1996 | ANSI/AAMI/ISO 7199:1996/(R)2002 | Identical |
| ISO 8637:2004 | ANSI/AAMI RD16:2007 | Major technical variations |
| ISO 8638:2004 | ANSI/AAMI RD17:2007 | Major technical variations |
| ISO 10993-1:2003 | ANSI/AAMI/ISO 10993-1:2003 | Identical |
| ISO 10993-2:2006 | ANSI/AAMI/ISO 10993-2:2006 | Identical |
| ISO 10993-3:2003 | ANSI/AAMI/ISO 10993-3:2003 | Identical |
| ISO 10993-4:2002 and Amendment 1:2006 | ANSI/AAMI/ISO 10993-4:2002 and Amendment 1:2006 | Identical |
| ISO 10993-5:1999 | ANSI/AAMI/ISO 10993-5:1999 | Identical |
| ISO 10993-6:2007 | ANSI/AAMI/ISO 10993-6:2007 | Identical |
| ISO 10993-7:1995 | ANSI/AAMI/ISO 10993-7:1995/(R)2001 | Identical |
| ISO 10993-9:1999 | ANSI/AAMI/ISO 10993-9:1999/(R)2005 | Identical |
| ISO 10993-10:2002 and Amendment 1:2006 | ANSI/AAMI BE78:2002<br>ANSI/AAMI BE78:2002/A1:2006 | Minor technical variations<br>Identical |
| ISO 10993-11:2006 | ANSI/AAMI/ISO 10993-11:2006 | Identical |
| ISO 10993-12:2002 | ANSI/AAMI/ISO 10993-12:2002 | Identical |
| ISO 10993-13:1998 | ANSI/AAMI/ISO 10993-13:1999/(R)2004 | Identical |
| ISO 10993-14:2001 | ANSI/AAMI/ISO 10993-14:2001/(R)2006 | Identical |
| ISO 10993-15:2000 | ANSI/AAMI/ISO 10993-15:2000/(R)2006 | Identical |

| International designation | U.S. designation | Equivalency |
|---|---|---|
| ISO 10993-16:1997 | ANSI/AAMI/ISO 10993-16:1997/(R)2003 | Identical |
| ISO 10993-17:2002 | ANSI/AAMI/ISO 10993-17:2002 | Identical |
| ISO 10993-18:2005 | ANSI/AAMI BE83:2006 | Major technical variations |
| ISO/TS 10993-19:2006 | ANSI/AAMI/ISO TIR10993-19:2006 | Identical |
| ISO/TS 10993-20:2006 | ANSI/AAMI/ISO TIR10993-20:2006 | Identical |
| ISO 11135:1994 | ANSI/AAMI/ISO 11135:1994 | Identical |
| ISO 11137-1:2006 | ANSI/AAMI/ISO 11137-1:2006 | Identical |
| ISO 11137-2:2006 (2006-08-01 corrected version) | ANSI/AAMI/ISO 11137-2:2006 | Identical |
| ISO 11137-3:2006 | ANSI/AAMI/ISO 11137-3:2006 | Identical |
| ISO 11138-1: 2006 | ANSI/AAMI/ISO 11138-1:2006 | Identical |
| ISO 11138-2: 2006 | ANSI/AAMI/ISO 11138-2:2006 | Identical |
| ISO 11138-3: 2006 | ANSI/AAMI/ISO 11138-3:2006 | Identical |
| ISO 11138-4: 2006 | ANSI/AAMI/ISO 11138-4:2006 | Identical |
| ISO 11138-5: 2006 | ANSI/AAMI/ISO 11138-5:2006 | Identical |
| ISO/TS 11139:2006 | ANSI/AAMI/ISO 11139:2006 | Identical |
| ISO 11140-1:2005 | ANSI/AAMI/ISO 11140-1:2005 | Identical |
| ISO 11140-3:2007 | ANSI/AAMI/ISO 11140-3:2007 | Identical |
| ISO 11140-4:2007 | ANSI/AAMI/ISO 11140-4:2007 | Identical |
| ISO 11140-5:2007 | ANSI/AAMI/ISO 11140-5:2007 | Identical |
| ISO 11607-1:2006 | ANSI/AAMI/ISO 11607-1:2006 | Identical |
| ISO 11607-2:2006 | ANSI/AAMI/ISO 11607-2:2006 | Identical |
| ISO 11737-1: 2006 | ANSI/AAMI/ISO 11737-1:2006 | Identical |
| ISO 11737-2:1998 | ANSI/AAMI/ISO 11737-2:1998 | Identical |
| ISO 11737-3:2004 | ANSI/AAMI/ISO 11737-3:2004 | Identical |
| ISO 13485:2003 | ANSI/AAMI/ISO 13485:2003 | Identical |
| ISO 14155-1:2003 | ANSI/AAMI/ISO 14155-1:2003 | Identical |
| ISO 14155-2:2003 | ANSI/AAMI/ISO 14155-2:2003 | Identical |
| ISO 14160:1998 | ANSI/AAMI/ISO 14160:1998 | Identical |
| ISO 14161:2000 | ANSI/AAMI/ISO 14161:2000 | Identical |
| ISO 14937:2000 | ANSI/AAMI/ISO 14937:2000 | Identical |
| ISO/TR 14969:2004 | ANSI/AAMI/ISO TIR14969:2004 | Identical |
| ISO 14971:2007 | ANSI/AAMI/ISO 14971:2007 | Identical |
| ISO 15223-1:2007 | ANSI/AAMI/ISO 15223-1:2007 | Identical |
| ISO 15225:2000 and A1:2004 | ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006 | Identical |
| ISO 15674:2001 | ANSI/AAMI/ISO 15674:2001 | Identical |
| ISO 15675:2001 | ANSI/AAMI/ISO 15675:2001 | Identical |
| ISO 15882:2003 | ANSI/AAMI/ISO 15882:2003 | Identical |
| ISO/TR 16142:2006 | ANSI/AAMI/ISO TIR16142:2006 | Identical |
| ISO 17664:2004 | ANSI/AAMI ST81:2004 | Major technical variations |
| ISO 17665-1:2006 | ANSI/AAMI/ISO 17665-1:2006 | Identical |
| ISO 18472:2006 | ANSI/AAMI/ISO 18472:2006 | Identical |
| ISO/TS 19218:2005 | ANSI/AAMI/ISO 19218:2005 | Identical |
| ISO 25539-1:2003 and A1:2005 | ANSI/AAMI/ISO 25539-1:2003 and A1:2005 | Identical |

## Committee representation

**Association for the Advancement of Medical Instrumentation**
**Chemical Indicators Working Group**

The adoption of ISO 11140-3:2007 as an American National Standard was initiated by the AAMI Chemical Indicators Working Group of the AAMI Sterilization Standards Committee. The AAMI Chemical Indicators Working Group also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Sterilization (ISO). U.S. representatives from the AAMI Chemical Indicators Working Group (U.S. Sub-TAG for ISO/TC 198/WG 6) played an active part in developing the ISO standard.

At the time this document was published, the **AAMI Chemical Indicators 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 AAMI adoption of ISO 11140-3:2007

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 Technical Committee 198, *Sterilization of health care products*, to fill a need to specify requirements for chemical indicators to be used in the steam penetration test for steam sterilizers for wrapped goods, e.g. instruments and porous materials.

U.S. participation in this ISO TC is organized through the U.S. Technical Advisory Group for ISO/TC 198, administered by the Association for the Advancement of Medical Instrumentation (AAMI). The U.S. TAG for ISO/TC 198 supports the requirements provided in this document.

The U.S. adoption of ANSI/AAMI/ISO 11140-3:2007 was approved by the American National Standards Institute (ANSI) on 12 April 2007. The AAMI Chemical Indicators Working Group (U.S. Sub-TAG for ISO/TC 198/WG 6, Chemical indicators) initiated the U.S. adoption of ISO 11140-3-2007.

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.

AAMI (and ANSI) have adopted other ISO standards. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI which gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

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 come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—Beginning with the foreword on page ix, this American National Standard is identical to ISO 11140-3:2007.

 

## 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 11140-3 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11140-3:2000) which has been technically revised.

ISO 11140 consists of the following parts, under the general title *Sterilization of health care products — Chemical indicators*:

— *Part 1: General requirements*

— *Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test*

— *Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration*

— *Part 5: Class 2 indicators for Bowie and Dick-type air removal tests*

# Introduction

The Bowie and Dick test is a performance test for steam sterilizers for wrapped goods and porous loads. As such it is performed during the demonstration of conformance of steam sterilizers to EN 285 and as a routine test of performance in ISO 17665-1. The test method is described in EN 285.

A failure of the Bowie and Dick test is symptomatic of a number of potential problems with the sterilizer that could compromise the uniform sterilization of a load to be processed. This failure is not conclusive proof that the fault in the sterilizer is due to air retention, air leakage or non-condensable gases and it can be necessary to investigate other causes of failure.

The Bowie and Dick test was conceived as a test for successful air removal from high-vacuum porous-load sterilizers used in the sterilization of health care products [1]. A successful Bowie and Dick test indicates rapid and even penetration of steam into the test pack. The presence of air within the pack, due to an inefficient air removal stage, an air leak during this stage or non-condensable gases in the steam supply, is a circumstance which can lead to failure of the test. The result of the test may also be affected by other factors which inhibit steam penetration. The test does not necessarily demonstrate either achievement of the required temperature or maintenance of that temperature for the required time to achieve sterilization.

A test pack for the Bowie and Dick test consists of two components:

a) a small standardized test load;

b) a chemical indicator to detect the presence of steam.

The Bowie and Dick test as originally described [1] utilized huckaback towels as the material for the test load. The test as described in EN 285 uses cotton sheets for this purpose.

Because a range of different tests in different countries has historically been termed the Bowie and Dick test, the term “Bowie and Dick-type test” is used in this part of ISO 11140.

 

# Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test

## 1 Scope

This part of ISO 11140 specifies the requirements for chemical indicators to be used in the steam penetration test for steam sterilizers for wrapped goods, e.g. instruments and porous materials. The indicator for this purpose is a Class 2 indicator as described in ISO 11140-1.

Indicators complying with this part of ISO 11140 are intended for use in combination with the standard test pack as described in EN 285. This part of ISO 11140 does not consider the performance of the standard test pack, but does specify the performance of the indicator systems.

## 2 Normative references

The following referenced documents are indispensable for the application 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 5-1, *Photography — Density measurements — Part 1: Terms, symbols, and notations*

ISO 5-3, *Photography — Density measurements — Part 3: Spectral conditions*

ISO 5-4:1995, *Photography — Density measurements — Part 4: Geometric conditions for reflection density*

ISO 187:1990, *Paper, board, and pulps — Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples*

ISO 2248, *Packaging — Complete, filled transport packages — Vertical impact test by dropping*

ISO 5457, *Technical product documentation — Sizes and layout of drawing sheets*

ISO 5636-3, *Paper and board — Determination of air permeance (medium range) — Part 3: Bendtsen method*

ISO 11140-1:2005, *Sterilization of health care products — Chemical indicators — Part 1: General requirements*

ISO/CIE 10526:1999, *CIE standard illuminants for colorimetry*

EN 285:2006, *Sterilization — Steam sterilizers — Large sterilizers*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11140-1 apply.

## 4 General requirements

**4.1** The requirements of ISO 11140-1 apply.

**4.2** Test samples shall be conditioned in accordance with ISO 187 prior to testing for performance.

## 5 Indicator system format

The indicator system format shall meet the following requirements.

a) It shall consist of indicator reagent uniformly distributed on a substrate to cover not less than 30 % of the surface area of the substrate. The distance between adjacent areas of indicator reagent shall not exceed 20 mm. The pattern of indicator reagent distribution should permit easy comparison of the color change at the margin with the color change in the central region.

b) It shall have an air porosity not less than 1.7 µm/(Pa·s) when tested in accordance with ISO 5636-3 at an air pressure of 1.47 kPa.

c) It shall have sufficient strength to withstand steam sterilization.

   Compliance shall be tested in accordance with Annex A.

d) It shall have a substrate of a color that is uniform to visual observation.

e) It shall have a difference in reflectance density of not less than 0.3 between the substrate and either the changed indicator or the unchanged indicator as specified by the manufacturer.

   Compliance shall be tested in accordance with Annex B.

f) It shall permit writing in permanent ink to be made legibly on both processed and unprocessed materials. Markings made before processing shall be legible after processing.

g) It shall be of size A4 in accordance with ISO 5457.

## 6 Performance requirements

**6.1** The indicator shall meet the following requirements.

a) It shall show a uniform color change complying with 5 e) after exposure to dry saturated steam at 134 $(^{+1.5}_{0})$ °C for 3.5 min ± 5 s or after exposure to dry saturated steam at 121 $(^{+1.5}_{0})$ °C for 15 min ± 5 s or both.

   Compliance shall be tested in accordance with Annex C.