Technical Information Report

AAMI TIR31:2008

Process challenge devices/test packs for use in health care facilities

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AAMI Technical Information Report

AAMI TIR31:2008
(Revision of AAMI TIR31:2003)

Process challenge devices/test packs for use in health care facilities

Approved 20 November 2008 by
Association for the Advancement of Medical Instrumentation

Abstract: This technical information report provides information that will assist health care facilities in the selection and use of process challenge devices.

Keywords: biological indicator, chemical indicator, dry heat sterilization, ethylene oxide sterilization, process challenge device, steam sterilization, table-top steam sterilization, vaporized hydrogen peroxide sterilization

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Contents

Page

Glossary of equivalent standards v

Committee representation vii

Foreword x

Introduction xi

1 Scope 1

2 Normative references 1

3 Definitions and abbreviations 2

4 Historical development of PCDs 3

5 Selection and use of process challenge devices and test packs 3

6 Process challenge devices 5

6.1 PCDs for steam sterilization 5
6.1.1 Introduction 5
6.1.2 Description 8
6.1.3 Reference BI PCDs—AAMI challenge and routine BI PCDs 8
6.1.4 Types of BI PCDs 8
6.1.5 Recommended practices—Application and frequency of use 9
6.2 BI PCDs for ethylene oxide sterilization 9
6.2.1 Introduction 9
6.2.2 Description 9
6.2.3 Reference BI PCDs 10
6.2.4 Types of BI PCDs 10
6.2.5 Recommended practices—Application and frequency of use 10
6.3 BI PCDs for table-top dry heat sterilization 11
6.3.1 Introduction 11
6.3.2 Description 11
6.3.3 Reference BI PCDs 11
6.3.4 Types of BI PCDs 11
6.3.5 Recommended practices—Application and frequency of use 11
6.4 BI PCDs for hydrogen peroxide sterilization 11
6.4.1 Introduction 11
6.4.2 Description 12
6.4.3 Reference BI PCDs 12
6.4.4 Types of BI PCDs 12
6.4.5 Recommended practices—Application and frequency of use 12
6.5 BI PCDs for ozone sterilization process 12
6.5.1 Introduction 12
6.5.2 Description 12
6.5.3 Reference BI PCDs 13
6.5.4 Types of BI PCDs 13
6.5.5 Recommended practices—Application and frequency of use 13

Annexes

A Regulatory perspective 14

B The Bowie-Dick test pack 15

C International perspectives on PCDs 19

D Development and qualification of the 16-towel PCD used for steam sterilization 21

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E Development and qualification of the routine PCD used for ethylene oxide sterilization 30

F Historical perspective 32

G Bibliography 34

Tables

Table 1: Examples of manufacturer devices' listed steam cycles that require extended cycle times 7

Table B.1—Comparison of ANSI/AAMI/ISO 11140 standards 17

Table D.1—16-towel pack survey 22

Table D.2—BI results from 250 °F (121 °C) gravity cycle 22

Table D.3—BI results from 270 °F (132 °C) deep-vacuum cycle 23

Table D.4—BI results from 270 ºF (132 ºC) pulsing vacuum cycle 23

Table D.5—Comparison of the 16-towel pack and the 12 × 12 × 20 inch–pack by most probable number and sterility assessment of spore strips in a 250 °F (121 °C) gravity cycle 24

Table D.6—Fraction-negative results in a 250 °F (121 °C) gravity cycle 25

Table D.7—BI results from a 250 °F (121 °C) steam-flush pressure-pulse cycle 25

Table D.8—BI results from a 270 °F (132 °C) steam-flush pressure-pulse cycle 26

Table E.1—Mean kill time (minutes) and standard deviation for BIs inside the PCD versus outside the PCD 31

Figures

Figure D.1—Temperature profiles performed at two different laboratories of 12 × 12 × 20–inch PCDs in a 250 °F (121 °C) gravity cycle 26

Figure D.2—Temperature profiles for huck and absorbent 16-towel packs in a 250 °F (121 °C) gravity cycle 27

Figure D.3—Average temperature profile for the 16-towel pack in a 250 °F (121 °C) gravity cycle performed at three different laboratories 28

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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 A1:1996	ANSI/AAMI II36:2004	Major technical variations
IEC 60601-2-20:1990 and A1:1996	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 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2001	ANSI/AAMI/IEC 60601-2-50:2006	Identical
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	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 A1:2006	ANSI/AAMI/ISO 10993-4:2002 and A1:2006	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008	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/(R)2008 ANSI/AAMI BE78:2002/A1:2006/(R)2008	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	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
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	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 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical

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ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	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 13408-1:2008	ANSI/AAMI/ISO 13408-1:2008	Identical
ISO 13408-2:2003	ANSI/AAMI/ISO 13408-2:2003	Identical
ISO 13408-3:2006	ANSI/AAMI/ISO 13408-3:2006	Identical
ISO 13408-4:2005	ANSI/AAMI/ISO 13408-4:2005	Identical
ISO 13408-5:2006	ANSI/AAMI/ISO 13408-5:2006	Identical
ISO 13408-6:2006	ANSI/AAMI/ISO 13408-6:2006	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003/(R)2008	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003/(R)2008	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998/(R)2008	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 and A1:2008	ANSI/AAMI/ISO 15223-1:2007 and A1:2008	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 15882:2008	ANSI/AAMI/ISO 15882:2008	Identical
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	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 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003 and A1:2005	Identical
ISO 25539-2:2008	ANSI/AAMI/ISO 25539-2:2008	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical

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Committee representation

Association for the Advancement of Medical Instrumentation

Sterilization Standards Committee

This technical information report was developed by the AAMI Process Challenge Device Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the TIR does not necessarily imply that all working group members voted for its approval.

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Foreword

This technical information report was developed by the AAMI Process Challenge Device Working Group under the auspices of the AAMI Sterilization Standards Committee. The objective is to provide technical information that will assist health care facilities in the selection and use of process challenge devices.

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

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Introduction

This AAMI technical information report (TIR) is a revision of the AAMI TIR31:2003 and is intended to provide technical information that will assist health care facilities in the selection and use of process challenge devices (PCDs). The PCD is intended to mimic the challenge presented by the product and packaging that is used in a sterilization process. It provides a repeatable challenge to the sterilization process by representing the worst-case conditions for the sterilizing agent to penetrate.

The current version of TIR31, as changed from the 2003 version, contains new sections on extended cycles and PCDs for the ozone sterilization process currently available to the health care user. Also, the hydrogen peroxide sterilization section has been updated.

The design choice (or selection) of a PCD for a particular application depends on the product being sterilized and the sterilization parameters required for the sterilization process. The PCD selected by the user should provide a challenge equal to or greater than the product and packaging that is the most difficult to sterilize. The PCD is designed to constitute a defined resistance to a sterilization process and is used to assess performance of the process. The PCD should be placed in the location deemed to be the most difficult for the sterilizing agent to penetrate. A PCD may contain a biological indicator, a chemical indicator, or a combination of both. The overall challenge of the PCD is a result of the combination of the PCD structure and the indicator. The indicator should not interfere with the function of the PCD. Typically, a biological indicator (BI) containing viable microorganisms is included in the PCD, so that sterilization can be demonstrated in a quantitative manner. Such PCDs are also referred to as *BI PCDs*.

The routine use of PCDs is important for monitoring of sterilization processes used in health care facilities. It is an integral part of a quality control program.

The information in this PCD TIR encompasses both instructions for the user in constructing an appropriate PCD and the proper use of PCDs for each sterilization process generally used in health care facilities. Commercially prepared PCDs are available from manufacturers. This TIR also provides the user with information on selecting a commercially available PCD and questions the user may want to ask the PCD manufacturer on the proper use of its PCD.

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Process challenge devices/test packs for use in health care facilities

1 Scope

This technical information report (TIR) is intended to provide technical information that will assist health care facilities in the selection and use of process challenge devices (PCDs). It is to serve as a resource that health care personnel can use when directing questions to the PCD manufacturer about the suitability, effectiveness, and safety of a specific PCD. Currently, there are no standards that define the performance of these medical devices or provide methods to evaluate them.

This TIR describes user-assembled PCDs that originally used biological indicators (BIs) to evaluate the ability of a sterilization process to sterilize a known challenge. It also describes user-assembled PCDs that use chemical indicators (CIs) to conduct the Bowie-Dick test for air removal/steam penetration in dynamic-air-removal steam sterilization processes.

Preassembled commercial PCDs for sterilization processes that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) can be used as alternatives to the original user-assembled PCDs.

PCDs used in liquid chemical sterilization processes are excluded from the scope of this TIR.

2 Normative references

The following normative documents contain provisions that, through reference in this text, constitute provisions of this technical information report. For dated references, subsequent amendments to or revisions of any of these publications do not apply. However, parties to agreements based on this TIR are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. The Association for the Advancement of Medical Instrumentation maintains a register of currently valid AAMI technical documents.

2.1 Association for the Advancement of Medical Instrumentation. *Chemical sterilization and high-level disinfection in health care facilities*. ANSI/AAMI ST58:2005. Arlington (VA): AAMI, 2005. American National Standard.

2.2 Association for the Advancement of Medical Instrumentation. *Comprehensive guide to steam sterilization and sterility assurance in heath care facilities.* ANSI/AAMI ST79:2006. Arlington (VA): AAMI, 2006. American National Standard (including amendment A1:2008).

2.3 Association for the Advancement of Medical Instrumentation. *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.* AAMI TIR12:2004. Arlington (VA): AAMI, 2004.

2.4 Association for the Advancement of Medical Instrumentation. *Dry heat (heated air) sterilizers.* ANSI/AAMI ST50:2004. Arlington (VA): AAMI, 2004. American National Standard.

2.5 Association for the Advancement of Medical Instrumentation. *Ethylene oxide sterilization in health care facilities: Safety and effectiveness.* ANSI/AAMI ST41:2008. Arlington (VA): AAMI, 2008. American National Standard.

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3 Definitions and abbreviations

For the purposes of this AAMI technical information report, the following definitions and abbreviations apply.

3.1 biological indicator (BI): Test system containing viable microorganisms providing a defined resistance to a specified sterilization process (ANSI/AAMI/ISO TIR11139:2006).

3.2 Bowie-Dick test: Diagnostic test of a dynamic-air-removal steam sterilizer's ability to remove air from the chamber and prevent air entrainment.

3.3 challenge test pack: Pack used in qualification, installation, and routine quality assurance testing of hospital sterilizers.

3.4 chemical indicator (CI): Test system that reveals a change in one or more predefined process variables based on a chemical or physical change resulting from exposure to a process (ANSI/AAMI/ISO TIR11139:2006).

3.5 *D* value, D_{10} value: Time or dose required to achieve inactivation of 90 % of a population of the test microorganism under stated conditions (ANSI/AAMI/ISO TIR11139:2006).

3.6 entrainment: Collecting or transporting of solid particles or a second fluid or vapor by the flow of the primary fluid or vapor at high velocity.

3.7 extended cycle: Steam sterilization cycle with longer exposure times, dry times, or both than those commonly provided by the sterilizer manufacturers (e.g., whereas a normal cycle might be 4 minutes at 270 °F, an extended cycle could be 15 minutes at 270 °F).

3.8 heat sink: Heat-absorbent materials; a mass that readily absorbs heat.

3.9 medical device: Instrument, apparatus, material, or other article, whether used alone or in combination, including the software necessary for its proper application, that is intended by the manufacturer to be used for human beings for the purpose of

a) diagnosis, prevention, monitoring, treatment, or alleviation of disease;

b) diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or handicap;

c) investigation, replacement, or modification of the anatomy or of a physiological process; or

d) control of conception

and that does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means but may be assisted in its function by such means.

3.10 process challenge device (PCD): Item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process (ANSI/AAMI/ISO TIR11139:2006).

3.11 routine PCD: Pack used for routine monitoring of hospital sterilizers.

3.12 sterility assurance level (SAL): Probability of a viable microorganism being present on a product unit after sterilization.

NOTE 1—SAL is normally expressed as $10^{-[n]}$.

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