Process challenge devices/test packs for use in health care facilities
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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
AAMI Technical Information Report

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

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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.

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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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**NOTE**—Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.
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.
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.
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.

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