Technical Information Report

AAMI TIR12:2004

Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

AAMI
ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION

AAMI Technical Information Report

AAMI TIR12:2004
(Revision of AAMI TIR12:1994)

Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

Approved 23 December 2004
Association for the Advancement of Medical Instrumentation

Abstract: This technical information report (TIR) covers design considerations that medical device manufacturers should take into account to help ensure that their products can be safely and effectively reprocessed. It also provides information on decontamination, disinfection, and sterilization processes commonly used in health care facilities so that manufacturers can validate reprocessing procedures that can be recommended to and performed adequately in health care facilities. Labeling recommendations and information on applicable regulations are also provided in the TIR, as well as a bibliography and other informative annexes.

Keywords: cleaning, decontamination, disinfection, instructions for use, medical device design, 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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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 60601-1-2:2001 and Amendment 1:2004	ANSI/AAMI/IEC 60601-1-2:2001 and Amendment 1:2004	Identical
IEC 60601-2-04:2002	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 TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	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 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002	ANSI/AAMI/ISO 10993-4:2002	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:2002	ANSI/AAMI BE78:2002	Minor technical variations
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
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	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical

International designation	U.S. designation	Equivalency
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995 and Amdt 1:2001	ANSI/AAMI/ISO 11137:1994 and A1:2002	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO TS 11139:2001	ANSI/AAMI/ISO 11139:2002	Identical
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations
ISO 11140-5:2000	ANSI/AAMI ST66:1999	Major technical variations
ISO 11607:2003	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 11737-3:2004	ANSI/AAMI/ISO 11737-3:2004	Identical
ISO TR 13409:1996	AAMI/ISO TIR13409:1996	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	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 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	Identical
ISO 15223:2000, A1:2002, and A2:2004	ANSI/AAMI/ISO 15223:2000, A1:2001, and A2:2004	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000 and A1:2004	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO TR 15844:1998	AAMI/ISO TIR15844:1998	Identical
ISO 15882:2003	ANSI/AAMI/ISO 15882:2003	Identical
ISO TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical
ISO 17864:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 25539-1:2003	ANSI/AAMI/ISO 25539-1:2003	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Instructions for Reusable Device Reprocessing Working Group

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

At the time this document was published, the **AAMI Instructions for Reusable Device Reprocessing Working Group** had the following members:

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Foreword

This AAMI Technical Information Report (TIR) was developed by the AAMI Instructions for Device Reprocessing Working Group under the auspices of the AAMI Sterilization Standards Committee.

The first edition of this TIR was published in 1994. This edition, the second, provides up-to-date information on cleaning processes, cleaning verification, and currently available sterilization technologies. Also, the text and reference material have been generally updated for currency.

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

Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers

Introduction

Scientific advances in diagnostic and therapeutic medicine have led to the development of new and sophisticated reusable medical devices and instruments for use by health care practitioners. These devices vary in size, complexity, fragility, immersibility, and sensitivity to cleaning, disinfecting, and sterilizing agents and processes. Manufacturers of reusable medical devices have the responsibility to support product label claims of reusability by providing complete and comprehensive written instructions for the handling, cleaning, disinfection, testing, packaging, sterilization, and, if applicable, aeration of their products. Manufacturers also have the responsibility to conduct and document any testing necessary to validate the suitability of these instructions. Manufacturers have these obligations under U.S. Food and Drug Administration (FDA) labeling regulations (21 CFR 801). Detailed FDA recommendations are provided in the FDA guidance document, *Labeling reusable medical devices for reprocessing in health care facilities: FDA reviewer guidance* (FDA, 1996; http://www.fda.gov/cdrh/ode/198.pdf).

Health care personnel have the responsibility to obtain and review manufacturers' data and recommendations and to ensure that they have the necessary resources to follow manufacturers' instructions thoroughly.

This TIR is intended to assist medical device manufacturers in the design, testing, and labeling of devices intended for reuse and reprocessing in health care facilities. Device manufacturers may wish to reassess the labeling of existing products in light of the recommendations of this TIR.

Secondarily, this TIR can also be a resource in identifying the questions health care professionals should ask manufacturers when considering a product for purchase or when devising a reprocessing protocol for a product already being used. See also AAMI TIR7.

NOTE—At this writing, AAMI TIR7 was under revision. A combined revision of AAMI TIR7 and ANSI/AAMI ST58 will ultimately be issued as ANSI/AAMI ST58, *Chemical sterilization and high-level disinfection in health care facilities.*

1 Scope

1.1 Inclusions

The scope of this TIR includes the following topics:

a) *Design considerations:* Assurance that a device can be safely and effectively reprocessed begins with the design of the device. Section 3 of the TIR describes categories of medical devices and the materials and other design characteristics that affect the ability of health care personnel to clean, disinfect, and/or sterilize devices adequately.

b) *Decontamination:* A device cannot be disinfected adequately or sterilized to an adequate sterility assurance level (SAL) if it cannot be cleaned thoroughly. Section 4 addresses variables associated with cleaning and other decontamination processes used in health care facilities, as well as the minimum information that the device manufacturer should supply to health care personnel.

c) *Disinfection:* Section 5 describes the levels of disinfection, the criteria for selecting chemical disinfectants, and the testing that device manufacturers should perform to establish the effectiveness of the disinfection processes recommended for their products.

d) *Sterilization:* Section 6 describes the sterilization processes commonly used in health care facilities, the minimum information that device manufacturers should provide with their products, and the procedures that device manufacturers should use to qualify the sterilization parameters that they recommend for their products.

This TIR also includes definitions of terms, a list of references, and annexes providing supplementary information.

1.2 Exclusions

This TIR does *not* cover the following topics:

a) the design, testing, and labeling of reusable textiles (see ANSI/AAMI PB70) or

b) the design, testing, and labeling of devices intended and labeled for single use.

Although this TIR refers to specifying water quality for cleaning and other elements of reprocessing, it does not address methods of ensuring adequate water quality. A TIR on defining, achieving, and maintaining appropriate water quality for reprocessing medical devices is under development by AAMI.

2 Definitions and abbreviations

2.1 aerator: Machine designed to speed the removal of ethylene oxide (EO) residuals from sterilized items by subjecting sterilized items to warm, circulating, filtered air.

2.2 antigen: According to *Dorland's Pocket Medical Dictionary* (1982), "any substance capable, under appropriate conditions, of inducing a specific immune response and of reacting with the products of that response . . . Antigens may be soluble substances, such as toxins and foreign proteins, or particulate, such as bacteria and tissue cells . . ."

2.3 bioburden: Population of viable microorganisms on a product and/or a package.

NOTE—When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units (CFUs) per single item.

2.4 biological indicator (BI): Microbiological test system providing a defined resistance to a specified sterilization process.

NOTE—BIs are intended to demonstrate whether the conditions were adequate to achieve sterilization. A negative BI does not prove that all items in the load are sterile or that all were exposed to adequate sterilization conditions.

2.5 CDC: Centers for Disease Control and Prevention.

2.6 chemical germicide: Disinfectant or sterilant that is labeled to disinfect or sterilize a medical device.

2.7 chemical indicator (CI): Device used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or used in specific tests of sterilization equipment.

NOTE 1—ANSI/AAMI ST60:1996, *Sterilization of health care products—Chemical indicators—Part 1: General requirements*, defines five classes of CIs and specifies performance requirements for them:

> **Class 1 (process indicator):** Chemical indicator intended for use with individual units (e.g., packs, containers) to demonstrate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units.
>
> **Class 2 (Bowie-Dick test indicator):** Chemical indicator designed for use in a specific test procedure (e.g., the Bowie-Dick test used to determine if air removal has been adequate in a steam sterilization process).
>
> **Class 3 (single-parameter indicator):** Chemical indicator designed to react to one of the critical parameters of sterilization and to indicate exposure to a sterilization cycle at a stated value of the chosen parameter.
>
> **Class 4 (multi-parameter indicator):** Chemical indicator designed to react to two or more of the critical parameters of sterilization and to indicate exposure to a sterilization cycle at stated values of the chosen parameters.
>
> **Class 5 (integrating indicator):** Chemical indicator designed to react to all critical parameters over a specified range of sterilization cycles and whose performance has been correlated to the performance of the stated test organism under the labeled conditions of use.

NOTE 2—CIs assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or sterilizer malfunctions. The "pass" response of a CI does not prove that the item monitored by the indicator is sterile.

2.8 chemical vapor sterilization: Specific sterilization process that uses a solution of alcohol, water, and inert ingredients, with trace formaldehyde (less than 0.25 %); the solution is heated to produce an unsaturated vapor with temperature, pressure, and exposure time within specified limits.

NOTE—Although "chemical vapor" can be taken to refer to gaseous chemical sterilants in general, the term is used here, as it is commonly used in the health care community, to refer to a specific process.