AAMI
Advancing Safety in Medical Technology

Resources

WHAT'S NEW?

- 22 Standards and a New Amendment to ST79
- Sterilization and Dialysis Guidance
- Anesthesia & Interoperability Section
- Benchmarking Resources

COST OF OWNERSHIP

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AAMI Resource Catalog 2014

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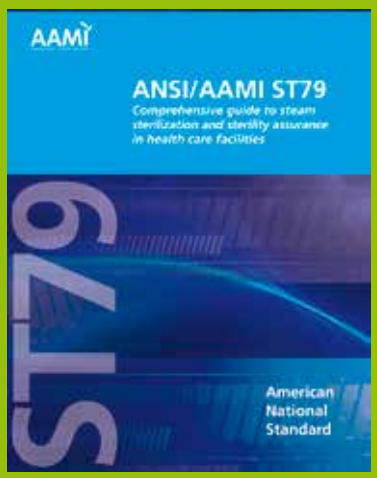
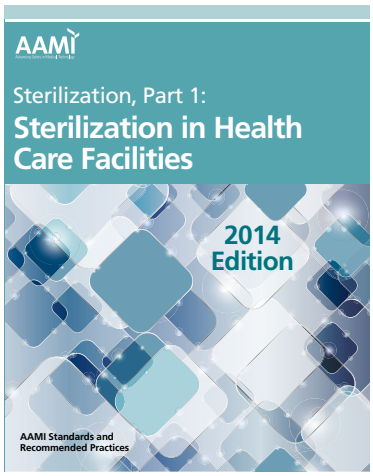
Best Sellers

AAMI Standards on CD: Complete Collection
Includes all 200+ AAMI standards and guidance documents for medical equipment, hospital sterilization, industrial sterilization, quality systems, dialysis, and more. Also features relevant articles from *BI&T* and a powerful search function. This subscription is the most economical way to ensure that your AAMI standards collection is always complete and up-to-date. A great resource for start-up companies!
What's New Recent additions to the collection include EC53, TIR44, TIR50, ST58, ST77, ISO 11137-2 and 24971, IEC 80001-2-4 and 60601-1-8, and a 2013 Amendment to the second edition of ST79.
Annual Subscription — Receive a new CD twice a year and stay current with FREE downloads between CDs.
Order code STDSCD
List $1,630 / AAMI member $1,060
Renewal rate is $895 or $580 for AAMI members.



Comprehensive guide to steam sterilization and sterility assurance in health care facilities
AAMI's best-selling standard has been expanded to incorporate a 2013 Amendment.
This recommended practice covers steam sterilization in healthcare facilities, both terminal sterilization and sterilization for immediate use, regardless of the size of the sterilizer or facility. The recommendations are intended to promote assurance of sterility and to guide healthcare personnel in the proper use of reprocessing equipment.
Published November 2013, 250 pages
ANSI/AAMI ST79:2010, A1:2010, A2:2011, A3:2012, & A4:2013
Order code ST79 or ST79-PDF
List $290 / AAMI member $174

Sterilization in Healthcare Facilities



This is AAMI's all-time, best-selling standards collection for hospitals and healthcare facilities.
It includes 11 AAMI standards and guidance documents covering steam sterilization, reusable medical devices, and ethylene oxide sterilization; chemical sterilization; biological indicators; safe handling and decontamination; cleaning; protective barriers; and more. It features ST79, the popular steam sterilization standard.
What's New Includes the 2013 edition of ST58 and the 2013 amendment to ST79. This collection is also available on a searchable and easy-to-use CD.
Published November 2013
Order code STBK14-1 or STBK14-1-CD
List $560 / AAMI member $360

STERILIZATION COLLECTIONS

Sterilization Three-Book Set
Save 25% when you purchase all three of AAMI's sterilization standards collections.
Order code STBK13-S
List $1,020 / AAMI member $714

Sterilization CD
Fully searchable and easy-to-use, this is the most convenient source for the full collection of more than 50 AAMI sterilization standards. It also includes key FDA and CDC guidance documents, along with peer-reviewed sterilization articles from AAMI's journal.
Order code STBKCD
List $795 / AAMI member $555

Multimedia Set
Includes all three of AAMI's sterilization standards books PLUS the AAMI Standards on CD—Sterilization Edition.
Order code STBKCDXL
List $1,625 / AAMI member $1,137

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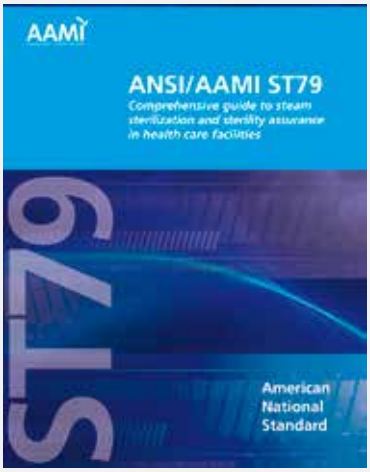


UPDATED! ST79—AAMI's Best-Selling Standard, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*

This recommended practice covers steam sterilization in healthcare facilities, both terminal sterilization and sterilization for immediate use, regardless of the size of the sterilizer or facility. The recommendations are intended to promote assurance of sterility and to guide healthcare personnel in the proper use of reprocessing equipment.

Specifically, ST79 covers:

- Functional and physical design criteria for steam sterilization
- Processing areas (decontamination, preparation, sterilization, and sterile storage areas)
- Staff qualifications, education, and other personnel considerations
- Reprocessing procedures
- Installation, care, and maintenance of steam sterilizers
- Quality control
- Quality process improvement

This is the consolidated text of ST79 and the four Amendments. It also includes the Immediate-Use Steam Sterilization Position Statement.

The print format of ST79 comes in a loose-leaf binder format. The attractive binder features sturdy metal rings, ledger-weight pages, and laminated tabs for easy navigation.

What's New The second edition includes guidance on the use and application of Class 6 emulating indicators. It has also been updated to incorporate Amendment 4, which includes new illustrations of the appropriate steps to wrap materials in preparation for sterilization.

Published November 2013, 250 pages

ANSI/AAMI ST79:2010, A1:2010, A2:2011, A3:2012, & A4:2013

Order code ST79 or ST79-PDF

List $290 / AAMI member $174

NEW! ANSI/AAMI ST79:2010/A4:2013

This redline document is available in print or as a free PDF.

Order code ST79-A4 or ST79-A4-PDF *(PDF is a FREE download)*

List $85 / AAMI member $50

ANSI/AAMI ST79:2010/A3:2012

This redline document is available in print or as a free PDF.

Order code ST79-A3 or ST79-A3-PDF *(PDF is a FREE download)*

List $85 / AAMI member $50

ANSI/AAMI ST79:2010/A2:2011

This redline document is available in print or as a free PDF.

Order code ST79-A2 or ST79-A2-PDF *(PDF is a FREE download)*

List $85 / AAMI member $50

Immediate-Use Steam Sterilization Position Statement

Don't miss this position statement adopted by AAMI, AORN, APIC, IAHCSMM, and others.

Free download at www.aami.org/publications/standards/st79.html

Steam Sterilization Posters

This nine poster set provides a quick and easy visual reminder of some key portions of ST79. These colorful and eye-catching 18" x 24" posters are laminated to extend their life and allow for cleaning. Originally five posters, the set has expanded to include wrapping of items prior to steam sterilization.

Expected Publication

May 2014

Order code POSTER-S

List $150 / AAMI member $90

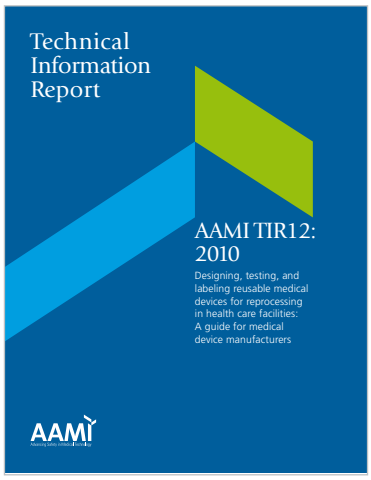
Most AAMI standards have FDA recognition, but the exact list of standards is continually changing. To confirm if an AAMI standard is currently recognized by FDA, please visit www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

GENERAL

COMING SOON! Water for the reprocessing of medical devices

This technical information report (TIR) covers the selection and maintenance of effective water quality suitable for reprocessing medical devices. It provides guidelines for selecting the water quality necessary for the reprocessing of categories of medical devices and addresses water treatment equipment, water distribution and storage, quality control procedures for monitoring water quality, strategies for bacterial control, and environmental and personnel considerations.

Expected Publication June 2014, 69 pages
AAMI TIR34:2014
Order code TIR34 or TIR34-PDF
List $150 / AAMI member $90



Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers, 3ed

Covers design considerations that medical device manufacturers should take into account to help ensure that their products can be safely and effectively reprocessed. Also provides information on decontamination, disinfection, and sterilization processes commonly used in healthcare facilities.

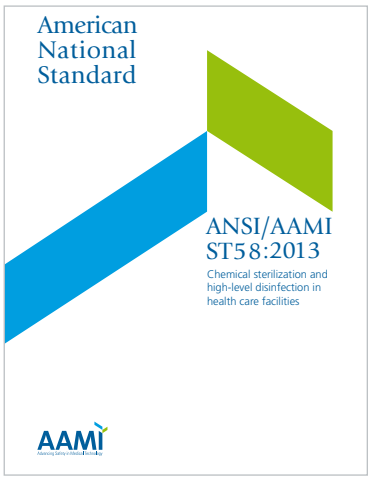
Published October 2010, 53 pages
AAMI TIR12:2010
Order code TIR12 or TIR12-PDF
List $140 / AAMI member $84
Redline format of TIR12
Order code TIR12-RD-PDF
List $160 / AAMI member $96

A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

Intended as a resource for manufacturers of medical devices who must validate the instructions for cleaning that they include with their devices. It also discusses underlying problems and challenges associated with validating a cleaning method.

Published September 2011, 46 pages
AAMI TIR30:2011
Order code TIR30 or TIR30-PDF
List $140 / AAMI member $84
Redline format of TIR30
Order code TIR30-RD-PDF
List $160 / AAMI member $96

CHEMICAL



NEW! Chemical sterilization and high-level disinfection in health care facilities

This recommended practice provides guidelines for the selection and use of liquid chemical sterilants (LCSs)/ high-level disinfectants (HLDs) and gaseous chemical sterilizers that have been cleared for marketing by the U.S. Food and Drug Administration for use in hospitals and other health care facilities.

Published September 2013, 154 pages
ANSI/AAMI ST58:2013
Order code ST58 or ST58-PDF
List $170 / AAMI member $102

PROTECTIVE GOWNS AND DRAPES

Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities

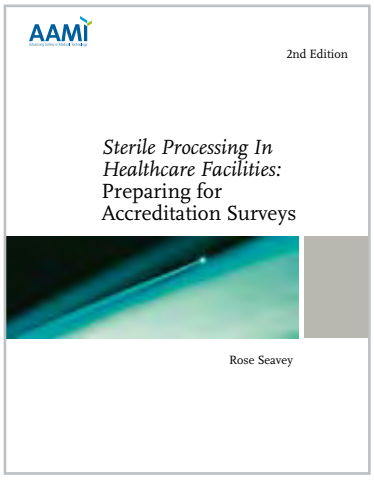
This standard establishes a system of classification for protective apparel and drapes used in healthcare facilities based on their liquid barrier performance and specifies related labeling requirements and standardized test methods for determining compliance. The standard is intended to ultimately assist end-users in determining the type(s) of protective product most appropriate for a particular task or situation.

Published August 2012, 26 pages
ANSI/AAMI PB70:2012
Order code PB70 or PB70-PDF
List $110 / AAMI member $66
Redline format of PB70
Order code PB70-RD-PDF
List $130 / AAMI member $78

Protective Barriers Resource Bundle

Includes PB70, ST65, and TIR11
Order code PBRB or PBRB-PDF
List $300 / AAMI member $180

Redline formats include a clean copy of the current document and a copy showing changes from the prior edition.



NEW! Sterile Processing in Healthcare Facilities: Preparing for Accreditation Surveys, 2ed

Now in its second edition, this publication is written as a guide to healthcare facilities seeking to comply with accrediting agency surveys as they relate to the reprocessing of surgical instruments and other reusable medical devices in any healthcare setting.

This popular resource features:

- Information on accreditation organizations and requirements
- The current National Patient Safety Goals
- Information on relevant evidence-based guidelines published by professional organizations
- Information on CDC's *Guide to Infection Prevention for Outpatient Settings*
- A step-by-step guide to preparation for a survey
- Guidelines on risk reduction
- An example of a sterile processing auditing tool

Among other things, this edition adds audit tools for immediate-use steam sterilization best practices.

Authored by Rose Seavey

Published March 2014, 209 pages

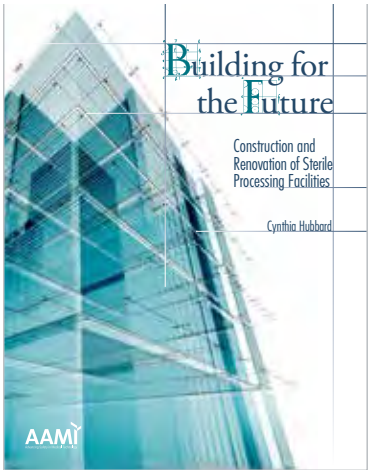
Order code SPHC2 or SPHC2-PDF

List $205 / AAMI member $120

BUY BOTH THE BOOK AND PDF AND SAVE!

Order code SPHC2SET

List $310 / AAMI member $185



Building for the Future: Construction and Renovation of Sterile Processing Facilities

The first of its kind, this popular publication includes practical resources and tips to explain the design process, support collaborative planning, and prepare a sterile processing department (SPD) for the future. It also includes valuable information on equipment purchases, testing, and implementation.

Specifically, this provides guidance on:

- Trends affecting design
- The critical components of the planning process for new construction
- The management of the design process
- Tools and methods for collaborative planning and accurate data collection
- Key operational issues related to renovation projects

Authored by Cynthia Hubbard, RN, an independent nurse consultant, this book is ideally suited for sterile processing professionals, managers, operating room managers, hospital administrators, architects, and equipment planners.

Published February 2013, 144 pages

Order code BFTF or BFTF-PDF

List $205 / AAMI member $120

BUY BOTH THE BOOK AND PDF AND SAVE!

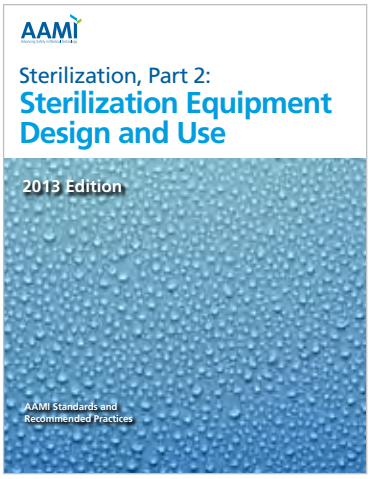
Order code BFTFSET

List $310 / AAMI member $185

OTHER STERILIZATION IN HEALTHCARE FACILITIES STANDARDS

ORDER CODE	TITLE	PUBLISHED	PAGES	PRICE (LIST/MBR)	GROUPING
ST40 or ST40-PDF	Table-top dry heat (heated air) sterilization and sterility assurance in health care facilities, 2ed (ANSI/AAMI ST40:2004/(R)2010)	Reaffirmed March 2010	45	$140 / $84	Thermal
ST41 or ST41-PDF	Ethylene oxide sterilization in health care facilities: Safety and effectiveness, 4ed (ANSI/AAMI ST41:2008/(R)2012)	Reaffirmed November 2012	168	$220 / $132	General
ST65 or ST65-PDF	Processing of reusable surgical textiles for use in health care facilities, 2ed (ANSI/AAMI ST65:2008/(R)2013)	Reaffirmed December 2013	55	$150 / $90	Gowns & Drapes
ST81 or ST81-PDF	Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices (AAMI ST81:2004/(R)2010)	Reaffirmed March 2010	17	$100 / $60	General
TIR11 or TIR11-PDF	Selection and use of protective apparel and surgical drapes in health care facilities, 2ed (AAMI TIR11:2005)	February 2006	38	$140 / $84	Gowns & Drapes

Sterilization Equipment

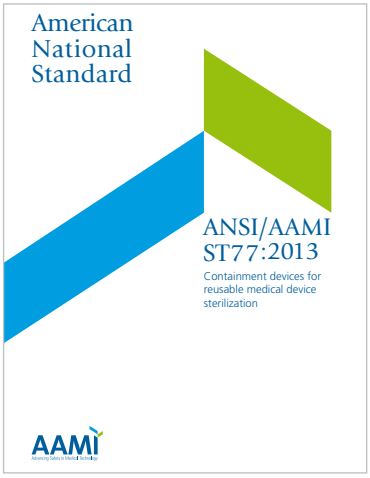


Sterilization Equipment Design and Use

This sterilization collection for manufacturers and users of sterilization equipment includes 23 AAMI standards and guidance documents. It features guidance on biological indicators (ISO 11138 series), documents covering chemical indicators (ISO 15882 and 11140 series), packaging (ISO 11607 series), and much more.

Published May 2013
Order code STBK13-2
List $495 / AAMI member $320

GENERAL



NEW! Containment devices for reusable medical device sterilization, 2ed

Covers minimum labeling and performance requirements for rigid sterilization container systems and for instrument cases, cassettes, and trays.
Published Aug 2013, 24 pages
ANSI/AAMI ST77:2013
Order code ST77 or ST77-PDF
List $110 / AAMI member $66

COMING SOON! Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging, 3ed, Amendment 1

Expected Publication July 2014, 19 pages
ANSI/AAMI/ISO 11607-1:2006/(R)2010/A1:2014
Order code 1160701-A or 1160701-A-PDF
List $100 / AAMI member $60

COMING SOON! Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing, and assembly processes, 3ed, Amendment 1

Expected Publication July 2014, 9 pages
ANSI/AAMI/ISO 11607-2:2006/(R)2010/A1:2014
Order code 1160702-A or 1160702-A-PDF
List $90 / AAMI member $54

COMING SOON! Packaging for terminally sterilized medical devices—Guidance on the application of ISO 11607-1 and ISO 11607-2

Addresses possible options for compliance with the requirements of Parts 1 and 2 as special concerns that may require attention due to regional or local conditions, practices, or regulations. Additional guidance on important packaging issues is also included. This is based on and revises AAMI TIR22:2007
Expected Publication June 2014, 122 pages
ANSI/AAMI/ISO TIR16775:2014
Order code 16775 or 16775-PDF
List $170 / AAMI member $102

NEW! Hospital steam sterilizers

Covers minimum construction and performance requirements for hospital sterilizers that use saturated steam as the sterilizing agent.
Published April 2013, 33 pages
ANSI/AAMI ST8:2013
Order code ST8 or ST8-PDF
List $140 / AAMI member $84

COMING SOON! Sterilization of health care products—Chemical indicators—Part 1: General requirements, 3ed

Specifies performance requirements and/or test methods for chemical indicators intended for use with sterilization processes employing steam, dry heat, ethylene oxide, "y" or "B" radiation, low temperature steam and formaldehyde or vaporized hydrogen peroxide.
Expected Publication Fall 2014, 33 pages
ANSI/AAMI/ISO 11140-1:2014
Order code 1114001 or 1114001-PDF
List $130 / AAMI member $78

The Science of Speed.

The Art of Trust.

Confidence, with a faster BI result

3M™ Attest™ Super Rapid Readout Biological Indicators for steam sterilization are the latest innovation in biological monitoring from 3M. With results in 30 minutes (for gravity displacement cycles) or 1 hour (for vacuum assisted cycles), you'll find the peace of mind that comes with biological results is just part of the Attest brand legacy.

...and support you can count on.

From the laboratory where the first self-contained BI was developed in 1971, to the front lines of Sterile Processing today, it's our mission to support you – with training, technical support, standards guidance, CE-credited education and more. We're thankful for the trust you have placed in us. And we're ready to help you meet your commitment to those who place their trust in you.

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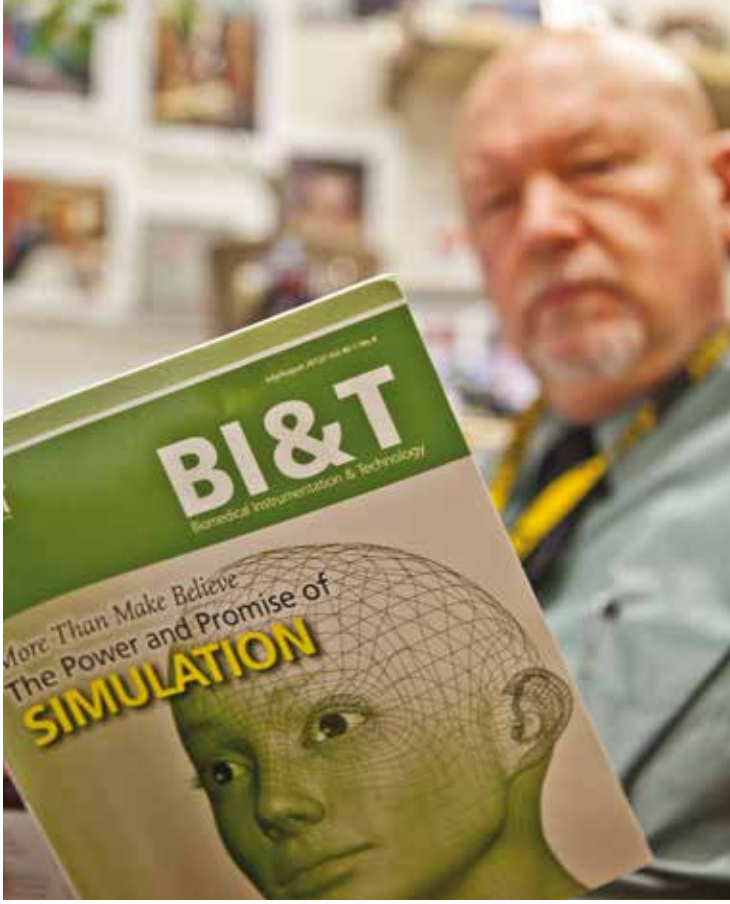
Shape the future of healthcare technology!



Spread the Word: Write for AAMI Publications or the AAMIblog
E-mail AAMI at communications@aami.org to get started!

Be Heard: Participate in Standards Development
Visit www.aami.org/standards for more information!

Join the Conversation: Participate in AAMI's Networking Communities.
See the full list of communities at www.aami.org/communities

Sharpen Your Skills: Register for an AAMI Training Session
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Find your Local Society: Network with Regional Peers
See the full list of regional biomedical societies at www.aami.org/communities/societies to connect with the one closest to you!

Ready to get involved?
Visit www.aami.org/membership/involved to complete a short volunteer form.

Not a member? Join AAMI Today!

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OTHER STERILIZATION EQUIPMENT STANDARDS

ORDER CODE	TITLE	PUBLISHED	PAGES	PRICE (LIST/ MBR)	GROUPING
11139 or 11139-PDF	*Sterilization of health care products—Vocabulary, 2ed (ANSI/AAMI/ISO TIR11139:2006)*	*April 2006*	*9*	*$60 / $30*	*General*
14161 or 14161-PDF	*Sterilization of health care products—Biological indicators—Guidance for the selection, use, and interpretation of results, 2ed (ANSI/AAMI/ISO 14161:2009)*	*November 2009*	*69*	*$150 / $90*	*General*
15882 or 15882-PDF	*Chemical indicators—Guidance for the selection, use, and interpretation of results, 4ed (ANSI/AAMI/ISO 15882:2008/(R)2013)*	*Reaffirmed October 2013*	*34*	*$140 / $84*	*Chemical Indicators*
18472 or 18472-PDF	*Sterilization of health care products—Biological and chemical indicators—Test equipment, 4ed (ANSI/AAMI/ISO 18472:2006/(R)2010)*	*Reaffirmed December 2010*	*31*	*$140 / $84*	*Bio/ Chemical Indicators*
1113801 or 1113801-PDF	*Sterilization of health care products—Biological indicators—Part 1: General requirements, 2ed (ANSI/AAMI/ ISO 11138-1:2006/(R)2010)*	*Reaffirmed April 2010*	*43*	*$140 / $84*	*Biological Indicators*
1113802 or 1113802-PDF	*Sterilization of health care products—Biological indicators—Part 2: Biological indicators for ethylene oxide sterilization processes, 3ed (ANSI/AAMI/ISO 11138-2:2006/(R)2010)*	*Reaffirmed April 2010*	*6*	*$90 / $54*	*Biological Indicators*
1113803 or 1113803-PDF	*Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization processes (ANSI/AAMI/ISO 11138-3:2006/(R)2010)*	*Reaffirmed April 2010*	*8*	*$90 / $54*	*Biological Indicators*
1113804 or 1113804-PDF	*Sterilization of health care products—Biological indicators—Part 4: Biological indicators for dry heat sterilization processes (ANSI/AAMI/ISO 11138-4:2006/(R)2010)*	*Reaffirmed April 2010*	*8*	*$90 / $54*	*Biological Indicators*
1113805 or 1113805-PDF	*Sterilization of health care products—Biological indicators—Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes (ANSI/AAMI/ISO 11138-5:2006/(R)2010)*	*Reaffirmed April 2010*	*7*	*$90 / $54*	*Biological Indicators*
1114003 or 1114003-PDF	*Sterilization of health care products—Chemical indicators—Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test (ANSI/AAMI/ISO 11140-3:2007/(R)2012)*	*Reaffirmed August 2012*	*23*	*$110 / $66*	*Chemical Indicators*
1114004 or 1114004-PDF	*Sterilization of health care products—Chemical indicators—Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration (ANSI/AAMI/ISO 11140-4:2007/(R)2012)*	*Reaffirmed August 2012*	*36*	*$140 / $84*	*Chemical Indicators*
1114005 or 1114005-PDF	*Sterilization of health care products—Chemical indicators—Part 5: Class 2 indicators for Bowie and Dick-type air removal tests, 2ed (ANSI/AAMI/ISO 11140-5:2007/(R)2012)*	*Reaffirmed August 2012*	*14*	*$110 / $66*	*Chemical Indicators*
1160701 or 1160701-PDF	*Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging, 3ed (ANSI/AAMI/ISO 11607-1:2006/(R)2010)*	*Reaffirmed December 2010*	*27*	*$110 / $66*	*General*
1160702 or 1160702-PDF	*Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing, and assembly processes, 3ed (ANSI/AAMI/ISO 11607-2:2006/(R)2010)*	*Reaffirmed December 2010*	*12*	*$100 / $60*	*General*
1588301 or 1588301-PDF	*Washer-disinfectors, Part 1: General requirements, terms and definitions and tests (ANSI/AAMI ST15883-1:2009) Adoption with deviations*	*October 2009*	*79*	*$150 / $90*	*General*
1588302 or 1588302-PDF	*Washer-disinfectors, Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc. (ANSI/AAMI ST15883-2:2013) Adoption with deviations*	*April 2013*	*12*	*$100 / $60*	*General*
1588303 or 1588303-PDF	*Washer-disinfectors, Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (ANSI/AAMI ST15883-3:2012) Adoption with deviations*	*April 2013*	*11*	*$100 / $60*	*General*
ST24 or ST24-PDF	*Automatic, general-purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities, 3ed (ANSI/AAMI ST24:1999/(R)2013)*	*Reaffirmed November 2013*	*22*	*$110 / $66*	*Sterilizers*
ST50 or ST50-PDF	*Dry heat (heated air) sterilizers, 2ed (ANSI/AAMI ST50:2004/(R)2010)*	*Reaffirmed March 2010*	*29*	*$110 / $66*	*Sterilizers*
ST55 or ST55-PDF	*Table-top steam sterilizers, 3ed (ANSI/AAMI ST55:2010)*	*March 2011*	*33*	*$140 / $84*	*Sterilizers*
TIR31 or TIR31-PDF	*Process challenge devices/test packs for use in health care facilities, 2ed (AAMI TIR31:2008)*	*January 2009*	*34*	*$140 / $84*	*General*

Sterilization—Industrial Process Control

Sterilization—Industrial Process Control

This collection of 38 documents is intended primarily for manufacturers who ship their products sterile.
What's New The collection features new guidance for sterilization of single-use medical devices incorporating materials of animal origins (ISO 14160), requirements for products labeled "sterile" (ST67), dry heat sterilization of health care products (ISO 20857), and radiation (ISO 11137-2).
Published December 2012
Order code STBK13-3
List $495 / AAMI member $346

GENERAL

UPDATED! Aseptic processing of health care products—Part 1: General requirements

Specifies the general requirements for, and offers guidance on, processes, programs, and procedures for development, validation, and routine control of the manufacturing process for aseptically processed health care products. Expanded to include Amendment.
Published January 2009, Amended July 2013, 22 pages
ANSI/AAMI/ISO 13408-1:2008(R)2011
Order code 1340801 or 1340801-PDF
List $110 / AAMI member $66

NEW! Aseptic processing of health care products—Part 1: General requirements, Amendment 1

Corrects spelling errors, clarifies a definition note, and replaces terms used in Table 1 and Table 2.
Published July 2013, 4 pages
ANSI/AAMI/ISO 13408-1:2008/(R)2011/A1:2013
Order code 1340801-A or 1340801-A-PDF
List $30 / AAMI member $18 (PDF is FREE)

NEW! Environmental Monitoring For Terminally Sterilized Healthcare Products

Assists in establishing an environmental monitoring program that is meaningful, manageable, and defendable, and provides guidance to avoid adverse environmental conditions during the manufacture of terminally sterilized healthcare products.
Published April 2014, 13 pages
AAMI TIR52:2014
Order code TIR52 or TIR52-PDF
List $90 / AAMI member $54

UPDATED! Aseptic processing of health care products—Part 6: Isolator systems

Specifies the requirements for isolator systems used for aseptic processing and offers guidance on qualification, bio-decontamination, validation, operation, and control of isolator systems used for aseptic processing of health care products. Expanded to include Amendment.
Published January 2009, Amended July 2013, 22 pages
ANSI/AAMI/ISO 13408-6:2005
Order code 1340806 or 1340806-PDF
List $110 / AAMI member $66

NEW! Aseptic processing of health care products—Part 6: Isolator systems, Amendment 1

Updates references, modifies definitions and informative notes, introduces new requirements, and updates the Bibliography.
Published July 2013, 4 pages
ANSI/AAMI/ISO 13408-6:2005/A1:2013
Order code 1340806-A or 1340806-A-PDF
List $30 / AAMI member $18 (PDF is FREE)

Compatibility of materials subject to sterilization, 2ed

Provides guidance for healthcare manufacturers in the selection and qualification of polymeric materials, ceramics, and metals in healthcare products that are sterilized by: a) radiation (gamma, electron beam, or x-ray); b) ethylene oxide (EO); c) moist heat (steam); d) dry heat; e) hydrogen peroxide; and f) ozone. Also includes an annex on accelerated aging.
Published November 2008, 84 pages
AAMI TIR17:2008
Order code TIR17 or TIR17-PDF
List $170 / AAMI member $102

Sterilization of health care products—Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled 'sterile', 2ed

Establishes requirements and guidance for selection of the appropriate sterility assurance level for terminally sterilized medical devices and acceptance criteria for maximum contamination rate of aseptically filled products.

Published August 2011, 11 pages
ANSI/AAMI ST67:2011
Order code ST67 or ST67-PDF
List $100 / AAMI member $60

Bacterial endotoxins—Test methodologies, routine monitoring, and alternatives to batch testing, 2ed

This edition provides additional guidance on out-of-specification test results and investigation.

Published December 2011, 34 pages
ANSI/AAMI ST72:2011
Order code ST72 or ST72-PDF
List $140 / AAMI member $84

Redline format of ST72

ANSI/AAMI ST72:2011
Order code ST72-RD-PDF
List $160 / AAMI member $96

Sterilization of health care products—Biological indicators—Guidance for the selection, use, and interpretation of results, 2ed

Provides guidance regarding the selection, use, and interpretation of results of biological indicators. Identical to ISO 14161/Ed.2.

Published November 2009, 69 pages
ANSI/AAMI/ISO 14161:2009
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List $130 / AAMI member $78

Redline format of 14161

ANSI/AAMI/ISO 14161:2009
Order code 14161-RD-PDF
List $160 / AAMI member $96

Sterilization of medical devices—Microbiological methods—Part 1: Determination of a population of microorganisms on products, 2ed

This combined revision of 11737-1:1995 and 11737-3:2004 specifies general criteria to be applied in the estimation of the population of viable microorganisms on a medical device or component, raw material, or package thereof. Identical to ISO 11737-1/Ed.2.

Published April 2006, Errata issued May 2007, Reaffirmed November 2011, 29 pages
ANSI/AAMI/ISO 11737-1:2006/(R)2011
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INDUSTRIAL EO STERILIZATION

COMING SOON! Guidance for the development, validation, and routine control of an ethylene oxide sterilization process utilizing flexible bag systems for the sterilization of medical devices

Expected Publication June 2014, 28 pages
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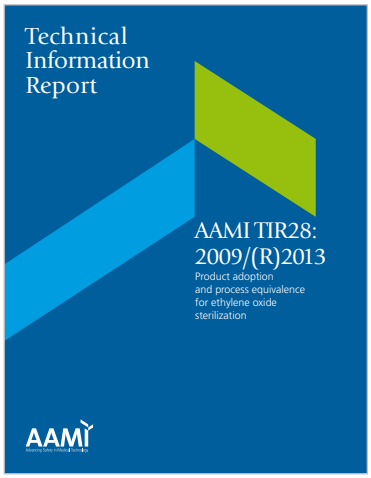

Product adoption and process equivalence for ethylene oxide sterilization, 2ed

Includes guidance for the adoption of a new or modified product into an existing validated sterilization process and for the determination of equivalence of a sterilization process as conducted with different equipment. This guidance is intended to augment the ANSI/AAMI/ISO 11135 series.

Published May 2009, Reaffirmed May 2013, 12 pages
AAMI TIR28:2009/(R)2013
Order code TIR28 or TIR28-PDF
List $100 / AAMI member $60

NEW! Industrial Sterilization: Research from the Field

This publication provides industrial sterilization scientists with a venue to publish their research. It also promotes the development of industrial sterilization science, furthering AAMI's goal of advancing safety in medical technology. This 100–page publication includes articles from leading experts on:

- Industrial ethylene oxide sterilization
- Microbiological methods
- Steam sterilization
- Quality management systems and sterility assurance

Published October 2013, 100 pages
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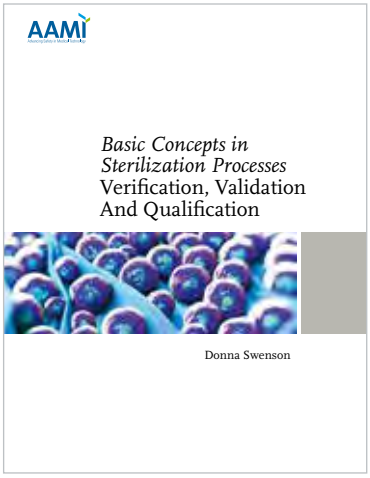

NEW! Basic Concepts in Sterilization Processes: Verification, Validation, and Qualification

This textbook reaches beyond sterilization engineers to provide personnel working in both healthcare and medical device manufacturing with the background they need to navigate the topic of sterilization processes. Discusses the science of sterilization in plain language and describes the principles on which sterilization verification, validation, and qualification are based.

Includes key definitions and abbreviations, as well as practical tools for real-world implementation of the concepts.

Expected Publication June 2014.
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COMING SOON! Sterilization of health care products—Radiation—Guidance on sterilization of biologics and tissue-based products

This TIR provides guidance on special considerations for sampling and testing techniques that are used in the validation of radiation sterilization of human tissue-based products.

Expected Publication May 2014, 27 pages
AAMI TIR37:2014
Order code TIR37 or TIR37-PDF
List $110 / AAMI member $66

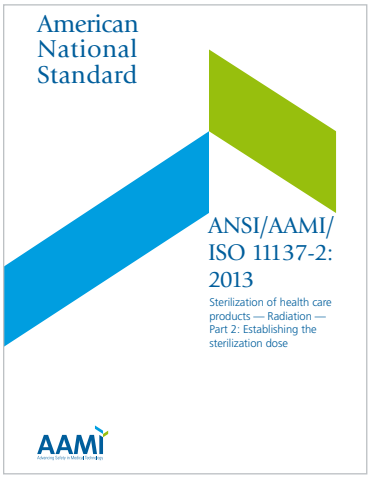
Sterilization of health care products—Radiation—Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices, 2ed

These requirements cover radiation processors employing irradiators using the radionuclide 60 Co or 137 Cs, a beam from an electron generator, or a beam from an X-ray generator.

Published May 2006, Reaffirmed April 2010, 40 pages
ANSI/AAMI/ISO 11137-1:2006/(R)2010
Order code 1113701 or 1113701-PDF
List $140 / AAMI member $84

COMING SOON! Sterilization of health care products—Radiation—Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices, 2ed, Amendment 1

Expected Publication June 2014, 4 pages
ANSI/AAMI/ISO 11137-1:2006/(R)2010/A1:2013
Order code 1113701-A or 1113701-A-PDF
List $30 / AAMI member $15 (PDF is FREE)



NEW! Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose, 3ed

Describes methods that can be used to determine the minimum dose necessary to achieve the specified requirement for sterility, including methods to substantiate 25 kGy as the sterilization dose.

Published Aug 2013, 74 pages
ANSI/AAMI/ISO 11137-2:2013
Order code 1113702 or 1113702-PDF
List $150 / AAMI member $90

Guide for process characterization and control in radiation sterilization of medical devices

Provides additional guidance for characterizing the irradiation process and for establishing requisite process controls to ensure the irradiation system remains in a validated state. This document complements activities defined in ANSI/AAMI/ISO 11137 for gamma, X-ray, and electron beam sterilization.

Published March 2013, 41 pages
AAMI TIR29:2012
Order code TIR29 or TIR29-PDF
List $140 / AAMI member $84

Sterilization of health care products—Radiation—Part 3: Guidance on dosimetric aspects

Provides guidance on ANSI/AAMI/ISO 11137-1 and 11137-2 relating to dosimetry, describing procedures related to the development, validation, and routine control of a radiation sterilization process.

Published May 2006, Reaffirmed April 2010, 17 pages
ANSI/AAMI/ISO, 11137-3:2006/(R)2010
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14937 or 14937-PDF	*Sterilization of health care products—General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices (ANSI/AAMI/ISO 14937:2009/(R)2013)*	*Reaffirmed December 2013*	*39*	*$140 / $84*	*General*
20857 or 20857-PDF	*Sterilization of health care products—Dry heat: Requirements for the development, validation and routine control of an industrial sterilization process for medical devices (ANSI/AAMI/ISO 20857:2010)*	*July 2011*	*62*	*$150 / $90*	*Thermal*
1113501 or 1113501-PDF	*Sterilization of health care products—Ethylene oxide—Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices, 2ed (ANSI/AAMI/ISO 11135-1:2007)*	*July 2007*	*47*	*$140 / $84*	*Industrial*
1113502 or 1113502-PDF	*Sterilization of health care products—Ethylene oxide—Part 2: Guidance on the application of ANSI/AAMI/ISO 11135-1, 2ed (ANSI/AAMI/ISO TIR11135-2:2008)*	*November 2008*	*43*	*$140 / $84*	*Industrial*
1173702 or 1173702-PDF	*Sterilization of medical devices—Microbiological methods—Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process, 2ed (ANSI/AAMI/ISO 11737-2:2009)*	*December 2009*	*13*	*$100 / $60*	*General*
1340802 or 1340802-PDF	*Aseptic processing of health care products—Part 2: Filtration (ANSI/AAMI/ISO 13408-2:2003/(R)2013)*	*Reaffirmed December 2013*	*17*	*$100 / $60*	*General*
1340803 or 1340803-PDF	*Aseptic processing of health care products—Part 3: Lyophilization (ANSI/AAMI/ISO 13408-3:2006/(R)2012)*	*Reaffirmed November 2012*	*24*	*$100 / $60*	*General*
1340804 or 1340804-PDF	*Aseptic processing of health care products—Part 4: Clean-in-place technologies (ANSI/AAMI/ISO 13408-4:2005/(R)2012)*	*Reaffirmed November 2012*	*31*	*$100 / $60*	*General*
1340805 or 1340805-PDF	*Aseptic processing of health care products—Part 5: Sterilization in place (ANSI/AAMI/ISO 13408-5:2006/(R)2012)*	*Reaffirmed November 2012*	*17*	*$100 / $60*	*General*
1340807 or 1340807-PDF	*Aseptic processing of health care products — Part 7: Alternative processes for medical devices and combination products (ANSI/AAMI/ISO 13408-7:2012)*	*September 2012*	*22*	*$110 / $66*	*General*
1766501 or 1766501-PDF	*Sterilization of health care products—Moist heat— Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices, 3ed (ANSI/AAMI/ISO 17665-1:2006/(R)2013)*	*Reaffirmed December 2013*	*43*	*$140 / $84*	*Thermal*
1766502 or 1766502-PDF	*Sterilization of health care products—Moist Heat—Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1 (ANSI/AAMI/ISO TIR17665-2:2009)*	*July 2009*	*50*	*$140 / $84*	*Thermal*
1099307 or 1099307-PDF	*Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals, 3ed (ANSI/AAMI/ISO 10993-7:2008/(R)2012)*	*Reaffirmed June 2012*	*98*	*$150 / $90*	*Industrial*
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TIR15 or TIR15-PDF	*Physical aspects of ethylene oxide sterilization (AAMI TIR15:2009/(R)2013)*	*Reaffirmed May 2013*	*23*	*$110 / $66*	*Industrial*
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TIR39 or TIR39-PDF	*Guidance on selecting a microbial challenge and inoculation sites for sterilization validation of medical devices (AAMI TIR39:2009)*	*November 2009*	*9*	*$90 / $54*	*General*
TIR40 or TIR40-PDF	*Sterilization of health care products—Radiation—Guidance on dose setting utilizing a Modified Method 2 (AAMI TIR40:2009)*	*March 2010*	*21*	*$110 / $66*	*Radiation*

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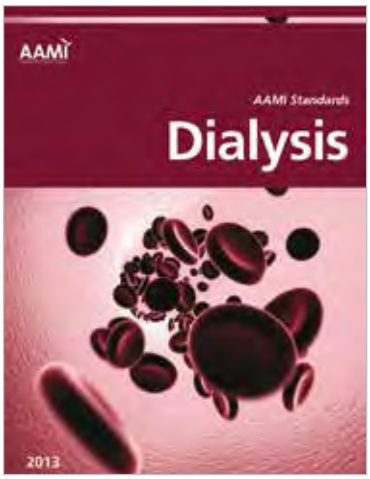
Dialysis



AAMI Dialysis Standards Collection

No dialysis professional, facility, or manufacturer of dialysis equipment or products should be without the complete collection of dialysis standards from AAMI. Select standards have been recognized by FDA, Centers for Medicare and Medicaid Services, and Centers for Disease Control and Prevention. The collection includes all AAMI dialysis standards on these two pages.

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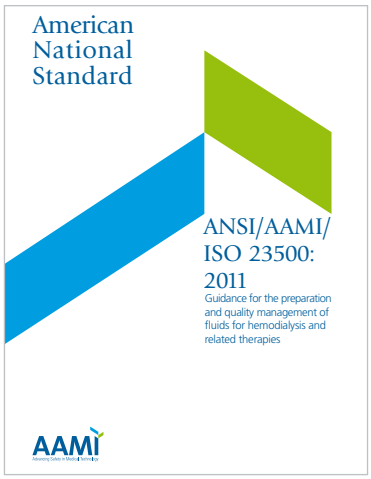
GENERAL

Quality of dialysis fluid for hemodialysis and related therapies

Specifies minimum requirements for dialysis fluids used for hemodialysis and hemodiafiltration, including substitution solution for hemodiafiltration and hemofiltration. It does not address the requirements for the water and concentrates used to prepare dialysis fluid or the equipment used in its preparation. This standard and 23500 revise RD52. Identical to ISO 11663.
Published January 2011, 17 pages
ANSI/AAMI/ISO 11663:2009
Order code 11663 or 11663-PDF
List $100 / AAMI member $60



Guidance for the preparation and quality management of fluids for hemodialysis and related therapies

Covers the appropriate prescription of dialysate, handling of concentrates, operation of water treatment equipment and handling of its product water, monitoring of systems and the dialysate produced, and risks and hazards of dialysate preparation failure. This standard and 11663 revise RD52. Identical to ISO 23500.
Published June 2011, 91 pages
ANSI/AAMI/ISO 23500:2011
Order code 23500 or 23500-PDF
List $170 / AAMI member $102

Concentrates for hemodialysis and related therapies

Specifies minimum requirements for concentrates used for hemodialysis and related therapies. This is a revision of RD61. Identical to ISO 13958.
Published June 2011, 25 pages
ANSI/AAMI/ISO 13958:2009
Order code 13958 or 13958-PDF
List $110 / AAMI member $66

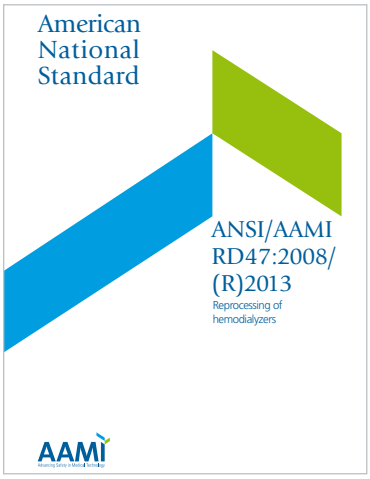
Water for hemodialysis and related therapies

Specifies minimum requirements for water to be used in the preparation of concentrates, dialysis fluids for hemodialysis, hemodiafiltration and hemofiltration and for the reprocessing of hemodialysers. This standard and 26722 revise RD62. Identical to ISO 13959.
Published June 2011, 15 pages
ANSI/AAMI/ISO 13959:2009
Order code 13959 or 13959-PDF
List $100 / AAMI member $60

ANSI/AAMI/ISO 26722:2009
Order code 26722 or 26722-PDF
List $130 / AAMI member $78

Water treatment equipment for hemodialysis applications and related therapies

The standard covers devices used to treat water intended for use in the delivery of hemodialysis and related therapies. This standard and 13959 revise RD62. Identical to ISO 26722.
Published June 2011, 33 pages



Reprocessing of hemodialyzers, 4ed

Covers personnel and patient considerations, records, equipment, physical plant and environmental safety, reprocessing material, patient identification and hemodialyzer labeling, reprocessing and storage procedures, disposition of rejected dialyzers, preparation for subsequent use, patient monitoring, and quality assurance and quality control.
Published June 2008, Reaffirmed October 2013, 55 pages
ANSI/AAMI RD47:2008/(R)2013
Order code RD47 or RD47-PDF
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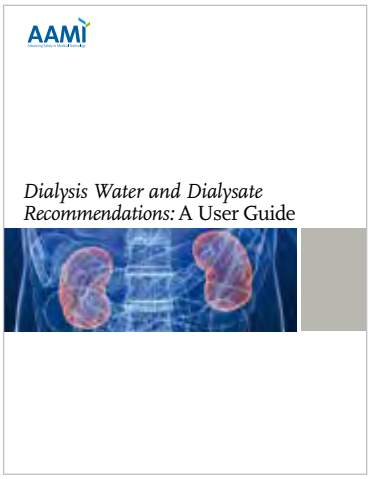

NEW! Dialysis Water and Dialysate Recommendations: A User Guide

This book provides a side-by-side comparison of the CMS regulations and interpretive guidance for the Condition of Water and Dialysate Quality and the section related to water and dialysate from the Condition of Care at Home with the suite of ISO Standards that have been adopted as replacement for ANSI/AAMI RD52:2004.
It aids individuals responsible for the oversight and operation of hemodialysis facilities in their understanding of the regulatory requirements and current AAMI guidance.
Published April 2014, 212 pages.
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UPDATED! Cardiovascular implants and extracorporeal systems—Hemodialyzers, hemodiafilters, hemofilters and hemoconcentrators

Published August 2010, Amendment 1 added June 2013, 21 pages.
ANSI/AAMI/ISO 8637:2010
Order code 8637 or 8637-PDF
List $100 / AAMI member $60

NEW! Cardiovascular implants and extracorporeal systems—Hemodialyzers, hemodiafilters, hemofilters and hemoconcentrators, Amendment 1

Revision to Figure 2 of 8637. **Published** June 2013, 1 page
ANSI/AAMI/ISO 8637:2010/A1:2013
Order code 8637-A or 8637-A-PDF
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OTHER DIALYSIS STANDARDS

ORDER CODE	TITLE	PUBLISHED	PAGES	PRICE (LIST/MBR)
8638 or 8638-PDF	*Cardiovascular implants and extracorporeal systems—Extracorporeal blood circuit for hemodialyzers, hemodiafilters and hemofilters (ANSI/AAMI/ISO 8638:2010)*	*August 2010*	*14*	*$100 / $60*
606216 or 601216-PDF	*Medical electrical equipment—Part 2-16: Particular requirements for basic safety and essential performance of hemodialysis, hemodiafiltration and hemofiltration equipment (ANSI/AAMI/IEC 60601-2-16:2012) [Also available in Redline Format]*	*November 2012*	*64*	*$150 / $90*
TIR43 or TIR43-PDF	*Ultrapure dialysate for hemodialysis and related therapies (AAMI TIR43:2011)*	*November 2011*	*19*	*$100 / $60*

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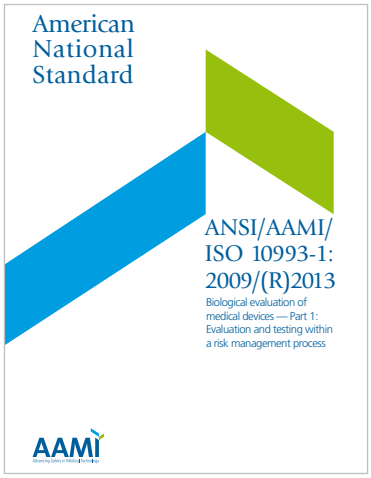


UPDATED! Part 1: Evaluation and testing within a risk management process, 4ed

Describes the general principles governing the biological evaluation of medical devices within a risk management framework; the general categorization of devices based on the nature and duration of their contact with the body; the evaluation of existing relevant data from all sources; the identification of gaps in the available data set on the basis of a risk analysis; the identification of additional data sets necessary to analyze the biological safety of the medical device; and the assessment of the biological safety of the medical device. Identical to ISO 10993-1/Ed.4.

Published November 2009, Reaffirmed December 2013, Errata June 2013, 24 pages

ANSI/AAMI/ISO 10993-1:2009/(R)2013

Order code 1099301 or 1099301-PDF

List $110 / AAMI member $66

Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity, 2ed

Published October 2003, Reaffirmed November 2013, 14 pages.

ANSI/AAMI/ISO 10993-3:2003/(R)2013

Order code 1099303 or 1099303-PDF

List $100 / AAMI member $60

Part 7: Ethylene oxide sterilization residuals, 3ed

Identical to ISO 10993-7/Ed.3.

Published January 2009, Reaffirmed June 2012, Errata January 2010, 98 pages

ANSI/AAMI/ISO 10993-7:2008/(R)2012

Order code 1099307 or 1099307-PDF

List $150 / AAMI member $90

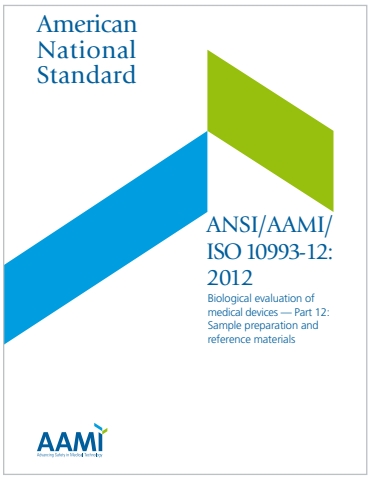
Part 9: Framework for identification and quantification of potential degradation products, 2ed

Published July 2010, 10 pages

ANSI/AAMI/ISO 10993-9:2009

Order code 1099309 or 1099309-PDF

List $100 / AAMI member $60



Part 12: Biological evaluation of medical devices—Part 12: Sample preparation and reference materials, 4ed

Specifies requirements and gives guidance on the procedures to be followed in the preparation of samples and the selection of reference materials for medical device testing in biological systems in accordance with one or more parts of the ISO 10993 series. Includes extraction procedures and soluble polymer procedures. Identical to ISO 10993-12.

Published September 2012, 23 pages

ANSI/AAMI/ISO 10993-12:2012

Order code 1099312 or 1099312-PDF

List $110 / AAMI member $66

Part 13: Identification and quantification of degradation products from polymeric devices, 2ed

Identical to ISO 10993-13/Ed.2.
Published November 2010, 16 pages
ANSI/AAMI/ISO 10993-13:2010
Order code 1099313 or 1099313-PDF
List $100 / AAMI member $60

Biological evaluation of medical devices—Guidance on the conduct of biological evaluation within a risk management process

This guidance is applicable to all biological evaluation of all types of medical devices. Identical to ISO 15499/Ed.1
Published February 2013, 16 pages
ANSI/AAMI/ISO TIR15499:2012
Order code 15499 or 15499-PDF
List $100 / AAMI member $60

OTHER BIOLOGICAL EVALUATION STANDARDS

ORDER CODE	TITLE	PUBLISHED	PAGES	PRICE (LIST/MBR)
13022 or 13022-PDF	*Medical products containing viable human cells—Application of risk management and requirements for processing practices (ANSI/AAMI/ISO 13022:2012)*	*July 2012*	*57*	*$150 / $90*
14155 or 14155-PDF	*Clinical investigation of medical devices for human subjects (ANSI/AAMI/ISO 14155:2011)*	*March 2011, Erata Dec 2011*	*69*	*$150 / $90*
1099302 or 1099302-PDF	*Part 2: Animal welfare requirements, 2ed (ANSI/AAMI/ISO 10993-2:2006/(R)2010)*	*Reaffirmed December 2010*	*17*	*$100 / $60*
1099304 or 1099304-PDF	*Part 4: Selection of tests for interactions with blood, 2ed and 2006 amendment (ANSI/AAMI/ISO 10993-4:2002/(R)2013 & A1:2006/(R)2013)*	*Reaffirmed November 2013*	*29*	*$110 / $66*
1099305 or 1099305-PDF	*Part 5: Tests for in vitro cytotoxicity, 3ed (ANSI/AAMI/ISO 10993-5:2009)*	*August 2009*	*37*	*$110 / $66*
1099306 or 1099306-PDF	*Part 6: Tests for local effects after implantation, 2ed (ANSI/AAMI/ISO 10993-6:2007/(R)2010)*	*Reaffirmed December 2010*	*23*	*$110 / $66*
1099310 or 1099310-PDF	*Part 10: Tests for irritation and skin sensitization, 3ed (ANSI/AAMI/ISO 10993-10:2010)*	*October 2010*	*74*	*$140 / $84*
1099311 or 1099311-PDF	*Part 11: Tests for systemic toxicity, 2ed (ANSI/AAMI/ISO 10993-11:2006/(R)2010)*	*Reaffirmed December 2010*	*27*	*$110 / $66*
1099312 or 1099312-PDF	*Part 12: Sample preparation and reference materials, 3ed (ANSI/AAMI/ISO 10993-12:2007)*	*December 2007*	*18*	*$100 / $60*
1099314 or 1099314-PDF	*Part 14: Identification and quantification of degradation products from ceramics (ANSI/AAMI/ISO 10993-14:2001/(R)2011)*	*Reaffirmed November 2011*	*9*	*$90 / $54*
1099315 or 1099315-PDF	*Part 15: Identification and quantification of degradation products from metals and alloys (ANSI/AAMI/ISO 10993-15:2000/(R)2011)*	*Reaffirmed November 2011*	*10*	*$100 / $60*
1099316 or 1099316-PDF	*Part 16: Toxicokinetic study design for degradation products and leachables (ANSI/AAMI/ISO 10993-16:2010)*	*July 2010*	*14*	*$100 / $60*
1099317 or 1099317-PDF	*Part 17: Establishment of allowable limits for leachable substances (ANSI/AAMI/ISO 10993-17:2002/(R)2012)*	*Reaffirmed November 2012*	*10*	*$110 / $66*
BE83 or BE83-PDF	*Part 18: Chemical characterization of materials (ANSI/AAMI BE83:2006/(R)2011) (Adoption of ISO 10993-18/Ed.1 with national deviations)*	*Reaffirmed December 2011*	*14*	*$100 / $60*
1099319 or 1099319-PDF	*Part 19: Physico-chemical, morphological, and topographical characterization of materials (ANSI/AAMI/ISO TIR10993-19:2006)*	*August 2006*	*16*	*$100 / $60*
1099320 or 1099320-PDF	*Part 20: Principles and methods for immunotoxicology testing of medical devices (ANSI/AAMI/ISO TIR10993-20:2006)*	*August 2006*	*19*	*$110 / $66*
2244201 or 2244201-PDF	*Medical devices utilizing animal tissues and their derivatives—Part 1: Application of risk management (ANSI/AAMI/ISO 22442-1:2007/(R)2011)*	*Reaffirmed November 2011*	*27*	*$110 / $66*
2244202 or 2244202-PDF	*Medical devices utilizing animal tissues and their derivatives—Part 2: Controls on sourcing, collection and handling (ANSI/AAMI/ISO 22442-2:2007/(R)2011)*	*Reaffirmed November 2011*	*17*	*$100 / $60*
2244203 or 2244203-PDF	*Medical devices utilizing animal tissues and their derivatives—Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents (ANSI/AAMI/ISO 22442-3:2007/(R)2011)*	*Reaffirmed November 2011*	*24*	*$110 / $66*
2244204 or 2244204-PDF	*Medical devices utilizing animal tissues and their derivatives—Part 4: Principles for elimination and/or inactivation of transmissible spongiform encephalopathy (TSE) agents and validation assays for those processes (ANSI/AAMI/ISO TIR22442-4:2010)*	*November 2011*	*16*	*$90 / $54*

Quality Systems

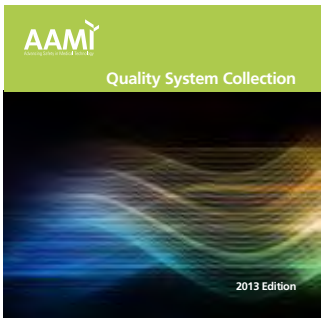
Medical devices—Quality management systems—Requirements for regulatory purposes, 2ed

Specifies requirements for a quality management system for medical devices where an organization needs to demonstrate its ability to provide products that consistently meet customer and applicable regulatory requirements. Identical to ISO 13485/Ed.2.

Published August 2003, Reaffirmed November 2009, 50 pages
ANSI/AAMI/ISO 13485:2003/(R)2009
Order code 13485 or 13485-PDF
List $140 / AAMI member $84

Quality management systems—Medical devices—Guidance on the application of ISO 13485:2003, 2ed

Published January 2005, 75 pages
ANSI/AAMI/ISO TIR14969:2004
Order code 14969 or 14969-PDF
List $150 / AAMI member $90



Quality System Collection

This CD of AAMI standards has it all for quality systems, design control, human factors, and software validation; important government guidance documents from FDA; and quick links to government resources such as the Recall, PMA, Recognized Standards, and MDR databases. The perfect resource for medical device professionals looking for a single source for guidance and advice on device development issues.

Published May 2013
Order code AQS-CD
List $660 / AAMI member $462

FDA's Guide to Inspections of Quality Systems (QSIT)

(Handbook and CD-ROM Training Program)
The 100+ page handbook provides guidance to FDA field staff who manage the QSIT process. Includes flow charts and checklists of information that will be verified during the QSIT process. The CD contains the same training program used by FDA to train its inspectors in QSIT.

Produced 1999, 100 pages
Order code QSIT or QSIT-CD
List $55 / AAMI member $33

The Quality System Compendium: GMP Requirements & Industry Practice, 2nd edition

The go-to resource for information on the requirements of FDA's Quality System Regulation. Each requirement of the regulation is defined, with accompanying discussion of the requirements and industry practice. Also includes:

- Chapters on combination products and risk management for medical devices
- A comprehensive index
- Bibliography that includes references and websites
- A full copy of the Final Rule for the Quality System Regulation, including Preamble
- User-friendly tabs for easy navigation

The Compendium is also available for purchase on CD. Have the electronic version of the document available for easy access at work or on the road!

Published November 2007
Order code QSC or QSC-CD
List $650 / AAMI member $390

Bundled Set of Textbook and CD

Order code QSC-S
List $985 / AAMI member $591

LEADING PRACTICE SERIES

COMING SOON! Operational Qualification: The Cornerstone of Successful Process Validation

Discusses the central role of the operational qualification in establishing a well-controlled process during process validation. (Expected May 2014)
Order Code LP-OQ or LP-OQ-PDF
List $60 / AAMI member $35

NEW! Laboratory Equipment Service Strategies

Provides instruction on hospital laboratory service procedures, and a synopsis of the general type of work that is required when starting a laboratory support program. (October 2013)
Order Code LP-LAB or LP-LAB-PDF
List $60 / AAMI member $35

NEW! Integrated Process Flow in the Modern Sterile Processing Department

Provides guidance on how modern sterile processing departments can streamline processes and promote efficiency by incorporating patient and employee safety with effective integrated processes and automation. (October 2013)
Order Code LP-IPF or LP-IPF-PDF
List $60 / AAMI member $35

Quality Audits: Strategy for Ensuring Effectiveness and Compliance of Quality System

Discusses the need for manufacturers to conduct regular quality audits led by individuals not directly responsible for the matters being audited, with management review of audit results. (Dec. 2011)
Order Code LP-QA or LP-QA-PDF
List $60 / AAMI member $35

Device Design Set: Save on the set of two design documents.
Order Code LP-DHI-S or LP-DHI-S-PDF
List $105 / AAMI member $63

Design History File—Tips for Creating a Successful DHF

Provides helpful background and tips on common compliance issues, design history file development and maintenance, as well as case studies to illustrate processes. (October 2012)
Order Code LP-DH or LP-DH-PDF
List $60 / AAMI member $35

Design Input—Designing the 'Right' Device

Provides practical at-a-glance tables, diagrams, and flowcharts to improve design input processes and requirements. (Oct. 2012)
Order Code LP-DI or LP-DI-PDF
List $60 / AAMI member $35

NEW! Quality Management: Achieving an Effective Training Program

Designed to help medical device firms better understand, implement, and comply with the training section of the Quality System Regulation 21 CFR 820.25(a) (b) as well as ISO 13485:2003 Section 6.2.2. (March 2014)
Order Code LP-QM or LP-QM-PDF
List $60 / AAMI member $35

Management Responsibility: Connecting Business Acuity and Quality Excellence

Designed to highlight the role of top management for medical device firms in ensuring effective and compliant operation of the Quality Management System. (December 2011)
Order Code LP-MR or LP-MR-PDF
List $60 / AAMI member $35

CAPA Set: Save on the set of four CAPA documents.
Order Code LP-CAPA-S or LP-CAPA-S-PDF
List $190 / AAMI member $114

System Implementation and Compliance (CAPA)

Provides medical device firms with a practical approach to better understand, implement, and comply with the CAPA section of the Quality System Regulation (21 CFR 820.100), specifically system implementation and compliance. (December 2012)
Order Code LP-SYSTEM or LP-SYSTEM-PDF
List $60 / AAMI member $35

Practical Approaches to Compliance: CAPA—Complaints

This document reviews the four most frequently cited observations related to Complaint Files, and provides examples and helpful tools for an effective complaint handling system. (July 2012)
Order Code LP-COMPLAINT or LP-COMPLAINT-PDF
List $60 / AAMI member $35

CAPA Verification and Validation: Practical Approaches to Compliance

Designed to help medical device firms better understand, implement, and comply with the CAPA section of the Quality System Regulation (21 CFR 820.100). (October 2011)
Order Code LP-CAPA or LP-CAPA-PDF
List $60 / AAMI member $35

Controlling Nonconforming Product (CAPA)

Provides medical device firms a practical approach to understand, implement, and comply with the CAPA section of the Quality System Regulation. (January 2013)
Order Code LP-CONTROL or LP-CONTROL-PDF
List $60 / AAMI member $35

AAMI's Leading Practices are concise documents that provide practical information and guidance on a wide range of specific topics facing medical technology professionals. Written by experts in the field, they undergo peer-review before publication.

Risk Management, Symbols, Nomenclature

Medical devices—Application of risk management to medical devices, 3ed

Specifies a process for a manufacturer to identify the hazards and hazardous situations associated with medical devices, including in vitro diagnostic (IVD) medical devices, to estimate and evaluate the resulting risks, to control these risks, and to monitor the effectiveness of that control. Identical to ISO 14971/Ed.3.

Published April 2007, Errata issued October 2007, Reaffirmed October 2010, 86 pages
ANSI/AAMI/ISO 14971:2007/(R)2010
Order code 14971 or 14971-PDF
List $170 / AAMI member $102

Medical device software—Part 1: Guidance on the application of ISO 14971 to medical device software

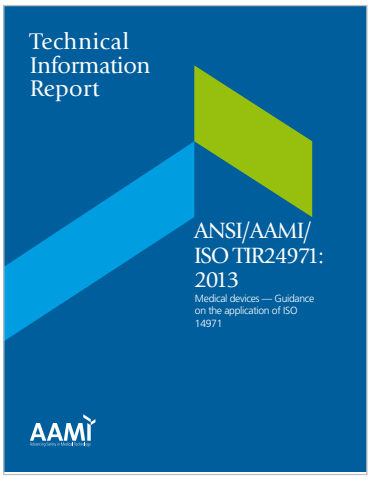
Provides information useful for the performance of effective software risk management, as part of the overall risk management process for medical devices containing software. Identical to IEC 62A/TR 80002-01/Ed.1.

Published December 2009, 64 pages
ANSI/AAM/IEC TIR80002-1:2009
Order code 8000201 or 8000201-PDF
List $150 / AAMI member $90

Medical devices—Symbols to be used with medical device labels, labeling, and information to be supplied—Part 1: General requirements, 2ed

Identifies requirements for the development and use of symbols that may be used to convey information on the safe and effective use of medical devices. Identical to ISO 15223-1/Ed.2.

Published November 2012, 24 pages
ANSI/AAMI/ISO 15223-1:2012
Order code 1522301 or 1522301-PDF
List $110 / AAMI member $66



NEW! Medical devices—Guidance on the application of ISO 14971

This document provides guidance that addresses specific areas that are problematic for those implementing a risk management system. Identical to ISO 24971.

Published Aug. 2013, 15 pages
ANSI/AAMI/ISO TIR24971:2013
Order code 24971 or 24971-PDF
List $100 / AAMI member $60

UPDATED! Medical devices—Hierarchical coding structure for adverse events—Part 1: Event type codes, 2ed

Specifies requirements for a coding structure for describing adverse events related to medical devices. This edition expands on the adverse event type and cause/effect structure and relevant codes previously developed. Identical to ISO TS 19218-1/Ed.2. Includes 2013 amendment.

Published November 2011, 17 pages
ANSI/AAMI/ISO TIR19218-1:2011 & A1:2013
Order code 1921801 or 1921801-PDF
List $100 / AAMI member $60

NEW! Medical devices—Hierarchical coding structure for adverse events—Part 1: Event-type codes, Amendment 1

Published December 2013, 9 pages
ANSI/AAMI/ISO TIR19218-1:2011/A1:2013
Order code 1921801-A or 1921801-A-PDF
List $30 / AAMI member $18

Application of risk management for IT Networks incorporating medical devices—Part 1: Roles, responsibilities and activities

ANSI/AAMI/IEC 80001-1:2010
Order code 8000101 or 8000101-PDF
List $140 / AAMI member $84

For more information, see page 28.

Medical Electrical Equipment Symbols and Safety Signs CD

This clip art CD includes more than 640 standardized graphical symbols and safety signs for medical equipment in EPS, TIF, and JPEG formats, labeled by symbol number with thumbnail views available for easy identification. Symbols from IEC 60878 and ISO 15223-1, 27185, 60601-2-2, and 60601-1 are included. These high–resolution vector graphics can be scaled to nearly any size. This also contains the full text of the IEC 60878 and ISO 15223 standards.

Published May 2013
Order code SYMBCD
List $660 / AAMI member $462

OTHER RISK MANAGEMENT, SYMBOLS, NOMENCLATURE STANDARDS

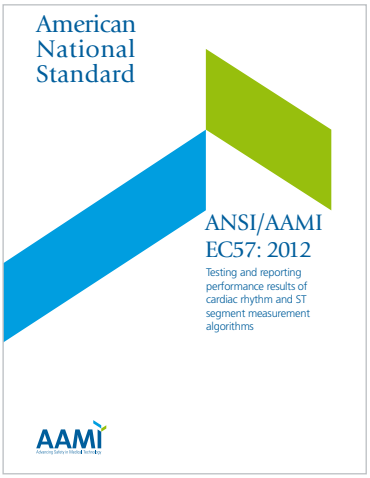
ORDER CODE	TITLE	PUBLISHED	PAGES	PRICE (LIST/MBR)
15225 or 15225-PDF	*Nomenclature—Medical device nomenclature data structure, 2ed (ANSI/AAMI/ISO 15225:2010)*	*August 2010*	*23*	*$110 / $66*
16142 or 16142-PDF	*Medical devices—Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices, 2ed (ANSI/AAMI/ISO TIR16142:2005)*	*March 2006*	*17*	*$100 / $60*
60878 or 60878-PDF	*Graphical symbols for electrical equipment in medical practice (ANSI/AAMI/IEC TIR60878:2003)*	*June 2004*	*149*	*$170 / $102*
1522302 or 1522302-PDF	*Medical devices—Symbols to be used with medical device labels, labeling, and information to be supplied—Part 2: Symbol development, selection and validation (ANSI/AAMI/ISO 15223-2:2010)*	*August 2010*	*17*	*$100 / $60*
1921802 or 1921802-PDF	*Medical devices—Hierarchical coding structure for adverse events—Part 2: Evaluation code (ANSI/AAMI/ISO TIR19218-2:2012)*	*December 2012*	*14*	*$100 / $60*
8036901 or 8036901-PDF	*Small bore connectors for liquids and gases in healthcare applications—Part 1: General requirements (ANSI/AAMI/ISO 80369-1:2010)*	*February 2011*	*18*	*$100 / $60*

Medical Equipment

ELECTROCARDIOGRAPHY

NEW! ECG trunk cables and patient leadwires

The objective of this standard is to allow ECG trunk cables and patient leadwires to be interchanged between ECG devices with isolated patient connections by establishing a common interface between the trunk cable and the patient leadwire connectors. Performance and safety criteria for trunk cables and patient leadwires used with isolated patient connectors are also specified.
Published February 2014, 13 pages
ANSI/AAMI EC53:2013
Order code EC53 or EC53-PDF
List $100 / AAMI member $60



Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms

Covers a method for testing and reporting the performance of algorithms used to detect cardiac rhythm disturbances, including the ST segment.
Published April 2013, 36 pages
ANSI/AAMI EC57:2013
Order code EC57 or EC57-PDF
List $140 / AAMI member $84

DIAGNOSTIC AND MONITORING EQUIPMENT

UPDATED! Medical electrical equipment—Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

Published January 2010, Updated with Amendment February 2014, 59 pages
ANSI/AAMI/IEC 80601-2-30:2009 & A1:2013
Order code 601230 or 601230-PDF
List $140 / AAMI member $84

NEW! Medical electrical equipment—Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers, Amendment 1

Published February 2014, 9 pages
ANSI/AAMI/IEC 80601-2-30:2009/A1:2013
Order code 601230-A or 601230-A-PDF
List $30 / AAMI member $18 (PDF is FREE)

NEW! Non-invasive sphygmomanometers—Part 2: Clinical investigation of automated measurement type

This is applicable to all sphygmomanometers that sense or display pulsations, flow, or sounds for the estimation, display, or recording of blood pressure. This standard is also applicable to the validation of electronically-controlled intermittent noninvasive blood pressure measurement medical electrical equipment, including blood pressure monitors for the home healthcare environment or self-measurement.
Published February 2014, 43 pages
ANSI/AAMI/ISO 81060-2:2013
Order code 8106002 or 8106002-PDF
List $140 / AAMI member $84

Sphygmomanometer Set

Includes ANSI/AAMI/ISO 81060-1:2007, ANSI/AAMI/ISO 81060-2:2013, and ANSI/AAMI/IEC 80601-2-30:2009. (Each of these standards is also available individually.)
Order code 81060-S or 81060-S-PDF
List $300 / AAMI member $210

NEW! Non-invasive blood pressure motion artifact—Testing and evaluation of NIBP device performance in the presence of motion artifact

This provides information on the sources and effects of artifact noise in non-invasive blood pressure measurement. The report also includes an overview of potential evaluation methods for the qualification and classification of device performance when varying levels of artifact noise are present during an NIBP cycle.
Published June 2013, 27 pages
AAMI TIR44:2012
Order code TIR44 or TIR44-PDF
List $110 / AAMI member $66

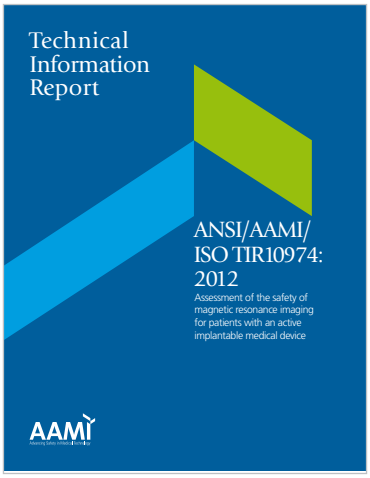
IMPLANTABLE MEDICAL DEVICES

Evaluation of particulates associated with vascular medical devices

This TIR offers guidance to medical device manufacturers in application of analytical methods for particulate testing, identifying potential sources of particulates, and developing particulate limits.
Published December 2010, 46 pages
AAMI TIR42:2010
Order code TIR42 or TIR42-PDF
List $140 / AAMI member $84

COMING SOON! Cardiovascular implants and extracorporeal systems—Cardiovascular absorbable implants

Outlines design verification and validation considerations for absorbable cardiovascular implants. Applicable to implants in direct contact with the cardiovascular system, where the intended action is upon the circulatory system.
Expected Publication July 2014
ANSI/AAMI/ISO TS 17137:2014
Order code 17137 or 17137-PDF
List $110 / AAMI member $66



NEW! Cardiovascular implants—Cardiac valve prostheses — Part 3: Heart valve substitutes implanted by transcatheter techniques

Outlines an approach for verifying/validating the design and manufacture of a transcatheter heart valve substitute through risk management. The selection of appropriate verification/validation tests and methods are to be derived from the risk assessment.
Published July 2013, 116 pages
ANSI/AAMI/ISO 5840-3:2013
Order code 584003 or 584003-PDF
List $170 / AAMI member $102

NEW! Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device

This contains test methods that are applicable to a broad class of active implantable medical devices (AIMDs) for the purpose of evaluating device operation against several hazards.
Published August 2013, 210 pages
ANSI/AAMI/ISO TIR10974:2012
Order code 10974 or 10974-PDF
List $230 / AAMI member $138

NEW! Implants for surgery—Cardiac pacemakers—Part 3: Low-profile connectors (IS-1) for implantable pacemakers

This specifies a connector assembly to be used to connect implantable pacemaker leads to implantable pacemaker pulse generators. Essential dimensions and performance requirements related to connector fit are specified, as are test methods.
Published August 2013, 14 pages
ANSI/AAMI/ISO 5841-3:2013
Order code 584103 or 584103-PDF

THERAPY AND SURGERY

NEW! Transcutaneous electrical nerve stimulators

This standard establishes labeling, safety, and performance requirements and referee tests for transcutaneous electrical stimulators intended for use in the treatment of pain syndrome.
Published July 2013, 13 pages
ANSI/AAMI NS4:2013
Order code NS4 or NS4-PDF
List $100 / AAMI member $60

BLOOD TRANSFUSION

NEW! Autologous transfusion devices, 4ed

This standard establishes labeling and performance requirements, test methods, and terminology that will help define a reasonable level of safety and efficacy for autologous transfusion devices.
Published August 2013, 19 pages
ANSI/AAMI AT6:2013
Order code AT6 or AT6-PDF
List $100 / AAMI member $60

Smart Infusion Pumps: Implementation, Management, and Drug Libraries

This book is a reference for hospitals and health systems that are using intelligent infusion device technology or considering smart pump implementation. It includes:

- An introduction to smart infusion pump technology
- A guide to choosing a pump and usability testing
- Guiding principles for implementation of smart infusion pumps
- Techniques for developing medication dosing limits
- Practice tips for implementation and management
- Sample drug libraries
- Checklists and other educational materials

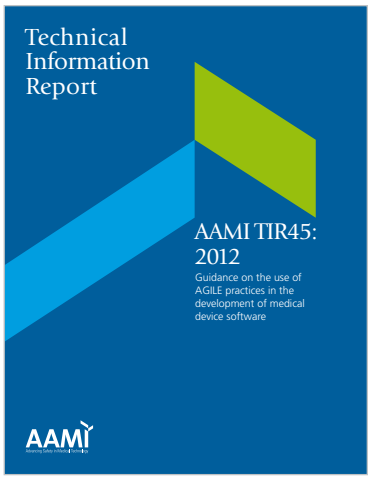
Written by Pamela K. Phelps, PharmD, FASHP, the book provides a comprehensive general drug library to assist in implementation and ongoing management of smart infusion pumps.
Published January 2011 by the American Society of Health-System Pharmacists, 200 pages
Order code SIP
List $99 / AAMI member $79

OTHER MEDICAL EQUIPMENT STANDARDS

ORDER CODE	TITLE	PUBLISHED	PAGES	PRICE (LIST/MBR)	GROUPING
CV5840 or CV5840-PDF	Cardiovascular implants—Cardiac valve prostheses, 4ed (ANSI/AAMI/ISO 5840:2005/(R)2010)	Reaffirmed April 2010	71	$150 / $90	Implantable Medical Devices
7198 or 7198-PDF	Cardiovascular implants—Tubular vascular prostheses, 3ed (ANSI/AAMI/ISO 7198:1998/2001/(R)2010)	Reaffirmed April 2010	42	$140 / $84	Implantable Medical Devices
7199 or 7199-PDF	Cardiovascular implants and artificial organs—Blood-gas exchangers (oxygenators), 2ed and amendment (ANSI/AAMI/ISO 7199:2009 & A1:2012)	Updated March 2012	12	$100 / $60	Implantable Medical Devices
11658 or 11658-PDF	Cardiovascular implants and extracorporeal systems—Blood/tissue contact surface modifications for extracorporeal perfusion systems (ANSI/AAMI/ISO 11658:2012)	October 2012	8	$90 / $54	Implantable Medical Devices
12417 or 12417-PDF	Cardiovascular implants and extracorporeal systems—Vascular device-drug combination products (ANSI/AAMI/ISO TIR12417:2011)	July 2011	52	$120 /$60	Implantable Medical Devices
14117 or 14117-PDF	Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators, 2ed (ANSI/AAMI/ISO 14117:2012)	December 2012	112	$170 / $102	Implantable Medical Devices
15674 or 15674-PDF	Cardiovascular implants and artificial organs—Hard shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags, 2ed (ANSI/AAMI/ISO 15674:2009)	May 2009	10	$90 / $54	Implantable Medical Devices
15675 or 15675-PDF	Cardiovascular implants and artificial organs—Cardiopulmonary bypass systems—Arterial line blood filters, 2ed (ANSI/AAMI/ISO 15675:2009)	May 2009	10	$90 / $54	Implantable Medical Devices
23810 or 23810-PDF	Cardiovascular implants and artificial organs—Checklist for preoperative extracorporeal circulation equipment setup (ANSI/AAMI/ISO TIR23810:2012)	August 2012	11	$100 / $60	Implantable Medical Devices
27185 or 27185-PDF	Active implantable medical devices—Symbols to be used with cardiac device labels, labeling and information to be supplied by the manufacturer (ANSI/AAMI/ISO 27185:2012)	April 2012	31	$150 /$90	Implantable Medical Devices
27186 or 27186- PDF	Active implantable medical devices—Four-pole connector system for implantable cardiac rhythm management devices—Dimensional and test requirements (ANSI/AAMI/ISO 27186:2010)	September 2010	87	$170 / $102	Implantable Medical Devices
61289 or 61289-PDF	High frequency surgical equipment—Operation and Maintenance (ANSI/AAMI/IEC TIR61289:2011)	March 2012	21	$110 / $66	Therapy & Surgery
601202 or 601202-PDF	Medical electrical equipment—Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories, 5ed (ANSI/AAMI/IEC 60601-2-2:2009)	July 2009	78	$150 / $90	Therapy & Surgery
601204 or 601204-PDF	Medical electrical equipment—Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators (ANSI/AAMI/IEC 60601-2-4:2010)	January 2011	74	$150 / $90	Therapy & Surgery
601219 or 601219-PDF	Medical electrical equipment—Part 2-19: Particular requirements for basic safety and essential performance of baby incubators, 4ed (ANSI/AAMI/IEC 60601-2-19:2009)	April 2009	33	$140 / $84	Therapy & Surgery
601220 or 601220-PDF	Medical electrical equipment—Part 2-20: Particular requirements for basic safety and essential performance of transport incubators, 3ed (ANSI/AAMI/IEC 60601-2-20:2009)	April 2009	38	$140 / $84	Therapy & Surgery
601221 or 601221-PDF	Medical electrical equipment—Part 2-21: Particular requirements for basic safety and essential performance of infant radiant warmers, 2ed (ANSI/AAMI/IEC 60601-2-21:2009)	April 2009	32	$140 / $84	Therapy & Surgery
601225 or 601225-PDF	Medical electrical equipment—Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs (ANSI/AAMI/IEC 60601-2-25:2011)	June 2012	94	$170 / $102	Electrocardiography
601227 or 601227-PDF	Medical electrical equipment—Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment (ANSI/AAMI/IEC 60601-2-27:2011)	September 2011	71	$150 / $90	Electrocardiography
601247 or 601247-PDF	Medical electrical equipment—Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems (ANSI/AAMI/IEC 60601-2-47:2012)	August 2012	64	$150 / $90	Electrocardiography
601250 or 601250-PDF	Medical electrical equipment—Part 2-50: Particular requirements for basic safety and essential performance of infant phototherapy equipment (ANSI/AAMI/IEC 60601-2-50:2009)	April 2009	21	$110 / $66	Therapy & Surgery

8106001 or 8106001-PDF	Non-invasive sphygmomanometers—Part 1: Requirements and test methods for non-automated measurement type (ANSI/AAMI/ISO 81060-1:2007/(R)2013)	Reaffirmed June 2013	40	$140 / $84	Diagnostic & Monitoring Equipment
1470803 or 1470803-PDF	Implants for surgery—Active implantable medical devices—Part 3: Implantable neurostimulators (ANSI/AAMI/ISO 14708-3:2008/(R)2011)	Reaffirmed Nov. 2011	47	$140 / $84	Neurosurgical Devices
1470804 or 1470804-PDF	Implants for surgery—Active implantable medical devices—Part 4: Implantable infusion pumps (ANSI/AAMI/ISO 14708-4:2008/(R)2011)	Reaffirmed November 2011	46	$140 / $84	Implantable Medical Devices
1470805 or 1470805-PDF	Implants for surgery—Active implantable medical devices—Part 5: Circulatory support devices (ANSI/AAMI/ISO 14708-5:2010)	April 2010	50	$150 / $90	Implantable Medical Devices
2553901 or 2553901-PDF	Cardiovascular implants—Endovascular devices—Part 1: Endovascular prostheses (ANSI/AAMI/ISO 25539-1:2003/(R)2009)	Reaffirmed August 2009	39	$130 / $78	Implantable Medical Devices
2553901-A or 2553901-A-PDF	Cardiovascular implants—Endovascular devices—Part 1: Endovascular prostheses—Amendment 1: Test methods (ANSI/AAMI/ISO 25539-01:2003/A1:2005/(R)2009)	Reaffirmed August 2009	37	$130 / $78	Implantable Medical Devices
2553902 or 2553902-PDF	Cardiovascular implants — Endovascular devices — Part 2: Vascular stents (ANSI/AAMI/ISO 25539-2:2012)	August 2012	104	$170 / $102	Implantable Medical Devices
2553903 or 2553903-PDF	Cardiovascular implants—Endovascular devices—Part 3: Vena cava filters (ANSI/AAMI/ISO 25539-3:2011)	August 2012	100	$170 / $102	Implantable Medical Devices
BF7 or BF7-PDF	Blood transfusion microfilters (ANSI/AAMI BF74:2013)	April 2013	19	$100 / $60	Blood Transfusion
BP22 or BP22-PDF	Blood pressure transducers, 2ed (ANSI/AAMI BP22:1994/(R)2011)	Reaffirmed December 2011	14	$100 / $60	Diagnostic & Monitoring Equipment
BF64 or BF64-PDF	Leukocyte reduction filters (ANSI/AAMI BF64:2013)	April 2013	12	$100 / $60	Blood Transfusion
EC12 or EC12-PDF	Disposable ECG electrodes (ANSI/AAMI EC12:2000/(R)2010)	Reaffirmed August 2010	14	$100 / $60	Electrocardiography
EC71 or EC71-PDF	Standard communications protocol—Computer assisted electrocardiography (ANSI/AAMI EC71:2001/(R)2013)	Reaffirmed September 2013	156	$170 / $102	Electrocardiography
ID26 or ID26-PDF	Medical electrical equipment—Part 2: Particular requirements for the safety of infusion pumps and controllers, 3ed (ANSI/AAMI ID26:2004/(R)2013)	Reaffirmed Nov. 2013	50	$150 / $90	Therapy & Surgery
ID54 or ID54-PDF	Enteral feeding set adapters and connectors (ANSI/AAMI ID54:1996/(R)2012)	Reaffirmed January 2012	5	Single Copies Free	Therapy & Surgery
NS28 or NS28-PDF	Intracranial pressure monitoring devices (ANSI/AAMI NS28:1988/(R)2010)	Reaffirmed Dec. 2010	10	$100 / $60	Neurosurgical Devices
TIR4 or TIR4-PDF	Apnea monitoring by means of thoracic impedance pneumography (AAMI TIR4:1989)	December 1989	60	$150 / $90	Diagnostic & Monitoring Equipment
TIR9 or TIR9-PDF	Evaluation of clinical systems for invasive blood pressure monitoring (AAMI TIR9:1992)	January 1993	58	$150 / $90	Diagnostic & Monitoring Equipment
TIR11 or TIR11-PDF	Selection and use of protective apparel and surgical drapes in health care facilities, 2ed (AAMI TIR11:2005)	February 2006	38	$140 / $84	Therapy & Surgery
TIR21 or TIR21-PDF	Systems used to forecast remaining pacemaker battery service life (AAMI TIR21:1998)	December 1998	53	$150 / $90	Implantable Medical Devices
TIR23 or TIR23-PDF	Signal averaging (AAMI TIR23:1999)	June 2000	30	$140 / $84	Electrocardiography
TIR24 or TIR24-PDF	Acquisition and use of physiologic waveform databases for testing of medical devices (AAMI TIR24:1999)	October 2000	44	$140 / $84	Diagnostic & Monitoring Equipment
TIR41 or TIR41-PDF	Active implantable medical devices—Guidance for designation of left ventricle and implantable cardioverter defibrillator lead connectors and pulse generator connector cavities for implantable pacemakers and implantable cardioverter defibrillators (AAMI TIR41:2011)	February 2012	7	$90 / $54	Implantable Medical Devices

IT & Software Resources



Guidance on the use of AGILE practices in the development of medical device software

This TIR provides recommendations for complying with international standards and FDA guidance documents when using AGILE practices to develop medical device software.

Published September 2012, 58 pages

AAMI TIR45:2012

Order code TIR45 or TIR45-PDF

List $150 / AAMI member $90

Application of quality management system concepts to medical device data systems

Provides information that will allow the Medical Device Data System manufacturer to implement a Quality Management System that is commensurate with the risk presented by the device, the complexity of device and manufacturing processes, and the size and complexity of the organization.

Published June 2012, 26 pages

AAMI SW87:2012

Order code SW87 or SW87-PDF

List $110 / AAMI member $66

Medical device software—Software life cycle processes

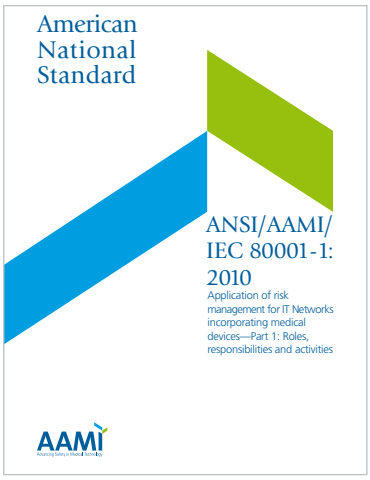
Specifies requirements for medical device software life cycle processes including primary life cycle development and maintenance processes, and supporting processes such as software hazard management, documentation, configuration management, verification, and problem resolution. Includes a compliance section based on whether or not the software can cause a hazard or controls risk. Revision of ANSI/AAMI SW68:2001. Identical adoption of IEC 62304:2006.

Published June 2006, 67 pages

ANSI/AAMI/IEC 62304:2006

Order code 62304 or 62304-PDF

List $150 / AAMI member $90



Application of risk management for IT Networks incorporating medical devices—Part 1: Roles, responsibilities and activities

Includes:

- Responsibilities for parties engaged in installing, using, reconfiguring, maintaining, and decommissioning IT-networks incorporating medical devices
- Essential properties such as safety, effectiveness, data & system security, and interoperability
- Risks related to patients, operators, and/or third parties

Published October 2010, 36 pages

ANSI/AAMI/IEC 80001-1:2010

Order code 8000101 or 8000101-PDF

List $140 / AAMI member $84

Getting Started with IEC 80001: Essential Information for Healthcare Providers Managing Medical IT-Networks

Includes:

- Important details about the standard, its purpose, roles and responsibilities, and integrating other IT and CE guidance
- Practical guidance to get started with 80001, CE-IT collaboration, assessing/managing risk, and reviewing overall risk
- Advice on maintaining what has been achieved—monitoring medical IT-network operation, safety incidents, and much more

Published March 2011, 76 pages

Order code 80001-GS or 80001-GS-PDF

List $150 / AAMI member $90

Save with the Set (80001-1 and Getting Started with ...)

Order code 80001-GS-S or 80001-GS-S-PDF

List $225 / AAMI member $135

Medical device software risk management

Published February 2005, 65 pages

AAMI TIR32:2004

Order code TIR32 or TIR32-PDF

List $150 / AAMI member $90

Application of risk management for IT-networks incorporating medical devices—Part 2-1: Step by step risk management of medical IT-networks; Practical application and examples

Published October 2012, 60 pages
ANSI/AAMI/IEC TIR 80001-2-1:2012
Order code 800010201 or 800010201-PDF
List $150 / AAMI member $90

Application of risk management for IT-networks incorporating medical devices—Part 2-2: Guidance for the communication of medical device security needs, risks and controls

Published November 2012, 52 pages
ANSI/AAMI/IEC TIR 80001-2-2:2012
Order code 800010202 or 800010202-PDF
List $150 / AAMI member $90

Application of risk management for IT-networks incorporating medical devices—Part 2-3: Guidance for wireless networks

Published October 2012, 43 pages
ANSI/AAMI/IEC TIR 80001-2-3:2012
Order code 800010203 or 800010203-PDF
List $140 / AAMI member $84

NEW! Application of risk management for IT-networks incorporating medical devices—Part 2-4: Application guidance—General implementation guidance for healthcare delivery organizations

Published July 2013, 20 pages
ANSI/AAMI/IEC TIR 80001-2-4:2012
Order code 800010204 or 800010204-PDF
List $110 / AAMI member $66

COMING SOON! Application of risk management for IT-networks incorporating medical devices—Part 2-6: Guidance for responsibility agreements

Provides guidance on implementing responsibility agreements, which are required in ISO/IEC 80001-1 for the purpose of defining the roles and responsibilities of all relevant stakeholders in the medical IT-network.
Expected Publication Fall 2014, 25 pages
ANSI/AAMI/IEC TIR 80001-2-6:2014
Order code 800010206 or 800010206-PDF
List $110 / AAMI member $66

Medical device software—Part 1: Guidance on the application of ISO 14971 to medical device software

See page 22
ANSI/AAMI/IEC TIR80002-1:2009
Order code 8000201 or 8000201-PDF
List $150 / AAMI member $90

Validation of software for regulated processes

Applies to any software used to automate device design, testing, component acceptance, manufacturing, labeling, packaging, distribution, and complaint handling, or to automate any other aspect of the quality system as defined by the Quality System Regulation (21 CFR 820). It also applies to software used to create, modify, and maintain electronic records and to manage electronic signatures subject to the validation requirements (21 CFR 11).
Published March 2008, 99 pages
AAMI TIR36:2007
Order code TIR36 or TIR36-PDF
List $170 / AAMI member $102

NEW! Medical Electrical Equipment—Part 1-8: General requirements for basic safety and essential performance—Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

This defines the roles, responsibilities and activities necessary for risk management of IT-networks incorporating medical devices to address safety, effectiveness, and data and system security.
Published April 2014, 87 pages
ANSI/AAMI/IEC 60601-1-8:2006 & A1:2012
Order code 6010108 or 6010108-PDF
List $560 / AAMI member $336

Medical Device Software: Verification, Validation, and Compliance

This book is designed to help medical device and software engineers and quality assurance and compliance professionals implement critical verification and validation processes.
Published October 2010 by Artech House, 428 pages
Order code DSV
List $145 / AAMI member $115

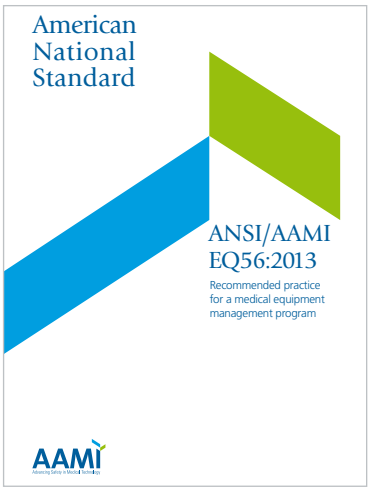
Medical Technology for the IT Professional

This practical guide provides details on medical technologies that are heavily IT-based or highly integrated into IT infrastructures. Each chapter examines a specific medical technology—what it is and how it works—and then dives into the issues affecting IT.
Published 2009 by ECRI Institute, 94 pages
Order code MT-IT
List $139 / AAMI member $99

NEW! IT Collection CD

This new collection is your one-stop resource for 80001 and Medical Device Data System (MDDS) guidance. Searchable and easy to use, it features 9 popular standards.
Expected Publication June 2014.
Order code ITCOL-CD
List $480 / AAMI member $268

General Safety, Design, & Maintenance



Recommended practice for a medical equipment management program

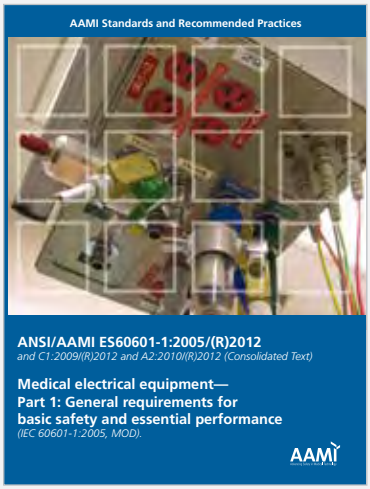
Published April 2013, 35 pages
ANSI/AAMI EQ56:2013
Order code EQ56 or EQ56-PDF
List $140
AAMI member $84

COMING SOON! Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral Standard: Electromagnetic disturbances—Requirements and tests

Specifies general requirements and tests for basic safety and essential performance with regard to electromagnetic disturbances of medical electrical (ME) equipment and ME systems.
Expected Publication June 2014, 88 pages
ANSI/AAMI/IEC 60601-1-2:2014
Order code 601102 or 601102-PDF
List $170 / AAMI member $102

COMING SOON! Medical electrical equipment—Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery

This standard aims to set appropriate safety and performance requirements to reduce the risk of detrimental impact on the medical treatment to an acceptable level for their intended use.
Expected Publication June 2014, 30 pages
ANSI/AAMI/IEC 80601-2-58:2014
Order code 601258 or 601258-PDF
List $130 / AAMI member $78



60601-1, 3rd Edition, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance

This standard, now in it's third edition, covers any medical device that requires an electrical outlet or a battery. It has come to be known throughout the industry as the 'bible' of medical electrical equipment standards. It:

- Includes a risk management model—based on ISO 14971
- Introduces the concept of essential performance—a measure of a device's effect on user and patient safety
- Offers flexibility in meeting requirements, for example, different requirement levels for parts that come into contact with the user vs. parts that come in contact with the patient
- Provides structured method for manufacturers to demonstrate equivalent safety of alternate means of compliance

You get the consolidated text of 60601-1 and Amendment 1 (60601-1:2005(R) 2012/A1:2012) showing the nearly 500 changes made by the amendment. Adoption, with national deviations, of IEC 60601-1/Ed.3.
Published March 2006, Reaffirmed January 2012, 402 pages
ANSI/AAMI ES60601-1:2005/(R)2012 (IEC 60601-1:2005, MOD)
Order code 606011 (print), 606011-PDF, 606011-CD, or 606011-PE (5.5" x 7" travel edition)
List $660 / AAMI member $396

60601-1, 3rd Edition, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance, Amendment 1

Identical adoption of IEC 60601-1 Amendment 1
Published November 2012, 118 pages
ANSI/AAMI ES60601-1:2005/(R)2012/A1:2012
Order code 606011-A or 606011-A-PDF
List $170 / AAMI member $102

Assessment of the impact of the most significant changes in Amendment 1 to IEC 60601-1:2005 and mapping of the clauses of IEC 60601-1:2005 to the previous edition

The second edition of this technical report for users of IEC 60601-1.
Published January 2013, 94 pages
ANSI/AAMI/IEC TIR62348:2012
Order code 62348 or 62348-PDF
List $170 / AAMI member $102

Medical Electrical Equipment—Part 1-11: General requirements for basic safety and essential performance—Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Adoption, with national deviations, of IEC 60601-1-11/Ed.1.
Published December 2011, 54 pages
ANSI/AAMI HA60601-1-11:2011 (IEC 60601-1-11:2010, MOD)
Order code 601111 or 601111-PDF
List $150 / AAMI member $90

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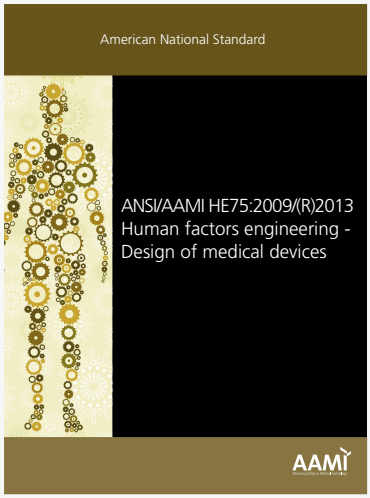
ORDER CODE	TITLE	PUBLISHED	PAGES	PRICE (LIST/MBR)
62296 or 62296-PDF	*Considerations of unaddressed safety aspects in the Second Edition of IEC 60601-1 and proposals for new requirements, 2ed (ANSI/AAMI/IEC TIR62296:2009)*	*April 2009*	*72*	*$150 / $90*
62354 or 62354-PDF	*General testing procedures for medical electrical equipment, 2ed (ANSI/AAMI/IEC TIR62354:2009)*	*March 2010*	*206*	*$250 / $150*
TIR18 or TIR18-PDF	*Guidance on electromagnetic compatibility of medical devices in healthcare facilities (AAMI TIR18:2010)*	*May 2010*	*66*	*$140 / $84*

Human Factors



Human factors engineering—Design of medical devices

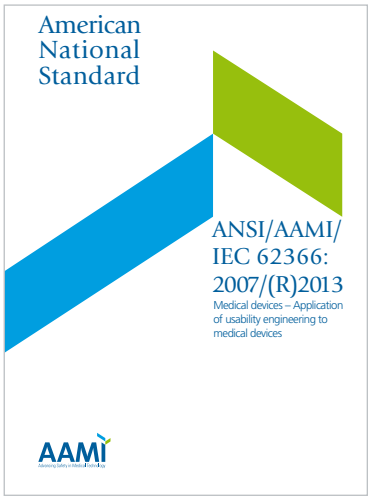
A virtual encyclopedia, ANSI/AAMI HE75:2009/(R)2013 builds off many decades of basic and applied research, as well as practical experience, which generated a substantial base of scientific knowledge about people and their interactions with each other, with technology, and with their environment. Filled with illustrations to make the content practical and relevant to all, HE75 provides comprehensive guidance to device manufacturers, clinical engineers, biomedical equipment technicians, regulators, and students.

The standard covers specific human factors topics including:

- General principles such as design priorities, accommodating user characteristics, capabilities, needs and preferences, and compatible designs
- Packaging design, design for post-market issues, cross-cultural issues, alarm design, accessibility considerations, connectors and connections, and controls
- Managing the risk of use error including specific methods for managing risk, use-related hazards, estimation and prioritization of use-related hazards, and implementation of risk control
- Usability testing, user documentation, basic human skills and abilities, and environmental considerations
- Visual displays, software-use interface, hand tool design, workstations, mobile medical devices, and home healthcare

The document complements ANSI/AAMI/IEC 62366:2007/(R)2013 and, together, these two revise AAMI HE48:1993.

Published March 2010, Reaffirmed November 2013, 445 pages
ANSI/AAMI HE75:2009(R)2013
Order code HE75 or HE75-CD (PDF on CD)
List $320 / AAMI member $192



Medical devices—Application of usability engineering to medical devices

This replaces HE74, which was incorporated into 62366 as Annex D.

Published November 2010, Reaffirmed March 2013, 103 pages
ANSI/AAMI/IEC 62366:2007/(R)2013
Order code 62366 or 62366-PDF
List $170
AAMI member $102

NEW! Post-market surveillance of use error management

This addresses the issue of use error detection for medical devices from clinical, manufacturer, and regulatory perspective regarding human factors assessment. It provides guidance on how clinicians and manufacturers can best collect and leverage post-market use error data to improve product safety and usability.

Published March 2014, 36 pages
AAMI TIR50:2014
Order code TIR50 or TIR50-PDF
List $140 / AAMI member $84

Design of training and instructional materials for medical devices used in non-clinical environments

Provides guidance to support safe, accurate, and efficient user performance.

Published April 2013, 33 pages
AAMI TIR49:2013
Order code TIR49 or TIR49-PDF
List $140 / AAMI member $84

Human Factors Collection CD

Just updated, this popular CD includes the AAMI human factors standards HE75, 62366, TIR49, and TIR50. Searchable and easy to use, this collection of more than 45 valuable resources includes guidance from the FDA and CMS, AAMI articles, and links to additional resources.

Published March 2014
Order code HFCOL-CD
List $480 / AAMI member $288

Handbook of Human Factors in Medical Device Design

Written as a complement to HE75, this handbook includes expanded discussions of design issues, product design case studies, and supporting illustrations. Members of the HF committee were involved in this, but it was not developed by the AAMI committee.

Published Dec. 2010 by CRC Press, 844 pages
Order code HFMDD
List $170 / AAMI member $115

Human Factors and Ergonomics in Health Care and Patient Safety

Published November 9, 2011 by CRC Press, 876 pages
Order code HFEH
List $180 / AAMI member $125

Patient Safety: A Human Factors Approach

Published May 2011 by CRC Press, 261 pages
Order code HFA
List $45 / AAMI member $32

Human Factors & IT: Connecting with Medical Devices

This issue of *Horizons* discuss HFE in the context of healthcare IT.

Published October 2013, 72 pages
Order code HOR13-2
List $35 / AAMI member $25

Anesthesia & Interoperability

ORDER CODE	TITLE	PUBLISHED	PAGES	PRICE (LIST/MBR)
4135 or 4135-PDF	*Anaesthetic and Respiratory Equipment—Vocabulary (ANSI/AAMI/ISO 4135:200I)*	*October 2001*	*64*	*$150 / $90*
5361 or 5361-PDF	*Anaesthetic and Respiratory Equipment—Tracheal Tubes and Connectors (ANSI/AAMI/ISO 5361:2012)*	*Expected July 2014*	*56*	*$150 / $90*
5362 or 5362-PDF	*Anaesthetic Reservoir Bags (ANSI/AAMI/ISO 5362:2006)*	*Expected July 2014*	*16*	*$100 / $60*
5364 or 5364-PDF	*Anaesthetic and respiratory equipment—Oropharyngeal airways (ANSI/AAMI/ISO 5364:2008)*	*July 2008*	*11*	*$100 / $60*
11195 or 11195-PDF	*Gas Mixers for Medical Use—Stand-alone Gas Mixers (ANSI/AAMI/ISO 11195:1995)*	*October 1995*	*8*	*$90 / $54*
11712 or 11712-PDF	*Anaesthetic and respiratory equipment—supralaryngeal airways and connectors (ANSI/AAMI/ISO 11712:2009)*	*Expected July 2014*	*28*	*$110 / $66*
14408 or 14408-PDF	*Tracheal tubes designed for laser surgery—Requirements for marking and accompanying information (ANSI/AAMI/ISO 14408:2005)*	*June 2005*	*6*	*$90 / $54*
535601 or 535601-PDF	*Anaesthetic and respiratory equipment—Conical connectors—Part 1: Cones and sockets (ANSI/AAMI/ISO 5356-1:2004)*	*May 2004*	*16*	*$100 / $60*
536601 or 536601-PDF	*Anaesthetic and Respiratory Equipment—Tracheostomy Tubes—Part 1: Tubes and Connectors for Use in Adults (ANSI/AAMI/ISO 5366-1:2000)*	*September 2001*	*13*	*$100 / $60*
536603 or 536603-PDF	*Anaesthetic and Respiratory Equipment—Tracheostomy Tubes Part 3: Paediatric Tracheostomy Tubes (ANSI/AAMI/ISO 5366-3:2001)*	*January 2003*	*12*	*$100 / $60*
601213 or 601213-PDF	*Medical electrical equipment—Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation (ANSI/AAMI/ISO 80601-2-13:2011)*	*Expected July 2014*	*99*	*$170 / $102*
601235 or 601235-PDF	*Medical electrical equipment—Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use (ANSI/AAMI/IEC 80601-2-35:2009)*	*October 2009*	*62*	*$150 / $90*
1007901 or 1007901-PDF	*Medical Suction Equipment—Part I: Electrically Powered Suction Equipment—Safety Requirements (ANSI/AAMI/ISO 10079-1:1999)*	*August 1999*	*28*	*$110 / $66*
1007902 or 1007902-PDF	*Medical Suction Equipment—Part 2: Manually Powered Suction Equipment (ANSI/AAMI/ISO 10079-2:1999)*	*August 1999*	*13*	*$100 / $60*
1007903 or 1007903-PDF	*Medical Suction Equipment—Part 3: Suction Equipment Powered from a Vacuum or Pressure Source (ANSI/AAMI/ISO 10079-3:1999)*	*August 1999*	*19*	*$100 / $60*
1065104 or 1065104-PDF	*Lung Ventilators—Part 4: Particular requirements for operator-powered resuscitators (ANSI/AAMI/ISO 10651-4:2002)*	*March 2002*	*22*	*$110 / $66*
1065105 or 1065105-PDF	*Lung Ventilators for Medical Use—Particular Requirements for Basic Safety- and Essential Performance—Part 5: Gas-powered emergency resuscitators (ANSI/AAMI/ISO 10651-5:2006)*	*February 2006*	*45*	*$140 / $84*

These standards were approved and published when the U.S. TAG for TC 121 was held by ASTM, but they are now AAMI standards. All of the documents on this page will be available from AAMI by August 2014. The original formatting is being maintained, so there are some variations from the typical AAMI style.

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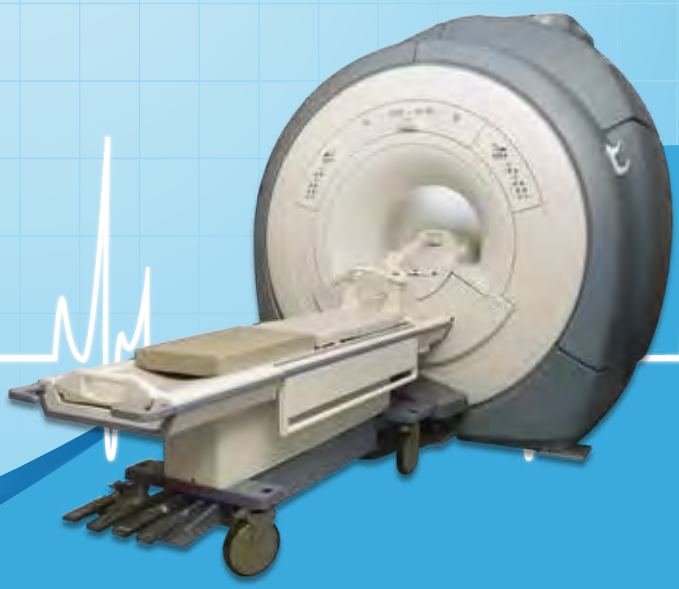

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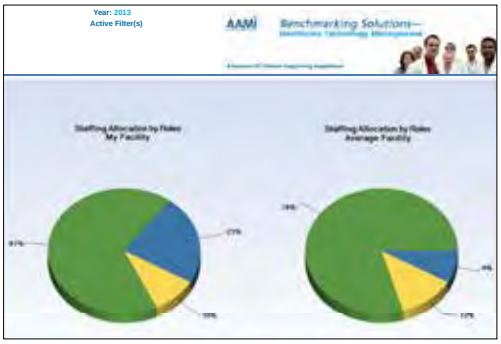

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Developed by leading sterilization and software experts, this web-based tool for sterile processing departments features more than 175 benchmarking measurements and metrics, including:

- Budgeting and finances
- Sterilization practices
- Volume and types of work performed
- Best practices, performance improvement
- Staffing, qualifications, and much more.

Designed to help sterile processing departments measure their practices, financial and personnel needs, and policies against others, it includes powerful, easy-to-use tools and charts to analyze data.

Subscribers save $150 on renewals.

Order code SPB List $850 / AAMI member $750

Results Only Option

AAMI also offers a "results only" version for consultants and manufacturers who want to access benchmarking data. The data are in aggregate form, but the information can be sliced and diced.

Order code SPB-RE List $2,400 / AAMI member $1,700

AAMI offers special pricing on bulk subscriptions for hospital systems to the HTM and Sterile Processing benchmarking solutions. Contact Kelly Poe at kpoe@aami.org.

As a subscriber to any AAMI benchmarking product, you receive year-long, 24/7 access to the web-based platform and data, the ability to update your data at any time, a comprehensive annual benchmarking report, and access to a subscriber-only listserv to ask benchmarking experts questions and share advice.

Benchmarking Solutions

Quality Management System for Medical Devices

Designed for medical device companies, this web-based tool features more than 100 measurements covering Risk Management and Corrective and Preventive Action (CAPA):

Risk Management:

- Adherence to industry standards
- Policy development
- Staff training
- Documentation and record keeping
- Hazards and hazardous situations

Corrective and Preventive Action (CAPA):

- Process performance
- Issue escalation
- Proposal, approval, and implementation of actions
- CAPA management and prioritization
- Preventive action statistics

Subscribers save $150 on renewals.
Order code QMS List $1,450 / AAMI member $1,100

Results Only Option

AAMI also offers a "results only" version for consultants and manufacturers who want to access aggregate benchmarking data.
Order code QMS-RE List $2,700 / AAMI member $2,200

Healthcare Technology Management

NEW! 2014 EDITION The Healthcare Technology Management Collection CD

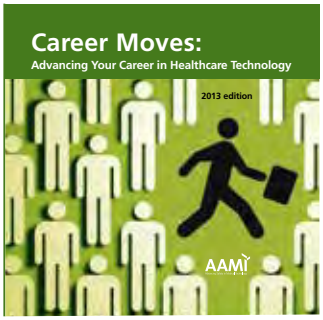
All of AAMI's most popular clinical engineering publications are featured on one convenient CD. This recently updated comprehensive collection now includes up-to-date guidance and practical information on IT, career, and medical equipment management.

The collection includes:

- EQ56:2013 (medical equipment management program), TIR18 (electromagnetic compatibility of medical devices), TIR62354 (testing procedures), TIR9 (invasive blood pressure monitoring), TIR11 (protective apparel and surgical drapes), and TIR21 (forecasting pacemaker battery life)
- Bright Ideas
- Medical Equipment Management Manual, 2009 edition
- Career Moves, 2013
- Health IT Collection: A Biomed's Guide, 2012
- The Fundamental Collection, 2013
- Computerized Maintenance Management Systems for Clinical Engineering
- The CE Management Guide: Lessons from the Field
- *Know When to Hold 'Em: Putting Your Poker Skills to Use in Management*
- *Horizons* publications on IT, healthcare technology, mobile health, wireless technology, sterilization and reprocessing, hemodialysis, human factors, home healthcare, imaging, and more

These detailed and practical resources have been written by and expressly for biomedical equipment technicians, clinical engineers, and other medical technology professionals. This CD is filled with essential "how to" information. Learn how to comply with the most up-to-date Joint Commission standards, maintain an effective electrical safety program, troubleshoot equipment repair, develop IT skills, prepare for a certification exam, and much more. This CD is quick and easy-to-use.

Latest edition to be published May 2014
Order code HTMC
List $710 / AAMI member $495



Career Moves: Advancing Your Career in Healthcare Technology

This comprehensive CD is the career bible for healthcare technology professionals. It includes more than 200 career-related articles that offer practical tips and important guidance for professionals of all experience levels.

Topics focus on:

- How to prepare for a certification exam
- Tips for finding jobs (resumes, interviews, etc)
- Guidance on information technology (IT) issues
- Improving customer relations
- Tips on strengthening your public speaking skills
- Developing specialties
- Management training, including hiring, staff motivation, etc.

Written by dozens of experts in the profession, this CD also includes a complete list of schools and associations as well as sample job descriptions, resumes, cover letters, and interview questions.

The CD is a compilation of the best career-related articles from AAMI. More than 50 articles have been added to this new edition.

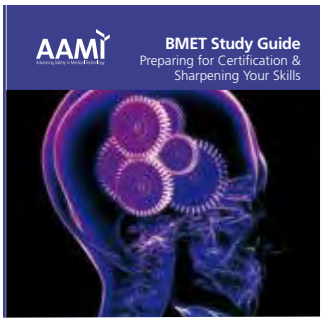
Released April 2013
Order code CAREER-CD
List $165 / AAMI member $99

Core Competencies for the Biomedical Equipment Technician (BMET): A Guide for Curriculum Development in Academic Institutions

The competencies and topics in this guide are relevant to BMETs entering the workforce, and reflect the knowledge and skills that BMETs are expected to perform in entry level positions.

This guide may also assist schools in preparing their graduates for professional certification, e.g., AAMI/International Certification Commission's (ICC) certification exams.

Published July 2011, 73 pages
Order code CORE-BMET or CORE-BMET-PDF
List $70 / AAMI member $42 (PDF is FREE)



BMET Study Guide: Preparing for Certification and Sharpening Your Skills

It's the most popular CD available for healthcare technology management. The interactive CD enables clinical engineers and biomedical equipment technicians to test their knowledge, sharpen their skills, and prepare for certification examinations.

This CD—updated in 2012 with 200 new and revised questions—helps you to identify your strengths and weaknesses, and to address any gaps in your knowledge of key areas: Anatomy and Physiology, IT, Medical Equipment Function and Operation, Safety in Healthcare Facilities, Medical Equipment Problem Solving, Electronics and Electrical Fundamentals.

Featuring nearly 500 interactive questions and answers—each with a detailed explanation—this CD is a valuable resource for professionals who want to assess and strengthen their knowledge—and advance in their careers.

If you manage healthcare technology, or supervise people who do, this educational tool is for you!

Released July 2012
Order code SGCD
List $165 / AAMI member $99

NEW! The Fundamentals Collection on CD: A Practical Medical Device Reference Guide

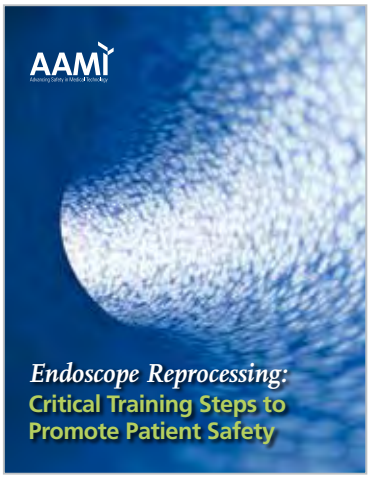
Just updated, this collection of more than 70 in-depth articles provides essential information and guidance for specific medical devices or systems. Each article provides an overview of the technology in question, tips for maintenance and management of the device or system, troubleshooting guidance, details on applicable regulations, advice on the type of training and equipment needed to service the device, and coverage of risk management issues.

Each of these practical articles includes a question-and-answer section designed to test the reader's knowledge. Devices covered in the series include:

- Anesthesia machines
- Pulse oximeters
- Robotic surgical systems
- Clinical laboratory equipment
- Portable X-ray machines
- Smart pump technology
- Diagnostic ultrasound
- Nuclear imaging
- Gas-flow analyzers
- And much more

This is a comprehensive resource for newcomers and veterans, as well as a great tool for certification preparation.

Released December 2013
Order code FUND-CD
List $160 / AAMI member $96



Endoscope Reprocessing: Critical Training Steps to Promote Patient Safety

This 30-minute instructional video provides training in endoscope reprocessing to promote patient safety. The video includes information about:

- Why endoscopes are important in healthcare
- What they do and how they work
- Correct endoscope handling

as well as troubleshooting tips

- The importance of proper endoscope reprocessing and how to follow manufacturers' IFU
- Step-by-step guidance of the critical stages in reprocessing
- How to do qualification testing of automated endoscope reprocessing equipment
- Professional organization guidelines and standards relevant to reprocessing
- The roles of different departments and staff associated with endoscope reprocessing

Published April 2013
Order code VID-ERCT
List $195 / AAMI member $117

Medical Equipment Management Manual

This best-selling manual provides essential guidance on how to comply with Joint Commission medical equipment management requirements. It's expressly designed to keep a hospital's medical equipment management program in complete and continuous compliance with Joint Commission standards. This edition includes 2009 changes by The Joint Commission, which reworded, revised, reformatted, consolidated, or deleted every standard in their accreditation manuals. It includes:

- An explanation of The Joint Commission's Standard Improvement Initiative
- A detailed template for writing your own medical equipment management plan
- Recommendations and examples of the documentation required in certain standards
- A description of the survey and accreditation process
- A recommended system for staying prepared for an unannounced survey

Published June 2009, 111 pages
Order code MEMM or MEMMCD
List $160 / AAMI member $96

BUY BOTH THE BOOK AND CD AND SAVE!
Order code MEMMSET
List $260 / AAMI member $155

A Practicum for Biomedical Engineering & Technology Management Issues

This textbook is the go–to resource for new and seasoned biomedical professionals, covering everything from The Joint Commission accreditation process and managing medical device safety to human factors engineering and evidence-based medical equipment maintenance management.

Written by 30 different experts in the profession, this publication also includes chapters on:

- Quality assurance
- Establishment of an in-house biomedical program
- Use errors
- Wireless spectrum management
- Medical equipment replacement
- Failure mode and effects analysis (FMEA)
- Introduction to imaging devices
- Customer satisfaction

Whether you are new to the field or an established professional, you will find this book to be an invaluable resource in your department, classroom, and personal or professional library.

Published June 2008, 948 pages
Order code BETM
List $230 / AAMI member $161

Introduction to Biomedical Instrumentation: The Technology of Patient Care

This practical textbook gives readers a thorough introduction to the essential information needed to work in a clinical setting as a biomedical engineering technologist/biomedical equipment technologist (BMET). This book covers::

- BMET as a career
- Patient safety
- Electrodes, sensors, and signals
- Cardiac assist devices
- Imaging
- Clinical laboratory equipment
- The operating room

In addition, fundamental information is provided on the heart, blood pressure, respiration, and the brain, as well as the underlying principles of a wide variety of medical instrumentation.

Clearly describing the technology used in different hospital settings, this textbook is ideal, whether you are a student or an experienced professional seeking to brush up on the basics.

Published April 2009, 248 pages
Order code IBI
List $95 / AAMI member $78

Know When to Hold 'Em: Putting Your Poker Skills to Use in Management

This engaging 24-page easy-read offers tips on how to become a better employee by—of all things—putting strong poker skills to use in the workplace. Full of fun, memorable illustrations.

Order Code POK
List $25 / AAMI member $15

Health IT Collection: A Biomed's Guide

This comprehensive CD includes more than 170 articles from AAMI publications, specifically on major IT issues in the medical technology profession. The collection features a detailed glossary of terms and a convenient search function.

Topics include:

- Device connectivity
- Cloud computing in healthcare
- Wireless security, malware, and spyware
- Integrating patient data
- Network management and applying 80001
- Mobile medical apps
- Unified communications
- Bluetooth wireless technology
- Security standards and FDA guidance documents
- Medical device data system (MDDS)

Published April 2012
Order code ITCD
List $165 / AAMI member $99

NFPA 99: Health Care Facilities Code and Handbook

The latest edition of the National Fire Protection Association's guidance for healthcare facilities has significant changes, reflecting a risk- vs. occupancy-based approach to healthcare and safety guidelines. The document covers a new understanding of operating rooms as 'wet' procedures locations and what that means for risk assessment. Reorganized, it also includes:

- A fully updated Chapter 5, *Gas and Vacuum Systems*, with details on additional maintenance requirements
- New chapters on security, fire protection, and IT

Published October 2011
Order code NFPA99
List $89 / AAMI member $59

Bright Ideas

This booklet features dozens of case studies and practical tips to help you improve technology management at your healthcare facility. Learn creative ways to save money, build a stronger staff, work with other departments, maximize resources, improve patient safety, and solve problems you may face at your facility. Ideal for all biomeds and clinical engineering managers, this easy-to-read resource is a compilation of AAMI's Bright Ideas (formerly known as Best Practices) articles.

Published July 2011, 65 pages
Order code BRIGHT
List $95 / AAMI member $57

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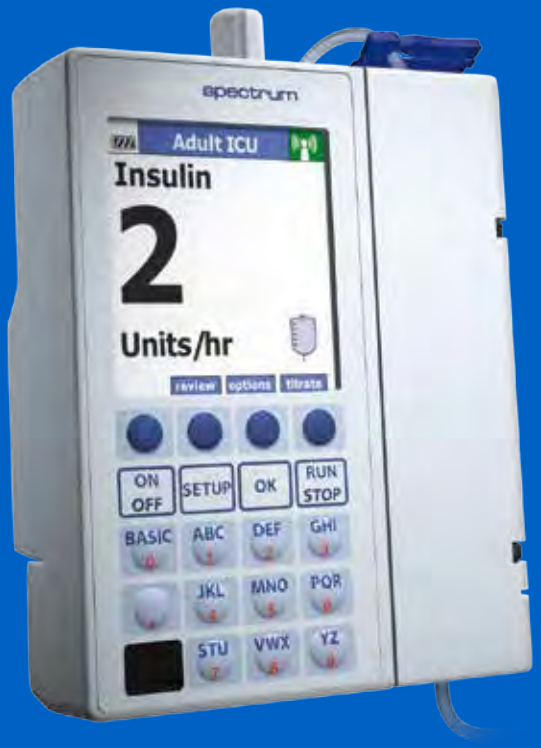

Best in KLAS for Smart Pumps – LVP[1]

SIGMA Spectrum Infusion System Three Years Running![1,2,3]

3

2

1

KLAS, an independent research firm, has again awarded the **SIGMA Spectrum** Infusion System with its "Best in KLAS" award for Smart Pumps — LVP as reported in the *Best in KLAS Awards: Medical Equipment & Infrastructure Report.*

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1 *2013 Best in KLAS Awards: Medical Equipment & Infrastructure, SIGMA Spectrum,* Best in KLAS for Smart Pumps – LVP, June 2013. ©2013 KLAS Enterprises, LLC. All rights reserved. www.KLASresearch.com

2 *2012 Best in KLAS Awards: Medical Equipment & Infrastructure, SIGMA Spectrum,* Best in KLAS for Smart Pumps – LVP, June 2012. ©2012 KLAS Enterprises, LLC. All rights reserved. www.KLASresearch.com

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