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Sample Reports and Charts from Benchmarking Solutions

**Common Causes Leading to Corrective Actions**

- Other (7%)
- Facilities failure (13%)
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- Equipment failure (33%)
- Insufficient human resources (40%)
- Insufficient work instructions or procedures (67%)
- Insufficient employee competence (67%)

**Allocation of SPD and Non-SPD Employees**

- **My Facility**
  - Full-time SPD Staff: 70% (4%)
  - Part-time SPD Staff: 13% (13%)
  - Full-time Non-SPD Staff: 13% (13%)
  - Part-time Non-SPD Staff: 16% (7%)
- **Average Facility**
  - Full-time SPD Staff: 74% (2%)
  - Part-time SPD Staff: 16% (7%)
  - Full-time Non-SPD Staff: 13% (13%)
  - Part-time Non-SPD Staff: 13% (13%)

*Sample reports use demo data.
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Determine how critical elements of your quality management system compare with those of your peers. Featuring 100+ measurements, this platform covers two specific areas: Risk Management and Corrective & Preventive Action (CAPA).

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— John Morkavich, Benchmarking Solutions—Sterile Processing Subscriber

For more information, visit [www.aami.org/benchmarking](http://www.aami.org/benchmarking) or call 877-249-8226. Would multiple facilities benefit from benchmarking? Consider a multiuser license.
NEW! Part 1: Sterilization in Health Care Facilities

The 2015 edition includes 14 AAMI sterilization standards and guidance documents needed by hospitals and healthcare facilities. It features the popular steam sterilization standard ST79, along with guidance on ethylene oxide and chemical sterilization; biological indicators; safe handling and decontamination; reusable medical devices; cleaning; protective apparel; and more.

What’s New?
• TIR55, Human factors engineering for processing medical devices
• TIR63, Management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection
• ST91, Flexible and semi-rigid endoscope processing in health care facilities

Published May 2015
Order code STBK15-1 or STBK15-1-CD
List $625 / AAMI member $435

ST79—AAMI’s Best-Selling Standard
This recommended practice covers steam sterilization in healthcare facilities, both terminal sterilization and sterilization for immediate use. 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. The attractive binder features sturdy metal rings, ledgerweight pages, and laminated tabs for easy navigation.

What’s New? Includes guidance on the use and application of Class 6 emulating indicators.

Published November 2013, Reaffirmed September 2014, 250 pages
Order code ST79 or ST79-PDF
List $310 / AAMI member $186

NEED ALL 70+ STERILIZATION STANDARDS?

Three-Book Set
Your print collection of AAMI’s sterilization standards.
• Part 1: Sterilization in Health Care Facilities
• Part 2: Sterilization Equipment Design and Use
• Part 3: Sterilization—Industrial Process Control

Order code STBK15-S
List $1,150 / AAMI member $805

Sterilization CD
This searchable CD includes all AAMI sterilization standards, key FDA and CDC guidance documents, and AAMI articles.

Order code STBKCD
List $875 / AAMI member $610

Order online at www.aami.org/store or call 1-877-249-8226
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 $90 / AAMI member $54

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 $90 / AAMI member $54

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 $90 / AAMI member $54

Immediate-Use Steam Sterilization Position Statement
Don’t miss this position statement adopted by AAMI, AORN, APIC, IAHCSSM, and others.
Free download at www.aami.org/publications/standards/st79.html

NEW! Flexible and semi-rigid endoscope processing in health care facilities
Provides guidelines for precleaning, leak-testing, cleaning, packaging (where indicated), storage, high-level disinfecting, and/or sterilizing of flexible gastrointestinal GI endoscopes, flexible bronchoscopes, surgical flexible endoscopes (e.g., flexible ureteroscopes), and semi-rigid operative endoscopes (e.g., choledochoscopes) in healthcare facilities. These guidelines are intended to provide comprehensive information and direction for healthcare personnel in the processing of these devices and accessories.
Published April 2015, 58 pages
ANSI/AAMI ST91:2015
Order code ST91 or ST91-PDF
List $195 / AAMI member $117

NEW! Steam Sterilization Posters
This nine-poster set provides a quick and easy visual reminder of 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. Only need some of these posters? You can also order just the original five or four new posters. Search for POSTER at http://my.aami.org/store.
Published May 2014
Order code POSTER-S
List $195 / AAMI member $117

NEW! Water for the reprocessing of medical devices
This technical information report (TIR) 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.
Published September 2014, 66 pages
AAMI TIR34:2014
Order code TIR34 or TIR34-PDF
List $195 / AAMI member $117
NEW! Human factors engineering for processing medical devices
Provides guidance on the application of human factors engineering principles to instructions provided by manufacturers for cleaning medical devices.
**Published** September 2014, 20 pages
AAMI TIR55:2014
Order code TIR55 or TIR55-PDF
List $135 / AAMI member $81

NEW! Management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection
This technical information report (TIR) identifies the necessary steps to effectively manage medical devices not owned by the healthcare facility in which they are used.
**Published** January 2015, 6 pages
AAMI TIR63:2014
Order code TIR63 or TIR63-PDF
List $95 / AAMI member $57

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 $185 / AAMI member $111
Redline format of TIR12
Order code TIR12-RD-PDF
List $230 / AAMI member $135

Ethylene oxide sterilization in health care facilities: Safety and effectiveness, 4ed
Published November 2008, Reaffirmed November 2012, 168 pages
ANSI/AAMI ST41:2008/(R)2012
Order code ST41 or ST41-PDF
List $242 / AAMI member $145

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 $185 / AAMI member $111
Redline format of TIR30
Order code TIR30-RD-PDF
List $230 / AAMI member $135

Steam Quality Testing
Does your steam comply with AAMI ST79 recommendations?

KSA SQ1-H Field Test Kit
Test for Steam Dryness, Non-Condensable Gases (NCG’S) & Superheat
Troubleshoot wet and/or dirty sterilizer loads & investigate Bowie Dick and biological indicator failures

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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 based on their liquid barrier performance and specifies related labeling requirements and standardized test methods for determining compliance. It aids end users in determining the type 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 $135 / AAMI member $81

Redline format of PB70
Order code PB70-RD-PDF
List $168 / AAMI member $100

Processing of reusable surgical textiles for use in health care facilities, 2ed
Reaffirmed December 2013
ANSI/AAMI ST65:2008/(R)2013

Order code ST65 or ST65-PDF
List $195 / AAMI member $117

Protective Barriers Resource Bundle

This important collection of protective apparel guidance documents includes TIR11, PB70, and ST65.

Order code PBRB or PBRB-PDF
List $300 / AAMI member $180

CHEMICAL

Chemical sterilization and high-level disinfection in health care facilities

This recommended practice provides guidelines for the selection and use of liquid chemical sterilants/high-level disinfectants and gaseous chemical sterilizers that have been cleared for marketing by the FDA for use in hospitals and other healthcare facilities.

Published September 2013, 154 pages
ANSI/AAMI ST58:2013

Order code ST58 or ST58-PDF
List $225 / AAMI member $135

Coming Soon! Sterilization Videos

AAMI is creating two instructional sterilization videos, both of which will be available this summer.

Personnel Safety in Sterile Processing Departments
Richard Warburton created the script and it is focused on ST58:2013.

Investigation of Sterilization Process Failures
Rose Seavey created the script.
Sterile Processing in Healthcare Facilities: Preparing for Accreditation Surveys, 2ed

Recently expanded, this guide is for healthcare facilities seeking to comply with accrediting agency surveys as they relate to the reprocessing of surgical instruments and other reusable medical devices. Authored by Rose Seavey, it features:
- A step-by-step guide to preparation for a survey
- Guidelines on risk reduction
- Information on accreditation organizations and requirements
- The current National Patient Safety Goals
- Information on relevant evidence-based guidelines
- Information on CDC’s Guide to Infection Prevention for Outpatient Settings
- An example of a sterile processing auditing tool

Published March 2014, 209 pages

Order code SPHC2 or SPHC2-PDF
List $215 / AAMI member $125

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 is full of practical resources and tips to prepare a sterile processing department for the future. Authored by Cynthia Hubbard, RN, an independent nurse consultant, it 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

Published February 2013, 144 pages

Order code BFTF or BFTF-PDF
List $215 / AAMI member $125

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List $310 / AAMI member $185

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Sterilization Webinars

**NEW! Best Practices in Endoscope Reprocessing**
Explore the trends driving endoscopy today, compare the different types of endoscopes and their anatomy, identify the types and parts of flexible and rigid endoscopes, and discuss how to reprocess endoscopes, including care and handling tips.
**Release Date** February 2015

Order code WASU1502CR
List $99 / AAMI member $79

**NEW! Best Practices in Ultrasound Reprocessing**
Stay compliant and adhere to the regulations related to probes and high-level disinfectants. This webinar explains how to keep safe during the disinfection process (vapor control, spill kits, etc.), and how to safely dispose of used high-level disinfectants after reprocessing.
**Release Date** April 2015

Order code WASU1504UR
List $99 / AAMI member $79

**NEW! High-Level Disinfection: Core-Skills Review**
This webinar will discuss the latest ‘hot buttons’ of high-level disinfection to include the biofilm production process, oxidative agents, oxidative chemistry concepts, and the current low- and high-temperature processing methods.
**Expected Release** May 2015

Order code WASU1505HD
List $99 / AAMI member $79

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AAMI University is your source for issue-specific webinars. Visit www.aami.org/university for more information.
NEW! Part 2: Sterilization Equipment Design and Use

This sterilization collection for manufacturers and users of sterilization equipment includes 26 AAMI standards and guidance documents. What's New? This features new guidance on chemical indicators (11140-1), packaging for terminally sterilized devices (16775 and updates to 11607-1 and 11607-2), and containment devices for reusable device sterilization (ST77).

Expected Publication June 2015
Order code STBK15-2
List $545 / AAMI member $380

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 August 2013, 24 pages
ANSI/AAMI ST77:2013
Order code ST77 or ST77-PDF
List $135 / AAMI member $81

Packaging for terminally sterilized medical devices

NEW! Part 1: Requirements for materials, sterile barrier systems, and packaging, 3ed, Amendment 1
Published October 2014, 19 pages
Order code 1160701-A or 1160701-A-PDF
List $110 / AAMI member $66

NEW! Part 2: Validation requirements for forming, sealing, and assembly processes, 3ed, Amendment 1
Published October 2014, 9 pages
Order code 1160702-A or 1160702-A-PDF
List $95 / AAMI member $57

NEW! 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 replaces AAMI TIR22:2007.
Published October 2014, 114 pages
Order code 16775 or 16775-PDF
List $225 / AAMI member $135

NEW! Sterilization of health care products—Chemical indicators—Part 1: General requirements
Specifies performance requirements for indicators that show exposure to sterilization processes by means of physical and/or chemical change of substances
Published January 2015, 29 pages
Order code 1114001 or 1114001-PDF
List $135 / AAMI member $81

NEW! Washer-disinfectors — Part 1: General requirements, terms and definitions and tests, Amendment 1
Published November 2014, 5 pages
Order code 1588301-A1 or 1588301-A1-PDF
List $30 / AAMI member $18
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Engage™ quickly connects caregivers using a real-time directory and patient-centric texting which improves collaboration and response times.

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Engage™ sends actionable medical device alarms and other clinical system alerts to caregiver’s mobile phones thus reducing unnecessary interruptions.

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Engage™ sends patient, alarm, and caregiver context with each notification which assists with clinical decision support.
NEW! Part 3: Sterilization—Industrial Process Control

This 40–document collection is intended primarily for manufacturers who ship sterile products.

What’s New? The collection features new guidance on EO sterilization (11135 and TIR56), radiation sterilization (TIR37 and 11137-1 and -2), and packaging (11607-1 and -2 amendments) and environmental monitoring of terminally sterilized healthcare products (TIR52).

Expected Publication June 2015

Order code STBK15-3
List $560 / AAMI member $390

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; b) ethylene oxide; c) moist heat (steam); d) dry heat; e) hydrogen peroxide; and f) ozone. Includes an annex on accelerated aging.
Published November 2008, 84 pages
AAMI TIR17:2008

Order code TIR17 or TIR17-PDF
List $225 / AAMI member $135

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 $95 / AAMI member $57

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 $185 / AAMI member $111

Redline format of ST72
ANSI/AAMI ST72:2011
Order code ST72-RD-PDF
List $230 / AAMI member $135

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.
Published April 2006, Errata issued May 2007, Reaffirmed November 2011, 29 pages

Order code 1173701 or 1173701-PDF
List $135 / AAMI member $81

INDUSTRIAL EO STERILIZATION

NEW! Guidance for the development, validation and routine control of an ethylene oxide sterilization process utilizing flexible bag systems for the sterilization of medical devices
This technical information report (TIR) provides information to be considered during the development, validation, and routine control of EO sterilization processes that are performed using gas diffusion within individually sealed flexible sterilization bags.
Published July 2014, 27 pages
AAMI TIR56:2014

Order code TIR56 or TIR56-PDF
List $135 / AAMI member $81
Sterilization—Industrial Process Control

NEW! Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices

Specifications requirements for the sterilization process for medical devices in both the industrial and health care facility settings, and it acknowledges the similarities and differences between the two applications.

Expected Publication
June 2015
ANSI/AAMI/ISO 11135:2015
Order code 11135 or 11135-PDF
List $225 / AAMI member $135

Industrial Sterilization: Research from the Field
This publication promotes the development of industrial sterilization science.

Published October 2013, 100 pages
Order code INDUST-STER or INDUST-STER-PDF
List $125 / AAMI member $75

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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 conducted with different equipment. This augments the 11135 series.
Published May 2009, Reaffirmed May 2013, 12 pages
AAMI TIR28:2009/(R)2013
Order code TIR28 or TIR28-PDF
List $110 / AAMI member $66

Microbiological aspects of ethylene oxide sterilization
Provides additional guidance to 11135-1:2007 and TIR11135-2:2008 for device manufacturers.
Published April 2010, Reaffirmed May 2013, 21 pages
AAMI TIR16:2009/(R)2013
Order code TIR16 or TIR16-PDF
List $135 / AAMI member $81

NEW! Basic Concepts in Sterilization Processes: Verification, Validation, and Qualification
This textbook provides personnel working in both healthcare and medical device manufacturing with the background needed to navigate the topic of sterilization processes. It discusses the science 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.
Published May 2014, 114 pages.
Order code SPVVQ or SPVVQ-PDF
List $215 / AAMI member $125
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Order code SPVVQSET
List $310 / AAMI member $185

RADIATION
NEW! Sterilization of health care products—Radiation—Guidance on sterilization of biologics and tissue-based products
This TIR provides guidance for development, validation and routine control associated with the radiation sterilization processing of biologics and tissue-based products.
Published July 2014, 17 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
Consolidated text of 11137-1 and Amendment 1.
Published May 2006, Reaffirmed April 2010, 40 pages
ANSI/AAMI/ISO 11137-1:2006/(R)2010
Order code 1113701 or 1113701-PDF
List $185 / AAMI member $111

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 August 2013, 74 pages
Order code 1113702 or 1113702-PDF
List $195 / AAMI member $117
Sterilization of health care products — Radiation — 
Substantiation of a selected sterilization dose: 
Method $V_D$max$^S D$

Published March 2013, 41 pages 
ANSI/AAMI/ISO TIR13004:2013 

Order code 13004 or 13004-PDF 
List $195 / AAMI member $117

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. 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 $185 / AAMI member $111

THERMAL

NEW! Sterilization of health care products — Moist 
Heat — Guidance on the designation of a medical 
product to a product family and processing category for 
steam sterilization 
This technical information report provides guidance about the 
attributes of a medical device to be considered by the user when 
assigning a medical device to a product family for the purpose of 
identifying and aligning it to a processing category for a specific 
moist heat sterilization process. 
Published November 2014, 51 pages 

Order code 1766503 or 1766503-PDF 
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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, CMS, and CDC. Available in print or on CD, this collection includes all 11 AAMI dialysis standards.

**What’s New?** Six of the standards were published in 2014 (23500, 11663, 13958, 13959, 26722, and TIR58).

**Published** October 2014

Order code DSBK15
List $495 / AAMI member $346

**Standards on CD—Dialysis**

Order code DSBKCD
List $495 / AAMI member $346

**Buy both the book and the CD!**

Combo order code DSBK15-S
List $725 / AAMI member $505

**NEW!** Water testing methodologies
Covers common test methods used to monitor hemodialysis water treatment systems and product water.

**Published** October 2014, 50 pages
AAMI TIR58:2014

Order code TIR58 or TIR58-PDF
List $185 / AAMI member $111

**NEW!** Quality of dialysis fluid for hemodialysis and related therapies
Specifies minimum quality requirements for dialysis fluids used in hemodialysis and related therapies. Includes dialysis fluids used for hemodialysis and hemodiafiltration, including substitution fluid for hemodiafiltration and hemofiltration.

**Published** September 2014, 18 pages

Order code 11663 or 11663-PDF
List $110 / AAMI member $66

**NEW!** Guidance for the preparation and quality management of fluids for hemodialysis and related therapies
Addresses the user’s responsibility. This covers dialysis water used for the preparation of dialysis fluid and substitution fluid, dialysis water used for the preparation of concentrates at the user’s facility, as well as concentrates and the final dialysis fluid and substitution fluid.

**Published** October 2014, 89 pages
ANSI/AAMI 23500:2014

Order code 23500 or 23500-PDF
List $225 / AAMI member $135

**NEW!** Concentrates for hemodialysis and related therapies
Specifies minimum requirements for concentrates, in liquid and powder forms, used for hemodialysis and related therapies. Also included are additives (spikes), which are chemicals that may be added to the concentrate to increase the concentration of one or more of the existing ions in the concentrate and thus in the final dialysis fluid. Gives requirements for equipment used to mix acid and bicarbonate powders into concentrate at the user’s facility.

**Published** September 2014, 27 pages
ANSI/AAMI 13958:2014

Order code 13958 or 13958-PDF
List $135 / AAMI member $81

Looking for more?
All AAMI products are available at www.aami.org/store.
**NEW! Water for hemodialysis and related therapies**

Specifies minimum requirements for water to be used in hemodialysis and related therapies. Includes water to be used in the preparation of concentrates, dialysis fluids for hemodialysis, hemodiafiltration and hemofiltration, and for the reprocessing of hemodialyzers.

*Published* September 2014, 17 pages

ANSI/AAMI 13959:2014

Order code 13959 or 13959-PDF
List $110 / AAMI member $66

**NEW! Water treatment equipment for hemodialysis and related therapies**

The standard covers devices used to treat water intended for use in the delivery of hemodialysis and related therapies. Included within the scope are all devices, piping and fittings between the point at which potable water is delivered to the water treatment system, and the point of use of the dialysis water.

*Published* September 2014, 36 pages

ANSI/AAMI 26722:2014

Order code 26722 or 26722-PDF
List $165 / AAMI member $99

**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.

Edited by Glenda M. Payne, MS, RN, CNN.

*Published* May 2014, 212 pages.

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**NEW! Acute Hemodialysis: Survey Readiness Handbook**

This handbook provides a clear explanation of the federal requirements applicable to the acute hemodialysis service and an overview of the expectations for compliance with the standards of the four accreditation organizations. Annex material includes self-assessment tools for dialysis water and dialysate, audit tools and checklists, and a glossary of definitions and abbreviations.

Authored by Jo-Ann B. Maltais, PhD, and Glenda M. Payne, MS, RN, CNN.

*Published* November 2014, 153 pages.

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Biological Evaluation of Medical Devices Series

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Order code BIOTCD
List $725 / AAMI member $505

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.

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 $135 / AAMI member $81

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

Specifies strategies for hazard identification and tests on medical devices for genotoxicity, carcinogenicity, and reproductive and developmental toxicity. Applicable when the need to evaluate a medical device for potential genotoxicity, carcinogenicity, or reproductive toxicity has been established.

Published August 2014, 36 pages.
Order code 1099303 or 1099303-PDF
List $165 / AAMI member $99

Part 7: Ethylene oxide sterilization residuals, 3ed

Specifies allowable limits for residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) in individual EO-sterilized medical devices, procedures for the measurement of EO and ECH, and methods for determining compliance so that devices may be released.

Published January 2009, Reaffirmed June 2012, Errata January 2010, 98 pages
Order code 1099307 or 1099307-PDF
List $195 / AAMI member $117

NEW! Cardiovascular biological evaluation of medical devices — Guidance for absorbable implants

Provides interim part-by-part guidance on potential adjustments to various test methods within the10993 series to account for the intentional release of soluble components or degradation products from absorbable medical devices.

Published January 2014, 15 pages
ANSI/AAMI/ISO TIR37137:2014
Order code 37137 or 37137-PDF
List $110 / AAMI member $66
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.
Order code 13485 or 13485-PDF
List $185 / AAMI member $111

Quality management systems—Medical devices—Guidance on the application of ISO 13485:2003, 2ed
Provides guidance on the application of requirements contained in ISO 13485:2003, including detailed guidance related to process validation, design control, and quality planning.
Published January 2005, 75 pages ANSI/AAMI/ISO TIR14969:2004
Order code 14969 or 14969-PDF
List $195 / AAMI member $117

Preventing Medical Device Recalls
A critical and often overlooked aspect of preventing medical device recalls is the ability to implement systems thinking.
Published July 2014 by CRC Press, 230 pages
Order code PMDR
List $105 / AAMI member $77

Quality System Collection
This CD of AAMI standards covers quality systems, design control, human factors, and software validation, and important government guidance documents from FDA. It has 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.
Order code AQS-CD
List $660 / AAMI member $462

NEW! The Quality System Compendium: CGMP Requirements & Industry Practice, 3rd 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 personalized medicine/companion diagnostics, software, 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 the Preamble
- User-friendly tabs for easy navigation
Published March 2015
Order code QSC3
List $650 / AAMI member $390

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Quality Systems

NEW! Quality Management System (QMS) Recommendations on Application of U.S. FDA’s CGMP Final Rule on Combination Products

This new TIR provides recommendations on the application of CGMPs for drugs, devices, biologics, and human cells, tissues, and cellular and tissue based products during development and marketing of combination products (drug-device, biologic-device, drug-biologic, or drug-device-biologic), in accordance with FDA’s final rule (21 CFR Part 4; 78 FR 4307, 2013). These recommendations are intended to inform the adoption and application of CGMPs for combination products.

**Expected Publication** June 2015, 35 pages
AAMI TIR48:2015

Order code TIR48 or TIR48-PDF
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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.
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 $225 / AAMI member $135

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.
Published December 2009, 64 pages
ANSI/AAMI/IEC TIR80002-1:2009
Order code 8000201 or 8000201-PDF
List $195 / AAMI member $117

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.
Published November 2012, 24 pages
ANSI/AAMI/ISO 15223-1:2012
Order code 1522301 or 1522301-PDF
List $135 / AAMI member $81

Medical devices—Symbols to be used with medical device labels, labeling, and information to be supplied—Part 2: Symbol development, selection and validations, 2ed
Published August 2010, 17 pages
ANSI/AAMI/ISO 15223-2:2010
Order code 1522302 or 1522302-PDF
List $110 / AAMI member $66

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 $185 / AAMI member $111
For more information on 80001 and a wealth of other resources on risk management for IT networks, see pages 26-29.

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, 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.
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NEW! **Guidance for the use of medical equipment maintenance strategies and procedures**
This standard is intended to provide basic information to healthcare technology management professionals by identifying and describing in general various maintenance strategies and methods for efficient, effective, and timely maintenance of medical equipment in healthcare facilities.

**Published** February 2015, 14 pages
ANSI/AAMI EQ89:2015

Order code EQ89 or EQ89-PDF
List $110 / AAMI member $66

**Recommended practice for a medical equipment management program**
This recommended practice addresses the structure of the program, documentation requirements, staffing, and resources allocated to those responsible for maintaining medical equipment.

**Published** April 2013, 35 pages
ANSI/AAMI EQ56:2013

Order code EQ56 or EQ56-PDF
List $185 / AAMI member $111

NEW! **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

Order code 601258 or 601258-PDF
List $165 / AAMI member $99

NEW! **Generating reports for human factors design validation results for external cardiac defibrillators**
Provides guidance on the formatting and content of reports generated for the purpose of submitting human factors data for evaluation.

**Published** December 2014, 14 pages
AAMI TIR61:2014

Order code TIR61 or TIR61-PDF
List $110 / AAMI member $66

NEW! **Generating reports for the purpose of submitting defibrillation waveform data for evaluation**
Provides guidance on the formatting and content of reports generated for the purpose of submitting defibrillation waveform data for evaluation.

**Published** December 2014, 4 pages
AAMI TIR62:2014

Order code TIR62 or TIR62-PDF
List $95 / AAMI member $57

**Sphygmomanometer Set**

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List $320 / AAMI member $220
ELECTROCARDIOGRAPHY

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 $110 / AAMI member $66

NEW! Common mode rejection in ECG monitoring
This technical information report (TIR) provides the details of how to build, calibrate, and use the CMR test circuit specified in ECG performance standards. It also preserves the history, rationale, and performance requirements of the test method, as included in ANSI/AAMI EC13:2002, Cardiac monitors, heart rate meters, and alarms, which was revised by the adoption and finalization of ANSI/AAMI/IEC 60601-2-27:2011, Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.

Published November 2014, 11 pages
AAMI TIR60:2014

Order code TIR60 or TIR60-PDF
List $110 / AAMI member $66
IMPLANTABLE MEDICAL DEVICES

Evaluation of particulates associated with vascular medical devices
This technical information report (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 $185 / AAMI member $111

NEW! Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

Specifies requirements that are generally applicable to active implantable medical devices. The tests that are specified in this document are type tests and are to be carried out on samples of an active implantable medical device to show compliance. This document is applicable not only to active implantable medical devices that are electrically powered but also to those powered by other energy sources. This document is also applicable to some non-implantable parts and accessories of the active implantable medical devices.

**Published** October 2014, 53 pages
ANSI/AAMI/ISO 14708-1:2014

Order code 1470801 or 1470801-PDF
List $195 / AAMI member $117

NEW! Cardiovascular implants and extracorporeal systems—Cardiovascular absorbable implants
Outlines design verification and validation considerations for absorbable cardiovascular implants. Applies to implants in direct contact with the cardiovascular system, where the intended action is upon the circulatory system.

**Published** September 2014, 26 pages

Order code 17137 or 17137-PDF
List $135 / AAMI member $81

NEW! Cardiovascular biological evaluation of medical devices — Guidance for absorbable implants
Published January 2014, 15 pages
ANSI/AAMI/ISO TIR37137:2014

Order code 37137 or 37137-PDF
List $110 / AAMI member $66
For more information on TIR37137, see page 18.

NEW! Implants for surgery — Cardiac pacemakers — Part 2: Reporting of clinical performance of populations of pulse generators or leads
Specifies requirements for reports on the clinical performance in humans of population samples of pulse generators or leads, intended for long-term implantation as cardiac pacemakers.

**Published** September 2014, 26 pages

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

This technical information report (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 $195 / AAMI member $117

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 the software can cause a hazard or controls risk. Revision of ANSI/AAMI SW68:2001.

Published June 2006, 67 pages
ANSI/AAMI/IEC 62304:2006

Order code 62304 or 62304-PDF
List $195 / AAMI member $117

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 $225 / AAMI member $135

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

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 on 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 $195 / AAMI member $117

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 12 popular standards.

Updated May 2015

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Why should **YOU** care about Risk Management for IT-Networks Incorporating Medical Devices?

Here are just a few unintended consequences of not considering this risk, all of which could easily harm your patients.

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- The application of security patches rebooted unintended systems, including some being used during surgery.

Your source for guidance:  
**80001: Application of risk management for IT-networks incorporating medical devices**  
(see pages 28-29)
80001: 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 and 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 $185 / AAMI member $111

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 $195 / AAMI member $117

Part 2-2: Guidance for the communication of medical device security needs, risks and controls
Published November 2012, 52 pages
Order code 800010202 or 800010202-PDF
List $195 / AAMI member $117

Part 2-3: Guidance for wireless networks
Supports the Healthcare Delivery Organizations (HDO) in the risk management of medical IT networks that incorporate one or more wireless links.
Published October 2012, 43 pages
Order code 800010203 or 800010203-PDF
List $185 / AAMI member $111

Part 2-4: Application guidance—General implementation guidance for healthcare delivery organizations
It identifies a series of decision points to steer the responsible organization through the process of understanding the medical IT network context and identifying any organizational changes required before undertaking the risk management process identified in IEC 80001-1.
Published July 2013, 20 pages
ANSI/AAMI/IEC TIR 80001-2-4:2012
Order code 800010204 or 800010204-PDF
List $135 / AAMI member $81

NEW! Part 2-5: Application guidance—Guidance for distributed alarm systems
It provides recommendations for the integration, communication of responses and redirection (to another operator) of alarm conditions from one or more sources to ensure safety, effectiveness and data and systems security.
Published March 2015, 35 pages
Order code 800010205 or 800010205-PDF
List $185 / AAMI member $111
NEW! 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 May 2015, 25 pages
ANSI/AAMI/IEC TIR 80001-2-6:2014

Order code 800010206 or 800010206-PDF
List $135 / AAMI member $81

NEW! Part 2-7: Application guidance—Guidance for Healthcare Delivery Organizations (HDOs) on how to self-assess their conformance with IEC 80001-1
Defines a PRM comprising a set of processes, described in terms of process purpose and outcomes that demonstrate coverage of the requirements of IEC 80001-1, and defines a PAM that meets the requirements of ISO/IEC 15504-2.

Published March 2015, 104 pages
ANSI/AAMI/IEC TIR 80001-2-7:2014

Order code 800010207 or 800010207-PDF
List $225 / AAMI member $135
NEW! Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral Standard: Electromagnetic disturbances—Requirements and tests
Published May 2014, 86 pages
Order code 601102 or 601102-PDF
List $225 / AAMI member $135

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
Specifies requirements and guidelines to reduce variability between particular pieces of medical electrical equipment and to improve patient safety and patient care via structured alarms.
Published April 2014, 87 pages
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List $690 / AAMI member $414

NEW! Medical device safety assurance case guidance
Includes a detailed, but strictly hypothetical example from the medical device domain on how to comply with the new additional FDA pre-market requirements for infusion pumps.
Published February 2015, 55 pages
AAMI TIR38:2014
Order code TIR38 or TIR38-PDF
List $195 / AAMI member $117

NEW! General testing procedures for medical electrical equipment
Published April 2015, 153 pages
ANSI/AAMI/IEC TIR62354:2015
Order code 62354 or 62354-PDF
List $390 / AAMI member $234

60601-1, 3rd Edition, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
This standard covers any medical device that requires an electrical outlet or a battery. 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
This is the consolidated text of 60601-1 and A1, 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
Order code 606011 (print), 606011-PDF, 606011-CD, or 606011-PE (5.5” x 7” travel edition)
List $850 / AAMI member $510

60601-1, 3rd Edition, Amendment 1
Identical adoption of IEC 60601-1 Amendment 1
Published November 2012, 118 pages
Order code 606011-A or 606011-A-PDF
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Published March 2015

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NEW! Medical devices - Part 1: Application of usability engineering to medical devices
This document specifies a process for a manufacturer to analyze, specify, develop, and evaluate the usability of a medical device as it relates to safety. This usability engineering (human factors engineering) process permits the manufacturer to assess and mitigate risks associated with correct use and use errors, i.e., normal use. It can be used to identify, but does not assess or mitigate risks associated with abnormal use. Partial revision of 62366:2007/(R)2013.
Published March 2015, 40 pages
ANSI/AAMI/IEC 62366-1:2015

Order code 6236601 or 6236601-PDF
List $185 AAMI member $111

Human factors engineering—Design of medical devices
A virtual encyclopedia, HE75 provides device manufacturers, clinical engineers, biomedical equipment technicians, regulators, and students with comprehensive human factors guidance. Filled with illustrations to make the content practical and relevant to all, HE75 covers:
• 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
• 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
Published March 2010, Reaffirmed November 2013, 445 pages
ANSI/AAMI HE75:2009/(R)2013

Order code HE75 or HE75-CD (PDF on CD)
List $350 / AAMI member $210

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 $185 / AAMI member $111

NEW! Human factors engineering – Guidance for contextual inquiry
Provides guidance on conducting contextual inquiry research that is used to provide information for improving medical procedures, environments, training, and/or devices.
Published November 2014, 12 pages
AAMI TIR51:2014

Order code TIR51 or TIR51-PDF
List $110 / AAMI member $66

NEW! Generating reports for human factors design validation results for external cardiac defibrillators
Published December 2014, 14 pages
AAMI TIR61:2014

Order code TIR61 or TIR61-PDF
List $110 / AAMI member $66
For more information on TIR61, see page 22.
Handbook of Human Factors in Medical Device Design
This complement to HE75 includes expanded discussions of design issues, product design case studies, and supporting illustrations. Some of the HF committee was involved in this. Published December 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 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

Post-market surveillance of use error management
This TIR addresses the issue of use error detection for medical devices from clinical, manufacturer, and regulatory perspective’s 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 $185 / AAMI member $111

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Covers general aspects of non-interchangeability and appropriate validation procedures for small-bore connectors for liquids and gases.
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