Technical Information Report

# AAMI TIR55: 2014

## Human factors engineering for processing medical devices



AAMI
Advancing Safety in Healthcare Technology

# Human factors engineering for processing medical devices

Approved 23 December 2014 by
**Association for the Advancement of Medical Instrumentation**

**Abstract** Provides guidance on the application of human factors engineering principles to instructions provided by manufacturers for cleaning medical devices.

**Keywords:** human factors engineering; instructions for use; medical device; processing

## AAMI Technical Information Report

A technical information report (TIR) is a publication of the Association for the Advancement of Medical Instrumentation (AAMI) Standards Board that addresses a particular aspect of medical technology.

Although the material presented in a TIR may need further evaluation by experts, releasing the information is valuable because the industry and the professions have an immediate need for it.

A TIR differs markedly from a standard or recommended practice, and readers should understand the differences between these documents.

Standards and recommended practices are subject to a formal process of committee approval, public review, and resolution of all comments. This process of consensus is supervised by the AAMI Standards Board and, in the case of American National Standards, by the American National Standards Institute.

A TIR is not subject to the same formal approval process as a standard. However, a TIR is approved for distribution by a technical committee and the AAMI Standards Board.

Another difference is that although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every 5 years but at least every 10 years. For a TIR, AAMI consults with a technical committee about five years after the publication date (and periodically thereafter) for guidance on whether the document is still useful—that is, to check that the information is relevant or of historical value. If the information is not useful, the TIR is removed from circulation.

A TIR may be developed because it is more responsive to underlying safety or performance issues than a standard or recommended practice, or because achieving consensus is extremely difficult or unlikely. Unlike a standard, a TIR permits the inclusion of differing viewpoints on technical issues.

**CAUTION NOTICE:** This AAMI TIR may be revised or withdrawn at any time. Because it addresses a rapidly evolving field of technology, readers are cautioned to ensure that they have also considered information that may be more recent than this document.

All standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633.

*Published by*

Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Dr., Ste. 301
Arlington, VA 22203-1633
www.aami.org



Printed in the United States of America

**ISBN 1-57020-573-6**

## Contents

## Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

## Committee representation

**Association for the Advancement of Medical Instrumentation**

**Human Factors for Device Reprocessing Working Group**

This standard was developed by the AAMI Human Factors for Device Reprocessing Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the standard does not necessarily mean that all working group members voted for its approval. At the time this standard was published, the **AAMI Human Factors for Device Reprocessing Working Group** had the following members:

*Chairs:*
Linda Condon, Johns Hopkins Hospital
David M. Zinkus, Baxter Healthcare Corporation

*Members:*
Mohamed Ali, Medline Industries Inc
Jahan Azizi, CBET, University of Michigan Health System
Ralph J. Basile, MBA, Healthmark Industries Company Inc
Eric D. Bergman, PhD, Fresenius Medical Care
Timothy Paul Burge, ASQ CQE CQA BS MBA, Alcon Laboratories Inc
Mike Cain, Getinge USA
Dennis Champagne, Microtest Laboratories Inc
Nancy Chobin, RN CSPDM, St Barnabas Healthcare System
Lena Cordie, Key Surgical Inc
Mary Dadone, Noxilizer Inc
Stacy DeMoss, NAMSA
Jeff Felgar, Zimmer Inc
Sarah Friedberg, Stryker Instruments Division
Marcia Ann Frieze, Case Medical Inc
Richard M. Granquist, BS, Cook Inc
Shelley Green, WuXi AppTec Inc
Seth Hendee, Fletcher Allen Health Care
Emily A. Hildebrand, Phoenix VA Health Care System
Rachel Hill, CareFusion
Sandra Iverson, Medivators Inc
Nupur Jain, Intuitive Surgical Inc
Susan G. Klacik, CCSMC FCS ACE IAHCSMM
Margaret Konja, Mount Clemens Regional Medical Center
Mary Kneece Lane, BS MHA CSPDM CSPDM
Jo Ann Barbara Maltais, PhD, Maltais Consulting
Theresa A. Matthews, RN BSN CNOR CSPDM, Community Medical Center @ Toms River
Marsha McArthur, Integrated Medical Systems
Cindy A. Miller, PhD, GE Healthcare
Emily Mitzel, MS, Nelson Laboratories Inc
Frank Myers, US PHS Indian Health Service
Karen Nauss, CRCST, Mount Auburn Hospital
Gerry A. O'Dell, MS, Gerry O'Dell Consulting
Richard William Schule, MBA CST FCS, Steris Corporation
Rose E. Seavey, RN MBA CNOR CRCST, Seavey Healthcare Consulting, LLC
Adam R. Simmes, Core Human Factors Inc
Kanwarjit Singh, Johnson & Johnson
Frank Smith, RN CNOR CRCST, Department of Veteran Affairs
Joan M. Spear, MBA RM CMPR, B Braun of America Inc
Karen Swanson, Connecticut Childrens Medical Center
Grace A. Thornhill, PhD, 3M Healthcare
Sharon Van Wicklin, MSN RN CNOR/CRNFA, Association of Perioperative Registered Nurses
James Sidney Wiggs, BSN CRCST, Legacy Health System
Don T. Williams, CRCST CIS CHL, Overlake Hospital Medical Center
Cheryl Work, Becton Dickinson & Company
Ann Young, Fletcher Allen Health Care
Eileen C. Young, RN CNOR, Olympus America Inc
Martha L. Young, Martha L Young, LLC

*Alternates:*
Greg Baumgardner, Zimmer Inc
William Brodbeck, Steris Corporation

Ramona Conner, RN MSN CNOR, Association of Perioperative Registered Nurses
Mary Ann Drosnock, MS, Olympus America Inc
Gordon M. Ely, WuXi AppTec Inc
Kristine Heideman, Baxter Healthcare Corporation
Scott A. Jelley, Johnson & Johnson
Tania Lupu, Case Medical Inc
Jim Maher, Becton Dickinson & Company
Richard M. Ormsbee, Medivators Inc
Mandy Ryan, Stryker Instruments Division
Barb Smith, Getinge USA
Raymond Taurasi, MBA CRCST CHL FCS AC, Healthmark Industries Company Inc
Angie V. Thornton, NAMSA
Brian Wallace, Intuitive Surgical Inc
Kelvin J. Witcher, 3M Healthcare

NOTE—Participation by federal agency representatives in the development of this recommended practice does not constitute endorsement by the federal government or any of its agencies.

At the time this document was published, the **AAMI Sterilization Standards Committee** had the following members:

*Co-chairs:*
Victoria M. Hitchins, PhD, FDA/CDRH
Michael H. Scholla, Dupont Protection Technologies

*Members:*
Christopher Anderson, Boston Scientific Corporation
Trabue D. Bryans, BryKor LLC
Nancy Chobin, RN CSPDM, St Barnabas Healthcare System
Charles Cogdill, Covidien
Ramona Conner, RN MSN CNOR, Association of Perioperative Registered Nurses
Jacqueline Daley, Sinai Hospital of Baltimore
Kimbrell Darnell, CR Bard
Lisa Foster, Medpoint LLC
Joel R. Gorski, PhD, NAMSA
Joyce M. Hansen, Johnson & Johnson
Douglas F. Harbrecht, Sterility Assurance LLC
Deborah A. Havlik, Hospira Worldwide Inc
Susan G. Klacik, CCSMC FCS ACE, IAHCSMM
Byron J. Lambert, PhD, Abbott Laboratories
Colleen Patricia Landers, RN, Timmins & District Hospital
Reynaldo Lopez, Cardinal Health (MP&S)
Jeff Martin, Alcon Laboratories Inc
Patrick J. McCormick, PhD, Bausch & Lomb Inc
Gerald E. McDonnell, PhD, Steris Corporation
Janet M. Prust, 3M Healthcare
Nancy Rakiewicz, Moog Medical Devices
Mark Seybold, Baxter Healthcare Corporation
Andrew Shaughnessy, PhD, Propper Manufacturing Co Inc
Mark N. Smith, Getinge USA
James Sydney Wiggs, BSN CRCST, Legacy Health System
Martell Kress Winters, BS SM, Nelson Laboratories Inc
William E. Young
William T. Young, Sterigenics International

*Alternates:*
Lloyd Brown, Covidien
Peter A. Burke, PhD, Steris Corporation
Dave Dion, Cardinal Health (MP&S)
Gordon M. Ely, WuXi AppTec Inc
Thomas J. Frazar, Johnson & Johnson
Martha M. Kadas, Sterigenics International
Jim Kaiser, Bausch & Lomb Inc
Natalie Lind, IAHCSMM
Ralph Makinen, Boston Scientific Corporation
Mary S. Mayo, CR Bard
David Ford McGoldrick, BS, Abbott Laboratories
Jerry R. Nelson, PhD, Nelson Laboratories Inc
Patrick Polito, Moog Medical Devices

Karen Polkinghorne, Dupont Protection Technologies
Shaundrea L. Rechsteiner, NAMSA
Mike Sadowski, Baxter Healthcare Corporation
Craig A. Wallace, 3M Healthcare

NOTE—Participation by federal agency representatives in the development of this recommended practice does not constitute endorsement by the federal government or any of its agencies.

## Foreword

This technical information report (TIR) was developed by the Human Factors for Device Reprocessing Working Group under the purview of the AAMI Sterilization Standards Committee.

Human factors engineering plays a significant role in the successful processing of medical devices. The objective of this TIR is to provide guidance to medical device manufacturers from a human factors perspective on the aspects of product design; design of processing instructions for use (IFU); education and training design; and development, verification, and validation of the device processing process to meet the needs of personnel working in a health care facility processing environment.

As used within the context of this document, “should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the TIR. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

# Human factors engineering for processing medical devices

## Introduction

Human factors engineering plays a significant role in the successful processing of medical devices. Understanding the full lifecycle of a reusable device from initial use through processing to subsequent use, and the limitations introduced by the intended use environments where processing occurs, could help implement design features to address the device usability and safety. Considering the volume and variety of devices processed in a health care facility, the broad spectrum of device manufacturers, and device similarities existing among manufacturers, a standardized approach to the development of processing instructions for use and subsequent education and training materials is needed to help ensure the processing function can be executed accurately, completely, and consistently.

## 1 Scope

This document provides guidance to medical device manufacturers from a human factors perspective on the aspects of product design; design of processing instructions for use (IFU); education and training design; and development, verification, and validation of the device processing process to meet the needs of personnel working in a health care facility processing environment. Limitations and challenges on human factors imposed by processing environments have a direct impact on the effectiveness of product designs, processing IFU, and the processing procedure. The processing lifecycle of the device is considered to be from the point-of-use at the end of a patient procedure to delivery to the point-of-use prior to the next patient procedure.

### 1.1 Inclusions

This technical information report (TIR) addresses processing as a design element; product design; processing procedures; the development of the IFU; education, training, and competency assessment; and validation from a human factors engineering perspective.

### 1.2 Exclusions

This TIR does not address processing requirements for devices (see ANSI/AAMI ST79); requirements for the manufacturer on what information should be provided to the user (see ANSI/AAMI ST81 and AAMI TIR12); or the processing of single-use devices.

## 2 Definitions and abbreviations

**2.1 cleaning:** Removal of contamination from an item to the extent necessary for further processing or for the intended use.

NOTE—In health care facilities, cleaning consists of the removal, usually with detergent and water, of adherent organic and inorganic soil (e.g., blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.

**2.2 cleaning validation:** Documented evidence of obtaining, recording, and interpreting the results required to establish that a cleaning process will consistently yield product complying with predetermined specifications.

**2.3 color coding:** (1) Assigning colors to different versions of a like object, typically with the purpose of using the inherent associated meaning of a color to help the user distinguish between the versions (e.g., stop lights, warnings, and error software messages). (2) Use of design elements, such as shape, color, texture, and placement, to communicate information, such as the priority of an alarm condition, or to differentiate user-interface components, such as pushbuttons.

**2.4 competency verification:** An activity designed to substantiate or confirm the ability of an individual to successfully complete a particular skill, task, complex series of tasks, or behavior necessary to perform effectively.

 