Technical Information Report

AAMI TIR99: 2024

Processing of dilators, transesophageal and ultrasound probes in health care facilities

AAMI
Advancing Safety in Health Technology

Processing of dilators, transesophageal and ultrasound probes in health care facilities

Approved 17 April 2024 by
AAMI

Abstract: Provides guidance for the proper processing of dilators and ultrasound probes in health care facilities to assist in making them safe and effective for use in patient care. Includes the information on selection and use of cleaning, disinfection, and sterilization systems that have been cleared for marketing by the FDA for use in hospitals and other health care facilities.

Keywords: dilators, ultrasound probes, cleaning, disinfection, sterilization

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that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years. A TIR must be acted on and the action formally approved usually every three years.

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CAUTION NOTICE: This AAMI TIR may be revised or withdrawn at any time.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 or 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, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

Published by

AAMI
901 N. Glebe Road, Suite 300
Arlington, VA 22203
www.aami.org

Printed in the United States of America

ISBN 978-1-57020-893-5

Contents

Page

Tables

Committee representation

Association for the Advancement of Medical Instrumentation

Endoscope Reprocessing Working Group

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

At the time this technical information report was published, the **AAMI Endoscope Reprocessing Working Group** had the following members:

Cochairs:
Melinda Benedict
Garland-Rhea Grisby

Members:
Cheri Ackert-Burr
Kareen Adorno
Anas Aljabo, SteriLabs Canada Inc.
Rebecca Alvino
Jaime Amaya
Eseosa Tony Amenaghawon, Cincinnati Childrens Hospital Medical Center
Edward Arscott, NAMSA
Melissa Austin, United Health Services
Sean Balagna, Mercy Hospital St Louis
Rebecca Bartles, Providence St Joseph Health
Melinda Benedict, Olympus America Inc
Lisa Berus, Treasure Valley Hospital
Kayleigh Lynn Bolitho
Rachel Bradley
Marie K. Brewer, UnityPoint Health - St. Luke's Hospital
William Brodbeck, STERIS Corporation | Healthcare
Lisa Shifflett Brown, UVA Health
Deborah Lynnette Bunn, University of Maryland Medical System
Jonathan Burdach, Nanosonics Limited
John-John Gacita Cabrillos
Ruth Carrico, University of Louisville
Frankie Catalfumo
Lori Chabot, Ascension | The Resource Group
Roxanne Charles
Kimberly Childress
Nancy Chobin
Horlando Cintron, Memorial Sloan Kettering Cancer Center Monmouth
James W. Collins, Cleveland Clinic Foundation
Edward Conklin, TidalHealth Peninsula Regional (fka Peninsula Regional Medical Center)
Jeremy Criss
Jeri Culbertson, Black Hills Surgical Hospital
Tanya Cuppy
Jacqueline A. Daley, Providence St Joseph Health System
Frank Daniels, Virginia Commonwealth University Health System
Tiffany Darville
Nick Dassatti, Intuitive Surgical Inc
Nicholas Day, University Hospitals of Cleveland
Christophe Deneux, Becton Dickinson & Company
Alisha Dorn, Nebraska Medical Center
Mary Ann Drosnock, Healthmark Industries
Loraine Durigan
Afif Jhoel Escheik, Crothall Healthcare
Deannard Esnard
Eden Essex, American Society for Gastrointestinal Endoscopy
Christine B. Estep

David Etzioni, American Society of Colon and Rectal Surgeons
Jon Fish, Endoscopy Repair Specialist Inc
Brian J. Fortier, Aorta Medical Inc
Sarah Frank, Element Materials Technology
Christopher Franklin, Indiana University Health (IU Health)
Sarah Friedberg, Stryker
Marcia Frieze, Case Medical Inc
Jeremy Gibson-Roark, Det Norske Veritas Region
Dusty Glass
Prerna Gopal, American Dental Association (ADA)
Steven L. Gray
David Greenwald, American College of Gastroenterology
Garland-Rhea Grisby
Michael D. Gudejko, Baystate Medical Center
Darrin R. Hagan
Roberta Harbison, AtlantiCare Regional Medical Center
Barbara Ann Harmer
Sunny Hays, Baylor Scott & White Medical Center - Frisco
Crystal Heishman, U of L Hospital - University of Louisville
Samantha Mashell Hodge, Medtronic Inc Campus
Ebow Holdbrook-Smith, WellSpan Health
Stephanie Jean Homuth, Hennepin County Medical Center Warehouse
Julie Hoover, Johnson & Johnson
Eric Houghton, Mesa Laboratories Biological Indicator Division- Bozeman Facility
Timothy Hurtado, UT Southwestern Medical Center
David M. Jagrosse, David Jagrosse Consulting LLC
Angela G. Jensen, Rush Foundation Hospital
Nicholas Kalanta, McLane Children's Hospital
Nalani Kalawe, Medical University of South Carolina (MUSC)
Sheri L. King, Henry Ford Health
Susan G. Klacik, Healthcare Sterile Processing Association (HSPA)
Theresa A. Klein, Corewell Health (fka Spectrum Health System)
Nikki Kluck (Einerson), 3M Health Care
Michael L. Kochman, American Gastroenterological Association
Marcy (Margaret) Konja, SpecialtyCare
Erin A. Kyle, Association of Perioperative Registered Nurses (AORN)
Rhashamekia Law, Memorial Hermann Healthcare System
Angela M. Lewellyn, Advantage Support Services Inc
Jessie Lopez, Robert Wood Johnson University Hospital (RWJ Barnabas Health)
Emily Lorcheim, ClorDiSys Solutions, Inc
Jonathan Manuel
Kelly Marcum, HCA Healthcare
Jason Charles Marosi, Roper St Francis Healthcare
Anne Mattern
Michael Matthews, Association of Medical Device Service Organizations (AMDSO)
Albert (Ted) E. May, Andersen Products Inc
Elaine S. Mayhall, FDA/CDRH
Josha McCarthy, Sierra Nevada Memorial Hospital
Betty McGinty, Boston Scientific Corporation
Kathleen McMullen
Shemicka McVey
Jason Minutillo
Emily Mitzel, GE HealthCare
Frank E. Myers, UC San Diego Health, Hillcrest
Karen Nauss, Mount Auburn Hospital
Brian Newton, Newton Technologies, LLC
Susumu Nozawa, Siemens Healthineers
Gerry A. O'Dell, Gerry O'Dell Consulting
Cori L. Ofstead, Ofstead & Associates
Mary D. Olivera, Quality Processing Resource Group LLC
Kia Parker, The Ohio State Wexner Medical Center-University Hospital
Alpa Patel, Sotera Health LLC

Chris Pennucci, MaineGeneral Medical Center
Rebecca Peplau
Bethany Louise Phillips, Association for Professionals in Infection Control & Epidemiology (APIC)
Shelle Powell
Janet M. Prust, St. Croix Standards Consulting LLC
Juan Miguel Ramos
Tracy Raymond, Vested Medical LLC
Vince Reed, VHA-National Office of Clinical Consultation & Compliance
Wayne Jerome Rogers, Wayne J Rogers Enterprises
Tyrone S. Rouse, Owens & Minor
Viktoria (Tori) Ruiz, Sutter Health
Vicki Sage, University of Rochester Medical Center
Ivan Salgo, Advanced Sterilization Products (ASP)
Debra Sams
Sachin Sankholkar, Neptune Medical
Richard William Schule, Cleveland Clinic
Anne Schuler, LexaMed Ltd
Harry L. Shaffer, Sterilization Consulting Services
Mikel E. Shans
Deirdre Smith
Joan M. Spear
Suzanne Stefanik, Tufts Medical Center
Dexter Stephen, New York Presbyterian Hospital CSP
Sherri Taylor
Ashley Thompson
James Treharn, St. Peter's Health
Cindy Turney Smith, St. Luke's Health System
Sara Vinson, University of Florida
Melissa Walters
Eric Warren
Adrienne C. Watson
Deanna Webster, Bausch & Lomb Inc
Jon H. Whinnery, Lee Health
James Sidney Wiggs, Legacy Health System
Nicole Williams, Sterilucent Inc
Matt Winchester
Jo Wood, Massachusetts General Hospital
Robin Woodland
Jarl Yeager, Powder River Medical Resources
Roberto Zumbado, Philips

Alternates:
Joseph Avila, Memorial Hermann Healthcare System
Dewey Barker, Case Medical Inc
Jennifer Barnickel, Vested Medical LLC
Nicola J. Bench, Becton Dickinson & Company
Damien S. Berg, Healthcare Sterile Processing Association (HSPA)
Jhmeid B. Billingslea, Advantage Support Services Inc
Marco Bommarito, 3M Health Care
Stephanie Cole, FDA/CDRH
Brad Conway, American College of Gastroenterology
Jeffery Daniels, Olympus America Inc
Christian Escobar, Cogentix Medical
Bill Facemire, Boston Scientific Corporation
Brianne Gallogly, Corewell Health (fka Spectrum Health System)
Shelley Green, NAMSA
Summer Griffis, Mesa Laboratories Biological Indicator Division- Bozeman Facility
Thomas Hsiu, Neptune Medical
Erin Huber, LexaMed Ltd
Terra Kremer, Johnson & Johnson
Philippe Labrie, STERIS Corporation | Healthcare
Marissa Jones Lewis, Veterans Administration (VA) Central Office
Daniel Lightfoot PhD, Nanosonics Limited

Paul Lorcheim, ClorDiSys Solutions, Inc
Courtney Lynn Mace Davis, North Shore University Health System Evanston Hospital
Kim Miller, HIGHPOWER Validation Testing & Lab Services Inc
Amiee Mingus, Ambulatory Surgery Center Association
Derek Mortisen, Intuitive Surgical Inc
Jennifer Ormsby, Association for Professionals in Infection Control & Epidemiology (APIC)
Konstantin Petrov, Duke University Health System - Clinical Engineering
Faith Rios, Andersen Products Inc
Klaus Roth, Quality Processing Resource Group LLC
Don Rotter, Ecolab
Reginald Rumwell, Siemens Medical Solutions USA Inc - Mountain View
Cynthia Seward, Kaiser Foundation Health Plan/Hospitals
Benjamin Sims, Sotera Health LLC
Steve Spencer, Owens & Minor
Dawn Tomac, Dawn Tomac Person
Jania Torreblanca, Michigan Medicine (University of Michigan Health System)
David Tran, Stryker
Marcelo Trevino, Advanced Sterilization Products (ASP)
Kavel Visrodia, American Society for Gastrointestinal Endoscopy
Rebecca Washburn, Henry Ford Health
John Whelan, Healthmark Industries
Daryl Woodman, Andersen Products Inc

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

At the time this technical information report was published, the AAMI Sterilization Standards Committee had the following members:

Cochairs: Janet M. Prust

Members:
Gregory Darnall Aldrich
Anas Aljabo, SteriLabs Canada Inc
Eseosa Tony Amenaghawon, Cincinnati Childrens Hospital Medical Center
Brett Anderson, Cochlear Ltd
Jennifer R. Asleson, Quality, Microbiology & Sterilization Services LLC
Richard Bancroft, STERIS Corporation | Healthcare
Leigh Anne Bartlett
Marie K. Brewer, UnityPoint Health - St. Luke's Hospital
Trabue Daley Bryans, BryKor LLC
Nicholas Brydon, NextBeam LLC
Jonathan Burdach, Nanosonics Limited
Emily Craven, Boston Scientific Corporation
Jacqueline A. Daley, Providence St Joseph Health System
Christophe Deneux, Becton Dickinson & Company
Chase Elms
Gordon M. Ely, LexaMed Ltd
Afif Jhoel Escheik, Crothall Healthcare
Deannard Esnard
Nicole Felderman, CIVCO Medical Solutions
Brian J. Fortier, Aorta Medical Inc
Daniel Fowler, WuXi AppTec Inc
Diah Ginem, Stryker
Jacqueline Gosier
Magnus Graham, BSI Healthcare
Shelley Hagan, Henry Ford Health
Ashley Hammer, Washington Regional Medical Center
Douglas F. Harbrecht, Sterility Assurance LLC
Jeanetta Harris
Deborah A. Havlik, DA Havlik Consulting
Amani Hawsawi
Crystal Heishman, UofL Hospital - University of Louisville

Ebow Holdbrook-Smith, WellSpan Health
Tisza Holt, Insulet Corporation
Mollie J. Holter, MicroBio Consulting LLC
Stephanie Jean Homuth, Hennepin County Medical Center Warehouse
Clark W. Houghtling, Cosmed Group Inc
Angela G. Jensen, Rush Foundation Hospital
Nicholas Kalanta, McLane Children's Hospital
Susan G. Klacik, HSPA
Erin A. Kyle, Association of Perioperative Registered Nurses (AORN)
Byron J. Lambert, Abbott Laboratories
Stacey Law
Alaina N Lett
Marissa Jones Lewis, Veterans Administration (VA) Central Office
Emily Lorcheim, ClorDiSys Solutions, Inc
Jonathan Manuel
Kelly Marcum, HCA Healthcare
John L. Mazzilli, Saddleback Memorial Medical Center
Patrick J. McCormick, Bausch & Lomb Inc
Gerald E. McDonnell, Johnson & Johnson
Russell (Rusty) Mills, Zimmer Biomet
Leslie Nichols, Mayo Clinic
Gerry A. O'Dell, Gerry O'Dell Consulting
James O'Reilly, St Joseph Health System - Trinity Health
Ken Paddock, Baxter Healthcare Corporation
Alberto Guzman Paret, Cordis US Corp
Kia Parker, The Ohio State Wexner Medical Center-University Hospital
Kimberly Patton, Performance Review Institute MedAccred
Annemarie Pelloski, Michigan Medicine (University of Michigan Health System)
Nancy Pickens
Karana M Pierre
Dawn Pierson, CS Medical LLC
Julissa Pina, Instylla, Inc.
Janet M. Prust, St. Croix Standards Consulting, LLC
Joan E. Rickard, Montefiore Medical Center
Angela Salmen
Linda Sue Schultz, Northside Hospital Surgical Services Atlanta
Joan M. Spear
Sopheak Srun, Quality Tech Services LLC
Mark Swanson, Quality and Regulatory Expert Partners (QRX)
Larry Talapa, 3M Health Care
Julie TerWee, Pfizer Parenteral Center of Excellence
James Treharn, St. Peter's Health
Melissa Vargas, Christiana Care Health Services
Sara Vinson, University of Florida
Adrienne C. Watson
James Sidney Wiggs, Legacy Health System
Martell Winters, Sotera Health LLC
Roberto Zumbado, Philips

Alternates:

Kendall Ashe, CS Medical LLC
Jennifer Benolken, DuPont Tyvek Medical and Pharmaceutical Protection
Damien S. Berg, HSPA
Stacy Bohl, Boston Scientific Corporation
Kevin Bovee, Insulet Corporation
Richard Burgess, BSI Healthcare
Densley Coke
Aaron David DeMent, Sotera Health LLC
April Doering, 3M Health Care
Anna M. Grayson, Grayson Associates
Rhashamekia Law
Cathy Leckwart, WuXi AppTec Inc
Paul Lorcheim, ClorDiSys Solutions, Inc

Michelle (Shelly) Luebke, Baxter Healthcare Corporation
James A. Maher, Becton Dickinson & Company
Shaun McGinley, Zimmer Biomet
David Ford McGoldrick, Abbott Laboratories
Shane Pinkston, Getinge USA
Christine L. Render, Cosmed Group Inc
Petra Richards, Kaiser Foundation Health Plan/Hospitals
Susan Rogers, Veterans Administration (VA) Central Office
Krista Schulte, Quality Tech Services LLC
Lisa Ward, STERIS Corporation | Healthcare

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

Foreword

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- “shall” and “shall not” are used to express requirements;
- “should” and “should not” are used to express recommendations;
- “may” and “may not” are used to express permission;
- “can” and “cannot” are used as statements of possibility or capability;
- “might” and “might not” are used to express possibility;
- “must” is used for external constraints or obligations defined outside the document; “must” is not an alternative for “shall”.

Suggestions for improving this document are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

Processing of dilators, transesophageal and ultrasound probes in health care facilities

NOTE This technical information report is not a standard, and the material contained herein is not normative in nature. The committee has used the term "shall" in a few instances, based on their knowledge of requirements contained in relevant standards and regulatory requirements.

1 Scope

1.1 General

This Technical Information Report (TIR) provides guidance for the proper processing of dilators and ultrasound probes in health care facilities to assist in making them safe and effective for use in patient care. It includes the information on selection and use of cleaning, disinfection, and sterilization systems that have been cleared for marketing by the US Food and Drug Administration (FDA) for use in hospitals and other health care facilities. It is intended to provide clear and comprehensive information and direction for health care personnel regarding the processing of these devices and accessories.

1.2 Inclusions

This TIR covers the processing of dilators (e.g., vaginal, esophageal, rectal, cervical, tracheal, nasal, urethral), ultrasound probes (e.g., intraoperative, transesophageal, transrectal, transvaginal, ophthalmic, and surface), and accessories. The TIR addresses criteria for selecting the proper cleaning, disinfection, and/or sterilization method based on the manufacturer’s written instructions for use (IFU) and types of procedure.

Specific topics addressed include:

a) information to be provided by the original equipment manufacturer (OEM);

b) assigning the Spaulding classification to clinical use of ultrasound probes and dilators;

c) use of probe covers;

d) use of ultrasound gel or an acoustic coupling agent and accessories;

e) functional and physical design criteria for processing areas;

f) medical device processing personnel qualifications, education, training, and competency verification and other personnel considerations;

g) receiving, transporting, and handling of contaminated devices;

h) cleaning and decontamination;

i) preparation and packaging;

j) disinfection;

k) sterilization;

l) transportation post-processing;

