American National Standard

ANSI/AAMI ST91:2021

Flexible and semi-rigid endoscope processing in health care facilities





Flexible and semi-rigid endoscope processing in health care facilities

Approval 1 October 2021 by **AAMI**

Approved 21 December 2021 by **American National Standards Institute, Inc.**

Abstract:

Provides guidelines for point of use treatment, transporting, leak testing (where indicated), cleaning, packaging (where indicated), high-level disinfecting and/or sterilizing, storage, and quality control procedures of flexible gastrointestinal (GI) endoscopes, flexible bronchoscopes, flexible ear, nose, and throat endoscopes, flexible urology endoscopes, and other types of reusable flexible endoscopes used in procedural and surgical settings, and semi-rigid operative endoscopes (e.g., choledochoscopes) used in health care facilities. These guidelines are intended to provide comprehensive information and direction for health care personnel in the processing of these reusable devices and accessories to render them safe for patient use.

Keywords:

endoscope processing, endoscope storage, flexible endoscopes, semi-rigid endoscopes, high-level disinfection, sterilization, leak testing, endoscope inspection

This is a preview. Click here to purchase the full publication.

AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than five years from the date of publication. Interested parties can obtain current information on all AAMI documents by calling or writing AAMI.

All AAMI 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.

Published by

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

© 2022 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this draft should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, et seq.) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violator's risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, visit the Copyright Clearance Center.

Printed in the United States of America

ISBN 978-1-57020-830-0

Contents		Page
Con	nmittee representation	v
Ackı	nowledgments	x
Fore	eword	xi
Intro	oduction	xii
1	Scope	1
2	Normative references	2
3	Terms and definitions	2
4	Design of endoscope processing area	11
5	Environmental cleaning	21
6	Personnel	22
7	Decontamination processes	28
8	High-level disinfection, liquid chemical sterilization, and terminal sterilization systems for flexible endoscopes	40
9	Sterile endoscope sheaths used as protective microbial barriers	51
10	Processing of endoscope accessories	51
11	Storage of processed endoscopes	52
12	Transport of processed endoscopes	57
13	Quality control	
14	Device repair and loaned endoscopes	
15	New product evaluation	85
Annex A (informative) Alternatives for keeping cool in the processing environment		87
	ex B (informative) Purchase considerations in selecting AERs and LCSPSs	
Ann	ex C (normative) Reference material for repairs	92
	ex D (informative) Manufacturer's written instructions for use (IFU) conflict management	
	ex E (informative) Endoscope visual inspection	
	ex F (informative) User verification of cleaning processes	
	ex G (informative) Effects of simethicone on flexible endoscopes	
	ex H (informative) Safety considerations for high-level disinfectants and liquid chemical sterilants	
	ex I (informative) Endoscope microbiocidal methods	
	ex J (informative) Endoscope storage risk assessment	
	ex K (informative) Endoscope drying	
Bibli	ography	155
Tal	bles	
Tabl	le 1—IES-recommended illuminance levels for work environments*	19
Tabl	le 2—Barrier Gown liquid barrier performance class	27
Tabl	le 3—Microbiological culture surveillance sampling advantages and disadvantages*	69
Tabl	le H.1—Examples of labeled contact conditions for high-level disinfection by FDA-cleared glutaraldehyde	444

Table I.1—Characteristics of microbicidal methods for endoscope processing	148
Table K.1—Summary of endoscope drying studies and methods of evaluation	152
Figures	
Figure E.1—Inspection of an endoscope using the unaided eye or magnification	95
Figure E.2—Anatomy of endoscope elevator mechanism of duodenoscope distal end	96
Figure E.3—Areas to inspect for damage on endoscope	97
Figure E.4—Control body (including valves and switches)	98
Figure E.5—Examples of insertion tube peeling and scratching	98
Figure E.6—Additional example of insertion tube defects	99
Figure E.7—Examples of denting and crush marks	99
Figure E.8—Examples of buckling	100
Figure E.9—Biopsy port	100
Figure E.10—Examples of cracked or damaged distal c-cover	101
Figure E.11—Examples of cracked or chipped objective or light guide lens	101
Figure E.12—Examples of residue buildup or staining	101
Figure E.13—Examples of residue buildup or staining	102
Figure E.14—Examples of bending section rubber glue joint separation	102
Figure E.15—Examples of cracks in glue joints	103
Figure E.16—Examples of cuts or punctures	103
Figure E.17—Examples of articulation	104
Figure E.18—Examples of moisture	104
Figure H.1. Endoscone markings example	115

Committee representation

Association for the Advancement of Medical Instrumentation

Endoscope Reprocessing Working Group

This standard was developed by the AAMI Endoscope 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 Endoscope Reprocessing Working Group** had the following members:

Cochairs: Mary Ann Drosnock

Garland-Rhea Grisby

Members: Cheri Ackert-Burr, Cantel Inc

Anas Aljabo, CMC Sterilization Ltd

Edward Arscott, NAMSA

Melissa Austin, United Health Services

Rebecca Bartles

Marcia Benedict, STERIS Corporation | Healthcare

Melinda Benedict, Olympus America Inc

Damien Berg Lisa Berus

Holger Biering, Holger Biering Consulting

Marie Brewer Deborah Bunn

Jonathan Burdach, Nanosonics Limited

Jennifer Burrell Ruth Carrico Lori Chabot

Shanaun Chavez, Intuitive Surgical Inc

Nancy Chobin

Jacqueline Cink, Mayo Clinic

Horlando Cintron James Collins

Linda Condon, Condon Healthcare Consulting

Edward Conklin Jeri Culbertson Jacqueline Daley Frank Daniels

Mary Ann Drosnock, Healthmark Industries Company Inc.

Loraine Durigan

Michelle Eppes, WuXi AppTec Inc Christine Estep, Fractyl Laboratories Inc

David Etzioni, American Society of Colon and Rectal Surgeons

Jon Fish, Endoscopy Repair Specialist Inc

Christopher Franklin

Sarah Friedberg, Stryker Instruments Division

Marcia Frieze, Case Medical Inc

Jeremy Gibson-Roark, Det Notske Veritas Region

Prerna Gopal, American Dental Association

David Greenwald, American College of Gastroenterology

Garland-Rhea Grisby Michael Gudejko Barbara Ann Harmer

Emily Hildebrand, Research Collective Rachel Hill, Becton Dickinson & Company Samantha Hodge, Medtronic Inc Campus

Julie Hoover, Johnson & Johnson

Charles Hughes, HIGHPOWER Validation Testing & Lab Services Inc

Timothy Hurtado

Sheri King, Henry Ford Health System

Susan Klacik, HSPA

Theresa Klein

Karla Klueber

Michael Kochman, American Gastroenterological Association

Margaret (Marcy) Konja, SpecialtyCare

Marcelo Kugelmas, AASLD-American Association for Study of Liver Diseases

Erin Kyle, Association of Perioperative Registered Nurses (AORN)

Mary (MK) Lane

Angela Lewellyn, Advantage Support Services Inc

Ann Mangskau, Ecolab

Regina Manning

Jason Marosi

Albert (Ted) May, Andersen Products Inc

Elaine Mayhall, FDA/CDRH

Josha McCarthy

Kathleen McMullen, Association for Professionals in Infection Control & Epidemiology

Terrence Mistalski, Germitec Emily Mitzel, GE Healthcare

Frank Myers

Karen Nauss

Brian Newton, Parametrik Holdings, LLC

Jake Nordaas

Gerry O'Dell, Gerry O'Dell Consulting Cori Ofstead, Ofstead & Associates

Adam Okada

Mary Olivera, Quality Processing Resource Group LLC Navid Omidbakhsh, Advanced Sterilization Products (ASP)

Kia Parker

Alpa Patel, Sotera Health LLC

Suzanne Patterson, CIVCO Medical Solutions

Deanna Pedeville, Bausch & Lomb Inc

Christopher Pennucci

Bret Petersen, American Society for Gastrointestinal Endoscopy

Michael Polozani, Case Medical Inc

Janet Prust, 3M Health Care

Natalie Reece, Key Surgical Inc

Vincent Reed, VHA-National Office of Clinical Consultation & Compliance

Wayne Rogers, Wayne J Rogers Enterprises

Vicki Sage

Jessica Schmidt, Analytical Lab Group

Anne Schuler, LexaMed Ltd

Harry Shaffer, Sterilization Consulting Services

Frank Smith

Donald Socha, Getinge USA

Alison Sonstelie

Joan Spear, Joan M. Spear (Independent Expert)

Suzanne Stefanik

Christopher Strafaci, Cogentix Medical

Grace Thornhill, Boston Scientific Corporation

James Treharn

Cindy Turney Smith

Sunny Vestal

Marjorie Wall

Richard Warburton, ChemDAQ Inc

James Wiggs

Nicole Williams, Sterilucent Inc

Jo Wood

Zheng Xue, Germitec

Jarl Yeager

Jennifer Zeck

Roberto Zumbado, Philips

Alternates: Jennifer Ayscue, American Society of Colon and Rectal Surgeons

Jhmeid Billingslea, Advantage Support Services Inc

Matthew Chitester, ChemDAQ Inc

Stephanie Cole, FDA/CDRH

Brad Conway, American College of Gastroenterology

Jeffery Daniels, Olympus America Inc

Lukejohn Day, American Society for Gastrointestinal Endoscopy

Shawn Engberg, MD Furniture & Supply Christian Escobar, Cogentix Medical Bill Facemire, Boston Scientific Corporation

Nancy Fellows, Advanced Sterilization Products (ASP)

Daniel Fowler, WuXi AppTec Inc

Ann Hewitt, Cantel Inc Meredith Hotchkiss Erin Huber, LexaMed Ltd

Henri Hubert, Quality Processing Resource Group LLC

Peter Kalkbrenner, Sterilucent Inc Marcus Keller, Getinge USA

Nikki Kluck (Einerson), 3M Health Care

Philippe Labrie, STERIS Corporation | Healthcare Jean-Luc Lemyre, Stryker Instruments Division

Alisha Lov

Courtney Mace Davis

Jacob Manthey, American Gastroenterological Association

Betty McGinty, Boston Scientific Corporation Derek Mortisen, Intuitive Surgical Inc Lia Moshkanbaryans, Nanosonics Limited Michael Neilson, Becton Dickinson & Company

Konstantin Petrov

Bethany Phillips, Association for Professionals in Infection Control & Epidemiology

Lionel Pineau, Germitec

Erin Romens, Analytical Lab Group

Klaus Roth, Quality Processing Resource Group LLC

Don Rotter, Ecolab Christopher Sczublewski

Benjamin Sims, Sotera Health LLC Ryan Swartz, CIVCO Medical Solutions

Jania Torreblanca

Brandon VanHee, Key Surgical Inc

Rebecca Washburn, Henry Ford Health System

Cheryl Weisbrod

John Whelan, Healthmark Industries Company Inc

Jon Wood, HSPA

Daryl Woodman, Andersen Products Inc

NOTE Participation by federal agency representatives in the development of this standard 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:

Cochairs: Janet Prust

Patrick Weixel

Members: Gregory Aldrich

Anas Aljabo, CMC Sterilization Ltd

Eseosa Amenaghawon Brett Anderson, Cochlear Ltd

Jennifer Asleson, Quality, Microbiology & Sterilization Services LLC

Richard Bancroft, STERIS Corporation

Marie Brewer

Trabue Bryans, BryKor LLC

Jonathan Burdach, Nanosonics Limited Charles Cogdill, Medtronic Inc Campus Emily Craven, Boston Scientific Corporation

Jacqueline Daley

Gordon Ely, LexaMed Ltd

Nicole Felderman, CIVCO Medical Solutions

Brian Fortier, Aorta Medical Inc.

Lisa Foster, Adiuvo QS & SA Consulting

Daniel Fowler, WuXi AppTec Inc

Joel Gorski, NAMSA

Magnus Graham, BSI Healthcare

Ashley Hammer

Joyce Hansen, Johnson & Johnson

Douglas Harbrecht, Sterility Assurance LLC

John Harper, Sterile Edge

Deborah Havlik, DA Havlik Consulting Mollie Holter, MicroBio Consulting LLC Clark Houghtling, Cosmed Group Inc

Susan Klacik, HSPA

Erin Kyle, Association of Perioperative Registered Nurses (AORN)

Byron Lambert, Abbott Laboratories Patrick McCormick, Bausch & Lomb Inc

Leslie Nichols, Mayo Clinic

Gerry O'Dell, Gerry O'Dell Consulting

Tarika Onishi, DexCom Inc

Ken Paddock, Baxter Healthcare Corporation

Kia Parker

Suzanne Patterson, CIVCO Medical Solutions

Kimberly Patton, Becton Dickinson & Company

Janet Prust, 3M Health Care

Nancy Rakiewicz, IUVO BioScience

Joan Rickard

Linda Schultz

Kristen Singleton, Getinge USA

Joan Spear, Joan M. Spear (Independent Expert)

Sopheak Srun, Quality Tech Services LLC

Mark Swanson, Quality and Regulatory Expert Partners (QRX)

Julie TerWee, Pfizer Parenteral Center for Excellence

James Treharn Marjorie Wall

Sean Weir

Patrick Weixel, FDA/CDRH

James Wiggs

Martell Winters, Sotera Health LLC

Roberto Zumbado, Philips

Alternates: Jennifer Benolken, DuPont Tyvek Medical and Pharmaceutical Protection

Stacy Bohl, Boston Scientific Corporation Carolyn Braithwaite-Nelson, Philips Richard Burgess, BSI Healthcare Greg Crego, IUVO BioScience

Kimbrell Darnell, Becton Dickinson & Company

Aaron DeMent, Sotera Health LLC Eric Einwalter, CIVCO Medical Solutions

Chad Geiger, DexCom Inc

Anna Grayson, Grayson Associates

David Kelman, Sterile Edge

Michelle (Shelly) Luebke, Baxter Healthcare Corporation

Gerald McDonnell, Johnson & Johnson David McGoldrick, Abbott Laboratories Nicole McLees, 3M Health Care Shane Pinkston, Getinge USA Christine Render, Cosmed Group Inc Jimmy Reyes, Alcon Laboratories Inc Molly Swanson, Quality Tech Services LLC

Lisa Ward, STERIS Corporation

Jon Wood, HSPA

Shelley Zimmerman, WuXi AppTec Inc

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