

Technical Information Report

AAMI TIR99: 2024

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

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

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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.

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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.

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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;

- m) storage;
- n) quality control;
- o) continuous quality improvement; and
- p) automated probe processors.

This TIR also provides definitions of terms and a bibliography. The informative annexes contain technical details pertaining to ultrasound probes and dilators.

1.3 Exclusions

This TIR does not cover:

- a) vascular and ophthalmic dilators;
- b) manometry catheters;
- c) processing of rigid, flexible and semi-rigid endoscopes, including those used for endoscopic ultrasound (see ANSI/AAMI ST91);
- d) processes performed within medical washers, washer–disinfectors, or automated endoscope reprocessors (see ANSI/AAMI ST79, ANSI/AAMI ST58, ANSI/AAMI ST91, and ANSI/AAMI/ISO 15883 series);
- e) steam sterilization (see ANSI/AAMI ST79);
- f) ethylene oxide sterilization (see ANSI/AAMI ST41, ANSI/AAMI ST24, and Danielson [1998]);
- g) gaseous chemical sterilization systems and liquid chemical sterilization/high-level disinfection systems not cleared by the FDA at the time this document was published;
- h) the processing of medical devices intended for single-use not intended to be processed by the health care facility prior to use (see FDA [2006]); or
- i) the processing of devices that might have been exposed to prions

NOTE For information about processing devices exposed to prions, see AORN (2019), Favero and Bond (2001), Rutala and Weber (2010), ANSI/AAMI ST79, and the recommendations of the Centers for Disease Control and Prevention (CDC) (<http://www.cdc.gov>) and the Healthcare Sterile Processing Association (<http://www.myhspa.org>).

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

automated endoscope reprocessor

AER

endoscope washer–disinfector machines designed for the purpose of cleaning and/or disinfecting or liquid chemically sterilizing endoscopes and components

Note to entry: The process can use a cleaning agent and always uses a high-level disinfectant (HLD) or liquid chemical sterilant (LCS) solution.

3.2

automated probe processor

APP

FDA-approved medical device that automates and achieves High Level Disinfection (HLD) of ultrasound probes, eliminating manual disinfection

3.3

biofilm

accumulated biomass of bacteria and extracellular material that is tightly adhered to a surface and cannot be removed easily [Donlan, 2002]

3.4

biohazardous containment system

containers, devices, or carts used for containing contaminated items must be marked with a visible red or orange red biohazard symbol and must meet OSHA (29 CFR 1910.1030) requirements for transporting hazardous items

3.5

biological indicator

BI

test system containing viable microorganisms providing a defined resistance to a specified sterilization process

Note 1 to entry: According to the Code of Federal Regulations, “a biological sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor adequacy of sterilization. The device consists of a known number of microorganisms, of known resistance to the mode of sterilization, in/on a carrier and enclosed in a protective package. Subsequent growth or failure of the microorganisms to grow under suitable conditions indicates the adequacy of sterilization.” [21 CFR 880.2800(a)(1)]

Note 2 to entry: Biological indicators are intended to demonstrate whether or not the conditions were adequate to achieve sterilization. A negative BI does not prove that all items in the load are sterile or that all were exposed to adequate sterilization conditions.

Note 3 to entry: See ANSI/AAMI/ISO 14161 for information on the selection, use, and interpretation of biological indicators.

3.6

cargo area

enclosure or structure of a transport vehicle consisting of an area that has been enclosed as space for storing cargo

3.7

chemical indicator

CI

devices used to monitor the presence or attainment of one or more of the process variables required for a satisfactory sterilization process or used in specific tests of sterilization equipment. Type 5 (integrating indicators): chemical indicators designed to react to all critical variables, with the stated values having been generated to be equivalent to, or exceed, the performance requirements given in the ANSI/AAMI/ISO 11138 series for BIs. Type 6 (emulating indicators): chemical indicators designed to react to all critical variables of specified sterilization cycles, with the stated values having been generated from the critical variables of the specified sterilization process. ANSI/AAMI/ISO 11140-1 refers to these indicators as cycle verification indicators.

3.8

cleaning

removal of contamination from an item to the extent necessary for further processing or for the intended use

Note to entry: In health care facilities, cleaning consists of the removal, usually with detergent and water, of adherent clinical 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.

3.9

containment system

reusable rigid sterilization container, instrument organizer, and any reusable accessories intended for use in health care facilities for the purpose of containing reusable medical devices for sterilization.

3.10

contaminated

presence of potentially infectious, pathogenic organisms (e.g., found in blood or other potentially infectious material) in or on an object

3.11

decontamination

According to the Code of Federal Regulations, “the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal” (29 CFR 1910.1030)

Note 1 to entry: The term is generally used in health care facilities with reference to all pathogenic organisms, not just those transmitted by blood.

Note 2 to entry: In the context of this standard, “use” refers to use by health care personnel, not use in patient care.

3.12

dilator

slender, solid or hollow, flexible or semi-flexible, instrument to be inserted into a body orifice or used surgically to dilate the structure/passage or to block an orifice

3.13

disinfection

process that kills pathogenic and other microorganisms by physical or chemical means

Note to entry: Disinfection destroys most recognized pathogenic microorganisms but not necessarily all microbial forms, such as bacterial spores. Disinfection processes do not ensure the margin of safety associated with sterilization processes.

3.14

United States Environmental Protection Agency EPA

3.15

United States Food & Drug Administration FDA

The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and by ensuring the safety of our nation’s food supply, cosmetics, and products that emit radiation (<https://www.fda.gov/about-fda/what-we-do>)

3.16

high-level disinfectant

HLD

germicide that inactivates all microbial pathogens except for bacterial endospores when they are present in large numbers, when used according to labeling (Rutala, 1990)

Note to entry: According to the FDA, an HLD is a liquid chemical sterilant (LCS) used for a shorter exposure time than that required to pass the AOAC International sporidical activity test as a sterilant.

3.17

high-level disinfection

process that kills all microbial organisms but not necessarily large numbers of bacterial spores

Note to entry: For a process that can be used for both liquid chemical sterilization and high-level disinfection, the contact time for high-level disinfection is shorter than that necessary for sterilization under otherwise identical conditions.