



Standard Test Method for Determination of Effectiveness of Cleaning Processes for Reusable Medical Instruments Using a Microbiologic Method (Simulated Use Test)¹

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INTRODUCTION

Cleaning is acknowledged as the critical first step in the reprocessing of reusable medical instruments. A test method to examine the efficacy and reproducibility of cleaning procedures would be valuable in optimizing decontamination of medical instruments, as well as increasing the margin of safety of subsequent disinfection and sterilization procedures. This test method is a means of determining the efficacy of the instrument manufacturer's cleaning instructions. In this simulated use test cleaning steps are performed with the instruments in a controlled laboratory environment. Within this environment, various parameters may be exaggerated to create worst-case conditions for the test. Among these are the amount or type of organic soil or microorganisms contaminating the instruments.

The test method was developed primarily for large medical instruments or instruments with internal channels or recesses (for example, flexible endoscopes) but may be used for any reusable medical instruments. It employs both direct inoculation and sampling methods for external surfaces and indirect inoculation and sampling methods for less accessible internal channels.

Cleaning is defined as the removal of foreign materials, most often mixtures of organic soil (for example, protein) and microorganisms, from medical instruments. Bacterial endospores are the preferred microorganisms in this simulated test because they would be more resistant to the potential microbiocidal effects of the cleaning processes and solutions. This method examines the reduction in the number of spores as a tracer of foreign materials and not necessarily the reduction in organic soil directly.

This test may be designed to either examine the efficacy of a complete cleaning cycle consisting of several integrated steps or individual cleaning step such as precleaning, manual cleaning, automated cleaning or rinsing.

1. Scope

1.1 This test method is written principally for large medical instruments or instruments with internal channels or recesses (for example, flexible endoscopes) but may be used for any reusable medical instruments.

1.2 This test method describes a procedure for testing the efficacy of a cleaning process for reusable medical instruments artificially contaminated with mixtures of microorganisms and simulated soil.

1.3 The test method utilizes bacterial spores as tracers for foreign materials and quantifies their removal as a means of determining the efficacy of a cleaning process.

1.4 The test method is designed for use by manufacturers of medical instruments and devices. However, it may also be employed by other individuals who have a knowledge of the instruments, techniques and access to appropriate facilities.

1.5 Worst-case conditions can be represented by exaggerating a specific test parameter or otherwise intentionally simulating an extreme condition such as performing the test without cleaning solutions or utilizing instruments which are not new.

1.6 The test procedure is devised to determine the efficacy of a cleaning process as applied to a particular instrument or group of instruments by simulating actual use situations.

1.7 The test procedure may be performed on test instruments using a complete cleaning cycle or be limited to

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particular phases of the cycle such as precleaning, manual cleaning, automated cleaning, or rinsing.

1.8 The test procedure is normally performed on a number of external and internal sites, but it may be restricted to one particular site on the instrument.

1.9 A knowledge of microbiological and aseptic techniques and familiarity with the instruments is required to conduct these procedures.

NOTE 1—Because contamination of the surfaces of instruments may occur as a result of rinsing with tap water, bacteria-free water should be used for all rinsing when a water rinse step is part of the cleaning directions.

NOTE 2—Test methods to determine the effectiveness of cleaning medical instruments has only recently been actively debated, and research efforts are in their infancy. Because published experimental results are scarce, it is premature to dictate experimental reagents, conditions or acceptance criteria.

NOTE 3—The total elimination of the target organisms is not the goal of cleaning. Therefore, there will almost always be a number of microorganisms surviving on the test instruments unless one of the solutions or processes disinfects or sterilizes the test instrument. The results of various clinical and laboratory tests suggest that cleaning processes alone can produce a 10^2 to 10^4 log₁₀ reduction in bioburden. The exact reduction will depend upon the precise experimental conditions. The criteria for judging cleanliness should be determined and recorded before initiation of the test procedure.

NOTE 4—This test protocol employs target spores as indicators or tracers for foreign materials and monitors their removal by the cleaning process. It is certainly possible that other particulate target materials, such as microbeads (latex beads) could be used in place of microbes. These alternate approaches would be more practical in those circumstances where microbiological expertise is limited.

1.10 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.11 *This standard may involve hazardous materials, operations, and equipment. This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 ASTM Standards:²

D1193 Specification for Reagent Water

E1054 Test Methods for Evaluation of Inactivators of Antimicrobial Agents

E1766 Test Method for Determination of Effectiveness of Sterilization Processes for Reusable Medical Devices

2.2 Other Source:

AAMI, TIR No. 30 A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices³

3. Terminology

3.1 Definitions:

² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

³ Available from Association for the Advancement of Medical Instrumentation (AAMI), 1110 North Glebe Road, Suite 220, Arlington, VA 22201-4795.

3.1.1 *accessible location*—a location on a reusable medical instrument(s) that may be contacted by bioburden, soil and cleaning agents.

3.1.2 *automated cleaning*—the removal of foreign material from medical instruments by means of a machine.

3.1.3 *bioburden*—the number and types of viable microorganisms that contaminate an instrument.

3.1.4 *CFU*—colony forming units.

3.1.5 *cleaning*—the removal of foreign materials, including organic soil (for example, protein) and microorganisms from medical instruments.

3.1.6 *cleaning solution*—a solution used to aid in the removal of foreign matter from medical instruments.

3.1.7 *manual cleaning*—the removal of foreign material from a medical instrument without the aid of a machine.

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *cleaning efficacy*—the efficacy of cleaning may be calculated as the log reduction of viable microorganisms recovered from the test instruments as compared to the control instruments.

3.2.2 *control instruments*—reusable medical instruments which are inoculated but not subjected to the Test Cycle.

3.2.2.1 *control instrument recovery*—the quantity of inoculum that can be recovered from the accessible locations (for example, external surface sites and lumens, if any) of the control instruments.

3.2.3 *neutralizer*—a reagent used to stop the antimicrobial activity of residual cleaning agent(s) that may be present on test instruments and eluted along with the target microorganisms. (See Practices **E1054** for recommended neutralizers.)

3.2.4 *reusable medical instrument*—any medical instrument that is claimed by the manufacturer to be usable after reprocessing.

3.2.5 *test cycle*—a cleaning process that utilizes all of the parameters selected by the tester.

3.2.6 *test instruments*—reusable medical instruments which are inoculated and subjected to the Test Cycle. These instruments are used to determine the efficacy of the cleaning process.

3.2.6.1 *test instrument recovery*—the quantity of inoculum that can be recovered from the accessible locations (for example, external surface sites and lumens, if any) of the test instruments.

3.2.7 *test soil*—a formulation of organic materials used in testing the efficacy of cleaning.

3.2.8 *worst-case*—the intentional exaggeration of one or more parameters of a test compared to the normal condition. For example, this could include exaggerated soil load or deletion of cleaning steps.

4. Summary of Test Method

4.1 This test method is performed by inoculating interior or exterior surfaces, or both, of reusable medical instruments.