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Designation: F3293 – 18

# Standard Guide for Application of Test Soils for the Validation of Cleaning Methods for Reusable Medical Devices[1]

This standard is issued under the fixed designation F3293; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

## 1. Scope

1.1 This guide provides methods and considerations for simulated soiling of reusable medical devices for the purpose of validating cleaning instructions. Techniques for application of soil, as well as incorporation of soil by various means (e.g., actuation of devices) will be described in order to assure worst-case contamination of the surface geometry of medical devices.

1.2 *Units*—The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.3 *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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

## 2. Referenced Documents

2.1 *ASTM Standards:*[2]

D1193 Specification for Reagent Water

D7225 Guide for Blood Cleaning Efficiency of Detergents and Washer-Disinfectors

F2809 Terminology Relating to Medical and Surgical Materials and Devices

F3208 Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices

2.2 *AAMI Standards:*[3]

AAMI TIR30 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

AAMI ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities

2.3 *ISO Standard:*[4]

ISO 10993-12 Biological evaluation of medical devices—Part 12: Sample preparation and reference materials

2.4 *Other References:*

ANSI/ASHRAE/ASHE Standard 170-2013 Ventilation of health care facilities; Atlanta: ASHRAE, 2013b[5]

Guidance for Industry and FDA Staff, Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, 2015[6]

## 3. Terminology

3.1 For definitions of terms in this Guide relating to the use of test soils for cleaning validation, refer to the Terminology Section of ASTM F3208.

## 4. Summary of Practice

4.1 The standard provides details on the application (inoculation) of the test soil for testing, evaluation, and validation of cleaning procedures. It includes:

4.2 The methods for soiling a medical device.

4.3 The selection of the appropriate method(s) for soiling a device based upon clinical use of the device.

4.4 Identification of area(s) of the device to soil based upon worst-case clinical use and device design.

4.5 Establishing the dwell time for the soiled device, prior to beginning cleaning procedures, based upon worst-case clinical conditions/practice.

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[1] This practice/guide is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Material Test Methods.

Current edition approved May 1, 2018. Published May 2018. DOI: 10.1520/F3293-18.

[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), 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633, http://www.aami.org.

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[5] https://www.ashrae.org/resources-publications/bookstore/health-care-facilities-resources

[6] www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf

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4.6 Identification of other worst-case clinical use conditions that represent a worst-case challenge to cleaning the device. These conditions could include the length of the procedure, condition of the patient, and/or extraordinary uses of the device (in compliance with the intended use of the device as established by the medical device manufacturer).

## 5. Significance and Use

5.1 This standard guide may be used by medical device manufacturers as part of their design plan and implementation of the validation of the cleaning instructions of their reusable medical devices.

5.2 It may help medical device manufacturers identify the most inaccessible locations on their device for inoculation with clinically relevant, simulated-use test soil (see ASTM F3208), thereby allowing testing to evaluate whether or not the medical device can be adequately cleaned.

5.3 Methods described include pipetting, brushing, immersing, spraying, handling, and other techniques for applying soil.

5.4 Guidance is given as to how to identify the clinically relevant areas of the device to soil, the time allowed for the soil to dry, and other conditioning considerations based upon assessment of worst-case clinical conditions.

## 6. Determining the Volume to Soil Each Device

6.1 The volume of test soil applied to a device should reflect worst-case clinical conditions.

6.2 ISO 10993-12 provides formulas for calculating the surface-to-area to volume ratios.

6.3 AAMI TIR30 provides formulas for calculating the surface area and volume of the internal channel of a device.

6.4 Special attention should be paid to the volume of the key soil markers (see ASTM F3208 for selection of test soil and soil markers) applied. This should not only reflect worst-case conditions, but also take into account expected recovery efficiency and the level of detection of the test method.

6.5 The method of application of soil (see Section 9) will also be a factor in the volume of test soil. For instance, if the entire device is to be immersed in the test soil (section 9.6), adequate volume of soil to accomplish this will be required. Another example is that if soiling involves perfusing internal channels of the device with test soil, the volume of soil to accomplish this must be calculated.

6.6 Other considerations include the physical characteristics of the test soil as it simulates clinical soiling (see ASTM F3208) including: Adhesion, Viscosity, and Solubility.

## 7. Determining the Most Difficult Areas to Soil

7.1 Special consideration should be given to ensure inoculation of the most difficult locations on the medical device to clean (i.e. worst-case location) such as crevices, narrow dead-end lumens, stopcocks, etc. (see AAMI TIR30:2011 Section 4.2 for list of difficult areas to clean).

7.2 Locations on the device that could potentially be contaminated during use should be considered for inoculation.

## 8. Determining Clinically Relevant Worst-Case Drying Time

8.1 *General Considerations:*

8.1.1 Duration of time for the application of test soil: A period of time should be established for the duration of the application of soil. The length of time that the test device is subjected to soiling should reflect worst-case clinical use to ensure that there is sufficient time to allow contaminants to adhere to and penetrate the device, thereby implementing worst-case soiling to the greatest degree practical.

8.1.2 If after clinical use of the device, drying of soil might occur and cleaning might not be performed immediately after use (such as with loaner devices that will be shipped without adequate reprocessing), the validation methods should allow soils to dry for a length of time that simulates worst-case (longest) duration.

8.1.3 To minimize variability of soiling, consider removing excess soil after soiling and before drying.

8.1.4 The drying phase could be performed in a number of ways. The most common approach is to dry the devices at room temperature (20-25°C) until the devices are not only visually dry, but to the touch using a gloved hand. Alternative methods to test the dryness of the soil include use of a dry cotton swab, toothpick, or similar tools.

8.1.5 If flaking of soil occurs during drying an alternative test soil or drying method should be used.

8.1.6 Accelerated drying processes generally do not reflect conditions of normal use and should be avoided. Methods to accelerate the drying process (elevated temperature, low humidity) may be considered, but may also alter the test soil, rendering it easier to remove.

8.2 *Temperature and Humidity*—The test soil should remain on the device/component and be allowed to dry in a temperature and humidity range that is similar to that found in healthcare facilities.

8.3 Current published guidelines (ASHRAE 170) for environmental conditions in areas where a soiled device will dwell include the operating theater, the operating room and procedure room.

8.4 The length of time allowed for drying should reflect the worst-case elapse of time that takes into consideration the time between patient use of the device (including the time during the clinical procedure when the device is no longer in-use) and reprocessing.

8.4.1 In busy healthcare facilities, the limitations of equipment and personnel can mean that hours elapse before cleaning procedures begin.

8.4.2 Reduced staffing on weekends can mean that cleaning procedures are delayed by 24 or 48 hours.

8.5 *Point of Use Treatment*—In general, worst-case soiling and conditioning for validating cleaning should exclude point of use pretreatment of a device.

8.6 *Repeated Soiling*—Simulated use conditions for the validation studies should be considered, especially for devices with features at risk for the accumulation of soil with repeated use. In such cases, validation studies should use devices that

have undergone some simulated use. Validation studies should incorporate multiple full-use cycles (e.g., soiling, use, cleaning, and disinfection/sterilization) and should be designed to assess the accumulation of soil over time. If the device is likely to be repeatedly subjected to "pushing" soil into a hard-to-reach area during use, validation soiling should include repeated soiling to adequately reproduce such a worst-case use situation. The number of simulated use cycles should be scientifically justified.

## 9. Application of Test Soil

9.1 *General Consideration*—The test soil solution may be applied to the surface of a medical device/component by various means. Selecting the method(s) for application of test soil should be based upon the clinical use of the device and the design considerations discussed in Section 6. Simulated use conditions should account for real-world use conditions to mimic worst-case clinical use (e.g., the worst-case duration of clinical exposure). All functional procedures (such as repeated articulations, flexure manipulations) for which the device is intended should be conducted in order to soil the device sufficiently to represent worst-case conditions should be conducted. Consideration should be given to the soiling process to ensure that reproducible contamination levels are achieved. Regardless of the chosen method, a defined surface area should be inoculated with an amount of soil (usually expressed as ug/cm$^2$) so that the samples can be compared to the pre-defined cleaning specification.

9.2 *Pipetting*—In this method, a defined amount of the selected test soil is pipetted onto a device. Using this method, soil can be pipetted on a desired area such as a lumen, box locks, hinges, crevices, or any surfaces of a device. This application method ensures that the user applies a specific amount of soil onto a specific location on the device. This method makes the soil application more reproducible. For lumens, the entire lumen should be filled with test soil. Templates could also be used to evenly pipette the soil to assure a uniform layer of thickness will cover a defined surface area.

9.3 *Paint Brushing*—In this method, the selected test soil is applied to a medical device using a dedicated paint brush. This application method applies a variable amount of soil to a particular location, and also varies the thickness of the soil coat at a particular location.

9.4 *Spraying*—In this method, the selected test soil is sprayed onto a medical device using a sprayer. This soil application method is used for applying an even coat of the simulated soil on test devices. This method is appropriate for devices for which the exterior of the device is soiled. An additional soiling method should be used if there are surface areas that can be soiled during clinical use that are not accessible to spraying (e.g., the interior of the device).

9.5 *Handling with Soiled Gloves*—In this method, the selected test soil is applied to the devices using soiled gloves. An operator dons the gloves and immerses the gloved hands in the test soil. Alternatively, a specified amount of test soil (Section 6) can be pipetted onto each gloved finger. (The operator then handles and operates the device using soiled, gloved hands. The amount of soil, the thickness of the coat, and area of soiling differs at each application. The soil is applied unevenly onto the device surfaces and often simulates handling of specific areas of the device during use, accounting for worst-case soiling of these devices.

9.6 *Immersion*—In this method, the device is immersed in the selected test soil, using a sufficient volume of test soil. This way the soil is applied to the entire device. If the immersed device has lumens and the soil is intended to perfuse the interior of the lumen, soil is injected using a syringe and an appropriate connector if needed to fully infuse the lumen with an excess of soil. This soil application method ensures all the areas of the device come in contact with the soil. Partial immersion of a device could also be applied to simulate devices that are used in the body cavity where the distal end is fully immersed in bodily fluids and the proximal is not.

9.7 *Flushing*—In this method, the lumens of medical devices/components can be perfused by flushing the test soil into the channel using a syringe connected to an appropriate tubing connector. The entire lumen should be flushed with an excess of test soil.

9.8 *Vacuum*—In this method, a vacuum is used to pull the selected test soil through the device. This method may be appropriate if it simulates soiling of the device more accurately than a flushing or immersion. This method is used if the soil hardens quickly upon mixing and has to be applied to a complex device with hard–to-reach areas or lumens. This soil application method ensures that the soil is applied to the desired location efficiently, before it hardens.

## 10. Report

10.1 Report should include:

10.1.1 The device(s) being tested.

10.1.2 The rationale (including any clinical studies) for the selection of the method for application of soil. This should include the description of the soil to be applied to the device because different methods of application may be required for specific soils and/or devices (see section 8.6).

10.1.3 The areas of the device to be soiled, including identifying the areas of the device determined to be most likely to be soiled during worst-case clinical use and to provide the greatest challenge to cleaning.

10.1.4 The steps for conditioning the soil (duration, temperature and humidity) and the rationale for this (including any clinical studies). This could include the weight of the device before soiling and after soiling as a measure of remaining contamination. Weighing should be done after drying. Weighing after conditioning at the same temperature and humidity may be considered as well, if applicable.

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