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Standard Guide for Using a Force Tester to Evaluate the Performance of a Brush Part Designed to Clean the External Surface of a Medical Device¹

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1. Scope

1.1 This guide describes methods for characterizing the efficacy, under prescribed laboratory conditions, of a brush part designed to clean the external surface of a medical device. The method utilizes force testers to mechanically actuate a brush part across a surface at a constant rate and constant pressure. In the first method, the force required to actuate across the surface is measured. In the next method, which utilizes the same force testers and protocol (actuation motion), the brush part is actuated on a soiled surface and the amount of soil removed is measured, as another indicator of performance.

1.2 Brushes designed to clean medical devices after clinical use play an important role in the effective reprocessing of those medical devices.

1.3 Inclusions:

1.3.1 This guide describes objective, quantifiable, and reproducible methods for evaluating the cleaning characteristics of a brush part, under prescribed laboratory conditions, with a test method that simulates the cleaning challenge of a defined target area(s) of a medical device. This also makes it possible to compare one brush part design to another.

1.3.2 By use of this guide, manufacturers of cleaning brushes will be able to evaluate and characterize the cleaning performance of their brushes for the target area(s) of medical device(s) and evaluate modifications to design and construction that might improve performance.

1.3.3 By use of this guide, this information can also be shared with the users of the brushes (medical device reproducers) to help them evaluate the performance of commercially available brushes.

1.4 Exclusions:

1.4.1 This guide is not intended to be used for brushes designed to clean medical devices using rotational motion.

1.4.2 This guide does not assess potential damage that may be inflicted by the brush, or degradation of the brush that may occur during repeated use. Brushes with rigid bristles (for example, stainless steel or other metals) are predicted to be more likely to damage medical devices than brushes with flexible bristles (for example, nylon); damage from rigid-bristled brushes should be assessed. Assessing repeated use would require a greatly increased number of test repetitions than what is described in this guide.

1.4.3 This guide does not specify acceptance criteria, and the results will be dependent on the specific parameters that are tested (for example, test soil, drying time, surface area, and materials, etc.) that are tested.

1.4.4 This guide is not intended to constitute all steps required to conduct validation of cleaning instructions for a medical device, including use of brushes for this purpose, but provides methods that may be part of a broader protocol to conduct a complete cleaning instructions validation. Separate medical device cleaning instruction validation studies must be conducted.

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

1.6 *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.*

1.7 *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.*

¹ This 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.

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2. Referenced Documents

2.1 ASTM Standards:²

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

2.2 ISO Standards:³

ISO/TS 15883-5 Washer-disinfectors—Part 5: Test soils and methods for demonstrating cleaning efficacy

ISO 22254:2005 Dentistry—Manual toothbrushes—Resistance of tufted portion to deflection

2.3 AAMI Documents:⁴

AAMI:TIR12 Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

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

2.4 FDA Document:⁵

FDA Guidance for Industry and FDA Staff Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, 2017

3. Terminology

3.1 Definitions:

3.1.1 *cleaning*—removal of contamination from a medical device to the extent necessary for further processing or for its intended use.

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *brush part*—working end of the brush that comes in contact with the targeted surface of the substrate.

3.2.2 *surface roughness*—the shorter frequency of real surfaces relative to the troughs.

4. Summary of Practice

4.1 This guide provides details for testing the resistance of a brush part moved across a surface to simulate the resistance of a brush used to clean the external surface of a medical device.

4.2 This guide also provides details for soiling a surface, actuating a brush part across that surface, and measuring the soil removed from that surface to simulate the cleaning of the external surface of a medical device.

4.3 Surface substrate selection is based upon the physical characteristics (that is, smoothness, material, etc.) of the medical device being simulated.

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 International Organization for Standardization (ISO), ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, <http://www.iso.org>.

⁴ Available from Association for the Advancement of Medical Instrumentation (AAMI), 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633, <http://www.aami.org>.

⁵ <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf>

4.4 Composition and application of the test soil should be based upon an evaluation of the clinical use of the device (Guide **F3208**, FDA 2017, AAMI TIR12, ISO/TS 15883-5).

5. Significance and Use

5.1 This guide provides two test methods for evaluating the performance characteristics of a brush part designed to clean external surface(s) of a medical device by utilizing force testers.

5.1.1 The first test method utilizes a force tester to measure the force required to actuate a brush part across a surface. This is an indicator of the friction a brush exerts on a surface, a parameter of cleaning effectiveness.

5.1.2 The second test method measures the removal of soil from a surface by a brush part actuated across the surface. This is a further indicator of the effectiveness of a brush part to loosen and remove soil from a surface.

5.2 By providing objective, repeatable methods for evaluating performance under test conditions, this guide can improve the ability to assess the effectiveness of various brush part designs

6. Description of Test Apparatus

6.1 A force testing machine with moving crosshead, force gauge, and a suitable clamp for substrates (see Fig. 2).

6.1.1 The crosshead shall be programmable for the speed and the distance it travels.

6.1.2 The force required to move the brush up and down shall be measured.

6.1.3 The clamp attaches to the crosshead and holds the test substrates in place.

6.2 Brush Fixture:

6.2.1 The brush fixture is secured underneath the crosshead of the force tester.

6.2.2 The clamp to hold brushes shall be adjustable to accommodate different size brushes.

6.2.3 The brush clamp shall be on a sliding track that is adjustable horizontally so the brush can be moved closer to and further from the substrate.

6.2.4 A force gauge is attached to the fixture to measure the force of the brush pushing against the substrate. This force gauge should be able to measure over 5 N force.

6.2.5 The brush fixture also includes a support to prevent the substrate holder from being deflected. This support also does not cause resistance against the substrate holder from being actuated up and down.

6.3 Sensitive Analytical Scale:

6.3.1 To determine the weight differences in the soiled substrates, the scale shall be sensitive to at least 0.1 mg.

6.3.2 The scale shall have a large enough stage to weigh the selected substrate size.

7. Selection Criteria for Testing Parameters

7.1 Selection of Surface Substrate for Testing:

7.1.1 The physical characteristics of the surface should be similar to the physical characteristics of the surface of the medical device(s) the brush is intended to clean. This includes