Designation: F3276 – 22

Standard Guide for Using a Force Tester to Evaluate the Performance of a Brush Part Designed to Clean the External Surface of a Medical Device[1]

This standard is issued under the fixed designation F3276; 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 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 reprocessors) 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.

Current edition approved Jan. 1, 2022. Published January 2022. Originally approved in 2019. Last previous edition approved in 2019 as F3276 – 19. DOI: 10.1520/F3276-22.

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.

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

[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

the surface roughness and any geometric features like crevices, ridges, etc. (AAMI TIR30). At a minimum, the following should be considered in selecting the surface substrate for testing: *(1)* material the substrate is made of (for example, stainless steel, polytetrafluoroethylene, silicone, etc.); *(2)* surface finish (for example, machined, ground, polished); and *(3)* device geometry (that is, crevices, ridges).

7.1.2 Since the same brush design may be used on more than one type of device, testing of multiple substrates with different material compositions may be necessary to fully characterize performance.

7.1.3 The length of the surface substrate should be at least long enough to allow the complete travel of the brush part across the surface. Complete travel may be defined as a displacement equal to the length of the brush part, with contact maintained between the full length of the brush part and the substrate during the entirety of travel.

7.2 *Selection of Test Soil and Application Method:*

7.2.1 The test soil should be similar in composition and physical qualities to the clinical soil the medical device comes in contact with during patient use (Guide F3208, FDA 2017).

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

7.2.3 The application of the soil should simulate the worst-case soiling that a medical device is likely to experience during clinical use (see Guide F3208, FDA 2017).

7.2.4 Soil is applied to the area of the substrate where the bristles of the brush will contact.

7.2.5 The time the soil is allowed to dry on the surface of the substrate should simulate worst-case drying during clinical use.

7.2.6 A cleaning solution that is similar to the cleaning solution likely to be used to clean the device after clinical use should be selected. Excess cleaning solution should be removed from the brush.

7.3 *Selection of Force:*

7.3.1 *Selection of Force Applied to Brush Part During Resistance Testing:*

7.3.1.1 Often, a brush intended to clean the surface of a medical device is similar in design and function to a brush intended to clean teeth, so the guidance in ISO 22254 is a reasonable starting point to determine the force to use. According to ISO 22254, the force applied to determine the resistance of bristles to deflection is set to 5 N. Place the brush in such a way so there is minimum contact of the bristles with the substrate, and then exert 5 N force on the brush against the substrate.

7.3.2 *Selection of Force Applied to Brush Part During Soil Removal:*

7.3.2.1 Applying a specific force to the brush against the substrate is suitable for testing the resistance of the bristles to deflection, but not for testing cleaning ability.

7.3.2.2 A stiffer bristle brush deflects less at a given force than a softer bristle brush. Therefore, when comparing brushes with different bristle firmness at a given force, a brush with softer bristles will have greater contact with the surface than a brush with stiffer bristles.

7.3.2.3 For purposes of this test method, the degree of bristle deflection should be kept constant while the brush is travelling over the soiled substrate. Bristle deflection may be monitored through visual confirmation. This approach allows a comparison at equivalent bristle deflection, since softer bristles will apply less force against a substrate than will stiffer bristles.

7.3.2.4 Before the program is run, the brush head is brought into contact with the substrate, such that there is minimum contact between the bristles and the substrate. Then exert a 5 N force on the brush against the substrate. The substrate holder should be deflected by less than 1 mm by the brush pushing against it, so as not to affect the force measured during resistance testing. This is achieved by a support behind the substrate holder that is part of the brush fixture (see Fig. 2).

8. Procedure for Testing Resistance on a Surface

8.1 Mount the brush part in the grip of the brush fixture (see Fig. 1).

8.2 Select a substrate for testing (see 6.1) and clamp the substrate into the substrate holder. Mount the substrate holder to the crosshead (see Fig. 2). The substrate holder mounted to the crosshead should have a deflection of ≤1 mm when the necessary force is applied.

8.3 Program the force tester for the following:

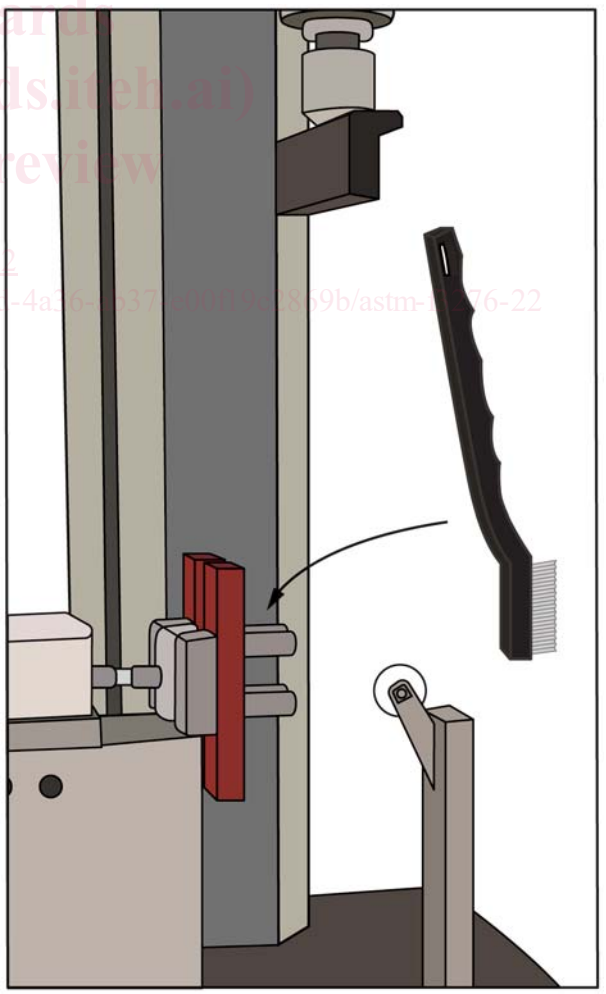

FIG. 1 Brush Part Mounted in Brush Fixture

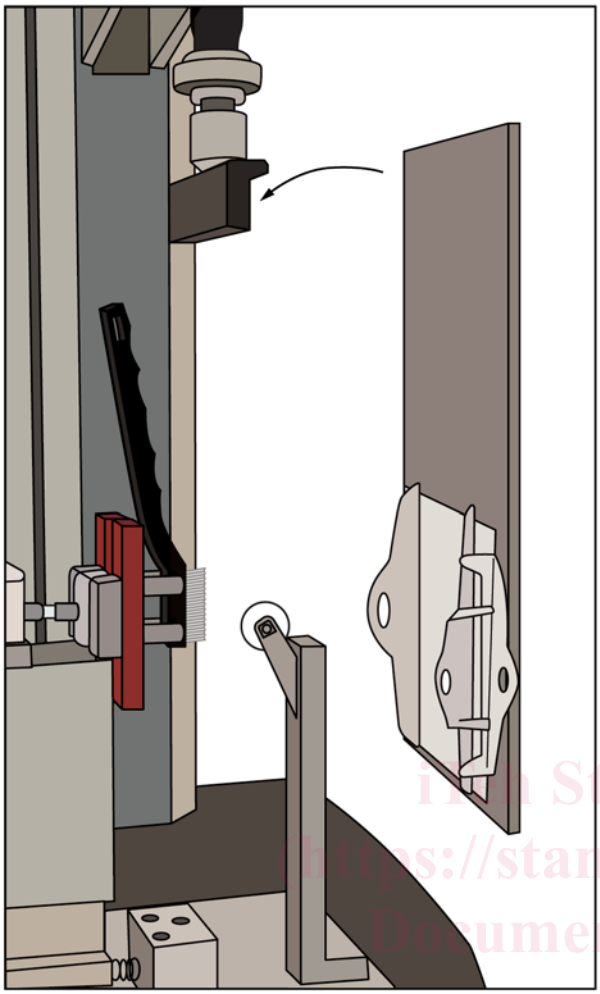

FIG. 2 Mounting Substrate on the Crosshead of the Force Tester

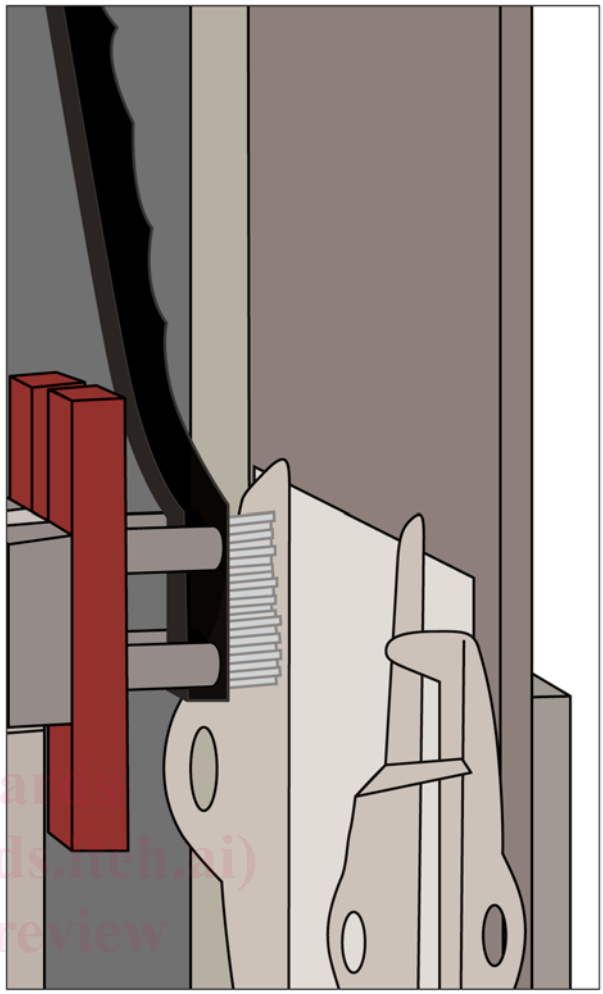

FIG. 3 Brush Aligned at the Top of the Substrate

8.3.1 The distance the substrate will travel along the brush part (see 6.1).

8.3.2 The speed at which the substrate will be moved down against the brush part.

8.3.3 The speed at which the brush substrate will be moved up against the brush part.

8.3.4 The number of times the substrate will be actuated against the brush part.

8.4 Align the brush part at the top of the substrate (see Fig. 3).

8.4.1 Using the brush fixture, position the brush to have minimum bristle contact with the substrate, then exert 5 N of force on the brush against the substrate as measured by the secondary force gauge (see Fig. 4).

8.4.2 Run the test program. Perform replicates as deemed necessary.

8.4.3 Record the results. The peak and average force measurement for both the upward and downward movement of the substrate should be measured and recorded.

9. Procedure for Evaluating the Cleaning of a Surface

9.1 Select the test soil (6.2) and prepare as needed.

9.2 Select the substrate for testing (6.1). If this testing follows the force testing described in Section 7, the same substrate should be used.

9.3 Weigh the substrate (see Fig. 5).

9.4 The volume of soil used to soil the substrate should be determined (7.2).

9.5 The length of time to allow soil to dry should be determined (7.2.5).

9.6 Soil the substrate (see Fig. 6) such that the soil is applied only where the bristles of the brush will be in contact. Allow it to dry overnight. In order to compare one brush part to another, the soil coverage should be uniform.

9.7 Weigh the soiled substrate (see Fig. 7).

9.8 Prepare a cleaning solution (see 7.2.6).

9.9 Dip the brush part in the cleaning solution (see Fig. 8). Remove excess solution from brush.

9.10 Mount the brush in the brush fixture as described in 8.1 (see Fig. 9).

9.11 Mount the substrate on the force tester as described in Section 7 (see Fig. 10).

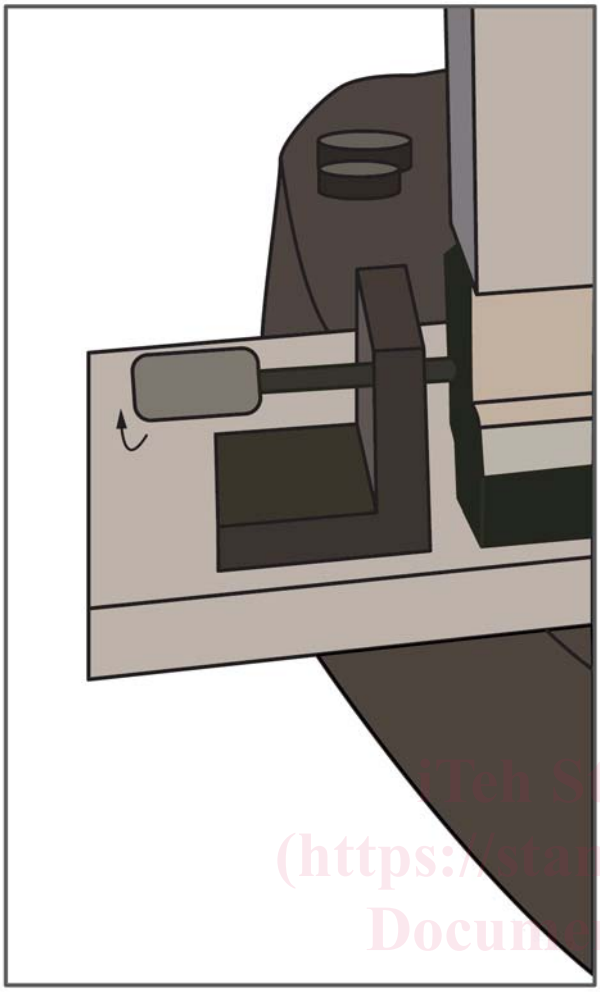

FIG. 4 Positioning Brush Against Force Gauge

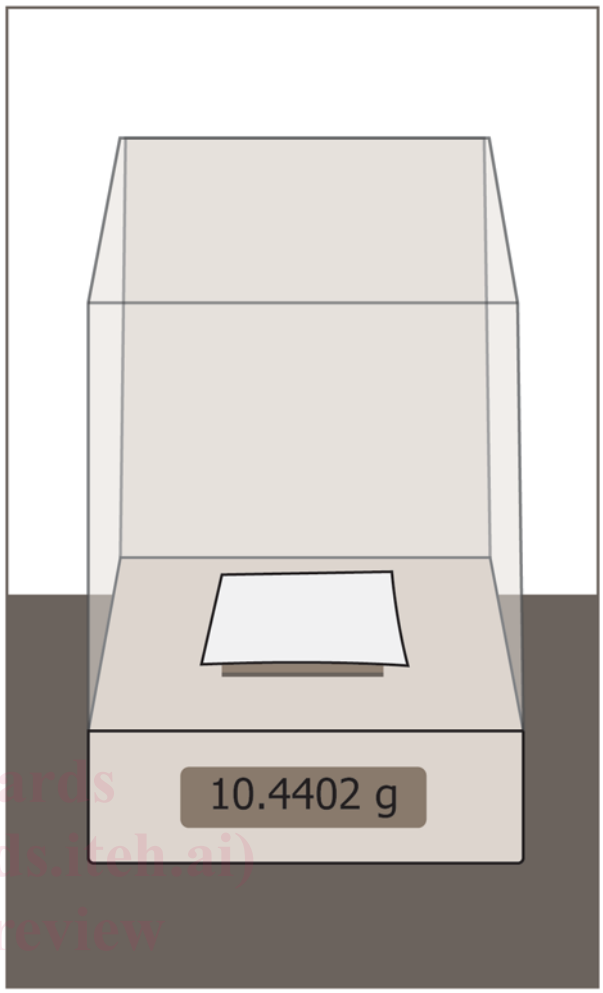

FIG. 5 Weighing the Substrate

9.12 Program the force tester for the following:

9.12.1 The distance the substrate will travel along the brush part (see 6.1).

9.12.2 The speed at which the substrate will be moved down against the brush part.

9.12.3 The speed at which the brush substrate will be moved up against the brush part.

9.12.4 The number of times the substrate will be actuated against the brush part.

9.13 Align the brush part to the top edge of the soil (see Fig. 11).

9.14 Using the brush fixture, position the brush to have bristles making minimum contact with the soil. Then exert 5 N of force on the brush against the substrate (see Fig. 12).

9.15 Run the test program.

9.16 Monitor that the brush bristles' deflection and contact against the surface remain the same throughout the test program through visual confirmation.

9.17 At the end of the procedure, rinse the coupons to remove the soil dislodged by the brushes. Allow the substrate to dry overnight. Convection may be used to speed the drying process. Then weigh the substrate to determine the amount of soil removed (see Fig. 13).

10. Report

10.1 Describe the physical composition of the brush part as follows:

10.1.1 The length of and density of the bristles. With a brush designed to clean an external surface, length will typically be expressed as the length of the bristles and the density will be expressed by the number of bristles per square centimeter.

10.1.2 The length of the brush part (see 3.2.1), measured from the distal end of the brush where the bristle area begins to the end of the bristle area.

10.1.3 Width of the brush part, measured from one side of the brush part to the other.

10.1.4 Overall length of the brush, measured from the distal end of the brush to the proximal end of the brush.

10.1.5 Material composition of the bristles. The medical device manufacturer may provide specifications and limitations on the material composition of brushes that can be used on their device. Materials typically used for brushes designed to clean medical devices include nylon of various sources, brass, stainless steel, and polymers.

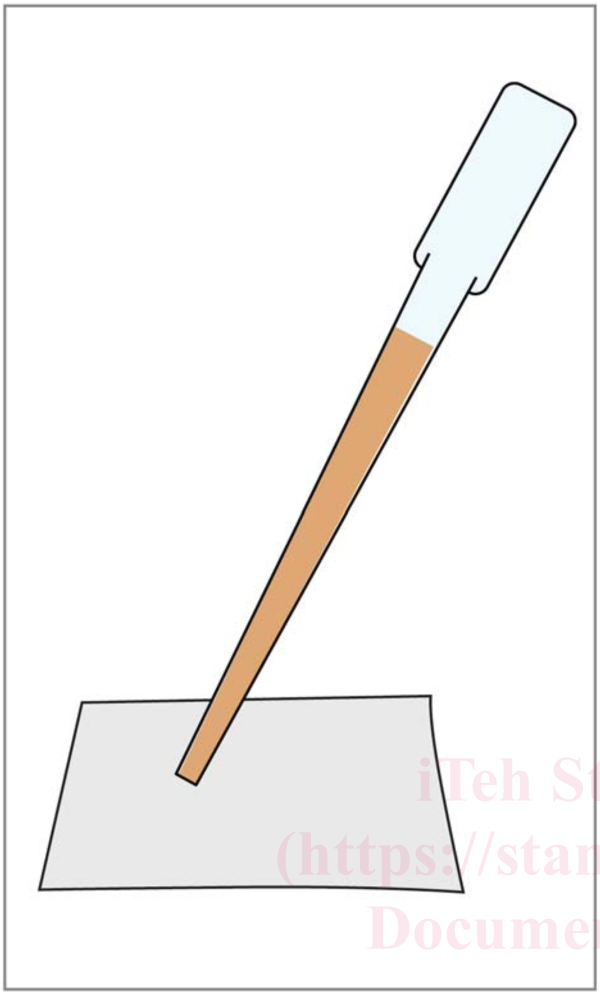

FIG. 6 Soiling the Substrate

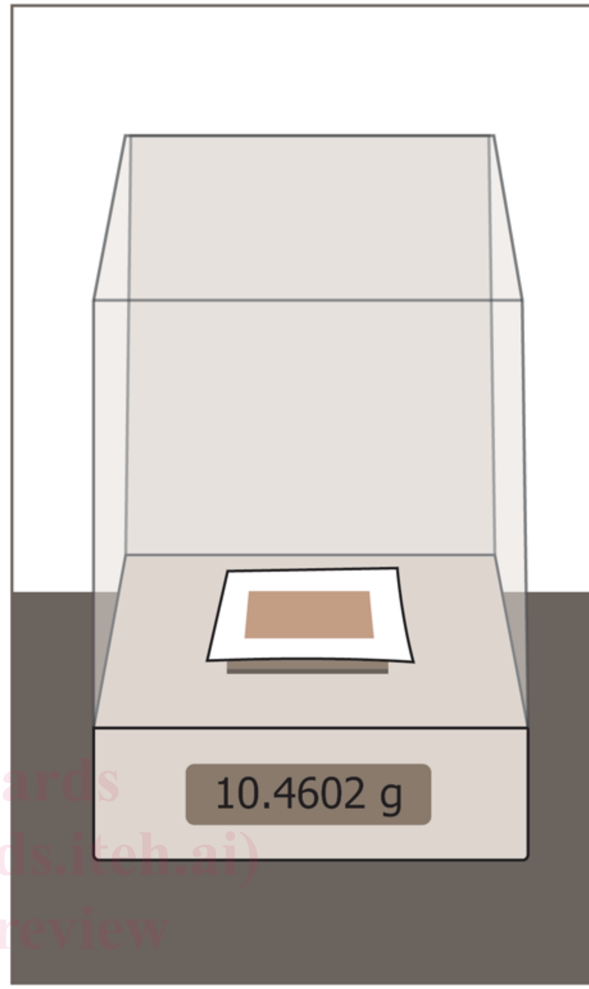

FIG. 7 Weighing the Dried Soil Substrate

10.2 *Force Testing:*

10.2.1 The parameters programmed in 8.3.1 – 8.3.4 should be recorded and reported.

10.2.2 The force measurements (peak and average) for actuating the brush against the surface of the substrate should be recorded and reported.

10.2.3 The recorded force, both at peak and the average, is a measure of friction caused by the contact of a brush part with the surface of the substrate. This indirectly indicates the ability of a brush to contact, loosen, and extract soil on a surface.

10.2.4 The amount of force utilized for minimum contact plus the 5 N of force exerted on the brush against the substrate (see 8.4.1) should be recorded and reported.

10.2.5 Evaluating the performance of a brush part will depend upon the clinical application. More force may mean more effective cleaning. Too much force, however, may lead to damage, depending upon the design and composition of the device. The medical device manufacturer's instructions for use (IFU) should be consulted for guidance in this regard. The IFU may also have specifications for the bristle composition and design of the brush.

10.3 *Removal of Soil:*

10.3.1 The total area covered in soil prior to testing should be recorded and reported for each sample.

10.3.2 The parameters programmed in 9.12.1 – 9.12.4 should be recorded and reported.

10.3.3 The amount and percentage removal of soil should be recorded and reported.

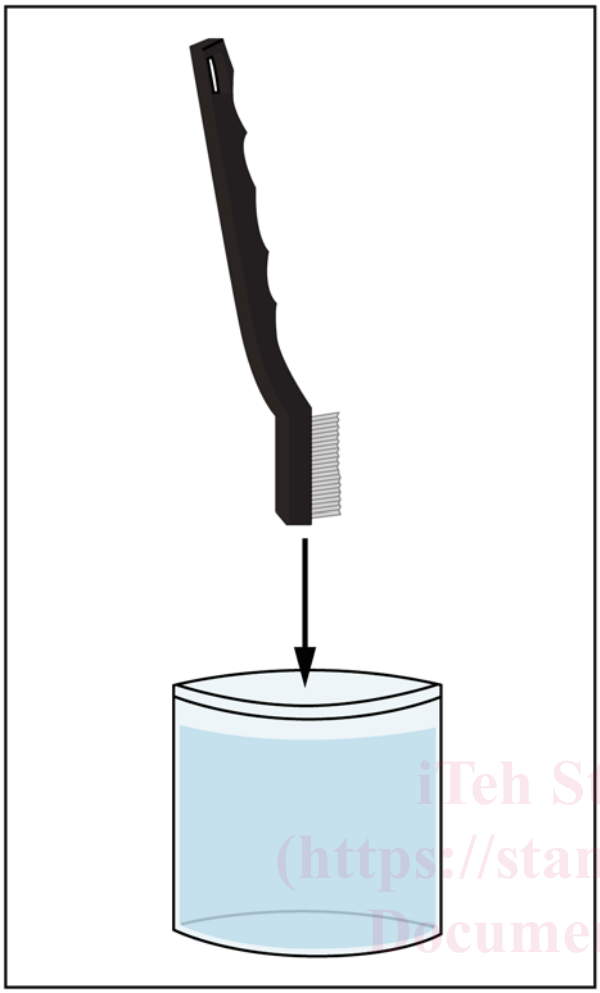

FIG. 8 Dipping the Brush in the Cleaning Solution

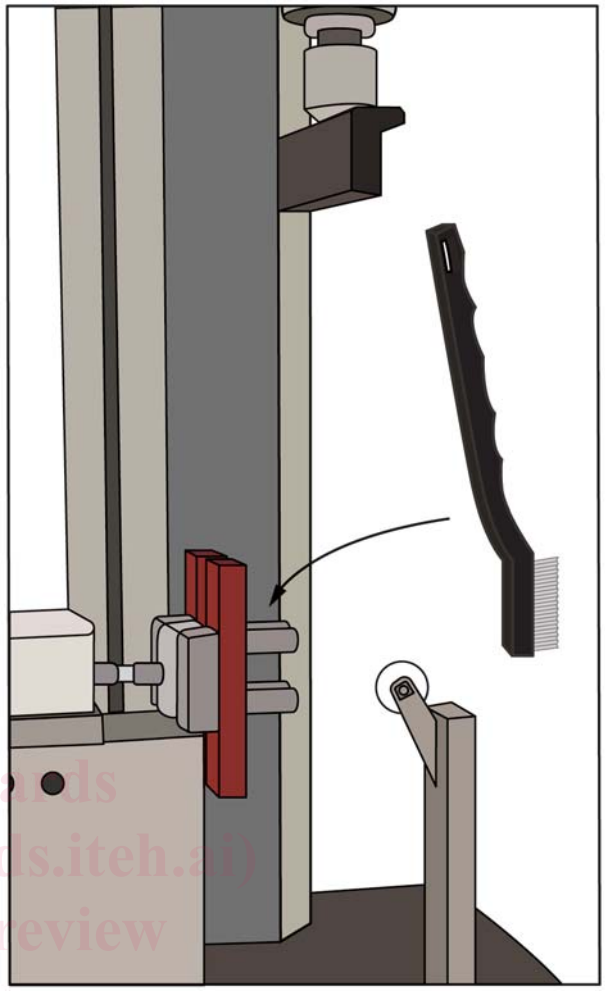

FIG. 9 Mounting the Brush in the Force Tester