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

This standard is issued under the fixed designation F3275; 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 Brushes used to clean a medical device after clinical use play an important role in effective reprocessing. This guide describes methods for characterizing, under prescribed laboratory conditions, the efficacy of brush parts designed to clean the internal channels of medical devices. The methods utilize a force tester to mechanically actuate a brush part within a channel: (*1*) Methods to measure, at an established speed, the force required to move a brush within a channel; (*2*) Methods utilize the same force tester and protocols to measure soil removal from a soiled tube, another indicator of performance.

1.2 *Inclusions:*

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

1.2.2 In this guide, a brush part is one that is intended to be moved within a tube.

1.2.3 Tubes used for testing described in this guide are cylindrical and uniform in diameter. The test methods describe may not apply to non-cylindrical tubes.

1.2.4 By use of this guide, medical device manufacturers can characterize the brush part designed for cleaning their device.

1.2.5 By use of this guide, manufacturers of cleaning brushes can evaluate and characterize the cleaning performance of their brushes for the target area(s) of medical device(s), including allowing a comparison with existing brush part designs offered on the market. Further, they are able to evaluate modifications to designs and construction that might improve performance.

1.2.6 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.

1.3 *Exclusions:*

1.3.1 This guide does not assess potential damage that may be inflicted by the brush. For instance, brushes with rigid bristles (for

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example, stainless steel or other ~~metals),~~metals) or other abrasive ~~materials,~~materials are more likely to damage medical devices than brushes with flexible bristles (for example, nylon) or more pliable materials. Potential damage from more abrasive materials should be assessed.

1.3.2 This guide does not specify acceptance criteria, and the results will be dependent on the specific parameters (for example, test soil, drying time, channel inside diameter and material, and so forth) that are tested.

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

1.3.4 If a brush is intended to clean a specific device(s), cleaning validation shall include testing with that device(s).

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

1.5 *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.*

1.6 *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]

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

2.2 *ISO Standards:*[3]

ISO 17664 Processing of health care products—Information to be provided by the medical device manufacturer for the processing of medical devices

ISO 15883-1 Washer-disinfectors—Part 1: General requirements, terms and definitions and tests

ISO/TS 15883-5 Washer-disinfectors—Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy

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]

~~Reprocessing Medical Devices in Health Care Settings:~~ Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff, issued March 17, 2015

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 is intended to come in contact with the targeted internal surface(s) of the lumen/tube.

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

3.2.2 *extraction of the brush part*—depending upon the method used, this may be the exit of the proximal end of the brush part from the tube (Section 8); or the exit of the distal end of the brush part from the distal end of the tube (Section 9~~)~~).

3.2.3 *insertion of the brush part*—the introduction of the proximal end of the brush part to the proximal end of the tube.

3.2.4 *inside diameter (ID)*—the internal diameter of a lumen/tube.

3.2.5 *jig*—the apparatus which holds the lumen or tube still on the force tester during testing.

3.2.6 *moving the brush part*—the movement of the brush part inside the tube.

3.2.7 *outside diameter (OD)*—the external diameter of a lumen/tube or brush part.

3.2.8 *soiled tube—for the purposes of this document*, refers to a tube that has been inoculated with test ~~soil and placed inside the tube.~~soil.

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

3.2.10 *tube—for the purposes of this document*, refers to the tube that is mounted into the jig.

4. Summary of Practice

4.1 This guide provides details for testing the resistance of a brush part moved inside a tube to simulate the resistance of a brush used to clean the internal channels of a medical device.

4.2 This guide also provides details for soiling a tube, moving a brush part inside that tube, and measuring the soil removed from that tube to simulate the cleaning of the internal channels of a medical device.

4.3 Tube size should be selected based upon the range of the inside diameter (ID) of the different lumens the brush is intended to clean.

4.4 Composition and application of the test soil should be based upon an evaluation of the clinical use of the device (Guide F3208, ISO 17664, AAMI TIR12, AAMI TIR30).

5. Significance and Use

5.1 This guide provides test methods for evaluating the performance characteristics of a brush part designed to clean internal channel(s) of a medical device.

5.1.1 The force required to move a brush part within a tube, an indicator of the friction a brush exerts on a surface, is a parameter of cleaning effectiveness and should be measured.

5.1.2 The removal of soil from a tube by a brush part moved in a tube is a further indicator of the effectiveness of a brush to loosen and remove soil from a tube and should be measured.

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

6. Description of Test Apparatus

6.1 A force testing machine with moving crosshead, a load cell, a chuck for holding the brush part, a set of tubes with various diameters for the brush part to be actuated into, and a holder for the tubes (see Fig. 1).

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

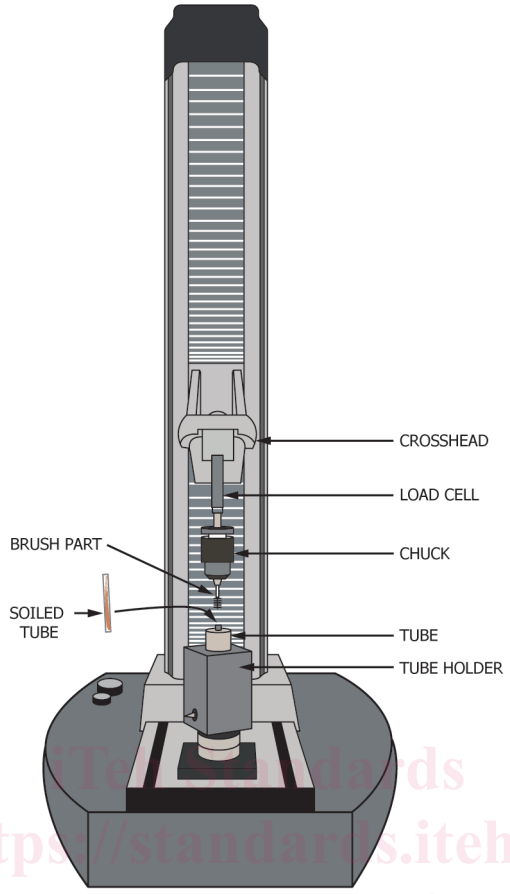

FIG. 1 Force Testing Machine

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

6.1.3 The chuck attaches to the crosshead and holds the brush part in place. The chuck must be able to tighten on the brush part and hold it securely in place.

6.1.4 The tubes should be composed of a material similar to the composition of the lumens of medical devices. The tubes should have accurate inner diameters similar to the diameters of the lumens of medical devices.

6.1.5 The tube holder should be able to accommodate the outer diameter of the tubes, and secure them in place.

6.2 *Sensitive Analytical Scale:*

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

6.2.2 The scale shall have a large enough stage to weigh the selected tube size.

7. Selection Criteria for Tubes and Test Soils

7.1 *Selection of Tubes for Testing:*

7.1.1 The internal diameter (ID) of the tube should be equivalent to the ID of the channel of the medical device(s) the brush is intended to clean.

7.1.1.1 Often there is a range of channel IDs that a brush is intended to clean. At a minimum, the tubes should include the smallest and largest channel IDs of that range.

7.1.2 The physical characteristics of the internal surface of the tube should be similar to the physical characteristics of the surface of the medical device(s) the brush is intended to clean. This includes the surface roughness and any geometric features like crevices, ridges, and so forth (AAMI TIR30). The following should be considered in the selection of surface substrate for testing: (*1*) the material (that is, stainless steel, polytetrafluoroethylene, silicone, and so forth) the tube is made of; (*2*) the surface finish (for example, machined, ground, polished); and (*3*) the device geometry (that is, crevices, ridges).

7.1.2.1 The same brush may be used on more than one type of device and therefore different substrates may be selected to evaluate performance.

7.1.3 The tube should be ~~long enough that the brush part can be completely inserted without reaching the~~ the same length as the brush part, such that the distal end of the ~~tube, a minimum of 2× the length of the brush part.~~brush reaches the distal end of the tube.

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 use (Guide F3208, AAMI TIR12).

7.2.2 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 and FDA Guidance Document (2015) for discussion of methods for determining worst-case soiling).

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

7.2.4 A cleaning solution that is similar to the cleaning solution likely to be used to clean the device after clinical use should be selected (AAMI TIR12, AAMI TIR30).

7.2.5 The testing protocol shall specify the number of replicates (AAMI TIR30 recommends a minimum of ~~3).~~three).

8. Procedure for Testing Resistance in a Tube by Actuation

8.1 Mount the brush part in the chuck of the force tester (see Fig. 2).

8.1.1 Alternative methods for holding the brush part may be employed, depending on the size and configuration of the brush head. One alternative is a vice grip.

8.2 Select the tube for testing (see 7.1.1) and mount to the base of the force tester (see Fig. 3).

8.3 Align the brush part at the mouth of the tube (see Fig. 4). To ensure a smooth transition, it will likely be necessary to align the brush while minimally inserted into the tube. This should be done so that the longitudinal axis of the tube sample is aligned with the longitudinal axis of the brush part such that the brush part will not bend or shift laterally as it moves in the tube.

8.4 Program the force tester for the following:

8.4.1 The distance the brush will travel in the tube (see 7.1.3). This distance should be to the point where the distal end of the brush part reaches the distal end of the tube.

8.4.2 The speed at which the brush will move forward in the tube.

8.4.3 The speed at which the brush will move backward in the tube.

8.4.4 The number of times the brush will be actuated in the tube.

8.5 Run the test program.

8.6 Measure and record the peak and average force measurements for inserting, extracting, and moving the brush through the tube.

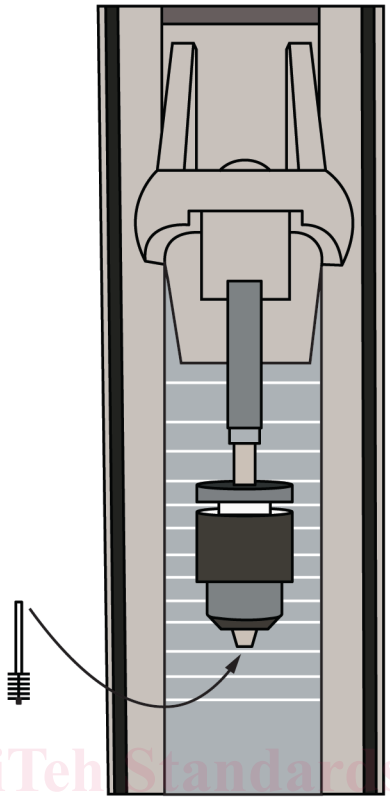

FIG. 2 Brush Part Mounted in Force Tester

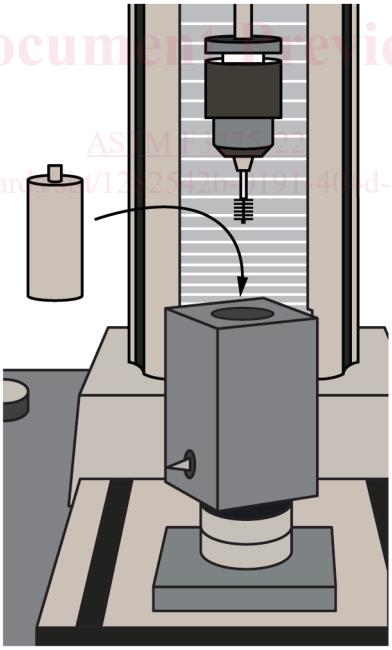

FIG. 3 Select the Tube for Testing

9. Procedure for Evaluating the Soil Removal from a Tube by Actuation

9.1 Select the test soil and prepare as needed (see 7.2).

9.2 Select the tube for testing (see 7.1). If this testing follows the force testing described in Section 7, the same size tubes should be used.

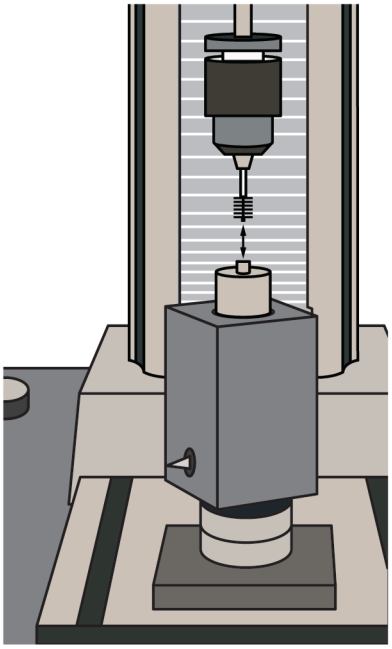

FIG. 4 Brush Aligned at the Mouth of the Tube

9.3 Weigh the tube (see Fig. 5). Alternative soil marker detection methods other than weighing could be used, but are not described in this document. AAMI TIR30 and ISO 15883 Part 1 and Part 5, for instance, describe such methods.

9.4 The volume of the test soil used to soil the tube should be determined (see 7.2).

9.5 The length of time to allow the test soil to dry should be determined (see 7.2).

9.6 Soil the tube (see Fig. 6) and allow to dry.

9.7 Weigh tube with dried soil (see Fig. 7).

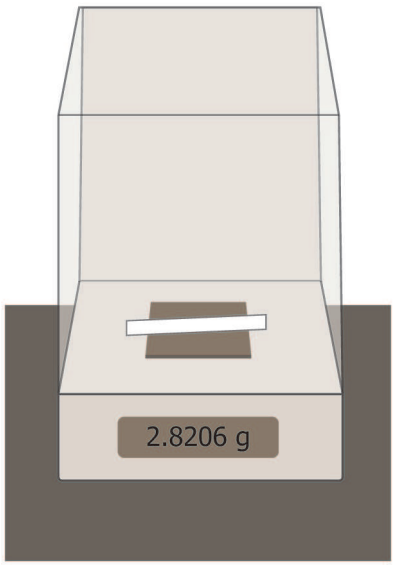

FIG. 5 Weighing the Tube

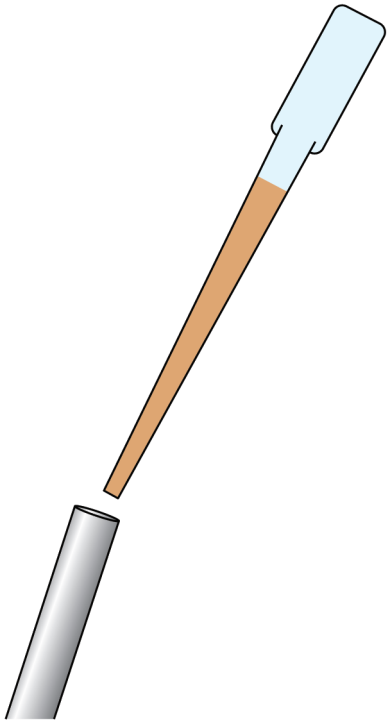

FIG. 6 Soiling the Tube

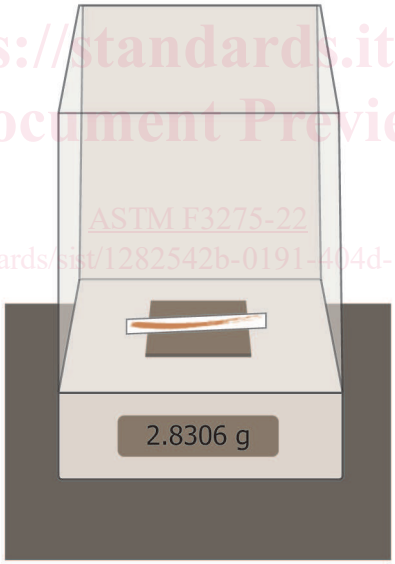

FIG. 7 Weighing Tube with Dried Soil

9.8 Prepare a cleaning solution (see 7.2.4).

9.9 Dip the brush in the cleaning solution ~~for a specified period of time~~ (see Fig. 8). Remove excess solution.

9.10 Mount the brush part in the force tester as described in Section 8 (see Fig. 9).

9.11 Mount the soiled tube in the force tester as described in Section 8 (see Fig. 10).

9.12 Follow steps in sections 8.3, 8.4, 8.5, and 8.6.

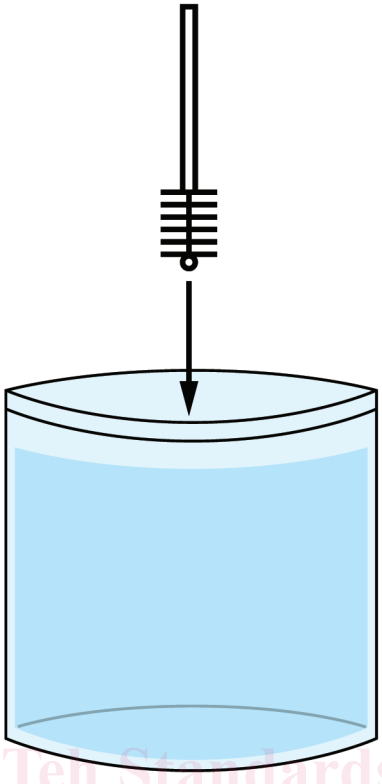

FIG. 8 Dipping the Brush in the Cleaning Solution

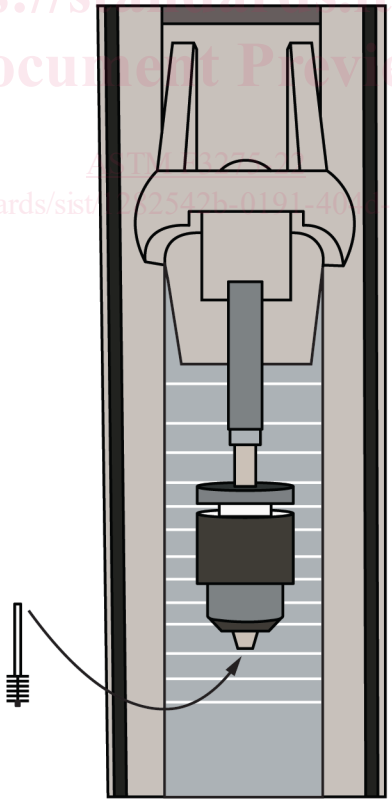

FIG. 9 Mounting the Brush in the Force Tester

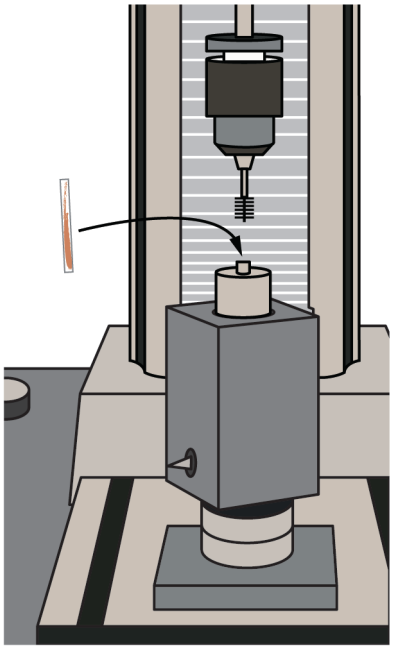

FIG. 10 Mounting the Tube in the Force Tester

9.13 At the end of the procedure, water may be flushed through the soiled tube to simulate the post-brushing flushing that is often done in clinical use (see Fig. 11).

9.14 Allow the soiled tube to ~~completely dry.~~dry overnight. Convection may be used to speed the drying process.

9.15 Weigh the soiled tube to determine the amount of soil removed (see Fig. 12).

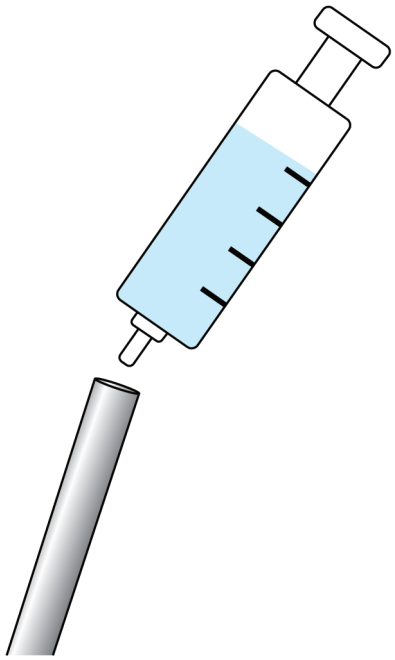

FIG. 11 Flushing Tube with Water

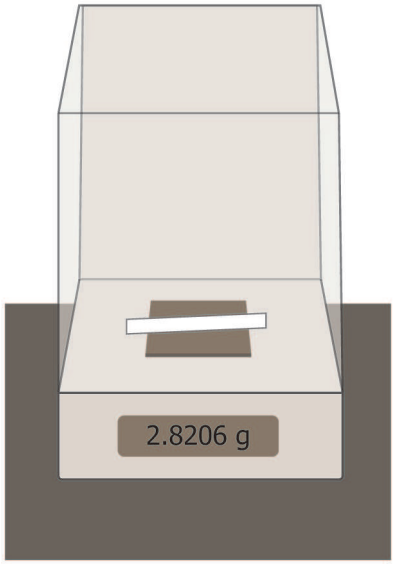

FIG. 12 Weighing Tube ~~after~~After Drying

10. Procedure for Testing Resistance in a Tube ~~using~~Using a Pull-Through (Single Direction) Method

10.1 Pull the shaft of the brush part through the tube until the brush head is at the proximal end of the tube (see Fig. 13).

10.2 Mount the tube onto the base of the force tester (see Fig. 14).

10.3 Lower the crosshead to be close to the shaft of the brush (see Fig. 15).

10.4 Secure the brush shaft in the chuck of the force tester (see Fig. 16).

10.4.1 Alternative methods for holding the brush part may be employed, depending on the size and configuration of the brush head. One alternative is a vice grip.

10.5 Program the force tester for the following:

10.5.1 The distance the brush part will travel ~~upwards (see~~upwards, which ~~7.1). This distance should be greater than the length~~should be the same length as the tube (see 7.1~~of the tube.~~).

10.5.2 The speed at which the brush part will be pulled through the tube.

10.6 Run the test program.

10.7 Measure and record the peak and average force measurements for inserting, extracting, and moving through the tube.

11. Procedure for Evaluating the Cleaning of a Tube ~~using~~Using the Pull-Through (Single Direction) Method

11.1 Select the test soil (see 7.2) and prepare as needed.

11.2 Select the tube (see 7.1) for testing. If this testing follows the force testing described in Section 7, the same size tubes should be used.

11.3 Weigh the tube (see Fig. 17).

11.4 The volume of soil used to soil the tube should be determined (see 7.2).