Designation: F3487 – 20

Standard Guide for Assessing the Service Life of a Brush Part Intended to Clean a Medical Device[1]

This standard is issued under the fixed designation F3487; 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 assessing the service life, under prescribed laboratory conditions, of a brush part designed to clean a medical device. The method utilizes force testers to mechanically actuate a brush part at a constant rate. This action continues until the brush part demonstrates a significant reduction in cleaning power as measured by the force exerted during testing.

1.2 The test methods utilized in this guide are those described in Guides F3275 and F3276. In this guide, the number of repetitions is open-ended and determined by the measurable fatigue of the brush part as measured by a reduction in force, as well as any observation of wear or damage to the brush part.

1.3 Brushes designed to clean medical devices after clinical use play an important role in the effective reprocessing of those medical devices. Instructions for use from the brush manufacturer should supply information related to the service life of the brush. This may be stated in terms of (*1*) a time period; (*2*) the number of uses; (*3*) inspection of the brush for wear and damage.

1.4 Inspection for wear should always be a part of the instructions for use of a brush. Application of this guide can help to determine like mode(s) of observable failure of a brush part.

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.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

F3275 Guide for Using a Force Tester to Evaluate Performance of a Brush Part Designed to Clean the Internal Channel of a Medical Device

F3276 Guide for Using a Force Tester to Evaluate the Performance of a Brush Part Designed to Clean the External Surface of a Medical Device

3. Terminology

3.1 *Definitions:*

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

4. Summary of Guide

4.1 This guide describes the application of test methods described in Guides F3275 and F3276 to assess the service life of a brush part intended to clean a medical device.

4.2 Through exhaustive repetitions of the applicable method, the service life of the brush part can be estimated and described.

4.3 Determination of end-of-life:

4.3.1 The end-of-life for a brush part may be determined by observable physical wear of the brush part. This may include (see Fig. 1):

4.3.1.1 Missing bristles,

4.3.1.2 Fallen bristles,

4.3.1.3 Twisted bristles,

4.3.1.4 Bent bristles,

4.3.1.5 Bent shaft of the brush (typically brushes intended to clean lumens),

4.3.1.6 Damage to the block of the brush part (typically brushes intended to clean surfaces), and

[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 Oct. 15, 2020. Published November 2020. DOI: 10.1520/F3487-20.

[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.

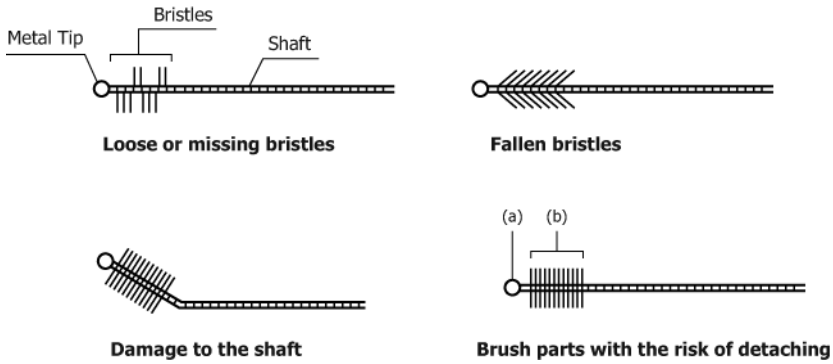

FIG. 1 Observable Physical Wear of Brush Part

4.3.1.7 Untwisting of the wires (in the case of a twisted wire brush).

4.3.2 The end-of-life may also be indicated by a reduction in the force measurements, peak force, average force, or both.

4.4 Inspection of the brush part should occur when:

4.4.1 Force measurements decline;

4.4.2 At established intervals during testing.

5. Significance and Use

5.1 This guide describes the use of test methods in Guides F3275 and F3276 to assess the service life of a brush part intended to clean a medical device.

5.2 In the case of a brush part intended to clean a lumen, the force required to move a brush part within a tube, an indicator of the friction a brush exerts on a surface, is a measurable parameter that can change over time and will decrease as the brush part loses integrity.

5.3 In the case of a brush part intended to clean the external surface, the force required to move the brush across a surface and the pressure the brush exerts on that surface are measurable parameters that can change over time and will decrease as the brush part loses integrity.

5.4 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. Application of Test Methods

6.1 Guide F3275 for brushes intended to clean lumens:

6.1.1 See Section 6.1 for Description of the Test Apparatus.

6.1.1.1 For this guide, an analytical scale is not required (Section 6.2 of F3275).

6.1.2 See Section 7.1 for the Selection Criteria for the Tubes for Testing.

6.1.2.1 For this guide, test soil is not required (Section 7.2 of F3275).

6.2 Guide F3276 for brushes intended to clean external surfaces:

6.2.1 See Sections 6.1 and 6.2 for Description of the Test Apparatus.

6.2.1.1 For this guide, an analytical scale is not required (Section 6.3 of F3276).

6.2.1.2 For this guide, test soil is not required (Section 7.2 of F3276).

6.2.2 See Section 7.3.1.1 for the Selection of Force Applied to Brush Part during Resistance Testing.

7. Procedure

7.1 Guide F3275 for brushes intended to clean lumens:

7.1.1 See Section 8 for the Procedure for Testing Resistance in a Tube by Actuation.

7.1.1.1 Cycle brush part testing procedure for a predetermined number of times.

(1) The number of times may be based upon: (*1*) prior testing; (*2*) anticipated service life of the brush part.

7.1.1.2 The threshold for the decline in measured force that indicates a loss in cleaning power should be established.

(1) This threshold may be based: (*1*) upon prior testing following F3275 test method.

7.1.1.3 Observe and record the peak and average force.

(1) If either measurement of force declines to the threshold value established in 7.1.1.2, stop testing and inspect the brush part for wear or damage.

(2) Note any observable change in the brush part.

7.1.1.4 If there is no significant change in force measurements, inspect the brush part for any wear or damage at the end of the predetermined number of cycles.

(1) If no observable wear or damage, then repeat step 7.1.1.1.

7.2 Guide F3276 for brushes intended to clean external surfaces:

7.2.1 See Section 8 for Procedure for Testing Resistance on a Surface.

7.2.1.1 Cycle brush part testing procedure for a predetermined number of times.

7.2.1.2 Observe record the peak and average force.

(1) If either of the measurements of force declines by 25 %, stop testing and inspect the brush part for wear or damage.

(2) Note any observable change in the brush part.

(3) If there is no significant change in force measurements, inspect the brush part for any wear or damage at the end of the predetermined number of cycles.

(4) Note any observable change in the brush part.

(5) If no observable wear or damage, then repeat step 7.2.1.1.

8. Report

8.1 See Section 12.1 of Guide F3275 and Section 12.1 of Guide F3276, respectively, for information to be reported on the physical composition of the brush part.

8.2 See Section 12.4 of Guide F3275 and Section 12.4 of Guide F3276, respectively, for information to be reported with regards to the force testing settings and results.

8.3 Reporting specific to this guide:

8.3.1 The predetermined number of cycles between inspection of the brush part for damage.

8.3.2 The peak and average force during the first cycle of the brush.

8.3.3 If the peak and average within 25 % of the starting value, report:

8.3.3.1 The number of repetitions.

8.3.3.2 The observed condition of the brush.

8.3.3.3 The total number of repetitions when testing was halted because of observed damage or exceeded the set threshold for the number of repetitions.

8.3.4 If the peak or average force dropped by 25 %, report:

8.3.4.1 The total number of repetitions when the test was halted.

8.3.4.2 The observed condition of the brush.

9. Keywords

9.1 brush part; service life

APPENDIXES

(Nonmandatory Information)

X1. EXAMPLE OF MEASURING THE SERVICE LIFE OF A BRUSH PART DESIGNED TO CLEAN THE INTERNAL CHANNEL OF A MEDICAL DEVICE IMPLEMENTING GUIDE F3275 (SECTION 7)

X1.1 Equipment

X1.1.1 Ametek Chatillon Force Tester.

X1.1.2 Adjustable diameter steel chuck attached to a 10 lb load cell with locating dowel. The chuck holds the tubing of the brush part and is adjustable to accommodate the various diameters of brush tubing.

X1.1.3 Stainless steel tube and polytetrafluoroethylene (PTFE) tube with applicable diameter per the brush being tested, mounted into a holder to prevent movement. The holder fits into the jig on the base of the force tester.

X1.2 Test Program

X1.2.1 Specifications of brush to be tested:

X1.2.1.1 Outer diameter of the brush part: 4.0 mm.

X1.2.1.2 Length of the brush part: 12.0 mm.

X1.2.1.3 Outer diameter of brush filament, or ‘density’ of fibers attached: 0.076 mm.

X1.2.1.4 Outer diameter of brush part wire: 0.356 mm.

X1.2.1.5 Over twist of wire: 0.838 mm.

X1.2.1.6 Wire material type: Stainless steel.

X1.2.1.7 Filament material type: Nylon.

X1.2.1.8 Overall length: 60.0 mm.

X1.2.2 Specifications of substrate materials to be tested:

X1.2.2.1 Substrate material: Stainless steel tubing.

X1.2.2.2 Substrate material internal surface geometry and surface roughness should be specified.

X1.2.2.3 Substrate material: PTFE tubing.

X1.2.2.4 Substrate material internal surface geometry: Smooth.

X1.2.3 Determine the parameters of the program.

X1.2.3.1 The brush is intended to clean lumens with an internal diameter from 1.0 mm to 1.5 mm. PTFE and stainless steel tubing of 1.0 mm and 1.5 mm will be used as substrates. A new brush will be tested with each material and diameter.

X1.2.3.2 The brush part is 12.0 mm long; travel inside the tube should be at least this length.

X1.2.3.3 The number of cycles is predetermined and assessed as testing progresses, determined by the decrease in average tension, average compression, maximum compression, and maximum tension. When any of these values decreases by 25.0 % or more, the testing is halted.

X1.2.3.4 Visual inspection of the brush before, after, and in between cycles is documented.

X1.2.4 Parameters of test program:

X1.2.4.1 Speed: 508.0 mm/min.

X1.2.4.2 Distance brush travels in tube: 24.0 mm.

(1) Internal Diameter of steel tubes: 1.0 mm and 1.5 mm.

(2) Internal Diameter of PTFE tubes: 1.0 mm and 1.5 mm.

X1.2.4.3 Number of repetitions of cycles: five, or whenever brush damage is visible, or one of the measured forces (average tension, average compression, maximum compression, and maximum tension) decreases by 25.0 %. The duration of each cycle is 10 min.

X1.2.5 Measure and record:

X1.2.5.1 The total number of repetitions when the test was halted.

X1.2.5.2 The maximum force traveling forward into the tube (maximum compression) during the first cycle.

X1.2.5.3 The average force traveling into the tube (average compression) during the first cycle.

X1.2.5.4 The maximum force traveling back out of tube (maximum tension) during the first cycle.

X1.2.5.5 The average force traveling out of the tube (average tension) during the first cycle.

X1.2.5.6 The maximum force traveling forward into the tube (maximum compression) when the first decrease in 25.0 % is noted or there is visible damage.