Designation: F3602 – 23

Standard Guide for Assessing the Compatibility of a Cleaning Brush Part with Different Substrates Used in the Construction of Medical Devices[1]

This standard is issued under the fixed designation F3602; 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 compatibility, under prescribed laboratory conditions, of a cleaning brush part with substrate materials used in the construction of medical devices. The method utilizes a force tester to mechanically actuate a brush part at a constant rate. This action continues until there is any level of visible degradation, including but not limited to scratching or shaving of the substrate material.

1.2 The test methods utilized in this guide are those described in Guide F3276. In this guide, the number of repetitions is determined by the demonstrable degradation, if any, of the substrate, up to a specified maximum number of repetitions.

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 compatibility, or more importantly, incompatibility with materials that make up the composition of a medical device. This may be stated in terms of being suitable for specific materials, not suitable for specific materials, or suitable for a limited number of uses for specific materials.

1.4 Selecting the correct brush for the medical device to be cleaned is always a key factor to achieve effective cleaning. One of the significant factors when selecting a brush is selecting one that will not cause damage to the medical device, including the material the medical device is constructed of. Assessing if a brush part could damage a medical device because of the material the device is made of is an important step in determining the appropriate (and inappropriate) use of a brush.

1.5 *Units*—The values stated in SI units are to be regarded as the 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]

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 part*—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 Guide F3276 to assess the compatibility of a brush part with the material substrate used in the construction of medical devices.

4.2 Through exhaustive repetitions of the applicable method, the compatibility of the brush part can be assessed and described.

4.3 The maximum number of repetitions may be specified and shall be justified.

[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 May 15, 2023. Published May 2023. Originally approved in 2022. Last previous edition approved in 2022 as F3602 – 22. DOI: 10.1520/F3602-23.

[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.

5. Significance and Use

5.1 This guide describes the use of test methods in Guide F3276 to assess the compatibility of a brush part with the material substrates used in the construction of medical devices.

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

6. Application of Test Methods

6.1 Guide F3276:

6.1.1 See subsections 6.1 and 6.2 for description of the test apparatus.

6.1.1.1 For this guide, an analytical scale is not required (subsection 6.3 of Guide F3276).

6.1.1.2 For this guide, test soil is not required (subsection 7.2 of Guide F3276).

6.1.2 See subsection 7.3.1.1 for the reference to determine the force to use during resistance testing.

7. Procedure

7.1 Guide F3276 for brushes intended to clean external surfaces:

7.1.1 See Section 8 for procedure for testing resistance on a surface.

7.1.1.1 Cycle brush part testing procedure for a predetermined number of times in accordance with 1.2 or until there is demonstrable degradation of the substrate.

7.1.1.2 Observe record the peak and average force.

7.1.1.3 Note any observable change in the substrate material.

7.1.1.4 Note the specified number of repetition in accordance with 1.2.

8. Report

8.1 See Section 10 of Guide F3276 for information to be reported in regard to the force testing settings and results.

8.2 Reporting specific to this guide:

8.2.1 The predetermined number of cycles between inspection of the substrate material for damage.

8.2.2 The number of repetitions.

8.2.3 The observed condition of the substrate material.

8.2.4 The total number of repetitions when testing was halted because of observed damage or exceeding the specified maximum number of repetitions.

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

9. Keywords

9.1 brush part; material compatibility; substrate

APPENDIX

(Nonmandatory Information)

X1. EXAMPLE OF ASSESSING THE COMPATIBILITY OF A BRUSH PART DESIGNED WITH DIFFERENT MATERIALS OF CONSTRUCTION OF MEDICAL DEVICES IMPLEMENTING ASTM F3276

X1.1 Equipment

X1.1.1 Ametek Chatillon Force Tester with minimum 10 lb load cell.

X1.1.2 Brush testing fixture with minimum 5 lb force gauge.

X1.1.3 Clamp to secure substrates to force tester arm.

X1.2 Test Program

X1.2.1 Specifications of brush to be tested:

X1.2.1.1 Length of filament: 13.0 mm.

X1.2.1.2 Width of the brush part: 10.0 mm.

X1.2.1.3 Length of brush part: 36.0 mm.

X1.2.1.4 Outer diameter of brush filament: 0.42 mm.

X1.2.1.5 Diameter of handle: Thickest point is 12.5 mm, thinnest point is 11.8 mm.

X1.2.1.6 Handle type: Plastic.

X1.2.1.7 Filament material type: Nylon.

X1.2.1.8 Overall length: 180.0 mm.

X1.2.1.9 Substrate material: Galvanized steel sheet.

X1.2.1.10 Substrate material surface: Smooth.

X1.2.2 Determine the parameters of the program:

X1.2.2.1 The brush is intended to clean a medical device for which brushing of surface contamination is a recommended step in the cleaning process.

X1.2.2.2 The brush part is 36.0 mm long; travel across the surface should be at least this length.

X1.2.2.3 The number of cycles is predetermined and assessed as testing progresses, determined by visual inspection of the substrate material between cycles. Testing stops if physical changes to the substrate are observed or a maximum of 30 cycles.

X1.2.2.4 Visual inspection of the substrate before, after, and in between cycles is documented. If visible degradation occurs, the testing is halted.

X1.2.3 Parameters of the test program:

X1.2.3.1 Speed: 635.0 mm/min.

X1.2.3.2 Distance brush part travels across the substrate: 65.0 mm.

X1.2.3.3 Number of repetitions of cycles: 30, or whenever substrate damage is visible.

X1.2.3.4 Measure and record:

(1) The total number of repetitions when the test was halted.