



Standard Test Methods for Enteral Feeding Devices with a Retention Balloon¹

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1. Scope

1.1 These test methods cover the establishment of performance requirements for the utilization of a single-use, enteral feeding device with a retention balloon, used by medical professionals for providing a means of nutrition and/or administration of medication to patients by means of natural orifice (nasal, oral, transluminal) and or a surgically created stoma. The product is manufactured in various sizes and materials such as silicone, urethane, and various polymers (as well as combinations of these) and is provided nonsterile for sterilization and sterile for single use only. Rationale for these test methods can be found in [Appendix X1](#).

1.2 *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 and health practices and to determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*²

[F623 Performance Specification for Foley Catheter](#)

2.2 *Other Standard:*

[Simulated Gastric Fluid, USP Official Compendia of Standards](#)³

3. Terminology

3.1 *Definitions:*

3.1.1 *balloon integrity (resistance to rupture), n*—volume of liquid that corresponds with balloon failure, or bursting.

3.1.2 *distal, n*—refers to the balloon end of the enteral feeding device

3.1.3 *enteral feeding device with retention balloon, n*—a two-way medical device intended to provide a means of nutrition or administration of medication, or both, to patients by means of natural orifice (nasal, oral, transluminal) or a surgically created stoma, or both, consisting of a drainage lumen and inflation lumen (see [Fig. 1](#)). Common balloon inflation sizes are 5 cm³, 15 cm³, and 20 cm³.

3.1.4 *French size (Fr), n*—a scale used for denoting the size of catheters and other tubular instruments. The French size value is three times the outer diameter of the tube as measured in millimetres. For example, a diameter of 18 Fr indicates a diameter of 6 mm.

3.1.5 *inflation volume, n*—volume of liquid used to inflate the retention balloon of the enteral feeding device for proposed testing in this standard.

3.1.6 *rated volume, n*—stated volume of inflation of the retention balloon of the enteral feeding device in the manufacturers labeling and instructions for use.

3.1.7 *simulated gastric fluid, n*—a solution consisting of hydrochloric acid, salt and pepsin with a pH of approximately 1.2, per USP standard recipe.

3.1.8 *sterility, n*—the state of being free from viable microorganisms.

4. Specimen Preparation

4.1 All test specimens for test methods listed below shall consist of the manufacturers' new, finished, untested, unsterilized product. At the minimum, statistically valid samples of the smallest and the largest diameter of enteral feeding devices shall be tested.

5. Test Methods

PROCEDURE A: FLOW RATE THROUGH FEEDING LUMEN

5.1 *Scope*—This test method covers the determination of flow rates through the drainage lumen of the enteral feeding device with retention balloon.

5.2 *Summary of Test Method*—The apparatus is set up as shown in [Fig. 2](#). The flow rate is adjusted through the water inlet to a rate sufficient to maintain flow through the overflow outlet while each enteral feeding device is tested. A head pressure of 20 ± 1.0 cm of water (196 ± 10 kPa) above the

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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 USP Official Compendia of Standards, available from U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852.