INTERNATIONAL

Designation: F2528 – 06 (Reapproved 2023)

Standard Test Methods for Enteral Feeding Devices with a Retention Balloon[1]

This standard is issued under the fixed designation F2528; 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 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.3 *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]

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 cm^3, 15 cm^3, and 20 cm^3.

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 manufacturer's 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 manufacturer's 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.

[1] These test methods are under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and are the direct responsibility of Subcommittee F04.35 on GI Applications.

Current edition approved July 1, 2023. Published July 2023. Originally approved in 2006. Last previous edition approved in 2014 as F2528 – 06 (2014). DOI: 10.1520/F2528-06R23.

[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.

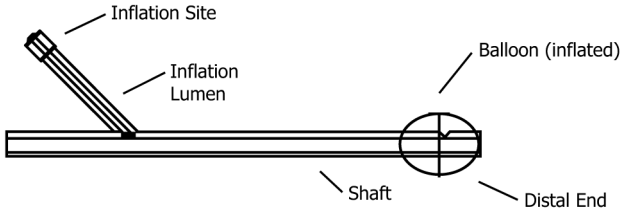

FIG. 1 Enteral Feeding Device with Retention Balloon

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 tank bottom shall be maintained throughout the test to approximate actual physiological conditions. The overflow outlet should not be covered by water.

5.3 *Significance and Use*—The flow rate is measured in reverse flow for ease in testing, since differences in the flow rate as a result of flow direction are theoretically insignificant.

5.4 *Apparatus:*

5.4.1 *Water Reservoir,* capable of maintaining 20 ± 1.0 cm (7.9 ± 0.4 in.) of water (196 ± 10 kPa) above the tip of the enteral feeding device connection throughout the test as shown in Fig. 2. (See Performance Specification F623.)

5.4.2 *Graduated Cylinder,* calibrated for suitable measurement of the effluent.

5.4.3 *Syringe,* with appropriate tip for inflation of enteral feeding device balloon.

5.5 *Hazards:*

5.5.1 Overflow should not be covered. Head pressure must be kept constant; water should always be exiting through the overflow outlet.

5.5.2 Establish equilibrium before testing.

5.5.3 Flow rates through all fittings must exceed that of the enteral feeding device being tested.

5.6 *Procedure:*

5.6.1 Test at 23 ± 4 °C (73.4 ± 7 °F).

5.6.2 Inflate the retention balloon of the test specimen with water to labeled volume.

5.6.3 Connect the enteral feeding device to enteral feeding device connector and open the stopcock. The tip of the enteral feeding device connection at the junction of enteral feeding device on-off valve should be level with the bottom of the tank ±1 cm and it should deliver fluid at 20 ± 1 cm (196 ± 10 kPa) head pressure at that junction.

5.6.4 Establish flow equilibrium before taking test measurements.

5.6.5 Record the amount of fluid through the device feeding lumen in 30 s.

5.7 *Interpretation of Results*—Flow rates for enteral feeding devices tested must meet or exceed 9 cm^3/min.

5.8 *Precision and Bias*—To be determined within five years.

PROCEDURE B: BALLOON BURST VOLUME

5.9 *Scope*—This test method covers the determination of balloon integrity of enteral feeding devices with retention balloon.

5.10 *Summary of Test Method*—The enteral feeding device with retention balloon is submerged in a small container filled with water. The balloon is then inflated with water until rupture, which enables the volume at which the balloon bursts to be observed.

5.11 *Significance and Use*—The balloon burst volume is measured to quantify the resistance to rupture of the enteral feeding device with retention balloon member.

5.12 *Apparatus*—The testing apparatus is set up as shown in Fig. 3.

5.12.1 *System Reservoir.*

5.12.2 *Syringe.*

5.12.3 *Water.*

5.13 *Hazards*—Water should be emptied from system reservoir through purge valve when fill marked is reached.

5.14 *Procedure:*

5.14.1 Test at 23 ± 4 °C (73.4 ± 7 °F).

5.14.2 Insert uninflated enteral feeding device into test orifice in system reservoir per Fig. 3.

5.14.3 Close orifice so that it is positioned proximal to the enteral feeding device with retention balloon member. The device is not to be immersed in water within the reservoir per Fig. 3.

5.14.4 Fill syringe with amount of water greater than that listed in Table 1 for the desired French size. Attach tip of syringe to enteral feeding device inflation valve.

5.14.5 Inflate retention balloon at 1 cm^3/s with water until balloon bursts. Record amount of water injected into balloon at time of burst.

5.15 *Interpretation of Results*—Burst volumes for enteral feeding devices tested must meet or exceed those listed in Table 1.

5.16 *Precision and Bias*—To be determined within five years.

PROCEDURE C: BALLOON VOLUME MAINTENANCE

5.17 *Scope*—This test method is applicable for enteral feeding devices with retention balloon to test the integrity of the inflation system to maintain balloon volume.

5.18 *Summary of Test Method*—The balloon retention device of the enteral feeding device is inflated with a test liquid. This test liquid contains a colorant which enables a leak of this fluid to be observed. If no leak is observed, the integrity of the inflation system is upheld, therefore maintaining the balloon volume.

5.19 *Significance and Use*—This test method establishes a standard test method for determining the functional integrity of the inflation system of the enteral feeding device with retention balloon by observing the consistancy of volume of the balloon after it is filled with test liquid. Additionally, since it is the

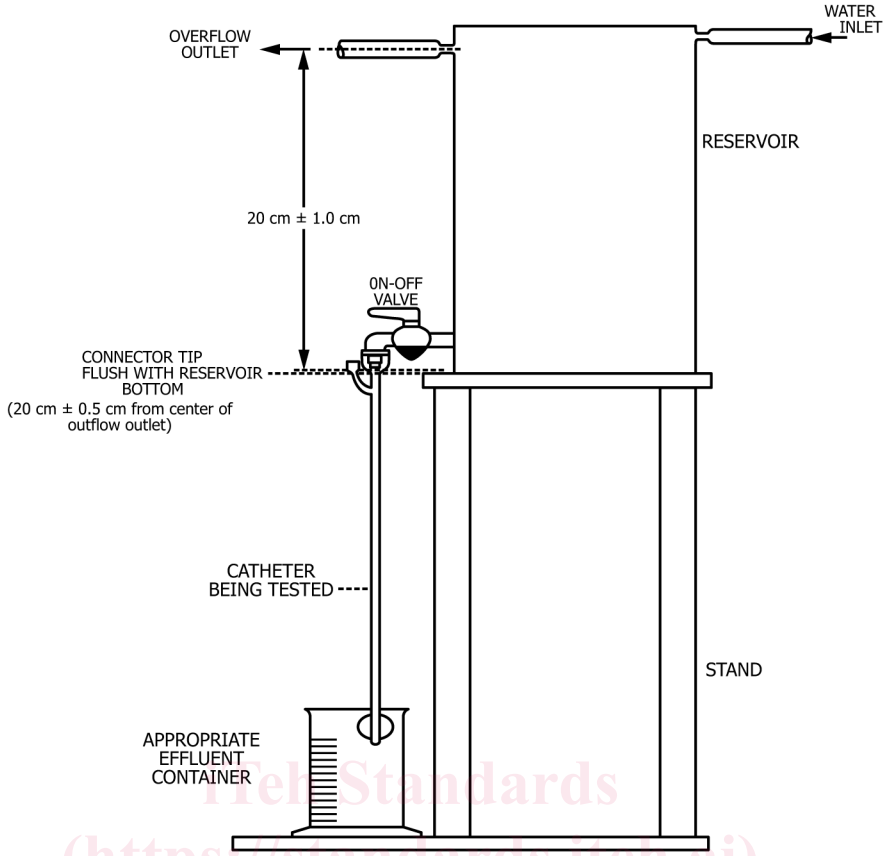

FIG. 2 Flow Rate Apparatus

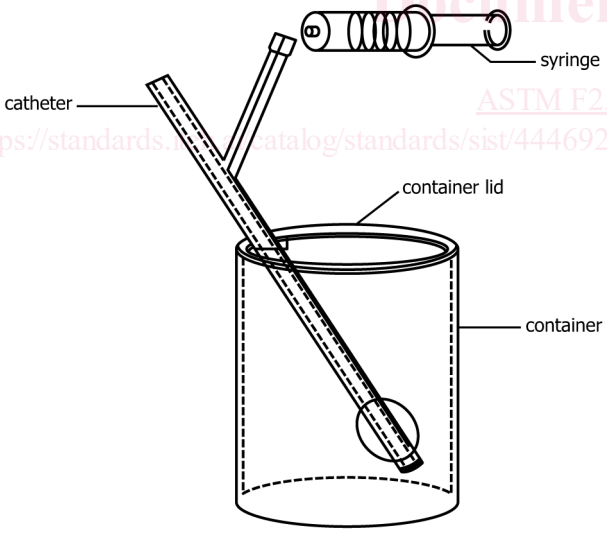

FIG. 3 Balloon Burst Apparatus

TABLE 1 Minimum Burst Volumes

Rated Balloon Inflation Volume (cm^3)	Minimum Burst Volume (cm^3)
5	10
10	20
15	30
20	40
All others > 20 cm^3	2× rated volume

function of the inflated balloon to retain the feeding device in position, the balloon must inflate, retain inflation volume, and release that volume when required.

5.20 *Apparatus:*

5.20.1 *Syringe.*

5.20.2 *Methylene Blue Crystal Solution or Equivalent*—Prepare 1 g of methylene crystals and dilute in 2000 cm^3 of water, to be detectable in the described retention test.

5.20.3 *Background Material,* suitable for detection of any leakage (for example, paper towel).

5.21 *Hazards*—Ensure that the syringe is properly seated in the valve.

5.22 *Procedure:*

5.22.1 Test at 23 ± 4 °C (73.4 ± 7 °F).

5.22.2 Inflate the balloon with the methylene blue solution to the labeled volume.

5.22.3 Place on a surface suitable for detection of color leakage for a 15 min period. Cover or protect the enteral feeding devices from light or ozone for the duration of the test.

5.23 *Interpretation Results:*

5.23.1 Failure to inflate is a failure of the liquid from the filling device (syringe) to enter the retention balloon.

5.23.2 Failure of retention is a discoloration of or leakage on the clean surface between the enteral feeding device.

5.24 *Precision and Bias*—To be determined within five years.

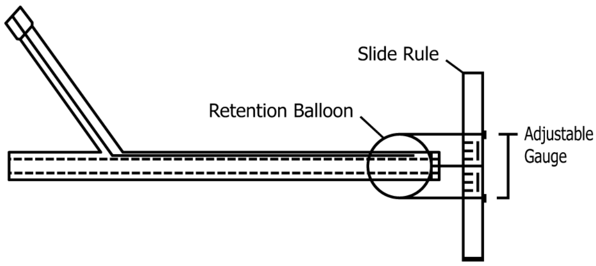

FIG. 4 Concentricity Test Apparatus

PROCEDURE D: BALLOON CONCENTRICITY

5.25 *Scope*—This test method is applicable for enteral feeding devices with retention balloon to test the concentricy of the balloon.

5.26 *Summary of Test Method*—The retention balloon of the enteral feeding device is inflated with water, and with the use of a gauge, evaluted for concentricty.

5.27 *Significance and Use*—This test is designed to quantify balloon concentricity and the overall shape geometry of the balloon. It is the purpose of the balloon to retain the feeding device in position during use; therefore, the balloon must be of a functional uniformity that will not allow the enteral feeding device to move from its desired position.

5.28 *Apparatus*—The testing apparatus is set up as shown in Fig. 4.

5.28.1 *Syringes*—1 cm^3, 5 cm^3, and 60 cm^3.

5.28.2 *Water.*

5.29 *Hazards—Not applicable*.

5.30 *Procedure:*

5.30.1 Test at 23 ± 4 °C (73.4 ± 7 °F).

5.30.2 Fill syringe with volume of water equal to balloon rating.

5.30.3 Attach syringe to enteral feeding device inflation valve and inflate with water.

5.30.4 Per Fig. 4, use snap gauge and measure the two sides of the balloon that visually appear to have the least symmetry. Measurement should be taken 180° from each other.

5.30.5 Divide larger measurement by smaller measurement and quotient equals Concentricity Ratio. Tabulate all results.

5.31 *Interpretation of Results*—Balloon concentricity ratio must not exceed those established in Table 2.

5.32 *Precision and Bias*—To be determined within five years.

PROCEDURE E: BALLOON SIZE AND SHAFT SIZE

5.33 *Scope*—This test method is to evaluate the retention balloon shaft size.

5.34 *Summary of Test Method*—Using a French size gauge, the distal balloon tip is measured to determine the size of the retention balloon over the shaft.

5.35 *Significance and Use*—The overall outside diameter of the enteral feeding device during passage should conform to the required clinical orifice size.

TABLE 2 Concentricity Ratios

Rated Balloon Inflation Volume (cm^3)	Maximum Concentricity Ratio
5	2:1
10	2:1
15	2:1
20	2:1
All others > 20 cm^3	2:1

5.36 *Apparatus*—The testing apparatus is as shown in Fig. 5.

5.36.1 *French Size Calibration Gauge,* tolerance of ±0.13 mm (±0.005 in.).

5.36.2 *Metric Scale Rule.*

5.37 *Hazards:*

5.37.1 No lubrication or undue force shall be applied to the enteral feeding device.

5.37.2 The edges of each hole should be smooth to avoid interference to the passage of the test enteral feeding device.

5.38 *Procedure:*

5.38.1 Test at 23 ± 4 °C (73.4 ± 7 °F).

5.38.2 Per Fig. 5, without lubrication, push the proximal end of the uninflated enteral feeding device through the various holes of the French size gauge, advancing it to the uninflated balloon.

5.38.3 Uninflated balloon should fit in appropriate French size gauge hole snugly without undue insertion force. Label each test unit and the measured French size. Remove device from gauge.

5.39 *Interpretation of Results*—The balloon section may wrinkle but shall not tear or distort, and the enteral feeding device shaft or tip may offer resistance but if distortion or stretching occurs it is considered a failure.

5.40 *Precision and Bias*—To be determined within five years.

PROCEDURE F: BALLOON INTEGRITY

5.41 *Scope*—This test method is to evaluate the integrtity of the retention balloon of the enteral feeding device.

5.42 *Summary of Test Method*—The retention balloons are inflated with water and submerged in water at 37.8 ± 3 °C (100 ± 5 °F) for seven days. The retention balloons are evaluated to determine if they hold their integrity and do not rupture.

5.43 *Significance and Use*—This test method is designed to subject the retention balloons to the inflation volume they would be subjected to during use in the field, in order to determine the integrity of the balloon. It is the purpose of the balloon to retain the feeding device in position during use; therefore, the performance of the retention balloon must be maintained and the balloon must not rupture.

5.44 *Apparatus*—The testing apparatus is as shown in Fig. 6.

5.44.1 *Corrosion-Resistant Tanks*—The tanks should contain no exposed iron, copper, or brass elements and have removable mixing elements. The tanks should also have sufficient covers/lids in order to prevent evaporation of solution.

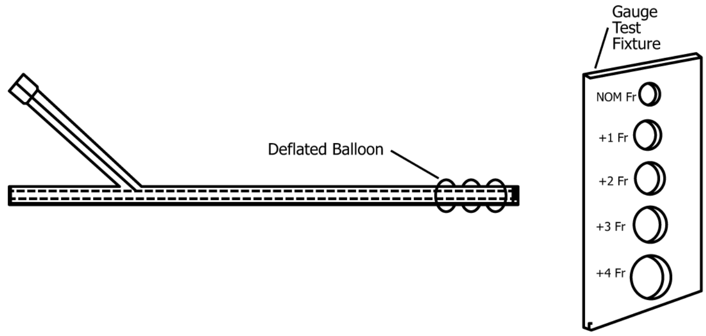

FIG. 5 Balloon Shaft and Size Test Apparatus

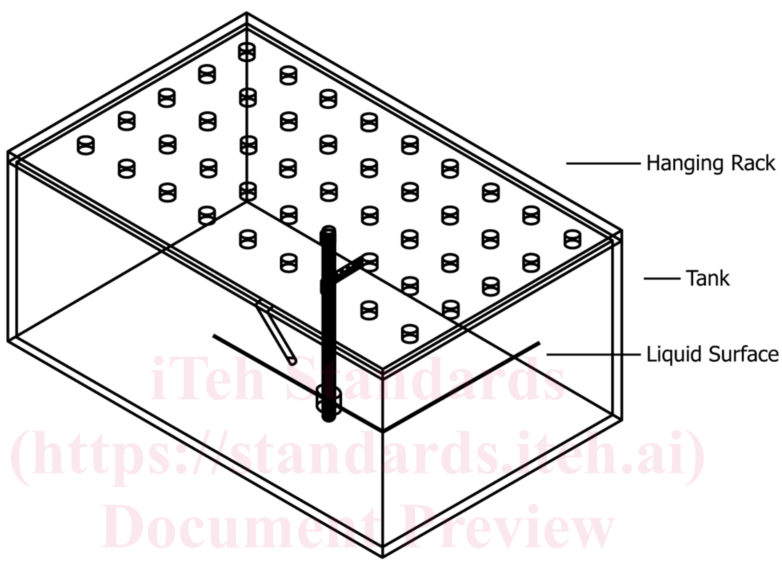

FIG. 6 Water Hang Test Apparatus

5.44.2 *Cover for Corrosion-Resistant Tank*—Permits enteral feeding devices with retention balloon to be placed vertically in the tank and inflated so that retention balloon is fully submerged in gastric fluid test solution. Cover should prevent evaporation.

5.44.3 *Graduated Cylinder,* calibrated for suitable measurement of the effluent.

5.44.4 *Water.*

5.44.5 *Syringe,* suitable for filling retention balloon to required volume.

5.45 *Hazards*—No materials/chemicals destructive to latex and/or silicone may contact balloons during test.

5.46 *Procedure:*

5.46.1 Fill tank with water to level indicated in Fig. 6, so that when hung all sample balloons are submerged under water. Maintain water temperature at 37.8 ± 3 °C (100 ± 5 °F).

5.46.2 Position device in apparatus per Fig. 6. Inflate the test samples with water to the labeled rated inflation volume, per Table 3.

5.46.3 Fill balloons with water to required volume per Table 3.

5.46.4 Fully submerge at least the entire balloon of the device under water.

TABLE 3 Inflation Volumes for Balloon Integrity Test

Rated Inflation Volume (cm^3)	Test Inflation Volume (cm^3)
5	5
10	10
15	15
20	20
All others > 20 cm^3	1× rated volume

5.46.5 After seven days, inspect the retention balloons for rupture.

5.47 *Interpretation of Results:*

5.47.1 Any enteral feeding device whose balloon burst during any period of the time of the test shall have failed the test.

5.47.2 Any enteral feeding device whose balloon does not burst but which does deflate during any period of the time of the test shall have failed the test.

5.47.3 Any enteral feeding device whose balloon does not burst but which does deflate during any period of the test because of some form of leakage shall be an invalid test sample.

5.48 *Precision and Bias*—To be determined within five years.