Frequently Asked Questions

ENFit® Connectors (ISO 80369-3)

1. **What is the orientation of the ENFit® system and why is it important?**

   For ENFit, the ISO 80369-3 female connector is on the administration or giving side of the system and the ISO 80369-3 male connector is on the patient access or receiving side of the system.

   This orientation choice was agreed to after advice from the UK's National Patient Safety Agency during development of the ISO standard, based on the UK experience of using the reverse orientation for enteral devices since NPSA Alert 19 (http://tinyurl.com/ht4hf9o) in 2007 to reduce the risk of delivering oral and enteral medicines via the wrong route. The reverse Luer formation connector has been widely adopted and accepted by the clinical, patient safety and regulatory communities in the UK for almost a decade.

   To ensure compatibility between components of an ISO 80369-3 compliant system, ENFit has a specified orientation. In an ENFit system, all administration sets (pump sets, gravity sets, bolus feeding devices) and ENFit Syringes have an ISO 80369-3 female connector that mates to the ISO 80369-3 male connector on the feeding tube (NG Tube, G-Tube, PEG, J-Tube).

   GEDSA members have aligned to the ENFit orientation so that all components, regardless of supplier, will fit together without the long term use of adapters.

2. **What is the advantage to having only one system in use?**

   This is a worldwide effort where patient portability is a critical issue that should be addressed with one system, in order to maintain continuity of care, reduce patient risks, and ensure ease of use for the caregiver.

3. **Can a syringe that is <u>NOT</u> ENFit be an ISO syringe/an ISO solution?**

   Yes.

   ISO 80369-3 defines the geometry, material characteristics and functional performance of a standard connector pair made of one male half and one female half. The standard does not define the orientation of the connectors within the enteral feeding system.

   The term “ENFit” implicitly means a connector design that complies with ISO 80369-3 while also defining the orientation of the connectors within the enteral feeding system (female on the administration device and male on the receiving device).

4. **If another component can be ISO compliant, why would I want to use only one design (e.g. ENFit) for my hospital and patients?**

   Patients are mobile and have the ability to travel between healthcare settings and implementing a single design is strongly encouraged by GEDSA, supporting organizations including ASPEN, ISMP, EPSG, ASHP and other clinical practice organizations. This is a global standard directed to drive standardization for caregivers, manufacturers, and clinician’s world-wide. GEDSA strongly encourages the standardization of not only the ISO 80369-3 compliant connector but the specific orientation (direction of flow) as outlined in the ENFit System (and as proposed in the ISO 20695

enteral device standard). This ensures compatibility between components, avoids the need for adapters' long term, and drives continuity and portability of care for the patients.

Therefore, it is possible to have an ISO compliant ISO 80369-3 connector, which is not compatible/compliant with ENFit. However, it is strongly encouraged that there be a single global solution.

5. Does ISO 80369-3 allow for manufacturers to choose from multiple designs?

No. ISO 80369-3 defines the geometry, material characteristics, and functional performances of a critical interface between a standard connector pair made of one male half and one female half. The standard does allow for some flexibility in design characteristics, however the intention is that all ISO 80369-3 connector pairs will be compatible with each other.

6. Is the connector orientation specified in ISO 80369-3 or in any other ISO standard?

The orientation is not defined in ISO 80369-3, however it is currently included in the approved committee draft of ISO 20695 enteral device standard.

7. What was the reason for the ENFit® Low Dose Tip Syringe design?

Concerns were raised regarding dose accuracy of low volume medications, when delivered with standard ENFit syringes (ISO 80369-3 female tip). A technical team of industry experts worked collaboratively to select and vet a solution to address small volume dose accuracy. This solution is now known as the ENFit Low Dose Tip (LDT) Syringe and, when used as instructed, performs similarly to other male oriented enteral/oral syringes available today. In addition, the ENFit Low Dose Tip design has better accuracy than existing female oriented syringes. For more information regarding dose accuracy, please review the *GEDSA ENFit Low Dose Tip Syringe Review* presentation, located on our home page at www.StayConnected.org.

8. Was the ENFit Low Dose Tip Syringe assessed for potential misconnections with other devices?

Yes. The Low Dose Tip design has been validated through rigorous misconnections risk analysis and performance testing, as well as usability and human factors testing.

The ENFit design, including the Low Dose Tip design, provides a solution for accurate enteral dosing while maintaining a high level of mitigation to the risk of inadvertent tubing misconnections.

9. Why does ISO 80369-3 not incorporate the Low Dose Tip design?

ISO 80369-3 was published on 07/01/2016 and is part of a larger initiative, the ISO 80369 series of standards. The scope of the parent standard, ISO 80369-1, is to develop a series of small bore connectors that are unable to connect to other systems, preventing misconnections.

ISO 80369-3 is the standard that specifically defines the connector design for enteral applications. The standard is limited to defining the connector geometry. Specifications regarding device performance, specifically related to dose accuracy, are out of scope for ISO 80369-3.

The ENFit Low Dose Tip design was adopted to meet clinicians' expectations regarding low volume dose accuracy. The performance requirements, including dose accuracy, are included in the approved committee DIS ISO 20695 (draft ISO standard) and are anticipated to be a requirement for all manufacturers complying with this standard in the future.

10. What were the results of the ENFit Low Dose Tip Syringe design testing?

Performance testing of ENFit LDT Syringes was completed by an accredited *third party lab* to quantify the accuracy of the syringe within the enteral system (i.e. accuracy of dose when delivered through an enteral catheter).

The ENFit LDT Syringe dose accuracy is substantially equivalent to the dose accuracy of male enteral/oral syringes in use today for low volume doses (e.g. 0.2mL dose delivered from a 1mL syringe with ± 10% accuracy) when used as instructed. The overview of the test data can be reviewed by downloading the *GEDSA ENFit Low Dose Tip Syringe Review* presentation, located at www.StayConnected.org. This summary includes a comparison of ENFit Syringes, ENFit LDT Syringes and currently available syringes used for enteral administration.

Results from the performance testing, usability testing, and misconnection risk analysis were submitted and thoroughly reviewed by the FDA in the form of a Device Masterfile.

11. Why was there an aggregate taken of three enteral/oral tip syringes used today during the ENFit Low Dose Tip Syringe testing?

Since there is currently no ISO design standard for enteral/oral syringes on dose accuracy, GEDSA evaluated 3 of the most commonly used enteral/oral syringes and took an aggregate of the results to determine a baseline for dose accuracy.

The results were aggregated for these three syringe designs to provide a baseline because they can be used interchangeably within the current/legacy enteral system. This provides an overall grasp at the dosing accuracy with this style of syringe when used as instructed, independent of the specific syringe chosen.

12. Is the performance data available for review?

Yes. A summary of the LDT performance data is available by downloading the GEDSA ENFit Low Dose Tip Syringe Review presentation at www.stayconnected.org

13. When do we expect FDA approval for the new low dose tip syringe?

As of June 17th, 2016, the FDA granted 510(k) clearance for the general Low Dose Tip design implemented by two manufacturers. This represents the Low Dose Tip design that has been tested, vetted, and recommended by the GEDSA members.

Other manufacturers are currently in the process of gaining FDA 510(k) clearance for their utilization of the ENFit LDT design for their syringes.

14. How does ENFit low dose accuracy compare to current enteral/oral syringes in use today?

An analysis of the dose accuracy was performed to determine if any statistically significant differences were observed between ENFit Syringes, ENFit LDT Syringes, and currently marketed enteral/oral syringes. The syringes were tested per the manufacturers' instructions for use. Testing indicates that the ENFit LDT Syringe performs equal to or better than existing enteral/oral syringes used in the market today. Refer to the *GEDSA ENFit Low Dose Tip Syringe Review* presentation, located on www.StayConnected.org.

15. Are there any existing standards that define dose accuracy requirements of enteral/oral syringes?

No, there is not a current standard (ISO, AAMI, ASTM, EN) for enteral/oral syringes that specifies dose accuracy. Since there is not a current standard that is specifically applicable to the dose accuracy of enteral/oral syringes intended to *connect* with other medical devices, many manufacturers refer to the performance requirements in ISO 7886-1, *Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for Manual Use* as a proxy.

16. What is the ISO 7886-1 standard?

ISO 7886-1 is a standard for manual hypodermic syringes, which includes requirements and test methods for various syringe parameters including tolerance on graduated capacity. Typically, enteral/oral syringe manufacturers apply the requirements of this standard, such as tolerance on graduated capacity, since there are no relevant standards in place for enteral/oral syringes.

17. Do all ENFit Low Dose Tip (LDT) Syringes comply with the tolerance on graduated capacity requirements of ISO 7886-1?

All tested ENFit Syringes and ENFit Low Dose Tip Syringes meet the requirements for tolerance on graduated capacity per ISO 7886-1.

18. What is the difference between tolerance on graduated capacity, as defined in ISO 7886-1, and dose accuracy?

Term	Technical Definition	Translation
Tolerance on Graduated Capacity	The technical definition of Tolerance on Graduated Capacity (TOGC) is the allowable variability of volume of water expelled from the syringe when the plunger traverses a given scale interval(s). This defines the required precision of the scale or markings on a syringe barrel. The tolerance is specific to the syringe and not the entire system. For a full definition refer to 7886-1 section 3.2.	The ability of the graduation markings to accurately measure the volume of the liquid drawn into and expelled from the syringe. TOGC is measured in an 'unconnected' state *(not attached to another device).*
Dosing Accuracy	The actual dose delivered to the patient by the syringe in relation to the intended dose within a feeding system. Dosing accuracy is concerned with the feeding system, not just the syringe. Dosing accuracy is impacted by multiple variables within the system, including tolerance on graduated capacity. Dose accuracy requirements are not defined in ISO 7886-1.	The ability of the entire system to deliver the desired dose volume when connected.

Today, dose accuracy can vary dramatically because of the multiple different designs of enteral/oral syringes and feeding tube ports that exist without a standard. These designs can be used in many combinations to create a feeding system. With the ISO standard ENFit design, both ends of the connector are now controlled designs, allowing for the dose accuracy to be more consistent across a feeding system regardless of the manufacturer.

19. What is the recommended TOGC that should be targeted for each syringe and dose combination?

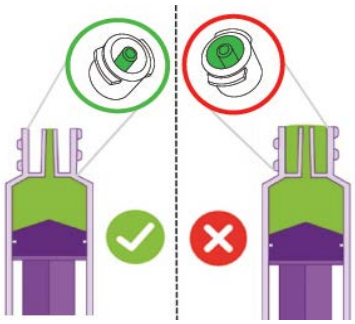
ISO 7886-1 defines the required accuracy levels for TOGC of syringes based upon the combination of the volume being delivered and the size of the syringe used.

There is not a single accuracy level that applies to all syringe sizes and all dose volumes but rather a series of mathematical formulas that establish the tight tolerances defined in ISO 7886-1. Additional observations are noted below.

- +/- 5% is not applicable to all syringe sizes, dose volumes or delivery scenarios.
- Tolerances on graduated capacity is **not** the same as the volume delivered to the patient or dose accuracy as defined above as this excludes the variability that can be introduced when connected to the patient tube set
- The TOGC in ISO 7886-1 takes into account the syringe size and prescribed dose. The TOGC of a 0.1ml dose delivered from a 1ml syringe can vary by ± 17%, while TOGC of a 10ml dose from a 10ml syringe is ± 4%. A table that provides some small volume dose examples of the calculated tolerance on graduated capacity requirements as per ISO 7886-1 can be found on the www.StayConnected .org website titled "Syringe Accuracy (TOGC) Estimates for ISO 7886-1, 1, 5, & 10mL"

20. Are new techniques required to accurately administer medication when using an ENFit Low Dose Tip (LDT) Syringe and how do I ensure the most accurate dose?

No, it is common practice to tap/flick a syringe to remove air bubbles *(or to remove fluid when filled from a dose cup)* for many different types of syringes on the market today. GEDSA recommends the same practice to remove fluid outside the fluid pathway. The area between the male lumen and the outer ring (the "moat") is not part of the fluid path and should be free of fluid.



21. Was the Low Dose Tip syringe evaluated by healthcare professionals?

Yes, a usability study was conducted with 148 respondents worldwide (including the US, Europe, Australia, and New Zealand) representing pharmacy, nursing, and caregivers. They evaluated the Low Dose Tip design using current practices and methods for filling and administering enteral doses. The Low Dose Tip design was found acceptable by users from all three user groups.