

# Dose Accuracy – Performance Testing of Enteral, Oral, ENFit®, and ENFit LDT Syringes

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## Introduction

ISO 80369 is a series of global standards, Part 1 of which was originally published in 2010, which defines the requirements for unique small bore connectors used to access different routes into the patient (e.g. neuraxial epidural, enteral, IV, respiratory). The objective of the ISO 80369 series of standards is to reduce the likelihood of tubing misconnections and wrong route errors. ISO 80369-3, published in 2016, specifically defines the enteral feeding connector. ENFit is the registered trademark term to define the ISO 80369-3 mating connectors in the female to male orientation.

Prior to the launch of ENFit connectors, industry and clinicians/clinical organizations held several open discussion sessions with stakeholders and end users. With the change in the connector orientation of many legacy systems from male-female to the new ENFit system's female-male orientation, users started to raise concerns regarding dose accuracy of the ENFit enteral feeding system (and all reverse formation systems such as the UK reverse Luer) when used for small volumes of medications.

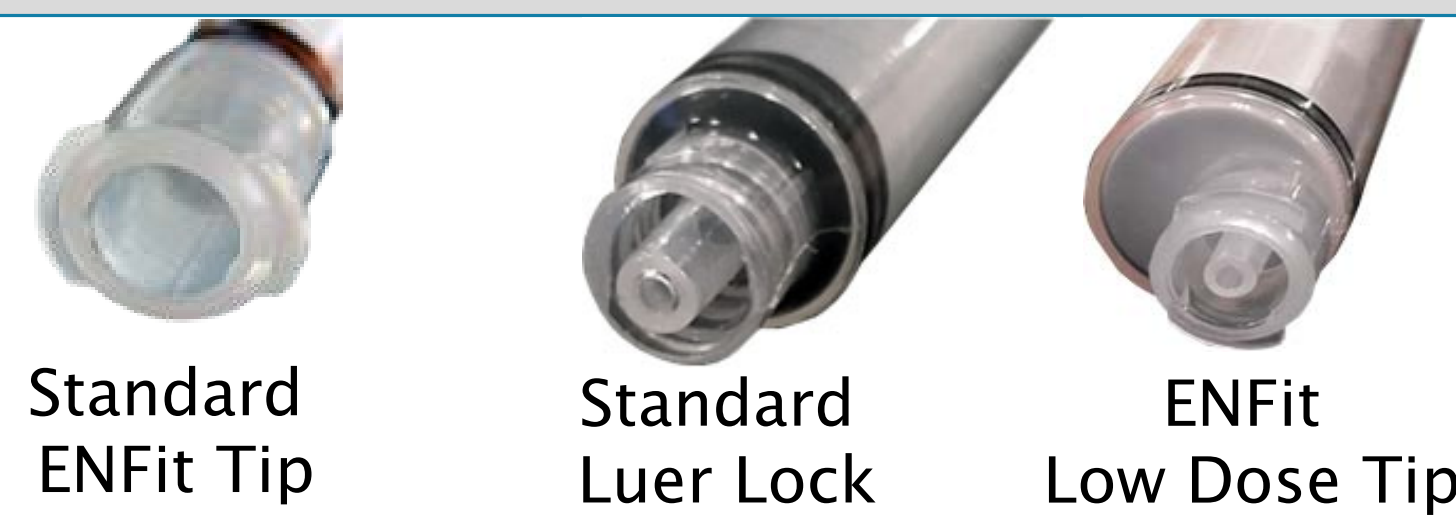
Consultation with various stakeholder groups, including ISMP, ASHP, ASPEN and other clinicians helped to understand what dose accuracy target would be considered acceptable. There was consensus that +/- 10% dose accuracy was acceptable for low volume doses (such as a 0.2ml dose from a 1ml syringe). In order to maximize the dose accuracy available within the geometry of 80369-3, the ENFit Low Dose Tip was developed. The resulting ENFit Low Dose Tip (LDT) design consists of a standard female ENFit connector syringe tip with an internal male lumen that mimics the functionality of a traditional male enteral/oral syringe and has a geometry/configuration that is similar to a Luer lock syringe (see Syringe Tip Designs box for graphic examples).

During the development process, two key issues came to light:

- No international design standard specifically for enteral/oral syringes
- No specification for dose accuracy for enteral/oral administration.

A dose accuracy test method was developed to address the use of these devices. The LDT configuration of the ENFit syringe tip design was tested following this protocol to assess performance against the dose accuracy targets identified by clinicians. Existing enteral/oral products in the global market were evaluated using the same protocol in order to compare the performance of the existing systems alongside the new ENFit, ENFit LDT, and targets identified by clinicians.

## Syringe Tip Designs



Standard ENFit Tip

Standard Luer Lock

ENFit Low Dose Tip

## Research Objectives

Evaluate current enteral/oral syringes available in the global market plus the proposed ENFit Low Dose Tip design to determine dose accuracy performance for a low volume dose.

## Test Method

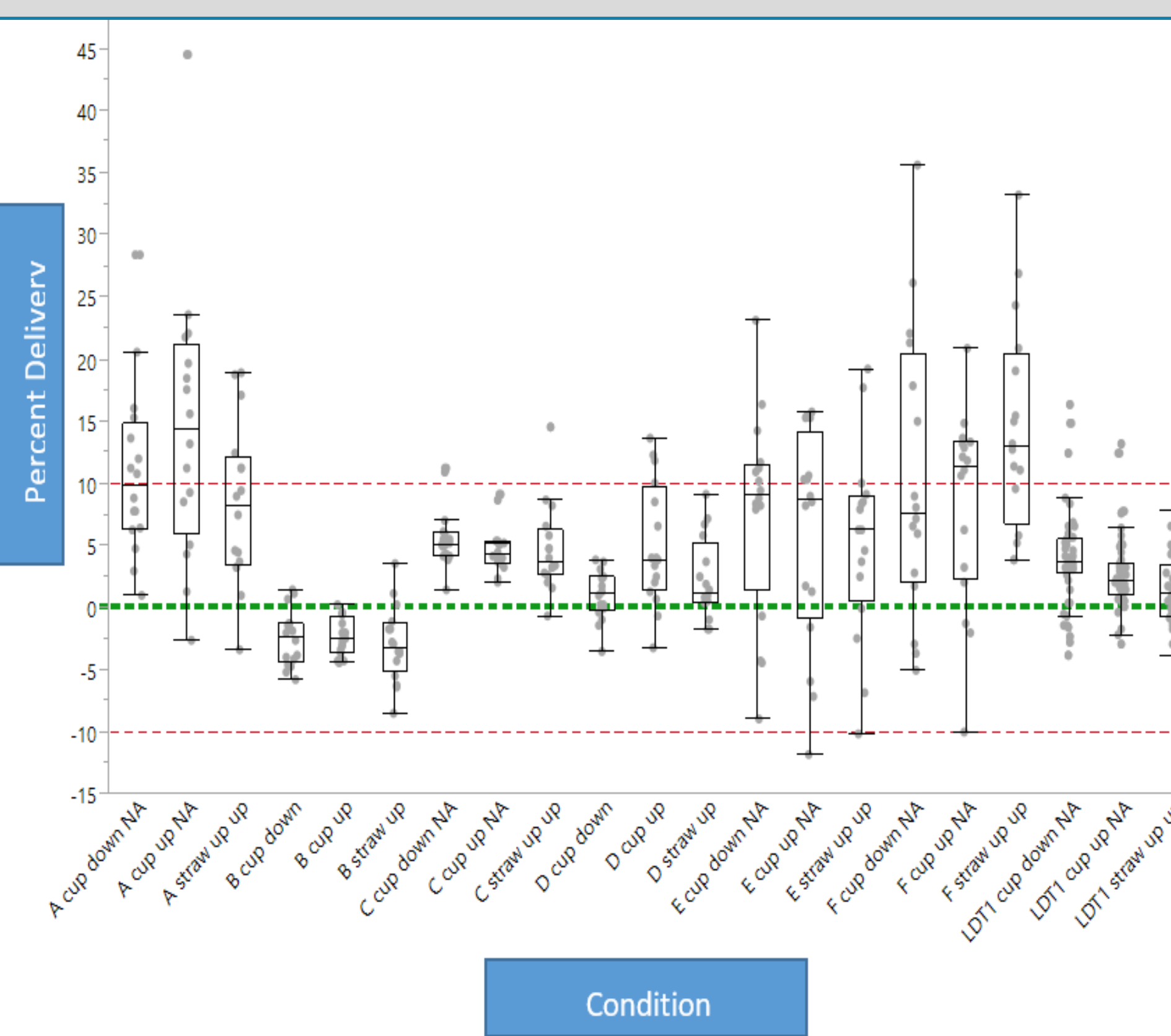
During the performance testing 1mL syringes were evaluated with various fill scenarios that represent the worst case in terms of their impact on system performance. For the LDT, any fluid that was outside of the fluid path (such as the 'moat' area between the male tip and the collar) was removed. In practical terms, this was achieved by tapping or flicking the syringe tip to clear out the moat.

## Syringes, Orientation & Samples Tested

Syringe Design Tested	Fill Type	Syringe Orientation	Feeding Tube Orientation	Samples Tested
Standard ENFit	Syringe A	Cup Down	Up/Down	16 x 2
	Syringe B	Straw Up	Up	16 x 1
Standard E/O (3 mfgs)	Syringe C	Cup Down	Up/Down	16 x 2
	Syringe D	Straw Up	Up	16 x 1
	Syringe E	Cup Down	Up/Down	16 x 2
	Syringe F	Straw Up	Up	16 x 1
Reverse Orientation (2 mfgs)	Syringe E	Cup Down	Up/Down	16 x 2
	Syringe F	Straw Up	Up	16 x 1
ENFit Low Dose Tip	LDT1	Cup Down	Up/Down	49 x 2
	LDT1	Straw Up	Up	36 x 1

## Results

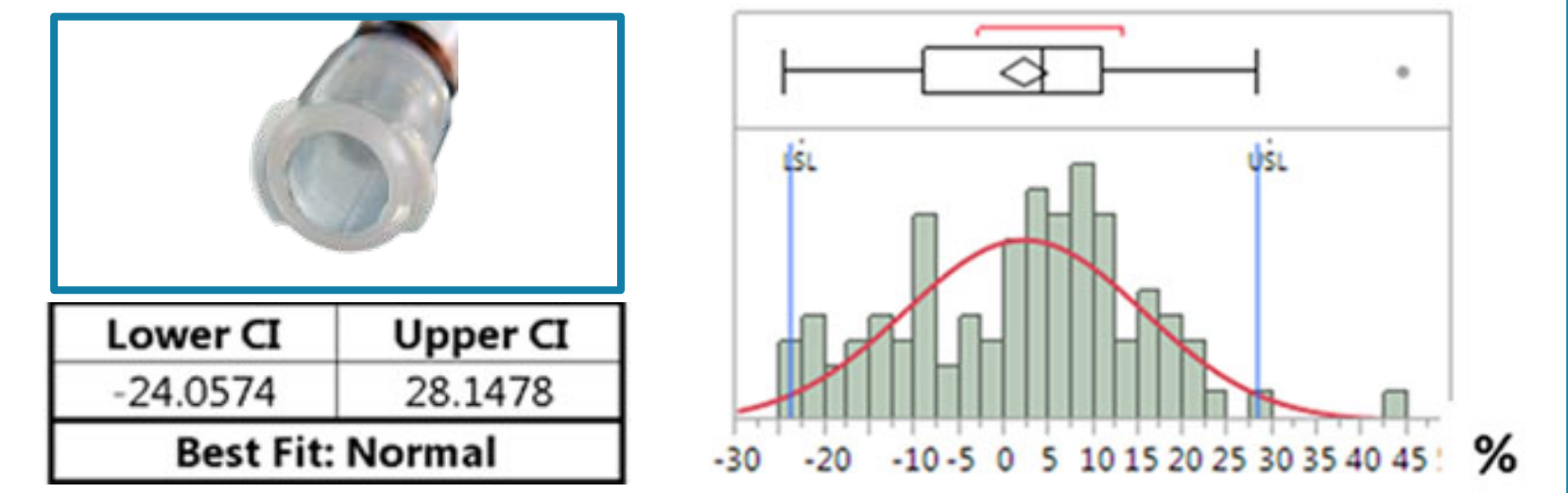
### Percent Delivery vs. Condition



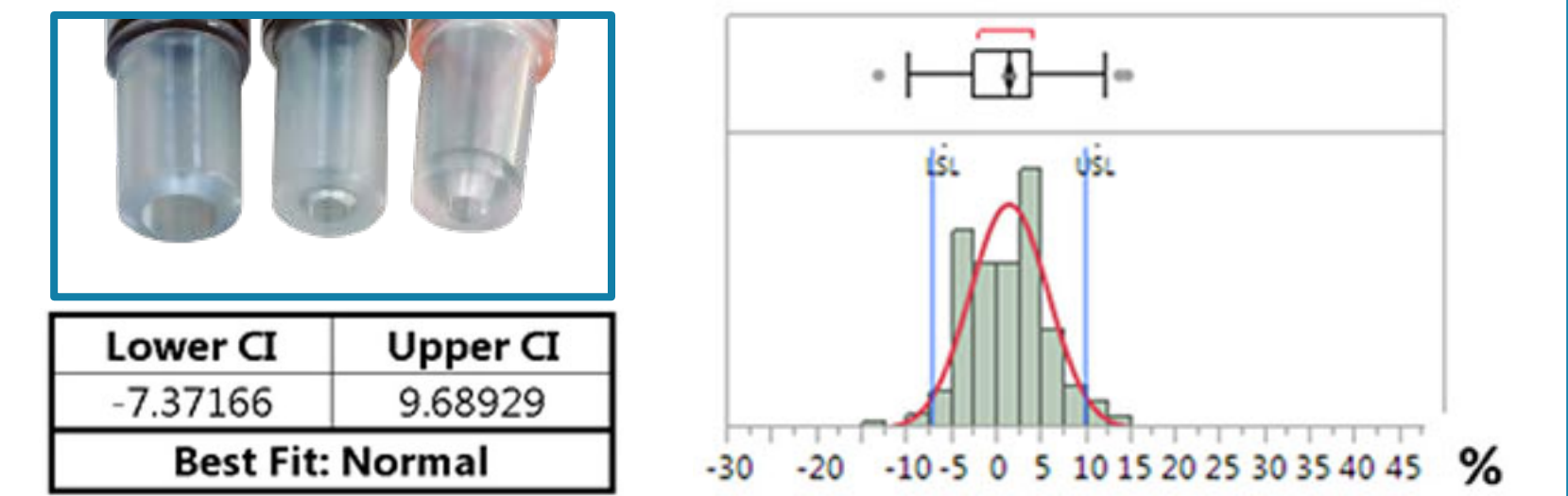
Data was pooled for analysis in the instance where multiple manufacturers' syringes were available for testing. This represents the common interchangeability that occurs in practice for enteral feeding systems that feature non-standardized male orientated syringes. Cup and straw fill methods were also pooled to express the overall results.

## Dose Accuracy Distribution

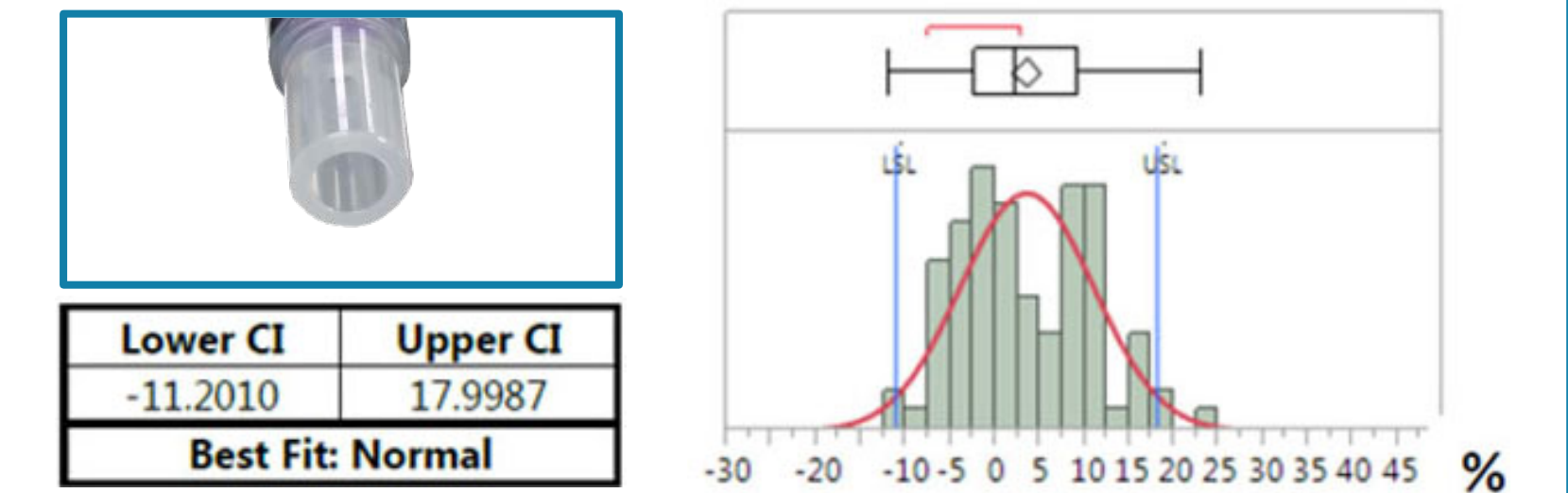
### ENFit Standard Syringes (A)



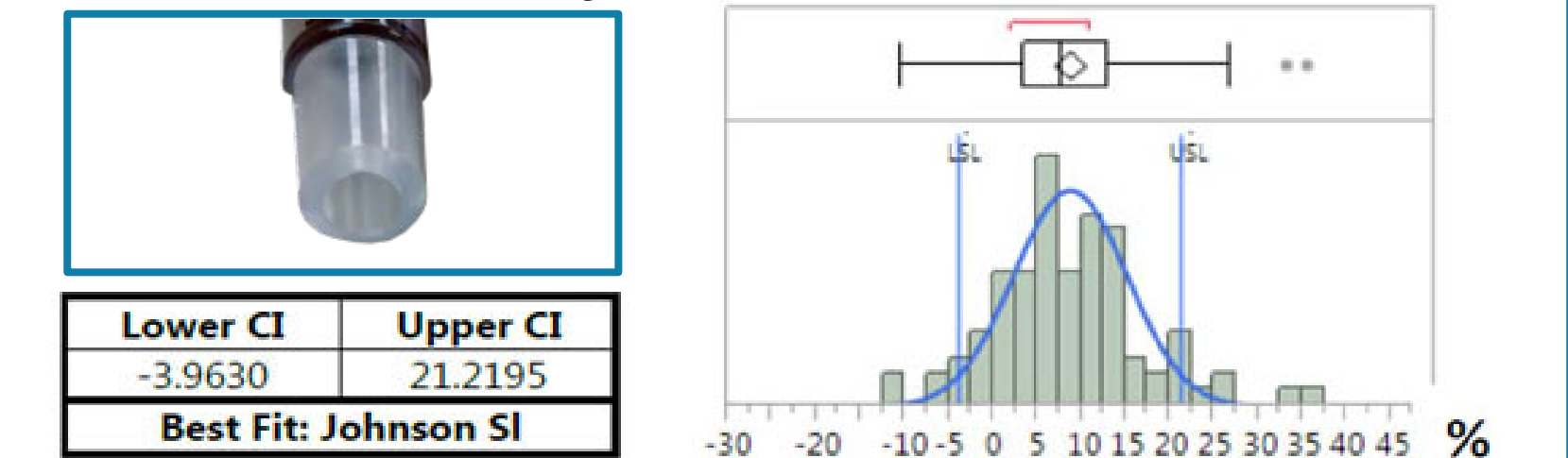
### Enteral/Oral Currently Marketed Syringes (B,C,D)



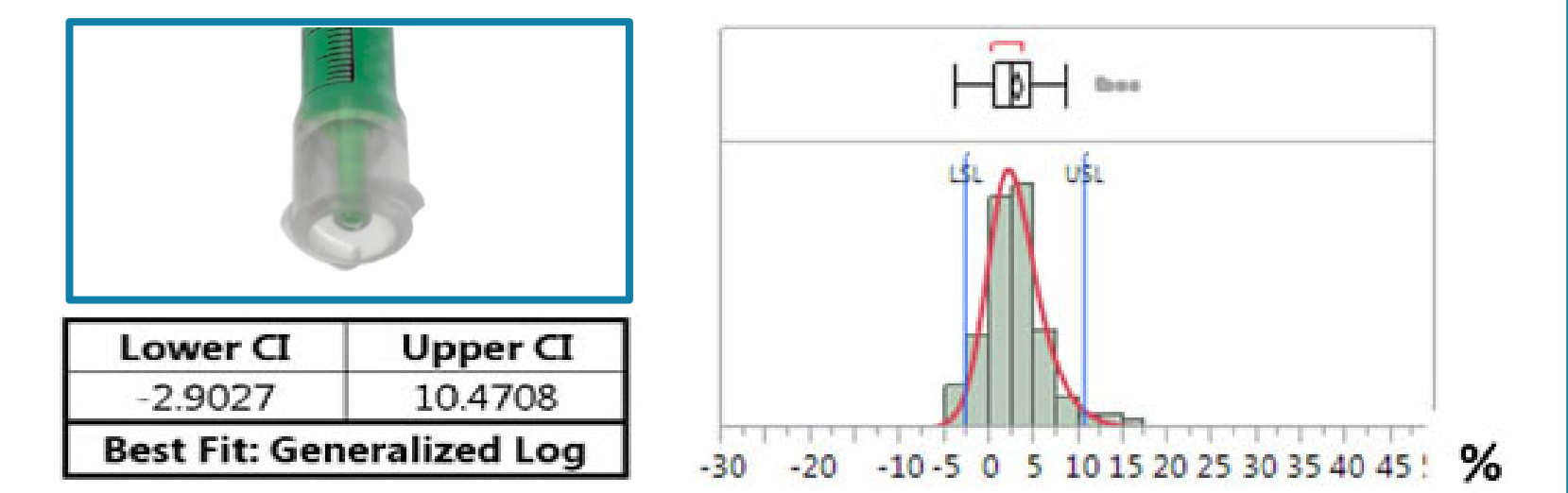
### Reverse Orientation Currently Marketed Syringes (E)



### Reverse Orientation Currently Marketed Syringes (F)



### ENFit Low Dose Tip Syringe (LDT1)



## Expected Upper & Lower Bounds

Syringe Type (1mL)	Lower Bound (Under-Dosing %)	Upper Bound (Over-Dosing %)
Standard ENFit Syringe(A)	-24.06%	28.15%
E/O (Male Tip) Syringes (B,C,D)	-7.37%	9.69%
Reverse Orientation Syringe (E)	-11.20%	18.00%
Reverse Orientation Syringe (F)	-3.96%	21.22%
ENFit Low Dose Tip Syringe (LDT1)	-2.90%	10.47%

## Conclusions

When used as per the instructions for use, the ENFit Low Dose Tip performs substantially equivalent to existing male (oral) tip syringes ( $p < 0.05$ ).

The ENFit Low Dose Tip provides a solution for accurate enteral dosing of low volumes while maintaining compatibility with the ENFit connector system.

## Authors Note

Performance data has been submitted to the FDA for ENFit LDT Syringes and multiple FDA 510(k) clearances have been obtained.