

Mitchell Goldstein M.D.  
Medical Director  
National Coalition for Infant Health  
1275 Pennsylvania Ave. NW, Suite 1100A  
Washington, DC 2000



Susan Hepworth  
Director of Media Affairs  
National Coalition for Infant Health  
1275 Pennsylvania Ave. NW, Suite 1100A  
Washington, DC 2000

To whom it may concern:

The Global Enteral Device Supplier Association (GEDSA) remains at the forefront of the important patient safety initiative to reduce the risk of tubing misconnections. This letter will formally clarify inaccurate information provided in your letter to The Joint Commission on October 5, 2017. The following outlines a clarifying response to each concern and inaccuracy expressed. This letter will be shared with The Joint Commission and others in receipt of your letter.

GEDSA supports the global communication effort to ensure a safe transition to ENFit® with a mission to promote safe and optimal delivery and connectivity of enteral devices. Extensive research, testing, verification and validation has been completed through the formal ISO process prior to the introduction of ENFit connectors. Today, the transition is well underway around the world with adoption rates close to 70-80% in countries such as the Netherlands, Belgium, Italy, France, Australia and New Zealand and over 90% in the United Kingdom and Ireland, with no reported adverse events. For these reasons we remain confident that ENFit is an ideal solution for even the most vulnerable patients including neonates in the NICU.

With regard to the NICU patient population, specific concerns were raised in 2015 regarding dose accuracy of low volume medications. It is important to note that there are currently no published standards applicable to dose accuracy for any syringe application in use today. Industry experts worked collaboratively to identify and vet a solution to address small volume dose accuracy. This design is commonly known today as the ENFit Low Dose Tip (LDT) syringe. Performance testing conducted by an accredited third-party lab and usability studies conducted around the world confirm that the ENFit LDT syringe, when used as instructed:

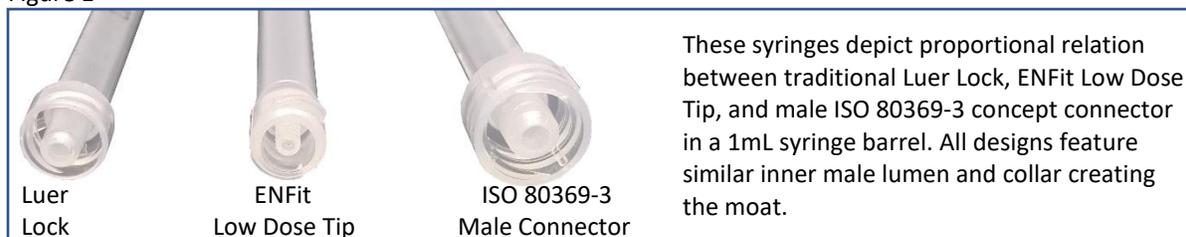
- Delivers an accurate dose substantially equivalent to current male enteral/oral syringes ubiquitously used prior to ENFit.
- Outperforms existing female orientated enteral syringes on the market today including the reverse Luer system (used for 10+ years in the UK) and a proprietary enteral connector.
- Fits into current practice and maintains compatibility with other ENFit devices.

Devices with this LDT connector design, along with robust performance and usability/human factors testing were submitted by several manufacturers to the FDA. After thorough review, several manufacturers have subsequently received 510(K) pre-market clearance.

In your letter, you make an unqualified statement “If the moat is not cleared, a premature infant may inadvertently receive up to 30% more medication per dose” lacks any precision or qualifiers such as target dose volume and syringe size. Third party testing revealed that the ENFit LDT Syringe, when used as instructed, delivers a highly accurate dose (i.e.  $\pm 10\%$  accuracy for a 0.2mL dose delivered with a 1mL syringe) even in the worst possible qualifying scenarios. Furthermore, it should be noted that:

- Clinical experts have deemed this level of accuracy acceptable and aligned with common clinical practice.
- Common fill scenarios, ie. medication bottle adapters or fill straws help ensure that no fluid occupies the moat of ENFit® LDT Syringes. This is very similar to fill scenarios for legacy enteral/oral syringes in which no fluid remains around the tip of the syringe.
- Luer lock syringes, used in healthcare settings throughout the world for nearly a century, feature a moat and inner lumen that is very similar in design (but of course dimensionally incompatible) to the ENFit LDT syringes.

Figure 1



Furthermore, there are no new techniques needed when using the ENFit or ENFit LDT syringe. Today it is very common practice to tap/flick a syringe to remove air bubbles for many different types of syringes, GEDSA and the manufacturers’ instructions for use recommend the same practice to remove any fluid outside the fluid pathway. Usability studies conducted with clinicians and caregivers worldwide found usage of the ENFit LDT Syringe consistent with common practice and acceptable by all user groups.

Clinicians have expressed concerns regarding tube cleaning as mentioned in the Clinical Investigation Articles available on your site “Used NG-tubes from infants in a neonatal department often yielded high densities of bacteria within the first day of use.”<sup>1</sup> Children’s Mercy Hospital (CMH) in collaboration with GEDSA and ASPEN developed cleaning procedures for various types of feeding tubes with ENFit connectors. Cleaning procedures and testing protocols were submitted to the CMH Institutional Biosafety Committee (IBC) in compliance with the NIH Guidelines. This testing will be completed late 2017. GEDSA will publish the cleaning procedure as well as the test results to reduce these concerns and improve clinical practice for all enteral patients around the world.

As ISO Joint Working Group 4 worked through identifications of new ISO standard connectors for enteral feeding, clinicians voiced the need for one universal connector to be introduced due to patient portability. Your encouragement “to look at other alternative manufacturer designs for the ISO 80369-3 standard” is extremely misguided, as that would result in the proliferation of multiple incompatible systems across patient settings, requiring the perpetual use of adapters and defeating the purpose of the standard itself. Since the ISO 80369-3 standard dimensions are tightly defined, the only proposed alternative would be the male to female orientation and that configuration has shown to pose a greater

<sup>1</sup> Sandra Meinich et al “Nasogastric feeding tubes from neonatal department yield high concentrations..” Sept 2016 Available: <https://www.ncbi.nlm.nih.gov/pubmed/27064248>

risk to misconnections. The reverse design (syringe with similar male inner lumen and moat – reference Figure 1, ISO 80369-3 Male Connector) would not resolve your concerns but rather create more concern, confusion, and distress for the broader healthcare community. In fact, that design would substantially increase the size of the moat that you have expressed concern with.

Before you promote another solution, we encourage you to fully evaluate actual production quality samples of non-ENFit proposed syringes **and** feeding tubes that meet the ISO 80369-3 standard in addition to dose accuracy, usability and human factors testing to determine if the connector alternative does in fact meet suggested safety requirements and satisfy your concerns. Since “Protecting Access for Premature Infants through Age Two” is your tagline, we strongly suggest you consider the massive complications of maintaining multiple enteral systems prior to proposing such a system to The Joint Commission or any other regulator. Although there is much speculation and perhaps even fearmongering around the ENFit system, GEDSA has yet to see any live samples or substantiated evidence to support those concerns to show that a male to female ISO 80369-3 connector configuration is as safe and effective as ENFit’s female to male configuration.

Our recommendation is for NCfIH to immediately retract and cease further dissemination of its letter until we have had the opportunity to provide a complete picture of all the benefits and background of ENFit. Before expressing such unfounded concerns, you should understand the comprehensive rigor that the ENFit® system has been through. You should also recognize that over the last two years since introduction, ENFit connectors have led to zero misconnections or reported adverse events from any hospitals adopting ENFit in the US, Europe, Australia or anywhere else that has converted. Currently we are aware of over 140 children’s hospitals in the US that have adopted ENFit without incident. To further clarify our position, GEDSA requests a formal conference call inviting attendees of the Infant Summit hosted on October 26<sup>th</sup>. We believe a conference call will allow GEDSA to provide a fair and balanced view of ENFit and testing that has gone into the system.

Deployment of the ENFit feeding system introduces an immediate patient safety benefit. Any delay in the introduction of ENFit continues to put patients including neonates worldwide at risk. It is GEDSA’s mission to promote safe and optimal delivery of enteral feeding and we would like to invite NCfIH to our monthly advisory meetings to provide input on this important patient safety initiative. We would greatly appreciate an open dialog and are happy to work together with NCfIH.

Respectfully,

A handwritten signature in black ink, appearing to read "Thomas J. Hancock". The signature is fluid and cursive, with a large initial "T" and "H".

Thomas J. Hancock  
Executive Director  
GEDSA