

Potential over-delivery: ENFit™ / Low Dose Tip / Nutrisafe2

1/ CONTEXT^{1 2}

As stated in ISO 80369-3, preterm infants and sick newborns are probably the most important paediatric cohort of patients for whom enteral tube feeding is used in combination with the use of intravenous, airway devices and ventilators on a daily basis. Therefore, connections in this patient group must be taken into account carefully.

However, neonates receive very small volumes of medicine (less than 0,1 ml) making dosing accuracy of paramount importance. There is no room for error.

But, with ENFit™, concerns have been raised about the possible risks of delivering inaccurate doses of medicines in certain clinical practices across high risk subpopulations (e.g. neonatal patients) if using a reversed connection system (female to male). This orientation can introduce inadvertent displacement of fluid originally contained within the female syringe connector.

2/ OBJECTIVE

The objective of this report are to determinate the volume contained in the syringe's connector (female) that could be displaced unintentionally to the feeding tube (male) during the connection, which means a potential over delivery.

Three connectors are investigated:

- ENFit™ (compliant with ISO 80369-3:2016)
- Low Dose Tip connector (compliant with ISO 20695:2020)
- Nutrisafe2 (patent: EP 1689343)

3/ PROTOCOL

3.1 Background

As laboratory tests can unintentionally lead to biases related to the human manipulation, Vygon decided to carry out an evaluation of the displaced volume by computer.

Hypothesis

The volume of fluid contained in the syringe's connector is initially considered as dead space. But, because this syringe's connector is female, when the connection with a feeding tube is done, the male connector of the feeding tube will enter into the female syringe's connector and will push away the fluid. It is the so-called "displaced volume of fluid".

¹ ISO 80369-3: 2016, Annex E, §E.5 Generic user needs

² ISO 80369-3:2016, Annex A, Subpopulations within the enteral clinical application

What did we learn from the previous Computational Fluid Dynamics simulation?³

An independent specialist company, called ANDHEO, simulated by computer the fluid displacements thanks to a high-tech software using the "Lattice-Boltzmann" method. This 3D dynamic simulation took into account:

- the properties of liquid (water): dynamic viscosity, density, surface tension, contact angle.
- the gravity
- the rotational speed of the male feeding tube's connector

The results showed:

- The effects of surface tension take precedence over the other parameters.
- The presence of a meniscus (=curved upper surface of liquid in the female syringe's connector) increases the value of the displaced volume.
- **The fluid is displaced entirely into the male connector (feeding tube). There is no fluid lost outside the connector. So, the displaced volume is confirmed as an over-delivery.**
- **The values of the total displaced volumes in the absence of meniscus are exactly equal to those obtained by the Computer-Aided Design (CAD) software called SOLIDWORKS®.**

3.2 Method

The evaluation is done with the Computer-Aided Design (CAD) software called SOLIDWORKS®.

3D models are performed thanks to this software in the requested configurations (see §2.3). Then, adequate functions of SOLIDWORKS® are applied to calculate the following volumes:

- Initial dead space (= maximum volume of fluid contained in the syringe's connector)
- Displaced volume (= maximum volume of fluid displaced into the feeding tube connector)

The 3D modeling of the connectors uses the following dimensions:

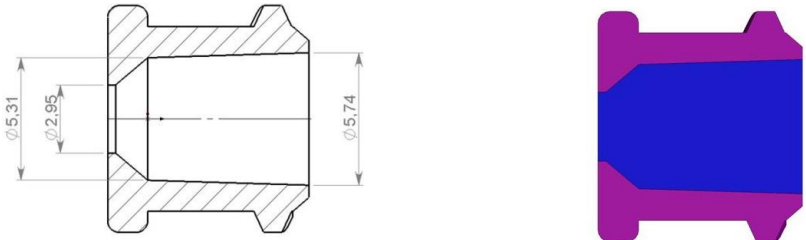

- ISO 80369-3:2016 for ENFit™ connectors
- ISO 20695:2020 for the "Low Dose Tip" female connector
- Internal data for the Nutrisafe2 connectors (patent: EP 1689343)

³ Computational Fluid Dynamics analysis: study on the over-dosing risk of the LDT syringe during its use – ANDHEO – March 2018

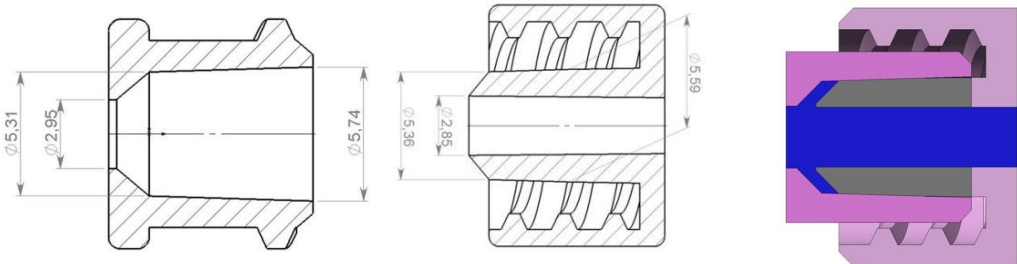
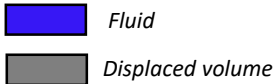
4/ COMPUTER-AIDED CALCULATIONS - SOLIDWORKS®

ENFit™ (compliant with ISO 80369-3:2016)

		Male		Female	
		Inner Diameter	Outer Diameter	Inner Diameter	Outer Diameter
Model 1	Maximum dead space	-	-	Max	-
Model 2	Maximum displaced volume	Min	Min	Max	-

Model 1		ENFit™ maximum calculated dead space (blue part)
		0.191 ml
ENFit™ Female Connector (syringe) 		

The dead space of the ENFit™ syringe is 0.191 ml.

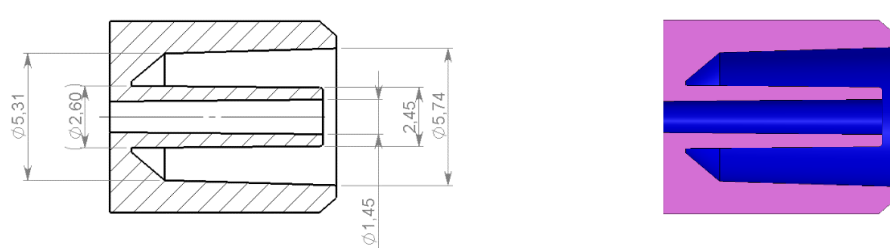
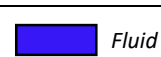
Model 2		ENFit™ maximum calculated displaced volume (grey part)
		0.120 ml
ENFit™ Female Connector (syringe) ENFit™ Male Connector (feeding tube) 		

The displaced volume leads to an over-delivery of 0.120 ml with the ENFit™ connectors.

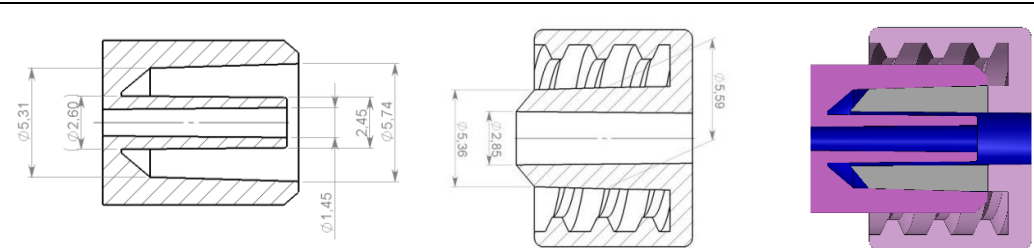
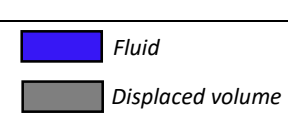
Note: Laboratory testing showed a mean displaced volume of 0.148 ml with the ENFit™ connectors, as stated in ISO 80369-3: 2016 – Annex A – Subpopulation within the enteral application.

Low Dose Tip (LDT) connector (compliant with ISO 20695:2020)

		ENFit™ Male		LDT Female	
		Inner Diameter	Outer Diameter	Inner Diameter	Outer Diameter
Model 3	Maximum dead space	-	-	Max	-
Model 4	Maximum displaced volume	Min	Min	Max	-

Model 3		LDT maximum calculated dead space (blue part)
		0.162 ml
<p>LDT Connector (syringe)</p> 		

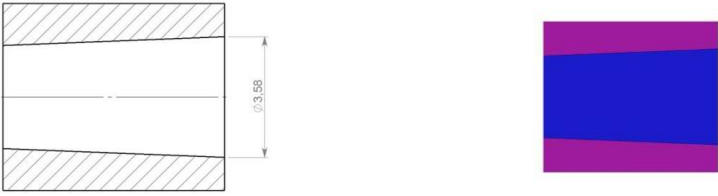

The dead space of the Low Dose Tip syringe is 0.162 ml.

Model 4			LDT maximum calculated displaced volume (grey part)
			0.120 ml
<p>LDT Connector (syringe) ENFit™ Male Connector (feeding tube)</p> 			

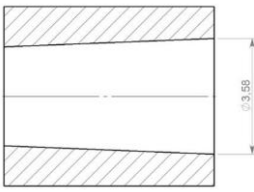
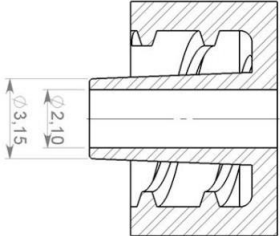
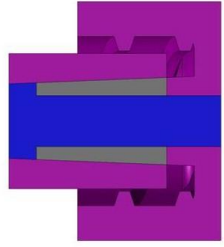
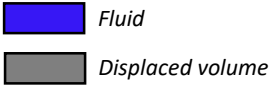
The displaced volume leads to an over-delivery of 0.120 ml with the LDT syringe.

Nutrisafe2 (patent: EP 1689343)

		Male		Female	
		Inner Diameter	Outer Diameter	Inner Diameter	Outer Diameter
Model 5	Maximum dead space	-	-	Max	-
Model 6	Maximum displaced volume	Min	Min	Max	-

Model 5	Nutrisafe2 maximum calculated dead space (blue part)
	0.056 ml
Nutrisafe2 Female Connector (syringe)  Fluid	

The dead space of the Nutrisafe2 syringe is 0.056 ml.

Model 6			Nutrisafe2 maximum calculated displaced volume (grey part)
			0.029 ml
Nutrisafe2 Female Connector (syringe)	Nutrisafe2 Male Connector (feeding tube) 		

The displaced volume leads to an over-delivery of 0.029 ml with the Nutrisafe2 connectors.

5/ RESULTS

	ENFit™	Low Dose Tip syringe	Nutrisafe2®
<i>Maximum dead space (ml)</i>	0.191	0.162	0.056
<i>Maximum displaced volume (ml)</i>	0.120	0.120	0.029

6/ CONCLUSION

- During the connection, the fluid contained in the female syringe connector (dead space) is partially displaced into the feeding tube. This leads to an over-delivery.
- There is no fluid lost outside the connectors. The entire displaced volume goes into the feeding tube.
- The potential maximum over-deliveries of the ENFit™ classic syringe and the Low Dose tip syringe are equivalent: 0.120 ml.
- Without changing the practices, Nutrisafe2 reduces the potential over-delivery by dividing it by 4 (from 0.120 ml to 0.029 ml).

Hospitals must be aware of this potential over-deliveries before adopting a safety enteral feeding system and particularly for NICUs, where the medication can be prescribed in a very small volume (e.g. 0.1ml).