



NEONATOLOGY

ENTERAL NUTRITION

nutrisafe2

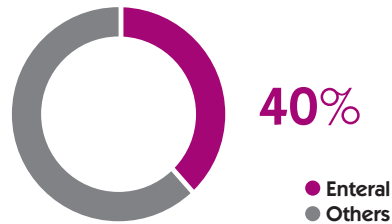
The safe enteral feeding system adapted to neonates



HISTORY OF nutri**safe**2

nutri**safe**2

MISCONNECTIONS



Misconnections in enteral nutrition have been a **recognized issue** at an international level for several years. **40%** of these misconnections are attributed to **enteral** clinical area, and the consequences are often **critical** and deadly ⁽¹⁾.

Vygon creates nutri**safe**1, a reverse Luer system

1995

2005

Vygon creates nutri**safe**2, a safe system fully incompatible with Luer systems

Creation of the **ISO 80369** for safety connections including **ENFit®**, with concerns regarding the adequation with neonatal patients⁽²⁾

2016

Today

Vygon keeps on track with nutri**safe**2, ISO 80369-1 compliant and designed for premature and newborn babies

IN NEONATOLOGY, THINK...



MORE THAN 20 YEARS OF EXPERIENCE IN NEONATOLOGY!

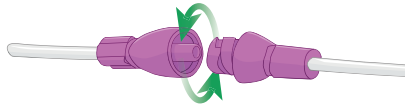
- No reported misconnection with nutri**safe**2
- Satisfied customers from more than 40 countries



SAFE

Specially designed for neonatal patients, nutri**safe2** is a unique safe enteral feeding system incompatible with Luer and other small-bore connectors in accordance with **ISO 80369-1** requirements. The risk of misconnection is minimized, and the patient safety is increased.

The lockable system provides additional security. Accidental disconnection is practically impossible, ensuring precious nutrients are received.



CLEAN

Feeding tubes must not create extra risk to neonates by introducing **bacteria** into their digestive tract.

The design of **ENFit®** comes with the need of setting up a cleaning procedure, and that even followed thoroughly, only **31%** of connectors were **off residues**⁽³⁾.

Even when using specific adapted tools, the **cleaning is not sufficient** and the bacterial count doesn't differ from other cleaning methods⁽⁶⁾.

nutri**safe2** is, by design, less prompt to keep residues. Indeed, nutri**safe2** connectors have a **less threaded interior** to sequester milk or medication and is **much smaller**.⁽⁵⁾



ENFit® nutri**safe2**



ACCURATE

Dose accuracy is of great importance in the **NICU** wards, especially for **critical drugs administration**. Fluid displacement creates an **overdosing risk** when using the syringe.

nutri**safe2**

Low dose tip

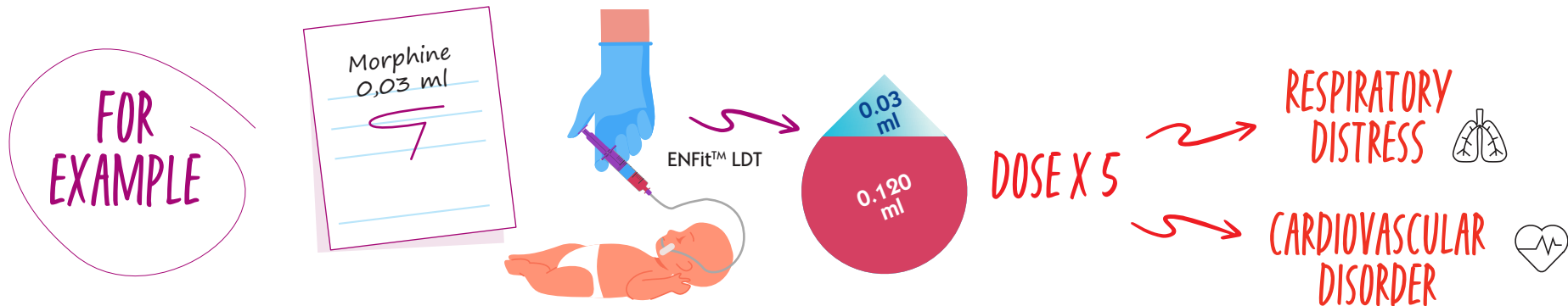
ENFit®

OVERDOSING RISK
DUE TO DESIGN⁽²⁾⁽⁴⁾

0.029 ml

0.120 ml

0.148 ml⁽²⁾



Using **ENFit® LDT** in neonatology is **more likely** to result in administering higher than prescribed **doses** to the neonates.

SCIENTIFIC EVIDENCE ON ACCURACY

Accuracy of ENFit® LDT syringes and nutri^{safe}2 syringes was compared⁽⁷⁾ using **Dosing Variance** calculation.

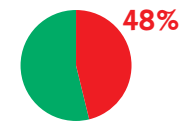


WHAT IS DOSING VARIANCE (DV)?

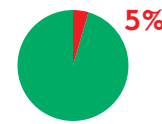
$$DV = \frac{\text{Actual Volume} - \text{Intended Volume}}{\text{Intended Volume}} \times 100$$

Dosing variance is acceptable within a range of +/- 10%

- 150 tests conducted for each type of syringe. Of those tests:



ENFit® LDT



nutri^{safe}2

- Acceptable DV
- Unacceptable DV

- Mean absolute dosing variance



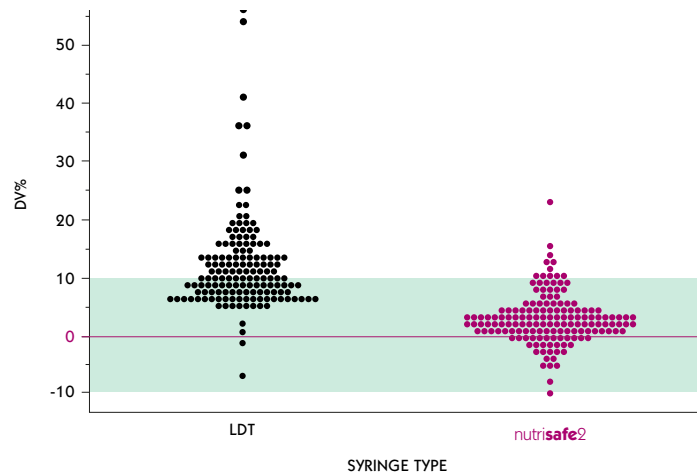
ENFit® LDT



nutri^{safe}2

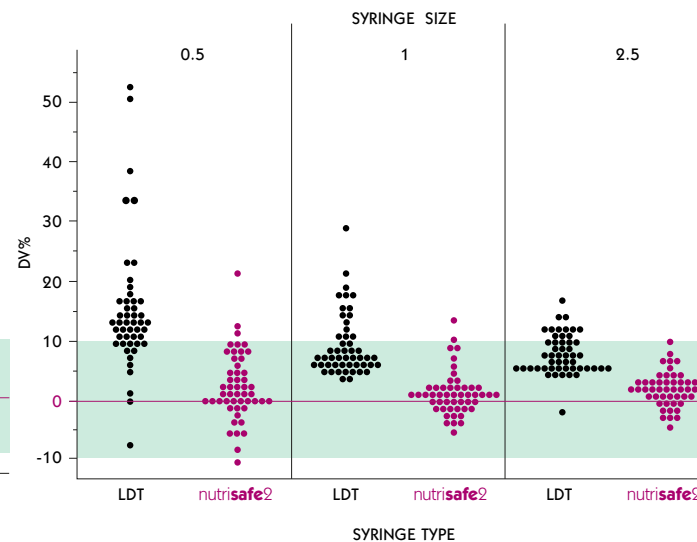
THE nutri^{safe}2 SYRINGE HAS GREATER
DOSING ACCURACY AS COMPARED
WITH ENFIT® LDT SYRINGE

IN MORE DETAILS...



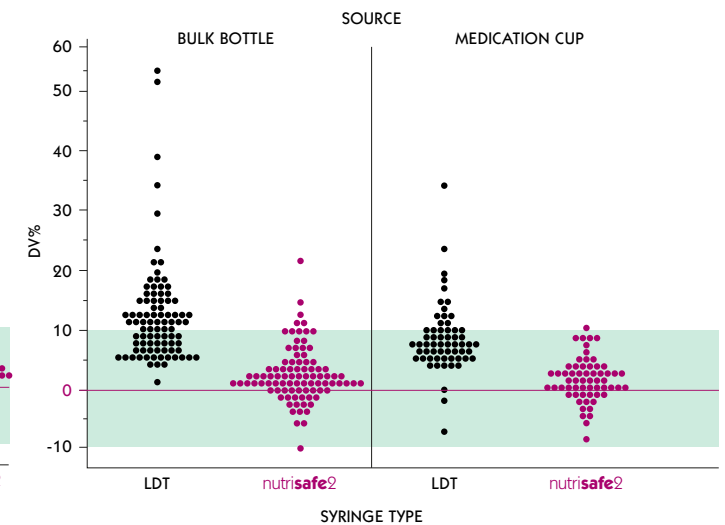
- Comparison between syringe type

nutri^{safe}2 is more accurate than the ENFit® LDT: 95% of the doses have an acceptable dosing variance.



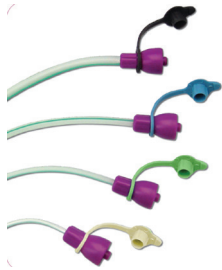
- Comparison between syringe types and sizes

Dosing variance increases while the syringe volume decreases. However nutri^{safe}2 still has a mean variance within the acceptability range for all volumes.



- Influence of adapter and medication cup

Bulk bottle adapters don't fix the inaccuracy issue with the ENFit® Low Dose Tip. Medication cup were associated with acceptable DV, nutri^{safe}2 is more accurate with these accessories.



FEEDING
TUBES



SYRINGES



EXTENSION
LINES



SAMPLING



ACCESSORIES



SYRINGE
PUMP

REFERENCES

- (1) O'Mara K, Campbell C. Dosing inaccuracy with enteral use of ENFit® low-dose tip syringes: The risk beyond oral adapters. J Clin Pharm Ther. 2020 Apr;45(2):335-339. doi: 10.1111/jcpt.13079. Epub 2019 Nov 22. PMID: 31755574.
- (2) International Standard Organization, (2016), Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications Annex A, ISO 80369-3:2016, ISO.
- (3) Lyman, B., Rahe, K. L., Keeler, D., Sherman, A. K., & Abdelhadi, R. A. (2020). Randomized Controlled Trial Assessing the Effectiveness of Two Cleaning Regimens for ENFit® Connectors. Medsurg Nursing, 29(6), 401-406
- (4) Study on the over-dosing risk of the « ENFit Low Dose Tip » syringe during its use, March 2018, Vygon & Andheo
- (5) Risks for Neonates Due to ENFit™ von Dr. Keliana O'Mara.; 2022. Accessed August 4, 2022. <https://www.youtube.com/watch?v=oq119-NwIhg&t=2160s>
- (6) Koya H, Ishino K, Kishimoto M, Kurata N: Comparison of Methods for Cleaning Enteral Feeding Tube Junctions of the New International Standard (ISO 80369-3). Ann Nutr Metab 2022;78:207-212. doi: 10.1159/000525367
- (7) O'Mara K, Campbell C, O'Mara R. Comparison of Dosing Accuracy Between the ENFit LDT and a Neonatal-Specific ISO-Compliant Enteral Syringe. J Pediatr Pharmacol Ther. 2023;28(3):255-261. doi: 10.5863/1551-6776-28.3.255. Epub 2023 Jun 2. PMID: 37303768; PMCID: PMC10249973.

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FOR FURTHER INFORMATION, PLEASE CONTACT: questions@vygon.com

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