

Information on ISO 20695 and the « Low Dose Tip » syringe

The ISO 20695 international standard is in the process of being created. It specifies the requirements for enteral feeding systems comprising enteral giving sets, enteral syringes, enteral feeding catheters and enteral accessories.

In September 2017, the first Draft of International Standard (DIS.1) was disapproved at the international level. **One of the main reasons was that the so-called "Low Dose Tip" (LDT) syringe had been integrated into ISO 20695 although its ability to reliably increase dose accuracy has not been demonstrated.**

As a result, the ISO 20695 draft was revised during 2018. The changes were as follows:

- The LDT syringe has been removed from the normative (mandatory) requirements of the standard. The design of the LDT syringe has been included for information only to allow manufacturers, who wish to manufacture it, to have the right dimensions.
- The term "Low Dose Tip" has been deleted as this syringe has not proven its ability to increase dose accuracy compared to ENFit. The LDT syringe is now called the "alternative enteral syringe tip".

In March 2019, the second Draft of International Standard (DIS.2) with the above-mentioned amendments was approved at the international level. Below are the main important extracts:

"Annex A – Rationale and guidance

[...] CEN/TC 205/WG 16 has decided to propose it [LDT] for information only as test results lead to contradictory conclusions on dose accuracy with this alternative enteral syringe tip."

"Annex K (INFORMATIVE ANNEX) - K.2 Dose accuracy performance

CEN/TC 205/WG 16 has not reached consensus regarding the ability of the alternative enteral syringe tip [...] to reliably increase dose accuracy.

In addition, the design of this alternative enteral syringe tip may not by itself ensure that the dose accuracy for enteral syringes is met; specific user information and education should accompany this alternative enteral syringe based upon the manufacturer's risk management file"



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