

ISO 20695 and the « Low Dose Tip » syringe

The ISO 20695 standard has been published in March 2020. It specifies the requirements for enteral feeding systems, comprising enteral giving sets, enteral syringes, enteral feeding catheters and enteral accessories.

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

As a result, ISO 20695 was revised as follows:

- The LDT syringe has been removed from the normative (mandatory) requirements.
- The design of the LDT syringe has been included for information only to allow manufacturers, who wish to produce it, to have the right dimensions.
- The term "Low Dose Tip" has been deleted from ISO 20695 as this syringe has not proven its ability to increase dose accuracy compared to the classic ENFit syringe. The LDT syringe is therefore called "alternative enteral syringe tip" in ISO 20695.

In the final version published in March 2020, ISO 20695 includes the following important information:

“Annex A – Rationale and guidance – Alternative enteral syringe tip

CEN/TC 205 has decided to propose Annex K for information only as test results [...] lead to contradictory conclusions on dose accuracy with this alternative enteral syringe tip.”

“Annex K (INFORMATIVE) - K.2 Dose accuracy performance

CEN/TC 205 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 might not ensure that the dose accuracy for enteral syringes is met; specific user information and education should accompany this alternative enteral syringe [...].”



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