INTERNATIONAL STANDARD

ISO 20695

First edition
2020-03

Enteral feeding systems — Design and testing

Cathéters de nutrition entérale — Conception et essais

Reference number
ISO 20695:2020(E)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in collaboration with ISO Technical Committee TC 84, *Devices for administration of medicinal products and catheters*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Enteral feeding systems are intended to facilitate the delivery of enteral nutrition, medications and hydration to, or aspiration of gastric content from, humans. They are designed to pass enteral fluids or substances through the nose or mouth, or by gastrostomy, jejunostomy or oesophagostomy. Enteral feeding catheters are terminally placed in the stomach, duodenum, or jejunum.

The requirements and test methods of this document are specified so that, when used in current clinical practice, these medical devices do not compromise the clinical condition or the safety of patients.

Incidents have been reported of enteral fluids or substances being administered via incorrect routes, including intravenously and into the airway. An international effort has been made to reduce these incidents and two series of International Standards have been developed to provide application specific connectors:

— ISO 80369-3 specifies connectors intended for use between an enteral giving set, enteral extension sets, enteral syringes, enteral catheters, and enteral accessories;

— ISO 18250-3 specifies connectors intended for use between an enteral giving set, an enteral accessory and an enteral reservoir.

The use of these enteral-specific connectors has been specified in this document as well as small-bore connectors as specified in ISO 80369-1:2018, Clause 6.

ISO 80369-3 and ISO 18250-3 ensure that connectors for enteral giving sets, enteral extension sets, enteral syringes, enteral feeding catheters and enteral accessories are unique and are not able to be connected to other small-bore connectors specified in the ISO 80369 series for the following applications: intravascular and hypodermic, breathing systems and driving gases, urethral and urinary, limb cuff inflation and neuraxial systems.

The small-bore connectors and reservoir connectors, as defined in ISO 80369-3 and ISO 18250-3, respectively, for use in enteral applications should not, but may connect with the following connectors/ports in common use within the same environment:

— the cones and sockets of ISO 5356-1 and ISO 5356-2;

— the temperature sensor ports made in conformity with ISO 80601-2-74:2017, Annex EE;

— the nipples of EN 13544-2 and EN 13544-2+A1.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true, if any combination of the conditions is true.

The verbal forms used in this document are as follows:

— “shall” means conformity with a requirement or a test is mandatory for conformity with this document,

— “should” means conformity with a requirement or a test is recommended but is not mandatory for conformity with this document, and

— “may” is used to describe a permissible way to achieve conformity with a requirement or test.

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Enteral feeding systems — Design and testing

1 Scope

This document specifies requirements for enteral feeding systems comprising enteral giving sets, enteral extension sets, enteral syringes, enteral feeding catheters, and enteral accessories.

This document is not applicable to oral syringes.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 7886-1:2017, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

ISO 7886-2:1996, *Sterile hypodermic syringes for single use — Part 2: Syringes for use with power-driven syringe pumps*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly process*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 18250-3:2018, *Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 3: Enteral applications*

ISO 25424, *Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 80369-1, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-3, *Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications*

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ASTM F640, *Standard Test Methods for Determining Radiopacity for Medical Use*

DIN 13273-7, *Catheter for medical use — Part 7: Determination of the x-ray attenuation of catheters; requirements and testing*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
distal end
end of the medical device furthest from the source of the nutrient or diet intended to be administered via an *enteral feeding catheter* (3.5)

Note 1 to entry: See Figure 1.

3.2
proximal end
end of the medical device closest to the source of nutrient or diet intended to be administered via an *enteral feeding catheter* (3.5)

Note 1 to entry: See Figure 1.

3.3
enteral feeding system
system comprising the following enteral feeding devices: *enteral giving sets* (3.6), *enteral syringes* (3.8), *enteral feeding catheters* (3.5), and *enteral accessories* (3.4)

3.4
enteral accessory
medical device that is used within the enteral system for the purposes of device placement or access of an enteral device; or for the purposes of filling, directing, stopping, or controlling flow of nutrients, medication, or aspirates

EXAMPLE Sheaths, guidewires, introducers.

3.5
enteral feeding catheter
indwelling tubular medical device to facilitate delivery or removal of fluids or substances into or from the gastrointestinal tract

3.6
enteral giving set
medical device for transferring enteral fluids or substances from an enteral reservoir to an *enteral feeding catheter* (3.5)

Note 1 to entry: Also known as enteral feeding sets.

Note 2 to entry: See Figure 1 for an example.

3.7
enteral extension set
medical device for transferring enteral fluids or substances from an *enteral giving set* (3.6) to an *enteral feeding catheter* (3.5)

Note 1 to entry: Also known as extension tubing.

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Note 2 to entry: See Figure 1 for an example.

3.8
enteral syringe
medical device for introduction or removal of fluids or substances into or from the gastrointestinal tract by means of pressure

Note 1 to entry: This does not include syringes for introducing fluids or substances directly into the mouth, i.e. oral-only syringes.

3.9
integral introducer
component that is attached to a percutaneous *enteral feeding catheter* (3.5) which is designed to facilitate initial catheter placement starting from inside the gastro-intestinal tract and ending outside the abdominal wall

4 General requirements

4.1 General

The following requirements apply to all components of the enteral feeding system unless superseded in the specific requirements in Clauses 5, 6, 7 and 8.

4.2 Risk management

An established risk management process shall be applied to the design and development of the enteral feeding system.

NOTE ISO 14971 provides requirements and guidance for risk management of medical devices.

Check conformity by inspection of the risk management file.

4.3 Usability

An established usability engineering process shall be applied to the design of the enteral feeding system to assess and mitigate risks caused by usability problems associated with correct use and use errors.

NOTE IEC 62366-1 provides requirements and guidance on the application of usability of medical devices.

Check conformity by inspection of the usability-engineering file.

4.4 Test methods

The medical device shall be tested in accordance with the test methods specified in Annexes B to J. Alternative test methods may be used if an equivalent degree of safety is obtained and the results of those alternative test methods can be related to the results obtained using the test methods specified in this document.

Check conformity by inspection of the technical file.

4.5 Materials

For certain materials, specific labelling and risk assessment requirements might apply, depending on national or regional regulations.

EXAMPLE Natural rubber latex, certain plasticizers used in polyvinyl chloride (PVC).

Check conformity by inspection of the technical file.

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