INTERNATIONAL STANDARD

ISO 18250-3

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Medical devices — Connectors for reservoir delivery systems for healthcare applications —

Part 3: Enteral applications

Dispositifs médicaux — Connecteurs pour systèmes de livraison de réservoir pour des applications de soins de santé —
Partie 3: Applications entérales

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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 on 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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword — Supplementary information.

This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

A list of all parts in the ISO 18250 series can be found on the ISO website.

In this document, the following print types are used:

— Requirements and definitions: roman type.

— Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

— TERMS DEFINED IN THIS STANDARD OR AS NOTED: SMALL CAPITALS.

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.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

Introduction

During the development of the Standard for ENTERAL SMALL-BORE CONNECTORS (ISO 80369-3:2016) it became clear that the RISK of MISCONNECTIONS was not limited to the PATIENT access CONNECTORS and that the whole ENTERAL system needed to be considered. The possible MISCONNECTION between ENTERAL RESERVOIR CONNECTORS and spikes was also reviewed. However as ENTERAL RESERVOIR CONNECTORS are not exactly within the definition of SMALL-BORE CONNECTORS it was decided to develop this separate Standard for these CONNECTORS, taking into account the RISKS of MISCONNECTION with other MEDICAL DEVICES such as intravascular (also referred as "IV") bags.

Two different designs of CONNECTORS have been included to reflect the varying types of feed RESERVOIRS in current use.

Medical devices — Connectors for reservoir delivery systems for healthcare applications —

Part 3: Enteral applications

1 *Scope

This document specifies dimensions and requirements for the design and functional performance of CONNECTORS intended to be used on ENTERAL RESERVOIRS.

This document does not specify the dimensions and requirements for the MEDICAL DEVICES or ACCESSORIES that use these CONNECTORS. Such requirements are given in particular International Standards for specific MEDICAL DEVICES or ACCESSORIES.

NOTE 1 MANUFACTURERS are encouraged to incorporate the CONNECTORS specified in this document into ENTERAL MEDICAL DEVICES or ACCESSORIES, even if not currently required by the particular MEDICAL DEVICE Standards. It is expected that when the particular MEDICAL DEVICE Standards are revised, requirements for RESERVOIR CONNECTORS, as specified in ISO 18250, will be included.

This document does not apply to screw and crown cork caps and necks as they are not CONNECTORS specific for MEDICAL DEVICES. They rather belong to the food and beverage packaging domain despite often ENTERAL giving sets are required to connect with them.

NOTE 2 Examples of screw caps and necks are defined in DIN 55525:1988, ASTM D2911-94 (reapproved 2001), DIN 6063-1:2004, DIN 6063-2:2004, DIN 168-1:1998. Examples of crown cork caps and necks are defined in DIN 6094-1:1998, ISO 12821:2013, EN 14635:2010.

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 18250-1, *Connectors for reservoir delivery systems for healthcare applications — Part 1: General requirements and common test methods*

ISO 80369-20:2015, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

ASTM D638-10, *Standard test method for tensile properties of plastics*

ASTM D790-10, *Standard test methods for flexural properties of unreinforced and reinforced plastics and electrical insulating materials*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18250-1 and the following 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
enteral
used for administration or removal of fluid (liquid or gas) to or from the gastrointestinal tract

[SOURCE: ISO 80369-3:2016, 3.1]

3.2
normal use
operation, including routine inspection and adjustments by any USER, and stand-by, according to the instructions for use

Note 1 to entry: NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, service, transport, etc. as well.

[SOURCE: IEC 60601-1:2005+A1:2012, 3.71, modified – The word 'OPERATOR' has been replaced with 'USER'.]

3.3
rated (value)
term referring to a value assigned by the MANUFACTURER for a specified operating condition

[SOURCE: IEC 60601-1:2005+A1:2012, 3.97]

3.4
rigid material
material with a modulus of elasticity either in flexure or in tension greater than 35 000 kg/cm^2 (3 433 MPa)

3.5
semi-rigid material
material with a modulus of elastic either in flexure or in tension, between 7 138 kg/cm^2 and 35 000 kg/cm^2 (700 MPa and 3 433 MPa)

4 General requirements

4.1 NON-INTERCONNECTABLE characteristics

Where the design of the CONNECTOR of this document relies on dimensions or features of the MEDICAL DEVICE or ACCESSORY to ensure NON-INTERCONNECTABLE characteristics, the MANUFACTURER shall verify the NON-INTERCONNECTABLE characteristics. When necessary, the CONNECTOR may be installed on the MEDICAL DEVICE or ACCESSORY to demonstrate compliance with NON-INTERCONNECTABLE characteristics.

NOTE 1 The summary of MEDICAL DEVICES and their attributes with CONNECTIONS within this APPLICATION is provided in Annex D.

NOTE 2 The summary of the usability requirements for ENTERAL RESERVOIR CONNECTORS is provided in Annex E.

NOTE 3 The summary of ENTERAL RESERVOIR CONNECTORS criteria and requirements is provided in Annex F.

NOTE 4 The summary of assessment of the design of ENTERAL RESERVOIR CONNECTORS is contained in Annex G.

4.2 *Materials

ENTERAL RESERVOIR CONNECTORS of MEDICAL DEVICES or ACCESSORIES shall be made of materials with a modulus of elasticity either in flexure or in tension greater than 700 MPa.

Compliance shall be checked by applying the tests of the relevant parts of ISO 527/ASTM D638-10 or ISO 178/ASTM D790-10.

The use of softer materials for sealing purposes is permitted provided that they do not affect the NON-INTERCONNECTABILITY and interoperability of the RESERVOIR CONNECTOR.

5 *Dimensional requirements

ENTERAL RESERVOIR CONNECTORS shall comply with the relevant dimensions and tolerances as given in:

— Figure B.1 and Table B.1 for cross CONNECTOR assembly (E1R);

— Figure B.2 and table B.2 for cross CONNECTOR shaft (E1R);

— Figure B.3 and Table B.3 for a cross port RESERVOIR CONNECTOR (E1R);

— Figure B.5 and Table B.5 for a male CONNECTOR (E2R);

— Figure B.6 and Table B.6 for a female CONNECTOR (E2R).

NOTE 1 CONNECTORS designed to fit the requirements of this document do not connect with the ports defined in ISO 1135-4 and ISO 3826-1. These ports utilize flexible material as used on intravenous (IV) bag ports that can expand to accept many dimensions of mating CONNECTORS. The design of the CONNECTORS in this document allows the CONNECTOR to penetrate the elastic IV bag port but without establishing a fluid flow.

NOTE 2 Figure B.4 shows the CONNECTION between the cross CONNECTOR and the cross port RESERVOIR CONNECTOR.

NOTE 3 Refer to Annex I for information relative to the specific geometric layout and functionality of the male and female CONNECTORS (E2R).

Check compliance by verifying the dimensions and tolerances specified in Annex B, as appropriate.

6 Performance requirements

6.1 General performance requirements

The tests described in this document are TYPE TESTS.

6.2 Positive pressure liquid leakage

ENTERAL RESERVOIR CONNECTORS shall be evaluated for fluid leakage performance with the positive pressure liquid leakage TEST METHOD and shall show no signs of leakage, sufficient to form a falling drop of water, over a hold period of 30 s to 35 s while being subjected to an applied pressure of between 40 kPa and 60 kPa. MANUFACTURERS may use a greater applied pressure or a longer hold period.

Compliance shall be checked by applying the tests of ISO 80369-20:2015, Annex C, applying a torque of between 0,08 N·m and 0,10 N·m while using the leakage reference CONNECTOR specified in Annex C, and considering the deviations listed in Annex H.

6.3 Subatmospheric-pressure air leakage

ENTERAL RESERVOIR CONNECTORS shall be evaluated for subatmospheric pressure air leakage, and shall not leak by more than 0,005 Pa·m^3/s while being subjected to an applied subatmospheric pressure of between 4,0 kPa and 4,8 kPa over a hold period of between 15 s and 20 s. MANUFACTURERS may use a greater applied subatmospheric pressure.

Compliance shall be checked by applying the tests of ISO 80369-20:2015, Annex D, while using the leakage reference CONNECTOR specified in Annex C, and considering the deviations listed in Annex H.

6.4 Stress cracking

ENTERAL RESERVOIR CONNECTORS shall be evaluated for stress cracking. ENTERAL RESERVOIR CONNECTORS shall meet the requirements of 6.2 after being subjected to stresses of ISO 80369-20:2015, Annex E.

Compliance shall be checked by applying the tests of ISO 80369-20:2015, Annex E, while using the stress cracking reference CONNECTOR specified in Annex C, and considering the deviations listed in Annex H.

6.5 Resistance to separation from axial load

ENTERAL RESERVOIR CONNECTORS shall be evaluated for separation from axial load. ENTERAL RESERVOIR CONNECTORS shall not separate from the reference CONNECTOR over a hold period between 10 s and 15 s while being subjected to a disconnection applied axial force between 32 N and 35 N. MANUFACTURERS may use a greater disconnection applied axial force or a longer hold period.

Compliance shall be checked by applying the tests of ISO 80369-20:2015, Annex F, while using the separation from axial load reference CONNECTOR specified in Annex C, and considering the deviations listed in Annex H.

6.6 Resistance to separation from unscrewing

ENTERAL RESERVOIR CONNECTORS shall be evaluated for separation from unscrewing. ENTERAL RESERVOIR CONNECTORS shall not separate from the reference CONNECTOR for a hold period between 10 s and 15 s while being subjected to an unscrewing torque of between 0,019 8 N·m to 0,02 N·m. MANUFACTURERS may use a greater applied unscrewing torque or a longer hold period.

Male CONNECTOR (E2R) in Figure B.5 and female CONNECTOR (E2R) in Figure B.6 are exempted from this requirement.

Compliance shall be checked by applying the tests of ISO 80369-20:2015, Annex G, while using the separation from unscrewing reference CONNECTOR specified in Annex C, and considering the deviations listed in Annex H.

6.7 Resistance to overriding

ENTERAL RESERVOIR CONNECTORS shall be evaluated for resistance to overriding. ENTERAL RESERVOIR CONNECTORS shall not override the threads or lugs of the reference CONNECTOR while being subjected to an applied torque of between 0,15 N·m to 0,17 N·m over a hold period between 5 s and 10 s. MANUFACTURERS may use a greater applied torque or a longer hold period.

Compliance shall be checked by applying the tests of ISO 80369-20:2015, Annex H, while using the resistance to overriding reference CONNECTOR specified in Annex C, and considering the deviations listed in Annex H.

6.8 Disconnection by unscrewing

ENTERAL RESERVOIR CONNECTORS shall be evaluated for disconnection by unscrewing. ENTERAL RESERVOIR CONNECTORS shall separate from the reference CONNECTOR with an applied unscrewing torque up to 0,26 N·m.

Single use ENTERAL RESERVOIR CONNECTORS are exempted from the requirement of this subclause.

Male CONNECTOR (E2R) in Figure B.5 and female CONNECTOR (E2R) in Figure B.6 are exempted from the requirement of this subclause.

Compliance shall be checked by applying the tests of ISO 80369-20:2015, Annex I, while using the disconnection by unscrewing reference CONNECTOR specified in Annex C, and considering the deviations listed in Annex H.

Annex A
(informative)

Rationale and guidance

A.1 General

This annex provides a rationale for some requirements of this document, and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper APPLICATION. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this document necessitated by those developments.

A.2 Rationale for particular clauses and subclauses

The clauses and subclauses in this annex have been numbered to correspond to the numbering of the clauses and subclauses of this document to which they refer. The numbering is, therefore, not consecutive.

Clause 1 **Scope**

Screw and crown cork caps and necks are excluded from the APPLICATION of this document because they are not CONNECTORS specific for MEDICAL DEVICES. Screw and crown cork caps and necks of various diameters and thread geometries are commonly used in food and beverage packaging industry and may vary from one geographical region to another. ENTERAL giving sets are often asked to connect to pre-existing food containers despite such containers almost always do not follow — and are not required to follow — the standards and regulations for MEDICAL DEVICES. Therefore, the need for a RESERVOIR CONNECTOR different from the specifically medical CONNECTORS herein defined may arise depending on the local market and customs. In order to avoid any claim of non-conformity of such caps and necks with this document, that deals with specifically designed MEDICAL CONNECTORS only, the screw and crown cork caps and necks are clearly excluded from the scope of this document.

Subclause 4.2 **Material requirements**

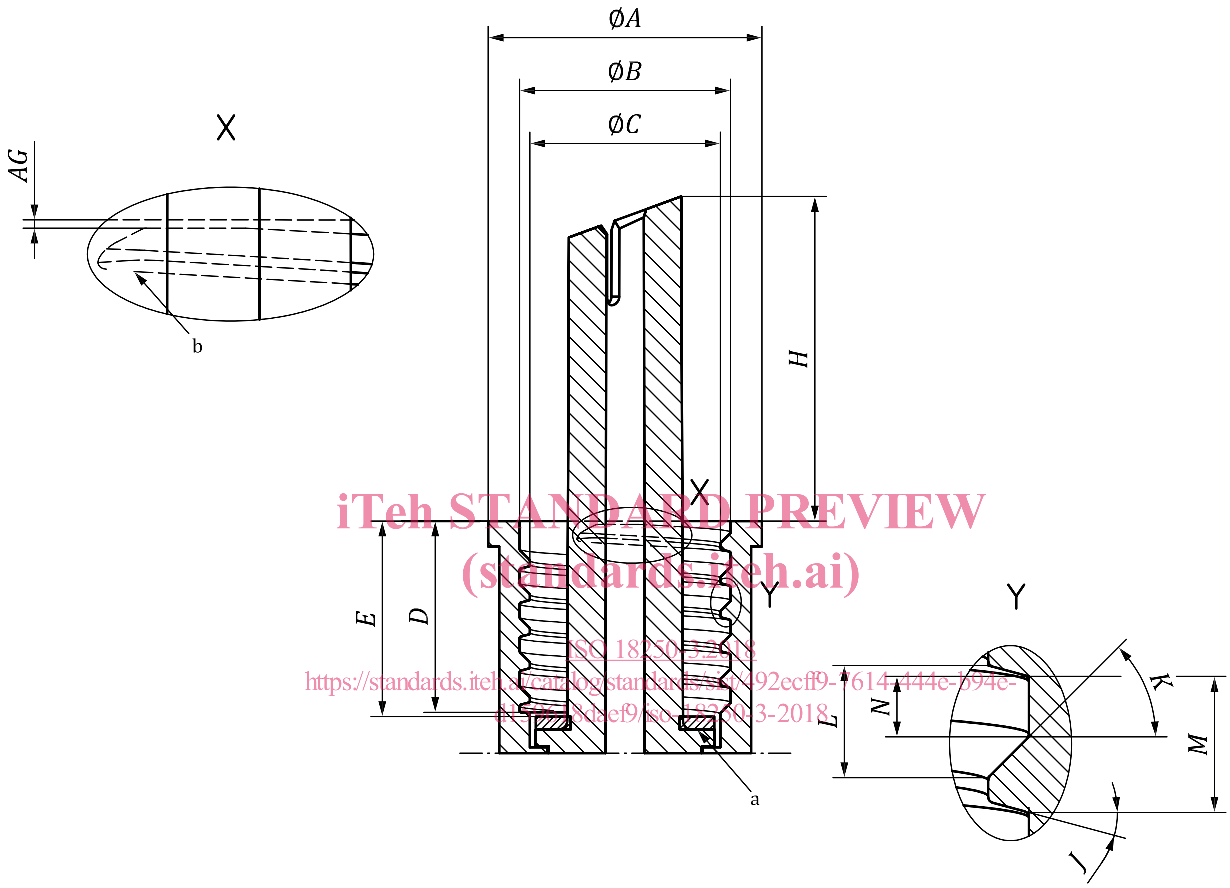
As this document is not a MEDICAL DEVICE standard specifying colour coding was considered inappropriate.

Subclause 5 **Dimensional requirements for ENTERAL RESERVOIR CONNECTORS**

The interface dimensions and requirements in this document have been developed taking into account the RISKS of misconnecting with other RESERVOIRS such as IV bags. It can therefore be assumed that if an ENTERAL RESERVOIR CONNECTOR is manufactured to the dimensions in this document then it will not provide a CONNECTION with other RESERVOIR CONNECTORS of other APPLICATIONS such that liquid will flow.

Annex B
(normative)

ENTERAL RESERVOIR CONNECTORS



a The sealing surface does not need to comply with 4.2 (e.g. be elastomeric). The use of softer materials for sealing purposes whereas they do not affect NON-INTERCONNECTABILITY and interoperability is permissible.

b The thread start fillet shape is MANUFACTURER-specific. Dimension AG refers to the first section with complete thread cross-section.

Figure B.1 — Cross connector assembly (E1R)

Table B.1 contains the dimensions for Figure B.1.

Table B.1 — Cross connector (E1R): Dimensions of the assembly of shaft and revolving lock

Dimensions in millimetres unless otherwise indicated

Revolving lock and cross CONNECTOR assembly (E1R)				
Reference	**Designation**	**Dimension**		
		Minimum	**Nominal**	**Maximum**
ØA	Revolving lock head outside diameter	16,00	—	—
ØB	Thread root internal diameter	12,30	12,40	12,65
ØC	Thread crest internal diameter	11,10	11,20	11,45
D	Thread length	10,80	11,15	11,50
E	Distance from revolving lock head and gasket surface or distance from revolving lock head and shaft basis plane if gasket is not used[a]	8,55	10,15	11,75
H	Tip protrusion from revolving lock	18,70[b]	19,10	23,05[c]
K	Front angle of thread profile (degrees)	30°	40°	50°
J	Rear angle of thread profile (degrees)	10°	15°	20°
L	Base length of thread section measured in correspondence of crest internal diameter *ØC* [d]	—	—	1,70
M	Thread pitch	—	2,00	—
N	Base length of thread section measured in correspondence of root internal diameter *ØB*	0,65	—	—
AG	Distance between revolving lock head and thread start	—	—	1,50

[a] Gasket features are MANUFACTURER-specific. The specified dimension range permits the use of very thick and soft gaskets.

[b] Minimum value can be reached with gasket only.

[c] Maximum value can be reached only without gasket, with revolving lock in least material condition and shaft in most material condition.

[d] Thread crest may have fillet radii provided that diameter *ØC* is achieved. Dimension *L* refers to the gross profile.