INTERNATIONAL STANDARD

ISO 18250-3

First edition
2018-06

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

Reference number
ISO 18250-3:2018(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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

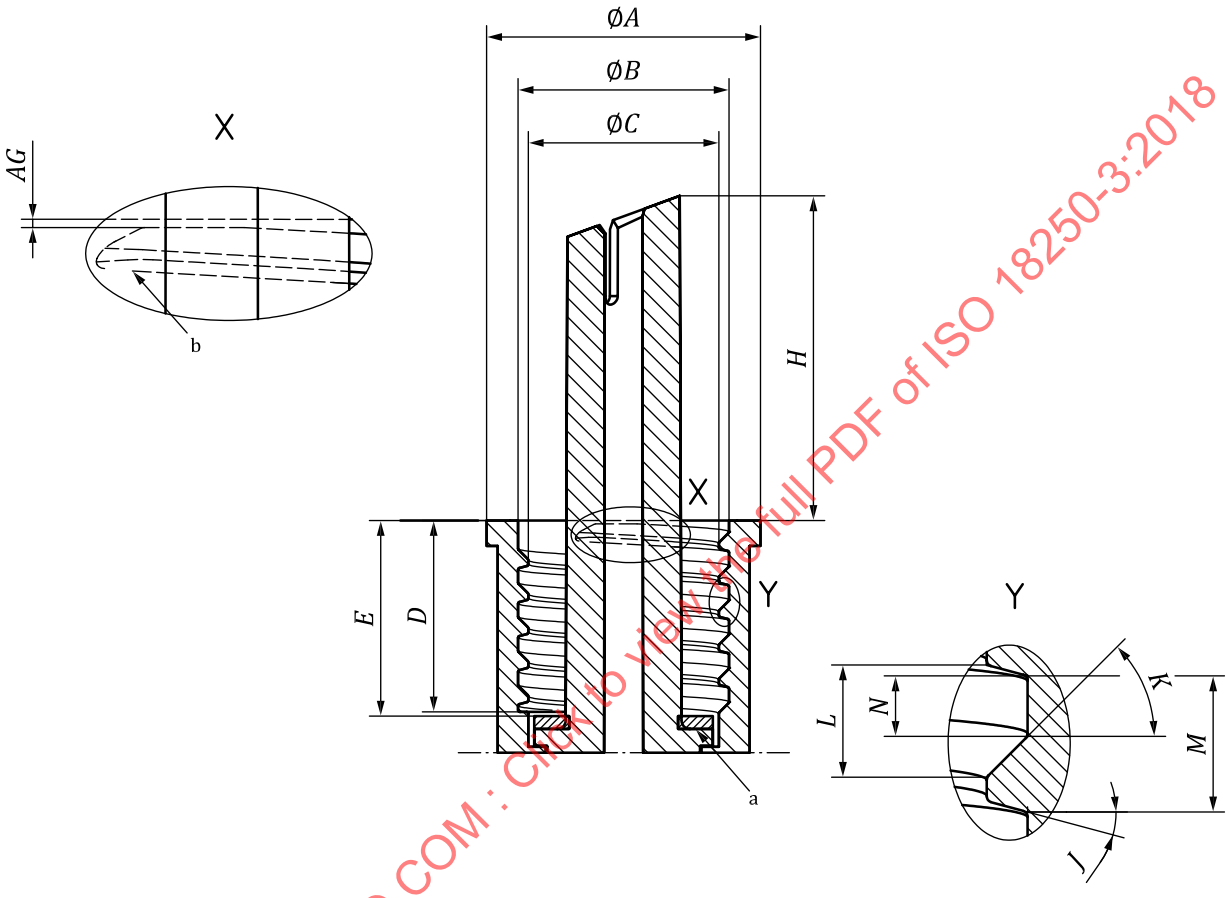
As this document is not a MEDICAL DEVICE standard specifying colour coding was considered inappropriate.

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.

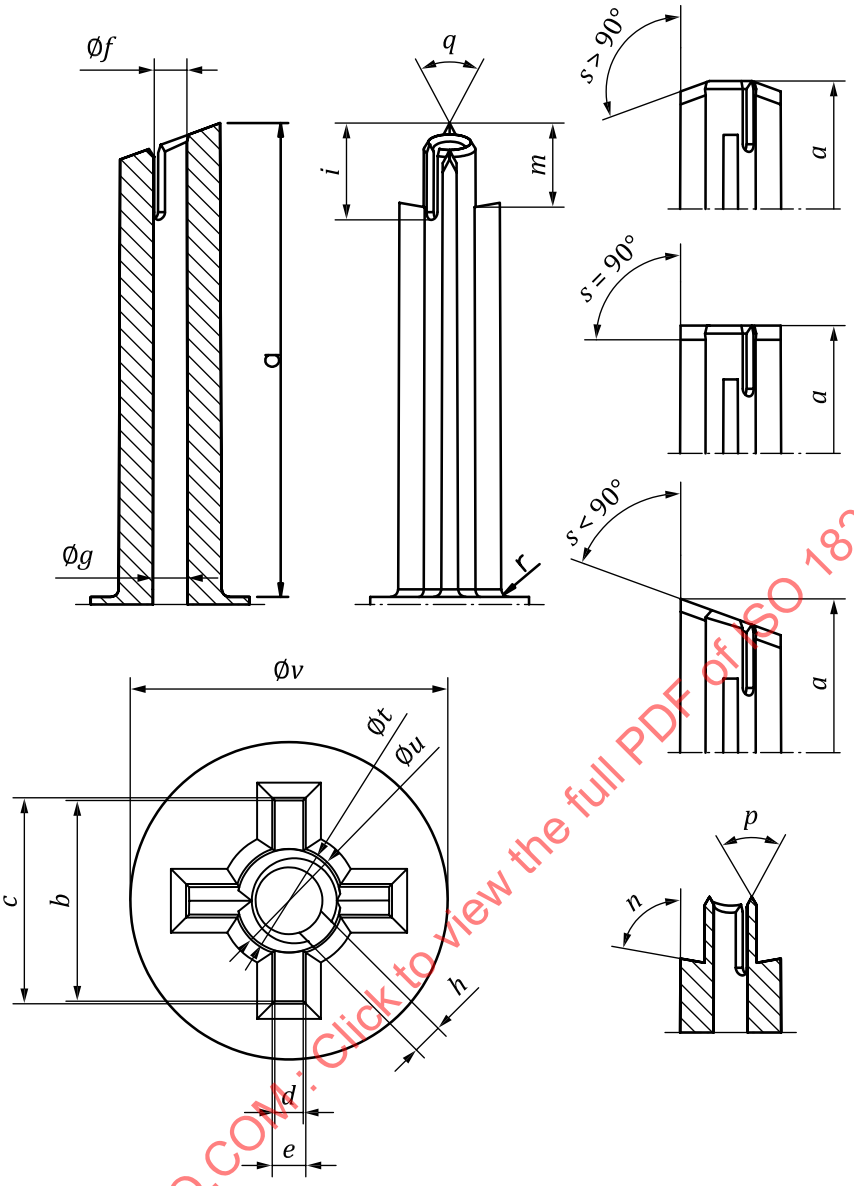


Figure B.2 — Cross connector shaft (E1R)

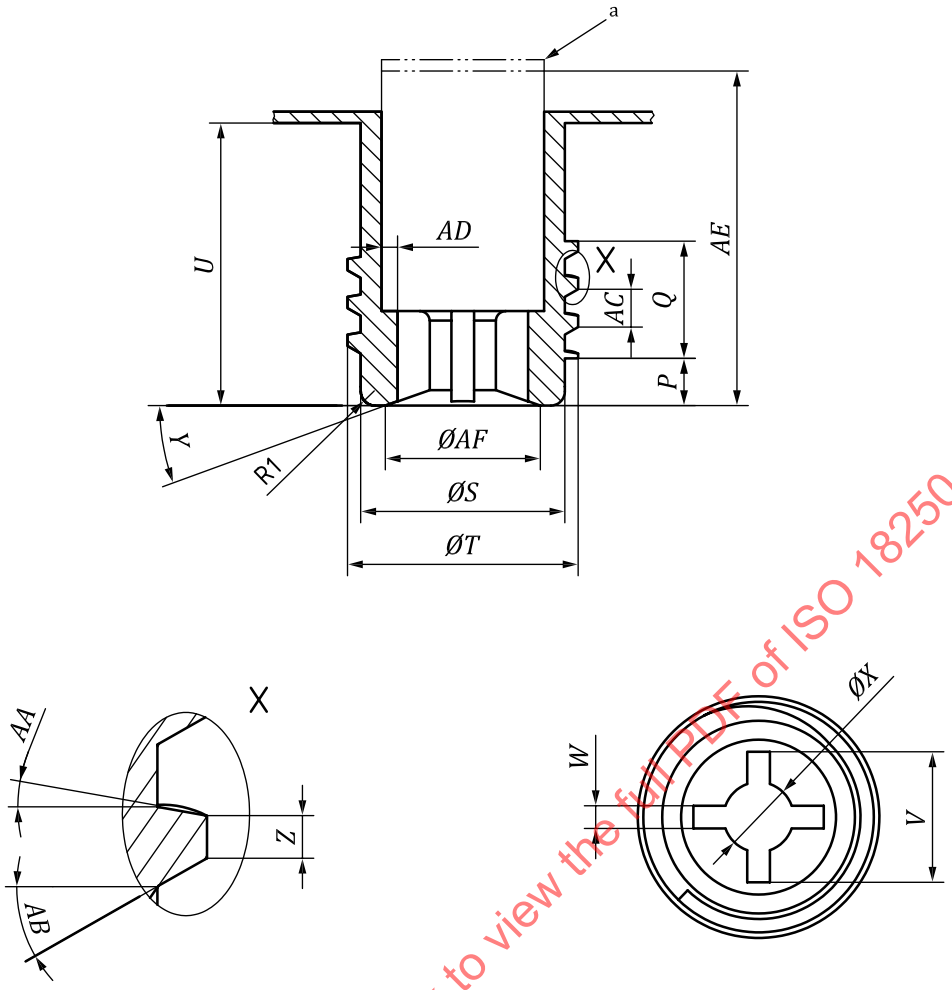
Table B.2 contains the dimensions for Figure B.2.

Table B.2 — Cross connector (E1R): Dimensions of the details of the shaft

Dimensions in millimetres unless otherwise indicated

Cross CONNECTOR (E1R): details of the shaft				
Reference	**Designation**	**Dimension**		
		Minimum	**Nominal**	**Maximum**
a	Shaft length from base to tip	31,00	31,30	31,60
b	Wing span projected on a plane orthogonal to shaft axis and that passes on tip	6,50	6,60	6,70
c	Wing span at shaft basis before fillet with base	6,70	6,80	6,90
d	Wing width at top	0,80	0,90	1,00
e	Wing width at bottom before fillet with base	1,00	1,10	1,20
Ø*f*	Inner diameter at top	2,10	2,20	2,30
Ø*g*	Inner diameter at bottom on a section that passes through the fillet start on shaft	2,10	—	—
h	Slit width	0,90	1,00	1,25
i	Slit depth from tip[a]	6,15	6,40	6,65
m	Lower wing start from tip	5,35	5,60	5,85
n	Lower wing head nook angle (degrees)	70°	80°	85°
p	Chamfer angle on channel head (degrees)	—	—	90°
q	Chamfer angle on upper wings blade (degrees)	—	—	60°
r	Fillet radius between shaft and basis	—	—	0,5
s	angle between wing blade and shaft axis (degrees)	65°	85°	105°
Ø*t*	Spike core diameter at top	—	—	3,5
Ø*u*	Spike core diameter at bottom	—	—	3,6
Ø*v*	Diameter of the basis	10,00	10,50	11,05

[a] Slit shape may be semi-circular.



a The sealing membrane does not need to comply with 4.2 (e.g. be elastomeric) and is MANUFACTURER-specific.

Figure B.3 — Cross port reservoir connector (E1R)

Table B.3 contains the dimensions for Figure B.3.

Table B.3 — Cross port reservoir connector (E1R) dimensions

Dimensions in millimetres unless otherwise indicated

Cross port RESERVOIR CONNECTOR (E1R)				
Reference	**Designation**	**Dimension**		
		Minimum	**Nominal**	**Maximum**
P	Distance from head to thread start[a]	1,90	—	6,85
Q	Thread length	4,00	—	—
ØS	Outside diameter at base of lugs[b,c]	9,90	10,60	11,00
ØT	Thread external diameter	11,75	12,00	12,30
U	Body length[d]	5,50	—	—
V	Wing span in cross bore (inscribed rectangle if wing tips are made of circular arches)	6,80	6,90	7,50
W	Wing width in cross bore	1,10	1,20	1,50
ØX	Diameter of cross bore core	3,60	3,70	3,80
Y	Angle of conical nook on head (degrees)	—	—	22°
Z	Crest length of thread section measured in correspondence of diameter *ØT*[e,g]	—	—	0,50
AA	Rear angle of thread profile (degrees)	—	—	25°
AB	Front angle of thread profile (degrees)	30°	40°	47°
AC	Thread pitch, single-start, right-handed		2,00	
AD	Clearance between wingspan and internal diameter	0,0	—	—
*R*1	Fillet radius between body and head	—	—	1,50
AE	Distance between head and foil to be pierced	—	—	23,75
ØAF	Base diameter of conical nook on head	—	—	8,75

[a] Different thread positions are allowed in order to include current adopted technologies and sealing systems. MANUFACTURERS shall provide experimental evidence for correct functionally according to functional requirements specified in this document and in ISO 18250-1.

[b] Several combinations of *ØS* and *R*1 are allowed in order to include current technologies and sealing systems. To prevent MISCONNECTION with the ISO 5356-1 8,5 mm female socket and to provide enough sealing surface against the gasket, these dimensions shall comply with the following inequality: $ØS - 2 \times R1 \geq 8{,}5$ mm.

[c] Dimension *ØS* refers to port rigid body only. The adoption of a deformable sealing foil on head (e.g. made of aluminium or multilayer composite) that exceeds *ØS* but not *ØT* does not create any additional MISCONNECTION issue.

[d] Different port lengths are allowed in order to include current adopted technologies and sealing systems. The body length ends on the nutrition source surface. This document specifies requirements for the CONNECTORS and not the MEDICAL DEVICES upon which they are placed.

[e] 0,50 mm is the maximum value of *Z* when angles *AA* and *AB* are set at their minimum values. The *Z* value depends from combination of diameters *ØS* and *ØT*, angles *AA* and *AB*.

[f] Internal diameter shall ensure free sliding of the shaft during insertion by circumscribing the cross bore profile along the port inside depth.

[g] Thread crest may have fillet radii provided that diameter *ØT* is achieved. Dimension *Z* refers to the gross profile.

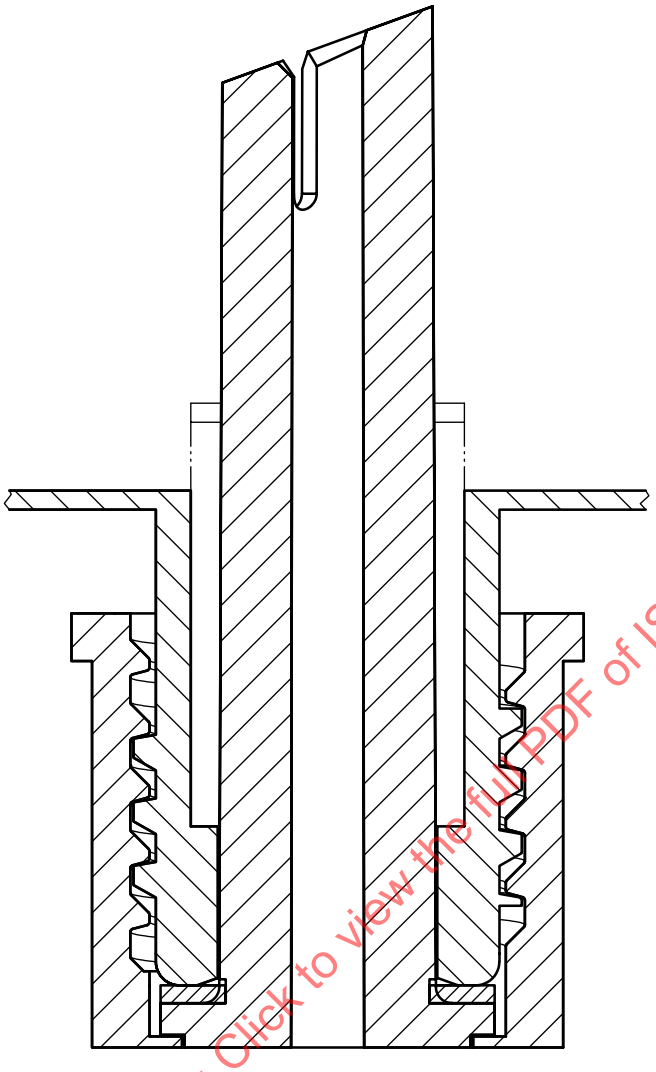
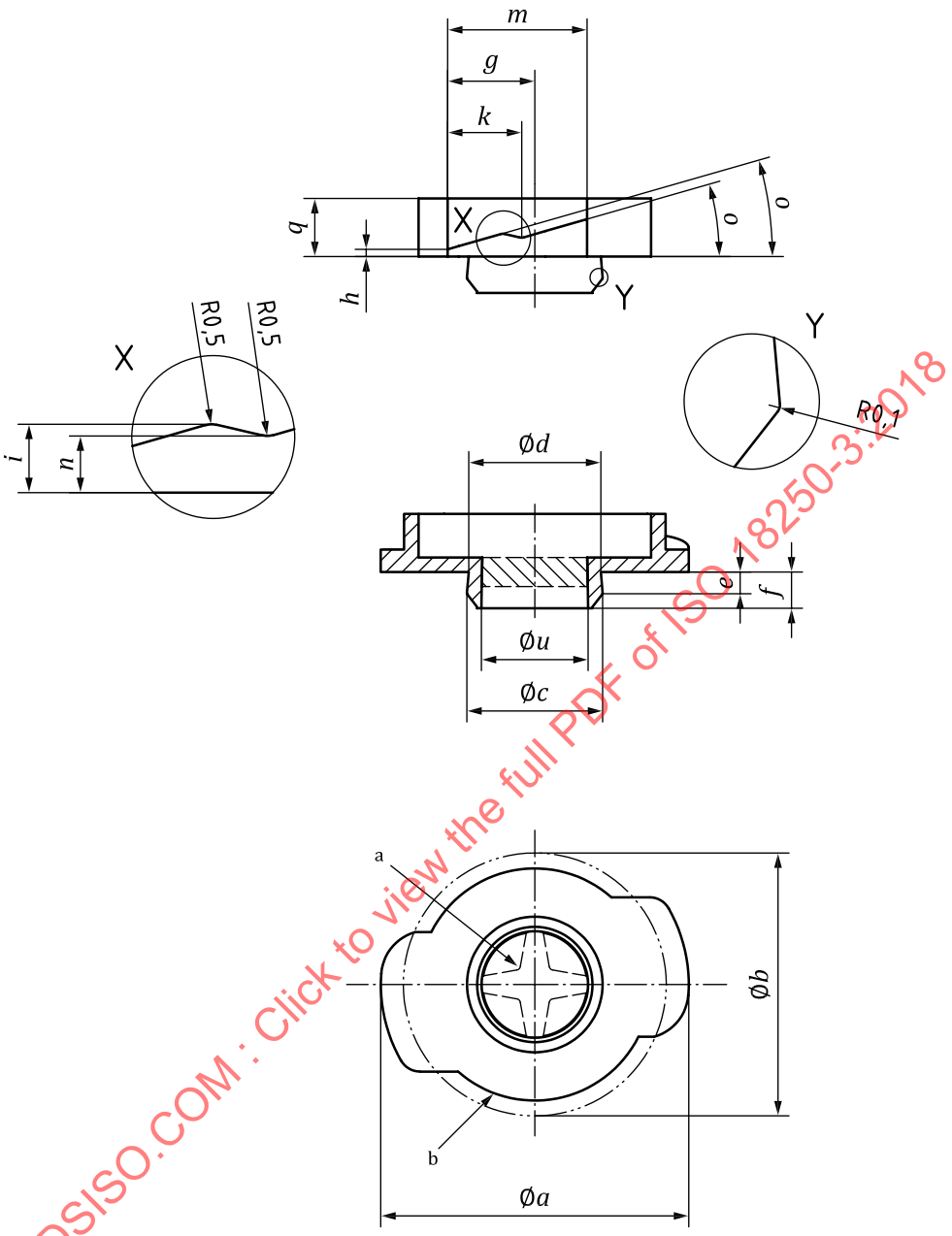


Figure B.4 — Connection of cross connector and cross port reservoir connector (E1R)

NOTE Figure B.4 is provided for informative purpose only in order to show the aspect of the correct CONNECTION between cross CONNECTOR and cross port RESERVOIR CONNECTOR.



a Structure to prevent connection with closure piercing device.

b No need to be an arc, but be satisfied in *Øb* range.

Figure B.5 — Male connector (E2R)

Table B.5 contains the dimensions for Figure B.5.

Table B.5 — Male connector dimensions (E2R)

Dimensions in millimetres unless otherwise indicated

Male CONNECTOR (E2R)				
Reference	Designation	Dimension		
		Minimum	Nominal	Maximum
Ø*a*	Maximum outside diameter of the lock lug	21,10	21,20	21,30
Ø*b*	Maximum outside diameter of the base	—	—	18,10
Ø*c*	Maximum outside diameter of the male nozzle	9,30	9,35	9,40
Ø*d*	Outside diameter of the male nozzle at the root	9,04	9,09	9,14
e	Length of the male nozzle from the root to the maximum outside diameter (Ø*c*)	1,45	1,50	1,55
f	Length of the male nozzle	2,40	2,50	2,60
g	Length from the axis to the lock lug start	5,95	6,00	6,05
h	Height at the lock lug start	0,45	0,50	0,55
i	Height at the top of the bump	1,52	1,57	1,62
k	Length from the bottom of the bump to the lock lug start	5,05	5,10	5,15
m	Width at the lock lug	9,60	—	—
n	Height at the bottom of the bump	1,25	1,30	1,35
o	Angle of the lock lug	15,00°	16,00°	17,00°
q	Length of the base	4,00	—	—
Ø*u*	Inside diameter at the tip of the male nozzle	7,15	7,35	7,55

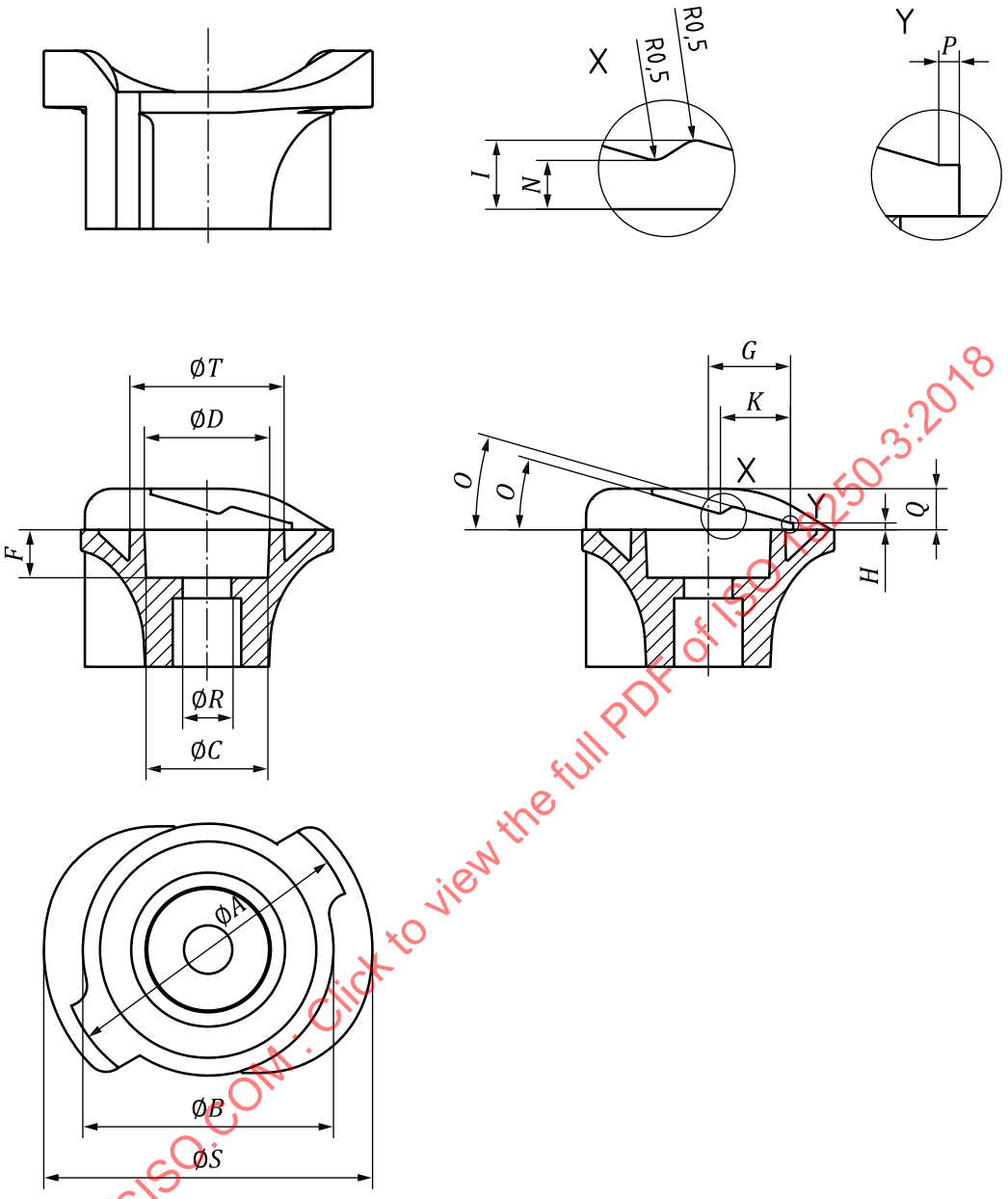


Figure B.6 — Female connector (E2R)

Table B.6 contains the dimensions for Figure B.6.

Table B.6 — Female connector (E2R)

Dimensions in millimetres unless otherwise indicated

Female CONNECTOR (E2R)				
Reference	Designation	Dimension		
		Minimum	Nominal	Maximum
ØA	Inside diameter of the locking part without the guide groove	21,50	21,60	21,70
ØB	Inside diameter of the locking part with the guide groove	18,20	18,30	18,40
ØC	Inside diameter of the smaller end of the female socket	8,85	8,90	8,95
ØD	Inside diameter at the open end of the female socket	9,10	9,15	9,20
F	Depth of the female socket	3,45	3,50	3,55
G	Length from the axis to the slope start	5,95	6,00	6,05
H	Minimum gap of the guide groove	0,45	0,50	0,55
I	Gap between the bottom of the bump to the open end surface	1,62	1,67	1,72
K	Length from the top of the bump to the slope start	5,05	5,10	5,15
N	Gap between the top of the bump to the open end surface	1,15	1,20	1,25
O	Angle of the guide groove	15,00°	16,00°	17,00°
P	Length from the guide groove end to the slope start	0,15	0,20	0,25
Q	Maximum height of the locking part with the guide groove	—	—	3,00
ØR	Inside diameter of the fluid lumen	3,30	3,55	3,80
ØS	Outside diameter of the locking part with the guide groove	23,50	24,00	24,50
ØT	Outside diameter of the female socket	11,10	11,25	11,40

Annex C
(normative)

Reference CONNECTORS

C.1 General requirements for reference CONNECTORS

Reference CONNECTORS shall be manufactured from corrosion-resistant RIGID MATERIALS with a surface roughness value R_a not exceeding 0,8 µm on critical surfaces.

C.2 Reference CONNECTORS

Dimensions in millimetres unless otherwise indicated

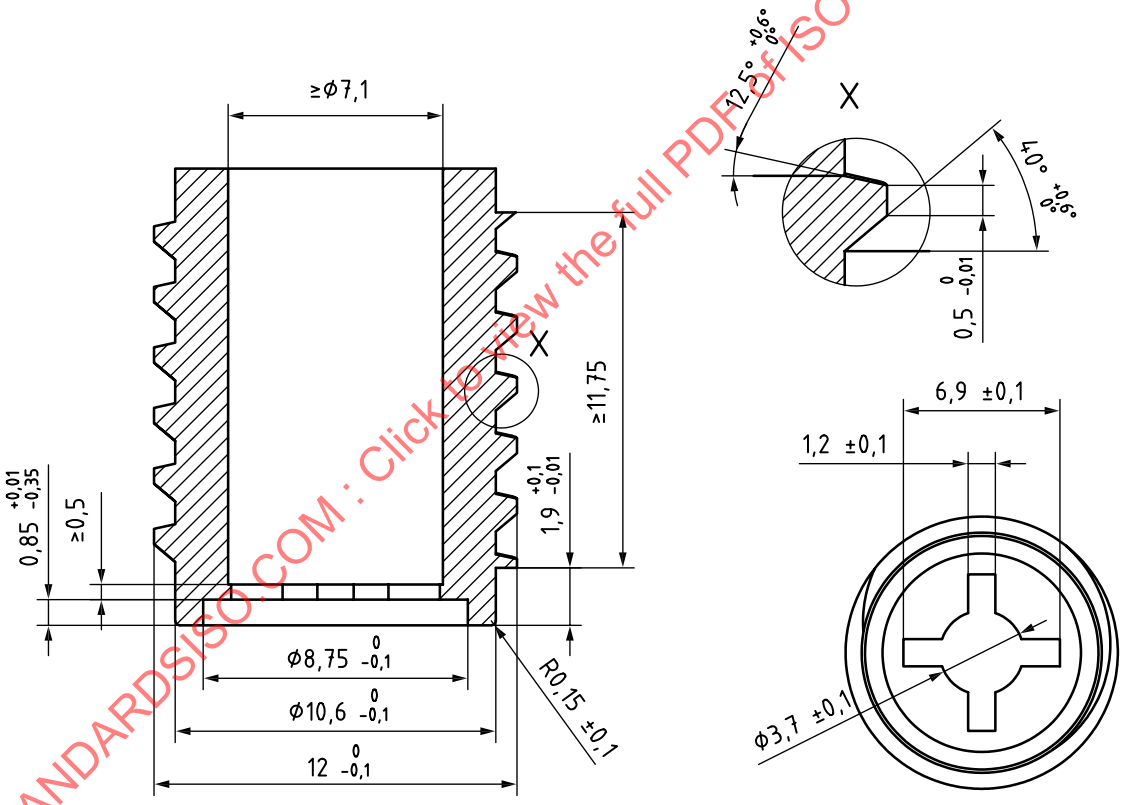


Figure C.1 — Cross port reference RESERVOIR CONNECTOR for testing cross connector (E1R) for positive pressure liquid leakage, subatmospheric pressure air leakage, stress cracking, disconnection by unscrewing, and separation from unscrewing

Dimensions in millimetres unless otherwise indicated

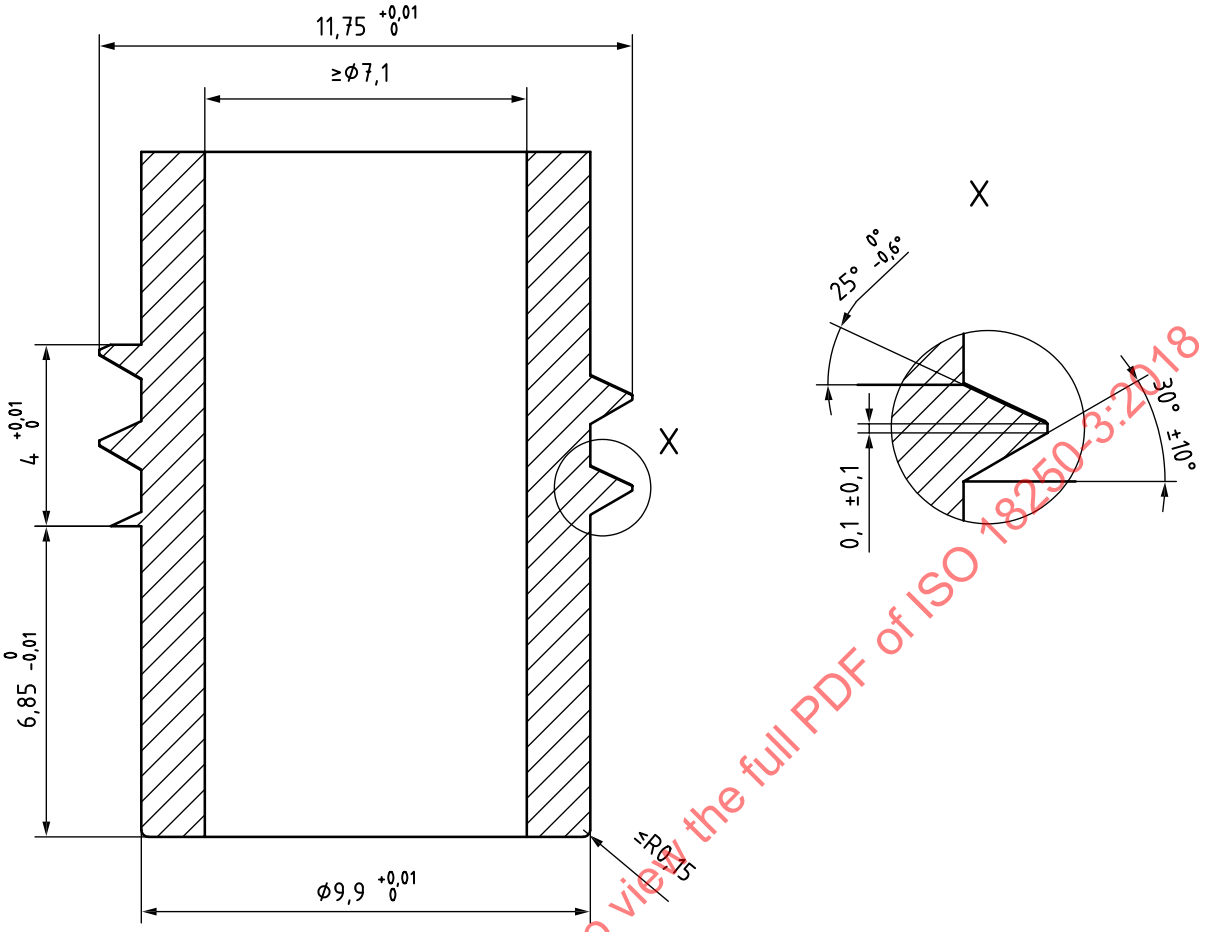
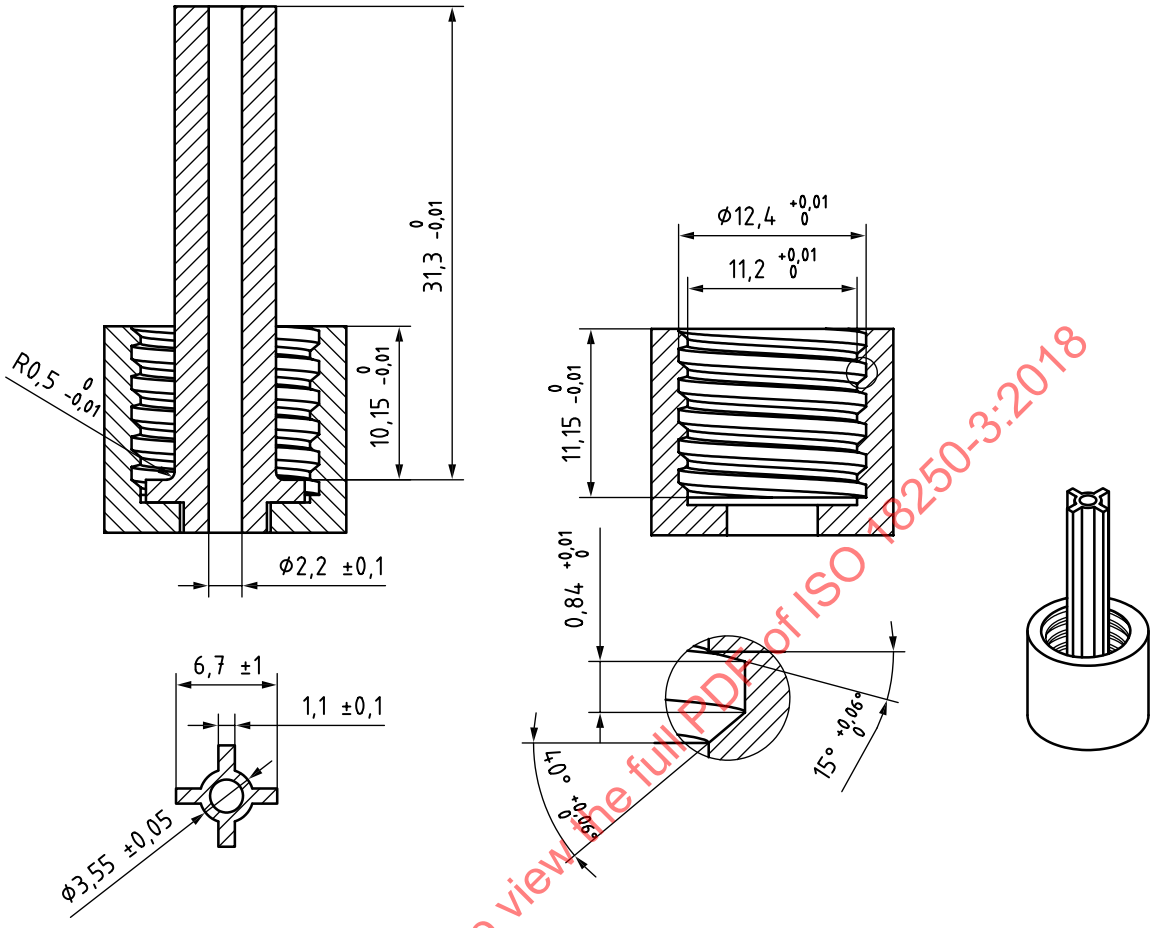


Figure C.2 — Cross port reservoir REFERENCE CONNECTOR for testing cross connector (E1R) for separation from axial load and resistance to overriding

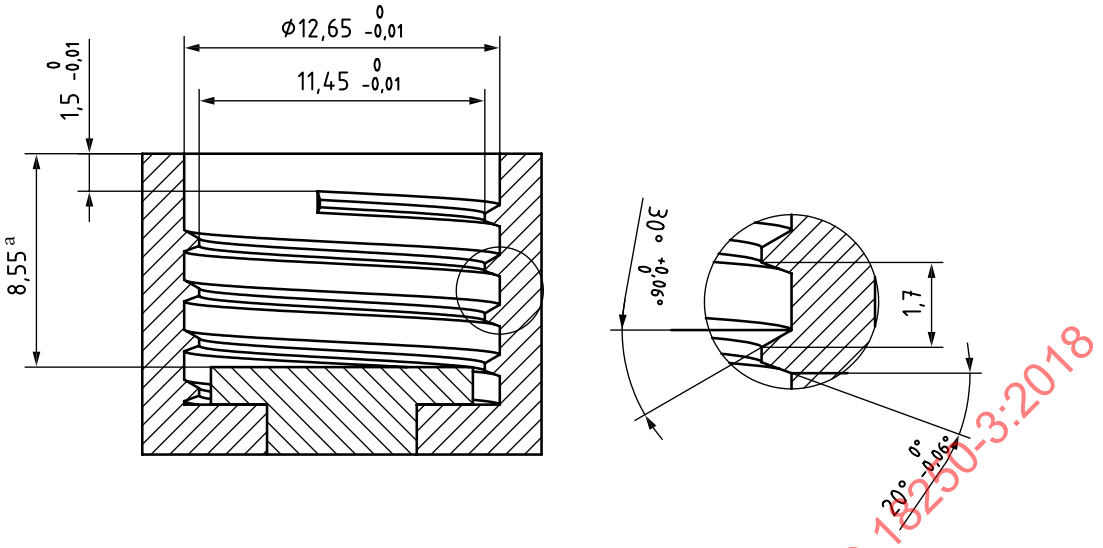
Dimensions in millimetres unless otherwise indicated



NOTE 1 This dimension does not include the thickness of the gasket.

Figure C.3 — Cross connector for testing cross port RESERVOIR CONNECTOR (E1R) for positive pressure liquid leakage, subatmospheric-pressure air leakage, stress cracking, disconnection by unscrewing, and separation from unscrewing

Dimensions in millimetres unless otherwise indicated



NOTE 1 This dimension does not include the thickness of the gasket.

Figure C.4 — Cross connector for testing cross port RESERVOIR CONNECTOR (E1R) for separation from axial load and resistance to overriding

Dimensions in millimetres unless otherwise indicated

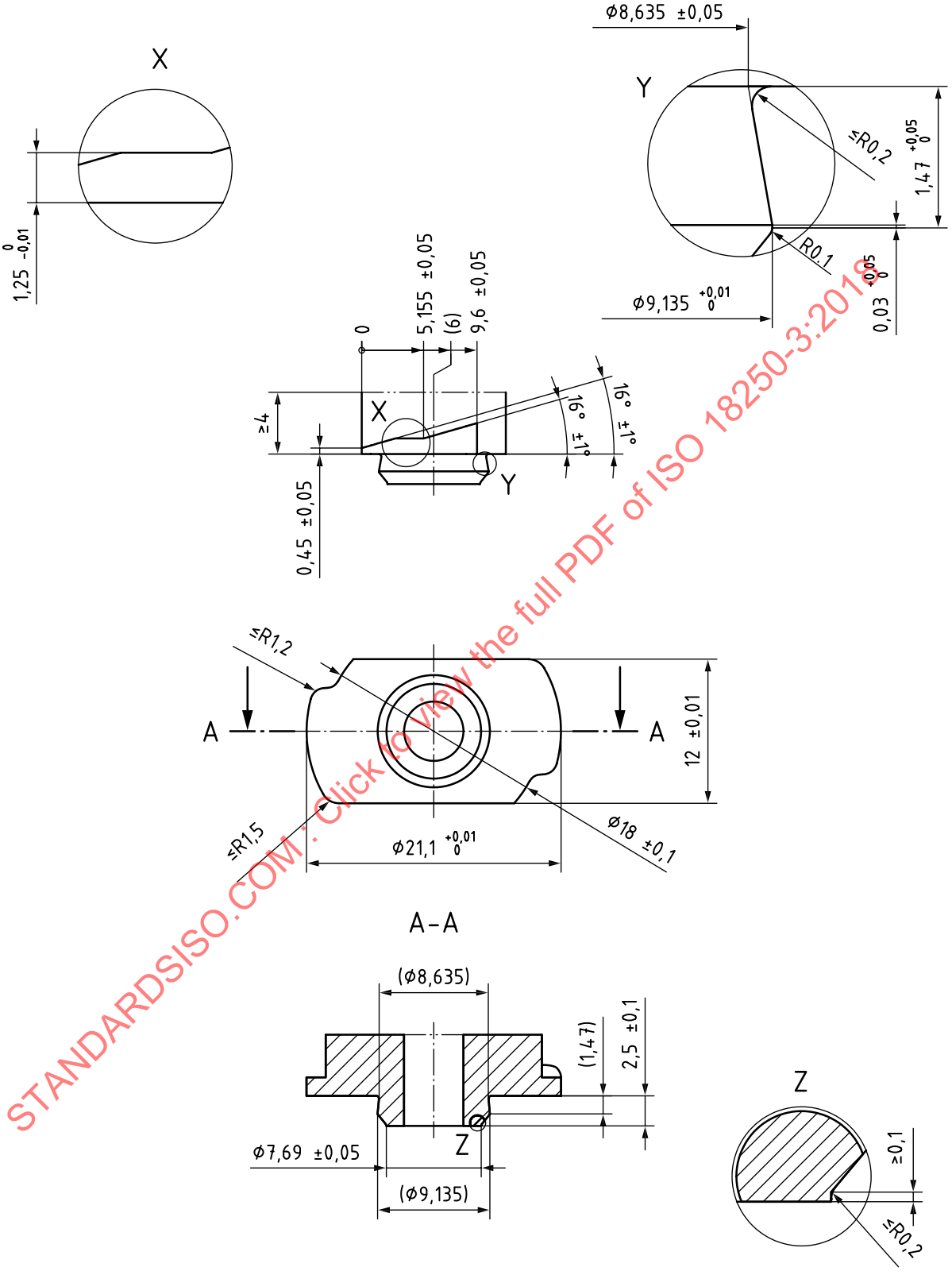


Figure C.5 — Male reference connector for testing female enteral RESERVOIR CONNECTOR (E2R) for positive pressure liquid leakage, subatmospheric-pressure air leakage, stress cracking, resistance to separation from axial load, and resistance to overriding

Dimensions in millimetres unless otherwise indicated

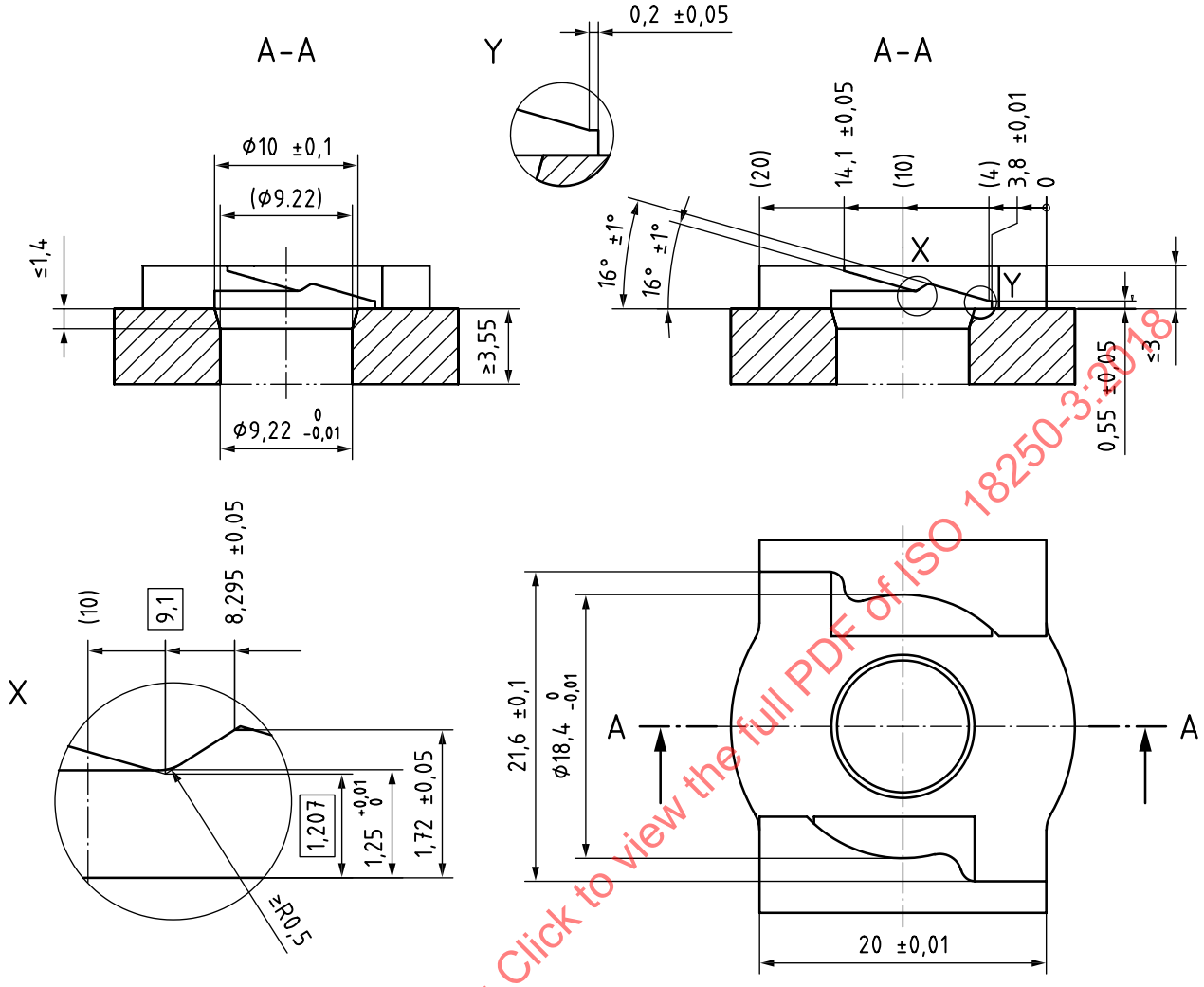


Figure C.6 — Female reference connector for testing male enteral RESERVOIR CONNECTOR (E2R) for positive pressure liquid leakage, subatmospheric-pressure air leakage, stress cracking, resistance to separation from axial load, and resistance to overriding

Annex D
(informative)

Assessment of MEDICAL DEVICES and their attributes with CONNECTIONS within this APPLICATION

Table D.1 contains examples of MEDICAL DEVICES and ACCESSORIES within ENTERAL APPLICATIONS. It also contains an assessment by the working group of the important attributes of MEDICAL DEVICES and ACCESSORIES as they relate to the intended CONNECTION.

Table D.1 — Examples of medical devices with connections within this application and their attributes

Part/component to which the CONNECTOR is applied	Flow rate range ml/h	Maximum pressure kPa	Type of fluid		Type of CONNECTION		Functionality			
			Air	Liquid	Connection	Disconnection	Locking needed	Disassembly	Positive pressure	Aspiration
ENTERAL feeding sets, RESERVOIR CONNECTIONS	0 to 3 000	80	No	Yes	Yes	Yes	Yes	Yes	Yes	No
Enteral reservoir connections	0 to 3 000	80	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No

Annex E
(informative)

Summary of the usability requirements for RESERVOIR CONNECTORS for ENTERAL APPLICATIONS

E.1 User profile

The USER PROFILE is a summary of the mental, physical and demographic traits of an intended USER population, as well as any special characteristics that can have a bearing on design decisions, such as occupational skills and job requirements.

USERS of RESERVOIR CONNECTORS for ENTERAL APPLICATIONS are comprised of the clinical, laboratory, or non-clinical persons using (i.e. operating or handling) the MEDICAL DEVICE, including, but not limited to, cleaners, maintainers and installers, PATIENTS, or other laypersons. USERS are expected to perform an intended action as an INTENDED USE of a product, PROCESS or service in accordance with the specifications, instructions and information provided by the MANUFACTURER.

USERS include:

a) PATIENTS, as the persons receiving ENTERAL nutrition that is also expected to perform an intended action.

b) Clinical USERS, as:

   — physicians, physician's assistants all levels;

   — nurses, at all levels;

   — home-care providers, visiting nurses and relatives;

   — pharmacists, pharmacy technicians, dieticians and other allied health professionals.

The USER PROFILE is summarized in Table E.1.

Table E.1 — User profile

	PATIENTS/primary caregivers	Clinical USERS
USER skills	No training[a]. USERS may have a disability: impaired sight, inability to manipulate small CONNECTORS, inability to read and understand written instructions	Clinical training at a variety of levels
PATIENT contact	Direct PATIENT contact	Direct PATIENT contact or limited PATIENT contact

[a] PATIENTS need be able to use ENTERAL CONNECTORS with little or no training.

E.2 Use scenarios

Use scenarios for RESERVOIR CONNECTORS for ENTERAL APPLICATIONS can differ by USER group and are comprised of the multitude of sub-APPLICATIONS of the CONNECTORS with different sub-specialties.

A summary of ENTERAL feeding (actual delivery of nutrients into the gastro-intestinal tract) use scenarios by USER group is summarized in Table E.2.

Table E.2 — Use scenarios, enteral feeding

	Use scenarios	PATIENTS/ primary caregivers	Clinical USERS
PATIENT populations	ICU PATIENTS including PICU and NICU		X
	Paediatrics/Infants and neonatal/ paediatric surgery PATIENTS (e.g., family-centred neonatal care)	X	X
Use environments	Adult medicine and surgery PATIENTS on wards		X
	Outpatient doctors' offices or clinics	X	X
	Emergency department		X
	Interventional radiology		X
	Extended care facilities including rehab or acute long-term care facilities		X
	Home	X	X
	School–day-care–summer camp	X	X
	Correctional facilities	X	X

A summary of medication delivery (mixing of drugs, filling syringes and RESERVOIRS, administration of drug into tube through CONNECTOR) use scenarios by USER group is summarized in Table E.3.

Table E.3 — Use scenarios, medication delivery

	Use scenarios	PATIENTS/ primary caregivers	Clinical USERS
PATIENT populations	ICU PATIENTS including PICU and NICU		X
	Paediatrics/Infants and neonatal/ paediatric surgery PATIENTS (family-centred neonatal care)		X
Use environments	Adult medicine and surgery PATIENTS on wards		X
	Emergency department		X
	Interventional radiology		X
	Operating room area		X
	Extended care facilities including rehab or acute long-term care facilities		X
	Outpatient doctors' offices or clinics	X	X
	Home	X	X
	School–day-care–summer camp	X	X
	Correctional facilities	X	X

E.3 Use environments

E.3.1 Facilities

Environments in which ENTERAL RESERVOIRS and feeding sets are used include hospitals, surgical suites, PATIENT rooms, homes, ICUs, ICU step-down units, doctors' offices or clinics, pharmacies, field hospitals, transport systems, infusion clinics, extended-care facilities, interventional radiology facilities, emergency departments, school–day-care–summer camp facilities, and correctional facilities.

E.3.2 Use temperature

a) Ambient temperature: −40 °C to +60 °C (for field use).

b) Body temperature: to 42 °C.

c) 5 °C to 40 °C temperature ranges at a relative humidity between 25 % and 65 %. One also needs to consider that some homes do not have air conditioning and that MEDICAL DEVICES may be left in hot or cold environments during transport to the institution or PATIENT.

E.4 Other attributes

The following other attributes are expected for ENTERAL RESERVOIR CONNECTORS:

a) USER stress can be created by absent or inconsistent supplies (e.g., as when purchasing changes introduce multiple products), time pressure (e.g., as applied by workload) and personal characteristics (i.e., fatigue);

b) proximity of liquids;

c) use of gloves;

d) proximity of other CONNECTOR-bearing equipment, e.g. NIBP, respiratory gases, IVs, urinary MEDICAL DEVICES;

e) duration, use-life;

f) low or variable light conditions; and

g) ambient activity levels.

E.5 Generic user needs

The following USER needs attributes are expected for ENTERAL RESERVOIR CONNECTORS:

a) CONNECTORS should be easy to connect, disconnect and manipulate, even with gloves. The CONNECTION should not require more force than a Luer CONNECTION (taking into account an aging population and increased physical limitations). The amount of rotation required to seal the CONNECTOR should also be considered, as many elderly caregivers do not have the finger dexterity to manipulate small CONNECTORS. RESERVOIR CONNECTIONS need to be durable so that a secure fit is maintained over time.

b) It is important that the CONNECTOR has a surface easy to keep clean (e.g. avoiding as much as possible other areas where bacteria and other contamination could gather).

c) CONNECTORS should not leak under NORMAL USE and should be secure enough to prevent inadvertent disconnection.

d) It is desirable to make MEDICAL DEVICES and their CONNECTORS distinctive by sight, feel, or function. Haptic confirmation of CONNECTION is important as practitioners and lay USERS often over-tighten CONNECTORS and then, when disconnecting (possibly using a tool or Kelly clamp), can damage the CONNECTOR. This consideration is especially important under conditions of low lighting and in-home care.

e) The compatibility of the CONNECTOR material with drugs is also a consideration.

f) The bore size needs to be sufficient to allow adequate nutrition flow and ease of fluid passage. The rate-limiting factors are the inner bore of the tubing and CONNECTOR and the viscosity of the solutions.

g) It is important that education, training, and information be provided to all kinds of USERS. For example, USERS should be informed regarding management of CONNECTORS and giving sets to diminish the RISK of contamination.

h) Preferably, there should only be one type of CONNECTOR in the immediate area (e.g., hospital or home). Paediatric/neonatal CONNECTORS can be of a different size and not be a choke hazard but have similar appearance.

Annex F
(informative)

Summary of RESERVOIR CONNECTOR criteria and requirements for ENTERAL APPLICATIONS

Table F.1 is a summary of the design criteria and requirements of the ENTERAL RESERVOIR CONNECTOR.

Table F.1 — Enteral connector-specific design criteria and requirements

	Criteria		Requirements	Remarks
1	**Fluid type**	a) Liquid b) Gas c) Both	a)	Deliver fluid of 25–150 cps.
2	**Operating pressure range**	maximum pressure minimum pressure subatmospheric? (yes/no)	Operating pressure: 0 kPa to 80 kPa RESERVOIR CONNECTION leak pressure up to 50 kPa Subatmospheric (yes)*	EN 1615 stipulates operating pressure of the pump and 50 kPa for CONNECTORS. ISO 80369-7 stipulates pressure between 300 kPa and 330 kPa for 30 s.
3	**RATED pressure range**	minimum maximum	0 kPa to 300 kPa	ISO 80369-7 stipulates pressure between 300 kPa and 330 kPa for 30 s.
4	**Is there a need for a leak test?**	a) No b) Yes Reference for TEST METHOD	b)	ISO 80369-7:2016 Clause 6.
5	**RATED flow-rate range**	minimum maximum	Min: 0,1 ml/h Max: 3 000 ml/h water Gravity (0,5 kPa) (no plunger): 3 000 ml/h	Range: Low flow at higher viscosities or very high flow with water.
6	**Internal CONNECTOR diameter range (through bore)**	minimum maximum	2,20 mm 2,95 mm	Fluid path needs to be as large as practicable.
7	**RATED temperature range, in use**	minimum maximum	0 °C 30 °C	
8	**Minimum range of CONNECTOR mating diameters**	minimum maximum	—	Not compatible with Luer or other ISO 80369 (series) CONNECTORS.
9	**General layout**	a) Parallel-sided, O-ring seal b) Parallel-sided, other seal c) Conical d) Other (specify)	c) or d)	
10	**Method of keying**	a) Collar b) Plug c) Other (specify)	None	Haptic features can be considered for inclusion.

Table F.1 *(continued)*

	Criteria		Requirements	Remarks
11	**Quick release?**	a) No b) Yes i) single-handed operation ii) double-handed operation	a)	
12	**Positive locking/ unlocking feature?**	a) No b) Yes	b)	Haptic features may be considered for inclusion.
13	**Need for visual indication of locking status?**	a) No b) Yes	a)	
14	**Need for indication of evidence of tampering?**	a) No b) Yes	a)	
15	**Need for a syringe in the APPLICATION?**	a) No b) Yes	b)	Not inclusive of 'oral only'.
16	**Need for an absence of sharp edges?**	a) No b) Yes	b)	For PATIENT access, no sharp edges.
17	**Minimum pull-apart force in NORMAL USE, when locked force** Reference for TEST METHOD		15 N	Defined in EN 1615.
18	**Construction materials**	a) RIGID MATERIAL (excluding seals) i) metal ii) plastic b) SEMI-RIGID MATERIAL	a) ii b) >700 MPa	
19	**Need for use of SEMI-RIGID MATERIAL?**	a) No b) Yes, mating part of CONNECTOR (apart from seal)	b) >700 MPa	
20	**MRI compatibility?**	a) No, with labelling b) No, without labelling c) Yes, with labelling d) Yes, without labelling	b)	
21	**Stress-cracking resistance?**	a) No b) Yes Specify limits	b)	
22	**Externally, how is CONNECTOR to be distinguishable from Luer?** (describe)		Shape and/or texture/tactile	
23	**Labelling/Symbols/ Marking?**	a) No (e.g. not for IV) b) Yes	a)	
24	**Other method for indicating INTENDED USE?**	a) No b) Yes Indicate method	a)	
25	**Biocompatibility needed?**	a) No b) Yes i) indicate tissue types	b) Indirect fluid path	

Table F.1 *(continued)*

	Criteria		Requirements	Remarks
26	**Reuse variants**	a) Multiple PATIENT use b) Single PATIENT use c) Single use d) Non-reusable (indicate method of auto-disabling)	b) and c)	
27	**Decontamination needed?**	a) No, single use only b) Yes, cleaning and disinfection indicate method c) Yes, cleaning and sterilization indicate method	a) or b) Rinsing under tap water/ Presaturated wipes.	
28	**How is ISO 18250-3 incompatibility achieved?**	a) Dimensional b) Other, Indicate method	This is the ENTERAL CONNECTOR.	
29	**How is ISO 18250-6 incompatibility achieved?**	a) Dimensional b) Other, Indicate method	a)	
30	**How is ISO 18250-7 incompatibility achieved?**	a) Dimensional b) Other, Indicate method	a)	
31	**How is ISO 18250-8 incompatibility achieved?**	a) Dimensional b) Other, Indicate method	a)	