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Small-bore connectors for liquids and gases in healthcare applications —

Part 3: Connectors for enteral applications

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé —

Partie 3: Raccords destinés à des applications entérales

Reference number
ISO 80369-3:2016(E)

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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 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

The committee responsible for this document is ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and IEC/SC 62D, *Electromedical equipment.* The draft was circulated for voting to the national bodies of both ISO and IEC.

ISO 80369 consists of the following parts, under the general title *Small-bore connectors for liquids and gases in healthcare applications*:

— *Part 1: General requirements*

— *Part 2: Connectors for breathing systems and driving gases applications*

— *Part 3: Connectors for enteral applications*

— *Part 5: Connectors for limb cuff inflation applications*

— *Part 6: Connectors for neuraxial applications*

— *Part 7: Connectors with 6 % (Luer) taper for intravascular or hypodermic applications*

— *Part 20: Common test methods*

An additional part on connectors for urethral and urinary applications is planned.

Introduction

This part of ISO 80369 was developed because of several incidents, with catastrophic consequences, resulting from firstly, the administration of inappropriate medication into the alimentary canal and secondly, from ENTERAL solutions being administered via incorrect routes, including intravenously and into the airway. Many incidents were reported leading to international recognition of the importance of these issues, and a need was identified to develop specific CONNECTORS for MEDICAL DEVICES and their ACCESSORIES used to deliver feed via the ENTERAL route.

The ISO 80369 series has been developed to prevent misconnection between SMALL-BORE CONNECTORS used in different APPLICATIONS. ISO 80369-1 specifies the requirements necessary to verify the designs of SMALL-BORE CONNECTORS to ensure that

a) they do not misconnect with other SMALL-BORE CONNECTORS, and

b) they safely and securely connect with their mating half.

ISO 80369-20 contains the common TEST METHODS to support the performance requirements for SMALL-BORE CONNECTORS.

This part of ISO 80369 specifies the design, the dimensions, and the drawings of SMALL-BORE CONNECTORS intended to be used in ENTERAL APPLICATIONS. Annex D to Annex G describe the methods by which this design has been assessed. Other parts of ISO 80369 include requirements for SMALL-BORE CONNECTORS used in different APPLICATION categories.

CONNECTORS manufactured to the dimensions set out within this part of ISO 80369 are dimensionally incompatible with any of the other CONNECTORS for APPLICATIONS identified in the ISO 80369 series for SMALL-BORE CONNECTORS, except as indicated in G.2. If fitted to the relevant MEDICAL DEVICES and ACCESSORIES, these CONNECTORS are to reduce the RISK of medication and liquid nutritional formula intended for ENTERAL administration from being delivered via an alternative route, such as intravenously or via an airway device.

During the development of this International Standard, the committee decided to cover the whole ENTERAL system but to have a separate International Standard for reservoir CONNECTORS. ISO 18250-3 specifies the requirements for ENTERAL reservoir CONNECTORS. This part of ISO 80369 includes the interface dimensions for SMALL-BORE CONNECTORS for access ports and PATIENT interfaces on ENTERAL feeding sets and ENTERAL syringes.

In this part of ISO 80369, 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 Clause 3 or as noted: small capitals.

In this part of ISO 80369, 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 International Standard conform to usage described in ISO/IEC Directives, Part 2, Annex H. For the purposes of this part of ISO 80369, the auxiliary verb

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this part of ISO 80369,

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this part of ISO 80369, and

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

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.

Small-bore connectors for liquids and gases in healthcare applications —

Part 3: Connectors for enteral applications

1 * Scope

This part of ISO 80369 specifies the dimensions and requirements for the design and functional performance of SMALL-BORE CONNECTORS intended to be used for CONNECTIONS on ENTERAL MEDICAL DEVICES and ACCESSORIES.

NOTE 1 ENTERAL MEDICAL DEVICES include ENTERAL feeding sets, ENTERAL drainage sets, ENTERAL syringes, and PATIENT interface devices including access ports.

This part of ISO 80369 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.

This part of ISO 80369 does not specify requirements for SMALL-BORE CONNECTORS that are used for the following:

— gastric suction-only MEDICAL DEVICES;

— oral-only MEDICAL DEVICES;

EXAMPLE An oral tip syringe that is not intended to connect to another MEDICAL DEVICE. It is intended to administer directly to the PATIENT'S mouth.

— pressurizing and depressurizing the retention mechanism (e.g. balloon) used to hold invasive ENTERAL MEDICAL DEVICES in place;

— MEDICAL DEVICES for rectal drainage, rectal administration of medicines or fluid, and any other rectal access MEDICAL DEVICE;

— gastrointestinal endoscopy equipment;

— skin level gastrostomy MEDICAL DEVICES.

NOTE 2 MANUFACTURERS are encouraged to incorporate the SMALL-BORE CONNECTORS specified in this part of ISO 80369 into ENTERAL MEDICAL DEVICES or ACCESSORIES, even if currently not required by the relevant particular MEDICAL DEVICE standards. It is expected that when the relevant particular MEDICAL DEVICE standards are revised, requirements for SMALL-BORE CONNECTORS, as specified in ISO 80369, will be included.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-6:2016, *Small-bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications*

ISO 80369-7:—[1)], *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications*

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 80369-1, ISO 80369-7, ISO 80369-20, and ISO 14971 and the following apply.

NOTE For convenience, the sources of all defined terms used in this part of ISO 80369 are given in Annex I.

3.1
ENTERAL
pertaining to the gastrointestinal tract

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—replaced "OPERATOR" 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, 3.97]

3.4
USER
person interacting with (i.e. operating or handling) the MEDICAL DEVICE

Note 1 to entry: This includes, but is not limited to, cleaners, maintainers and installers

Note 2 to entry: PATIENTS or other laypersons can be USERS

[SOURCE: IEC 62366-1:2015, 3.24]

3.5
USER PROFILE
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

[SOURCE: IEC 62366-1:2015, 3.29]

1) To be published.

4 General requirements

4.1 General requirements for the ENTERAL APPLICATION

SMALL-BORE CONNECTORS of MEDICAL DEVICES or ACCESSORIES intended for use in ENTERAL APPLICATIONS made in compliance with this part of ISO 80369 comply with ISO 80369-1 unless otherwise indicated in this part of ISO 80369.

The sealing surface of female E1 CONNECTOR may contact the thread surfaces of the N_2 female CONNECTOR, as specified in ISO 80369-6 in LMC conditions when evaluating the NON-INTERCONNECTABLE characteristics tests of ISO 80369-1:2010, Annex B. Additional information is provided in G.2.

Because the following CONNECTORS are inadequately specified, SMALL-BORE CONNECTORS for use in ENTERAL APPLICATIONS should not, but may connect with the following:

— the cones and sockets of ISO 5356-1:2004, ISO 5356-1:2015, ISO 5356-2:2006 and ISO 5356-2:2012;

— the temperature sensor and mating ports made in compliance with ISO 8185:2007, Annex DD;

— the nipples of EN 13544-2:2002 and EN 13544-2:2002+A1:2009.

The reference CONNECTORS for evaluation of the NON-INTERCONNECTABLE characteristics are described in Annex C.

Where the design of the SMALL-BORE CONNECTOR of this part of ISO 80369 relies on dimensions or features of the MEDICAL DEVICE or ACCESSORY to ensure NON-INTERCONNECTABLE characteristics, the NON-INTERCONNECTABLE characteristics shall be VERIFIED.

Check compliance by applying the tests of ISO 80369-1:2010, 5.1, and ISO 80369-1:2010, Annex B. Compliance also may be shown by applying a computer aided design (CAD) analysis of the dimensions of all of the ISO 80369 series SMALL BORE CONNECTORS and the SMALL BORE CONNECTOR under test, in conjunction with physical testing of the SMALL BORE CONNECTOR per Annex B where the CAD analysis does not demonstrate the NON-INTERCONNECTABLE characteristics. When necessary, the SMALL-BORE CONNECTOR may be installed on the MEDICAL DEVICE or ACCESSORY to demonstrate compliance with the NON-INTERCONNECTABLE characteristics test requirements of ISO 80369-1:2010, Annex B.

NOTE 1 MEDICAL DEVICES using the SMALL-BORE CONNECTORS of this part of ISO 80369 that do not rely on the dimensions or features of the MEDICAL DEVICE or ACCESSORY to ensure NON-INTERCONNECTABLE characteristics are presumed to comply with the NON-INTERCONNECTABLE characteristics test requirements of this part of ISO 80369.

NOTE 2 The summary of MEDICAL DEVICES and their attributes with CONNECTIONS within this APPLICATION is provided in Annex D.

NOTE 3 The summary of the usability requirements for ENTERAL SMALL-BORE CONNECTORS is provided in Annex E.

NOTE 4 The summary of ENTERAL SMALL-BORE CONNECTORS criteria and requirements is provided in Annex F.

NOTE 5 The summary of assessment of the design of ENTERAL SMALL-BORE CONNECTORS according to ISO 80369-1:2010, Clause 7, is contained in Annex G.

4.2 Material used for ENTERAL SMALL-BORE CONNECTORS

In addition to the requirements of ISO 80369-1:2010, Clause 4, ENTERAL SMALL-BORE CONNECTORS shall be made of materials with a nominal modulus of elasticity either in flexure or in tension greater than 700 MPa.

Check compliance by applying the tests of ASTM D638-10 or ASTM D790-10.

4.3 TYPE TESTS

Compliance with the requirements of this part of ISO 80369 shall be determined by TYPE TESTS.

5 Dimensional requirements for ENTERAL SMALL-BORE CONNECTORS

ENTERAL SMALL-BORE CONNECTORS shall comply with the relevant dimensions and tolerances as given in

— Figure B.1 and Table B.1 for a male E1 CONNECTOR, and

— Figure B.2 and Table B.2 for a female E1 CONNECTOR.

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

6 Performance requirements

6.1 Fluid leakage

6.1.1 Fluid leakage requirement

ENTERAL SMALL-BORE CONNECTORS shall be evaluated for leakage using either the leakage by pressure decay TEST METHOD or the positive pressure liquid leakage TEST METHOD.

6.1.2 Leakage by pressure decay

ENTERAL SMALL-BORE CONNECTORS evaluated for fluid leakage performance with the leakage by pressure decay TEST METHOD shall not leak by more than 0,005 Pa·m^3/s while being subjected to an applied pressure of between 300 kPa and 330 kPa over a hold period between 15 s and 20 s using air as the medium. MANUFACTURERS may use a greater applied pressure.

Check compliance by applying the tests of ISO 80369-20:2015, Annex B, while using the leakage reference CONNECTOR specified in Annex C.

6.1.3 Positive pressure liquid leakage

ENTERAL SMALL-BORE CONNECTORS evaluated for fluid leakage performance with the positive pressure liquid leakage TEST METHOD 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 300 kPa and 330 kPa. MANUFACTURERS may use a greater applied pressure or a longer hold period.

Check compliance by applying the tests of ISO 80369-20:2015, Annex C, while using the leakage reference CONNECTOR specified in Annex C.

6.2 Stress cracking

ENTERAL SMALL-BORE CONNECTORS shall be evaluated for stress cracking. ENTERAL SMALL-BORE CONNECTORS shall meet the requirements of 6.1.1 after being subjected to stresses of ISO 80369-20:2015, Annex E.

Check compliance by applying the tests of ISO 80369-20:2015, Annex E, while using the stress cracking reference CONNECTOR specified in Annex C.

6.3 Resistance to separation from axial load

ENTERAL SMALL-BORE CONNECTORS shall be evaluated for separation from axial load. ENTERAL SMALL-BORE 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.

Check compliance by applying the tests of ISO 80369-20:2015, Annex F, while using the separation from axial load reference CONNECTOR specified in Annex C.

6.4 Resistance to separation from unscrewing

ENTERAL SMALL-BORE CONNECTORS shall be evaluated for separation from unscrewing. ENTERAL SMALL-BORE 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 0,020 0 N·m. MANUFACTURERS may use a greater applied unscrewing torque or a longer hold period.

Check compliance by applying the tests of ISO 80369-20:2015, Annex G, while using the separation from unscrewing reference CONNECTOR specified in Annex C.

6.5 Resistance to overriding

ENTERAL SMALL-BORE CONNECTORS shall be evaluated for resistance to overriding. ENTERAL SMALL-BORE 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.

Check compliance by applying the tests of ISO 80369-20:2015, Annex H, while using the resistance to overriding reference CONNECTOR specified in Annex C.

6.6 Disconnection by unscrewing

ENTERAL SMALL-BORE CONNECTORS shall be evaluated for disconnection by unscrewing. ENTERAL SMALL-BORE CONNECTORS shall separate from the reference CONNECTOR with an applied unscrewing torque of no greater than 0,35 N·m.

Check compliance by applying the tests of ISO 80369-20:2015, Annex I, while using the disconnection by unscrewing reference CONNECTOR specified in Annex C.

Annex A
(informative)

Rationale and guidance

A.1 General guidance

A.1.1 Guidance

This Annex provides a rationale for some requirements of this part of ISO 80369 and is intended for those who are familiar with the subject of this part of ISO 80369 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper use. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this part of ISO 80369 necessitated by those developments.

A.1.2 CONNECTOR selection

It is understood that SMALL BORE CONNECTOR systems cannot be designed to overcome all chances of misconnection or to eliminate deliberate misuse. However, a number of steps that would improve the current situation and lead to greater patient safety can be taken.

The PATIENT CONNECTOR needs to be one that is intended to be NON-INTERCONNECTABLE with CONNECTORS in the PATIENT care area. Care should be taken to ensure misconnection testing and associated risk analysis is performed to ensure safety and efficacy of the system.

A.1.3 Colour coding

Relative to this part of ISO 80369, it is not considered appropriate to specify a colour because this is a CONNECTOR standard as opposed to a MEDICAL DEVICE standard. The CONNECTORS specified will be physically unable to fit into a non-ENTERAL CONNECTOR and a designation of colour is deemed insufficient to signal, and ineffective in preventing, a misconnection. Other APPLICATIONS such as intravascular MEDICAL DEVICES and suction catheters might use colour, and these colours are not standardized across APPLICATIONS and countries. Identification of ENTERAL with any specific colour (e.g. purple, orange, yellow) could contribute to additional instances of MEDICAL DEVICE misconnection.

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 part of ISO 80369 to which they refer. The numbering is, therefore, not consecutive.

Clause 1 **Scope**

In 2000, a Task Group of the European standards organization, CEN, proposed a strategy to reduce incidents of accidental misconnection of PATIENT therapy lines by the use of a series of NON-INTERCONNECTABLE CONNECTORS, differentiated by design, for use in different medical APPLICATIONS.[12] The strategy reserves the use of LUER CONNECTORS solely for use in MEDICAL DEVICES used to access the vascular system or for hypodermic syringes so that they can achieve their intended function.

Exclusion of gastric suction-only MEDICAL DEVICES:

The committee determined that MEDICAL DEVICES and ACCESSORIES intended for gastric suction-only use would be excluded from the scope of this part of ISO 80369. Many gastric suction-only uses

require an inner diameter larger than 8,5 mm, the defined maximum inner diameter for a SMALL-BORE CONNECTOR, therefore falling outside of the scope of ISO 80369-1.

Exclusion of oral-only MEDICAL DEVICES:

The committee determined that delivery of fluids orally to the gastrointestinal tract would be excluded from the scope of this part of ISO 80369. The delivery of fluids orally does not require a CONNECTION to be made as defined in this part of ISO 80369; therefore, it is considered to be out of the scope of this part of ISO 80369.

The CONNECTORS detailed in this part of ISO 80369 are specifically intended to be used as a CONNECTION system (i.e. female CONNECTOR mating to a male CONNECTOR). If a CONNECTOR that is not intended to be used exclusively as part of this CONNECTION system is incorporated into an ENTERAL MEDICAL DEVICE or ACCESSORY, then the MEDICAL DEVICE MANUFACTURER needs to evaluate and control the associated RISKS as appropriate.

Orientation of CONNECTION:

This part of ISO 80369 does not specify the orientation of the E1 CONNECTORS, allowing each jurisdiction to designate the direction of flow they see most appropriate because the CONNECTORS specified in this part of ISO 80369 have been designed with NON-INTERCONNECTABLE characteristics preventing misconnection with any other male and female CONNECTORS of the ISO 80369 series. Individual jurisdictions or MANUFACTURERS should consider the potential RISKS associated with orientation, such as contamination and ease of cleaning prior to implementation.

User studies for misconnection were performed on the E1 CONNECTOR with a specified orientation in which the indwelling enteral MEDICAL DEVICE incorporated the male CONNECTOR, and the connecting MEDICAL DEVICES (syringe, feed sets, etc.) incorporated the female design. Misconnection analysis using CAD modelling and associated risk analyses have been performed to identify risk of misconnection regardless of orientation.

Subpopulations within the ENTERAL clinical application:

Concerns have been raised about the possible RISKS of delivering inaccurate doses of medicines in certain clinical practices across high RISK subpopulations (e.g. neonatal PATIENTS) if using a reversed connection system (female to male). This orientation can introduce inadvertent displacement of fluid originally contained within the female SMALL-BORE CONNECTOR. This displacement occurs when fluid is drawn up into the syringe without the use of an adaptor or drawing-up ACCESSORY that is then administered through a CONNECTION being made to a feeding tube. Laboratory testing has demonstrated that the majority of this fluid is displaced into the male SMALL-BORE CONNECTOR and the MEDICAL DEVICE behind it.

Laboratory testing also shows a mid-tolerance E1 CONNECTOR pair in a female to male orientation displaces a mean average of 0,148 ml (min 0,089 ml and max 0,179 ml with an n = 32) of fluid. For comparative purposes, a reverse LUER CONNECTOR (EN 1615) tested in similar conditions displaced a mean average 0,103 ml (min 0,074 ml and max 0,122 ml with an n = 64). To date, RISKS associated with dose accuracy in MEDICAL DEVICES designed with a reversed orientation have not been fully evaluated, and therefore, there is no proven need to explicitly exclude any subpopulations within the ENTERAL clinical application. It is therefore recommended that the E1 SMALL-BORE CONNECTOR be used for all PATIENTS to reduce the RISKS of misconnection. MANUFACTURERS incorporating the E1 SMALL-BORE CONNECTOR in MEDICAL DEVICES intended for use with high RISK subpopulations (e.g. neonatal PATIENTS) should evaluate any RISK associated with this potential displacement and, if objective evidence indicates such a potential RISK exists, should make the USER aware of the potential for fluid displacement.

The fluid that could be delivered into a male E1 CONNECTOR, due to the insertion of the cone of male CONNECTOR into the female CONNECTOR filled with fluid, is the over delivered volume (displaced fluid volume delivered in excess of the intended dose). When highly accurate dose delivery is required using the E1 CONNECTION in a female to male orientation, the use of draw up adapters (e.g. a draw up straw) is recommended. Preliminary data suggests that with the correct use of a draw up adapter, the volume of fluid delivered (the overdose amount) has been shown to be 0,003 ml. Manufacturers of devices

incorporating the ISO 80369-3 CONNECTOR will need to conduct validation studies to ensure dose accuracy meets the requirements of the device.

Displaced delivered volume should not be confused with the volume between the female port and male cone surfaces once connected, which is often referred to as dead space.

MANUFACTURERS and RESPONSIBLE ORGANIZATIONS are encouraged to report their experience with the SMALL-BORE CONNECTORS specified in this part of ISO 80369 to the Secretariat of ISO/TC 210, so that it can consider this feedback during the revision of the relevant part of the ISO 80369 series.

Table B.1 Male E1 SMALL-BORE CONNECTOR dimensions

The design of the ENTERAL CONNECTORS incorporate features for which functionality might not be readily apparent. Many of those reasons affect either the NON-INTERCONNECTABLE characterizes or the performance requirements of these CONNECTORS.

c **Projection of the tip of the CONNECTOR from thread collar**

This feature provides a visual cue for the USER to ease alignment during assembly. A rotatable, internally threaded lock fitting is permitted, but dimension *c* is required to be maintained.

e **Length of male taper (Ø*d* to Ø*g*)**

The taper length is specified to define the taper angle with a transition to a lesser angle. The taper length defines a minimum length necessary for sealing. The angle beyond the taper is permitted to be as large as 0,5° (1° included angle) or the area beyond the taper is permitted to be smaller than the end of the taper (Ø*g*) at the discretion of the MANUFACTURER.

Øg **Outside diameter of the larger end of the male taper at *e* from the tip (small end) of the male taper**

The maximum size of the nozzle is limited in order to provide NON-INTERCONNECTABLE characteristics with the inside diameter of the male cone of the 8,5 mm CONNECTOR as defined by ISO 5356-1.

***s*3 Length of nozzle from end of collar**

The maximum thread length is not specified but is required to provide clearance and support for the thread of the female ENTERAL CONNECTOR when both CONNECTORS are at least material condition (LMC).

***x*3 Chord length of thread minor diameter (Ø*j*) at thread start**

This feature performs two functions. The minimum dimension provides two edges on Ø*j* to provide NON-INTERCONNECTABLE characteristics for other SMALL-BORE CONNECTORS as determined by the misconnection evaluation. The maximum dimension creates a blunt thread and was incorporated to reduce the likelihood of inadvertent cross threading when mating male and female E1 CONNECTORS during non-axial insertion.

Øw **Diameter of the smallest cylinder that encompasses the outside surfaces of external features at the open end of the collar**

The dimensions specified for the diameter of the smallest cylinder that encompasses the outside surfaces of external features at the open end of the collar (Ø*w*) have been demonstrated to exhibit NON-INTERCONNECTABLE characteristics. MANUFACTURERS are permitted to deviate from these dimensions (Ø*w* for depth *s*3), but then the MEDICAL DEVICE incorporating the ENTERAL CONNECTOR needs to demonstrate NON-INTERCONNECTABLE characteristics using ISO 80369-1:2010, Annex B to ensure that misconnections cannot occur.

When the male CONNECTOR is used as a source of flow (e.g. on an administration set, syringe, or other similar MEDICAL DEVICE) a collar, wings, or other feature with a minimum diameter of Ø*w* is required for the purpose of preventing misconnection with the unspecified inside diameter of most 15 mm CONNECTORS as defined by ISO 5356-1.

When the male CONNECTOR is not used as a source of flow (e.g. on a PATIENT access MEDICAL DEVICE), a collar or wings with the dimensions specified for the diameter *Øw* have been demonstrated to exhibit NON-INTERCONNECTABLE characteristics.

***z*3 Face angle at thread start**

This feature was incorporated to reduce the likelihood of inadvertent cross threading when mating male and female E1 CONNECTORS during non-axial insertion.

Table B.2 Female E1 small-BORE CONNECTOR dimensions

The design of the ENTERAL CONNECTORS incorporate features for which functionality might not be readily apparent. Many of those reasons affect either the NON-INTERCONNECTABLE characteristics or the performance requirements of these CONNECTORS.

***R*3 Length of clearance for male CONNECTOR collar and threads, and**

***ØW* Diameter of the smallest cylinder that encompasses the outside surfaces of the external features at *R*3**

When the female CONNECTOR is used as a source of flow (e.g. on an administration set, syringe, or other similar MEDICAL DEVICE) a ring, wings, or other feature is required by this part of ISO 80369 behind the thread with a minimum diameter of *ØW* located within the range of dimension *R*3 for the purpose of preventing misconnection with the unspecified inside diameter of most 15 mm CONNECTORS as defined by ISO 5356-1.

When the female CONNECTOR is not used as a source of flow (e.g. on a PATIENT access MEDICAL DEVICE) a ring, wings or other feature are not required by this part of ISO 80369. A ring or wings behind the thread are at the discretion of the MANUFACTURER and are permitted by this part of ISO 80369 to be a feature of the MEDICAL DEVICE.

MANUFACTURERS are permitted to deviate from these dimensions (*R*3 and *ØW*), but then the MEDICAL DEVICE incorporating the ENTERAL SMALL-BORE CONNECTOR needs to demonstrate NON-INTERCONNECTABLE characteristics using ISO 80369-1:2010, Annex B to ensure that misconnections cannot occur.

***X*3 Chord length of thread major diameter (*ØH*) at thread start**

This feature performs two functions. The minimum dimension provides two edges on *ØH* to provide NON-INTERCONNECTABLE characteristics for other SMALL-BORE CONNECTOR as determined by the misconnection evaluation. The maximum dimension creates a blunt thread and was incorporated to reduce the likelihood of inadvertent cross threading when mating male and female E1 CONNECTORS during non-axial insertion.

***Y* Chord length at extremity of thread in a plane at a right angle to axis of the CONNECTOR**

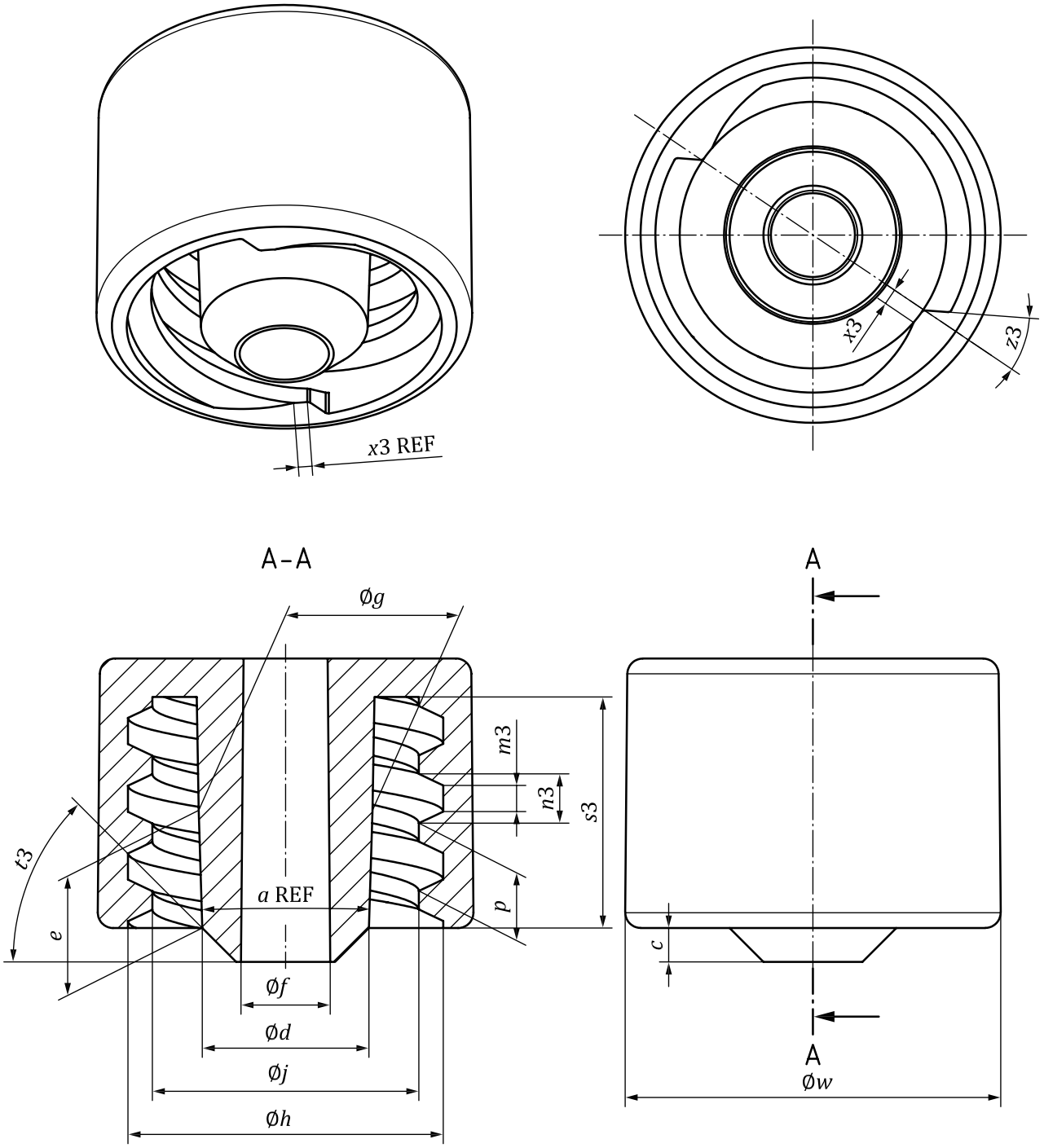
This feature can be achieved in many ways, such as a lug thread as shown or a full thread continuing to some other feature. This is at the discretion of the MANUFACTURER as long as the final design meets the performance requirements of Clause 6.

***Z*3 Face angle at thread start**

This feature was incorporated to reduce the likelihood of inadvertent cross threading when mating male and female E1 CONNECTORS during non-axial insertion.

Annex B
(normative)

ENTERAL SMALL-BORE CONNECTORS



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

Figure B.1 — Male E1 SMALL-BORE CONNECTOR

In Figure B.1, the male ENTERAL SMALL-BORE CONNECTOR may utilize a rotatable collar. The requirements for dimension *c* shall be maintained.

Table B.1 — Male E1 SMALL-BORE CONNECTOR dimensions

Dimensions in millimetres unless otherwise indicated

Male E1 SMALL-BORE CONNECTOR				
Reference	**Designation**	**Dimension**		
		Minimum	**Nominal**	**Maximum**
(*a*)	Angle of taper (6 % taper nominal) (degrees, reference)	—	(3,44°)	—
* *c*	Projection of the tip of the connector from thread collar	1,00	1,10	1,20
Ø*d*	Outside diameter at the tip of the male taper	5,36	5,41	5,46
* *e*[a]	Length of male taper (Ø*d* to Ø*g*)	3,72	3,82	3,92
Ø*f*	Inside diameter at the tip of the male taper	0,0	2,90	2,95
* Ø*g*[a]	Outside diameter of the larger end of the male taper at *e* from the tip (small end) of the male taper[a b]	5,59	5,64	5,69
Ø*h*	Major inside thread diameter (diameter at thread root)	10,13	10,23	10,33
Ø*j*	Minor inside thread diameter (diameter at thread crest)	8,55	8,65	8,75
(*L*)	Length of engagement (reference) (see Figure B.3)	(3,00)	(4,67)	(6,33)
*m*3	Width of the thread groove at the root (symmetrical with *n*3)	1,05	1,15	1,25
*n*3	Width of the thread groove at the crest (symmetrical with *m*3)	1,80	1,90	2,00
p	Pitch of double-start, right-hand thread (reference 5 mm lead)	2,45	2,50	2,55
* *s*3[a]	Length of nozzle from end of collar[a b]	6,82	—	—
*t*3	Angle of projection of nozzle from end of collar (degrees)	40°	45°	50°
* Ø*w*[c]	Diameter of the smallest cylinder that encompasses the outside surfaces of external features of the collar[d]	13,30	—	—

a Region of male taper between dimensions *e* and *s*3 defined by Ø*g* may have draft in the direction of pull no greater than 1,0° inclusive (0,5°/side).

b This dimension is required to provide clearance for the inside diameter at the open end of the female taper (Ø*D*) and face of female CONNECTOR. Maximum thread profile length is not specified but shall provide clearance for the thread of the male CONNECTOR. The geometry defined by Ø*d* is flush to the face of the collar.

c This dimension is only required where the male CONNECTOR is a source of fluid flow.

d The minimum value of *w* shall be maintained for the length of 1,00 mm, and the maximum value shall be maintained for the length of *e*. This dimension may be achieved by either the CONNECTOR or the MEDICAL DEVICE which incorporates this CONNECTOR. Alternatively, NON-INTERCONNECTABLE characteristics may be demonstrated using ISO 80369-1:2010, Annex B.

e This dimension is only required where the male CONNECTOR is not a source of fluid flow.

f Other geometries that begin and end at the limits of the specified angle line may be used.

Table B.1 *(continued)*

Male E1 SMALL-BORE CONNECTOR				
Reference	**Designation**	**Dimension**		
		Minimum	**Nominal**	**Maximum**
* Ø*w*[e]	Diameter of the smallest cylinder that encompasses the outside surfaces of external features of the collar[d]	12,00	12,20	—
* *x*3	Chord length of thread minor diameter (Ø*j*) at thread start	0,25	0,50	1,50
* *z*3	Face angle at thread start[f] (degrees)	—	—	40°

[a] Region of male taper between dimensions *e* and *s*3 defined by Ø*g* may have draft in the direction of pull no greater than 1,0° inclusive (0,5°/side).

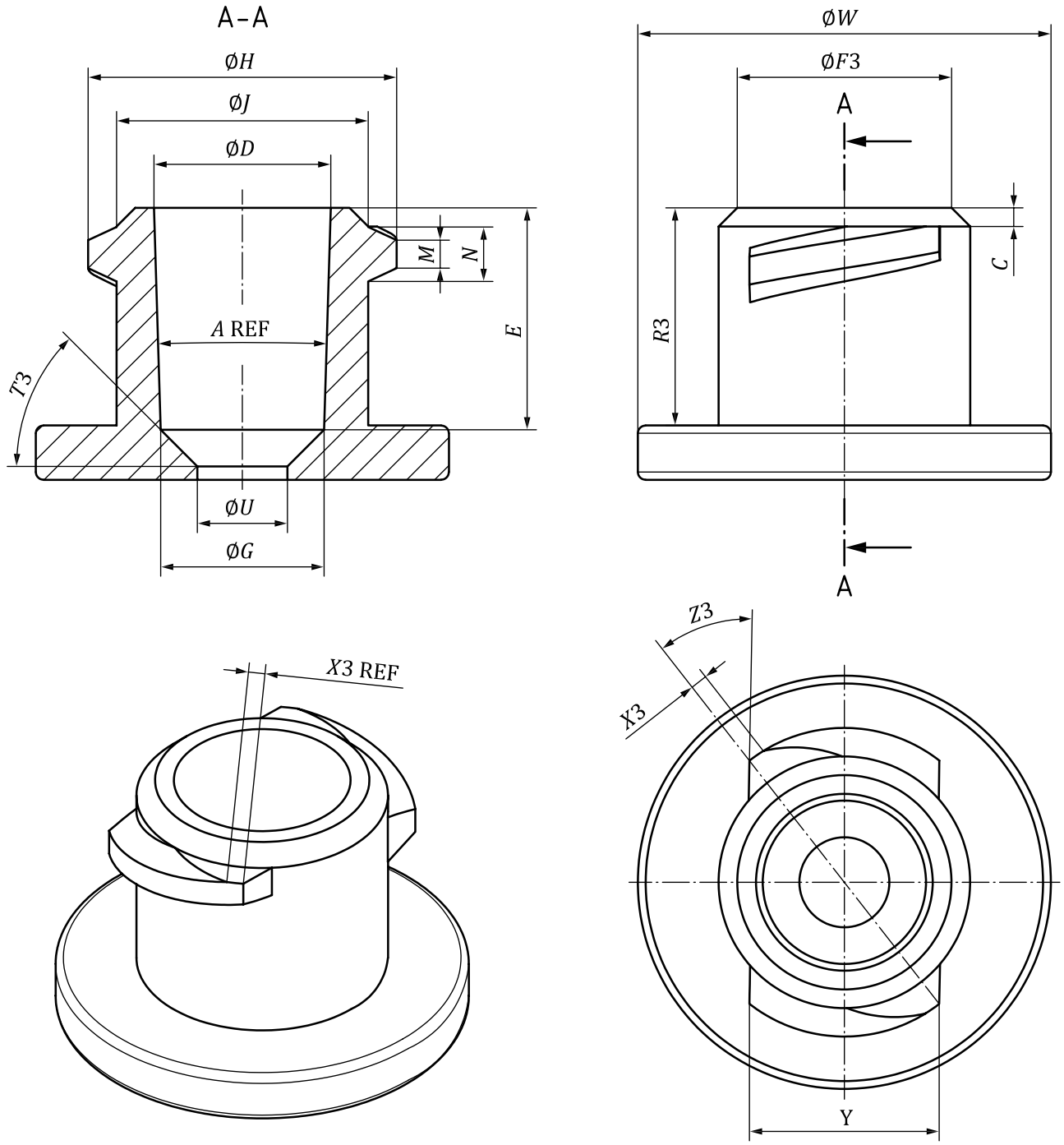
[b] This dimension is required to provide clearance for the inside diameter at the open end of the female taper (Ø*D)* and face of female CONNECTOR. Maximum thread profile length is not specified but shall provide clearance for the thread of the male CONNECTOR. The geometry defined by Ø*d* is flush to the face of the collar.

[c] This dimension is only required where the male CONNECTOR is a source of fluid flow.

[d] The minimum value of *w* shall be maintained for the length of 1,00 mm, and the maximum value shall be maintained for the length of *e*. This dimension may be achieved by either the CONNECTOR or the MEDICAL DEVICE which incorporates this CONNECTOR. Alternatively, NON-INTERCONNECTABLE characteristics may be demonstrated using ISO 80369-1:2010, Annex B.

[e] This dimension is only required where the male CONNECTOR is not a source of fluid flow.

[f] Other geometries that begin and end at the limits of the specified angle line may be used.



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

Figure B.2 — Female E1 SMALL-BORE CONNECTOR

In Figure B.2, the thread profile length is not specified but shall provide clearance for the thread on the male CONNECTOR.

Table B.2 — Female E1 SMALL-BORE CONNECTOR dimensions

Dimensions in millimetres unless otherwise indicated

Female E1 SMALL-BORE CONNECTOR				
Reference	**Designation**	**Dimension**		
		Minimum	**Nominal**	**Maximum**
A	Angle of taper (6 % taper nominal) (degrees, reference)	—	(3,44°)	—
C	Projection of the female taper from the thread start	0,50	0,60	0,70
Ø*D*	Inside diameter at the open end of the female taper	5,64	5,69	5,74
E	Depth of female taper	7,04	7,14	7,24
Ø*F*3	Outside diameter at the tip of the female taper	6,80	6,90	7,00
Ø*G*	Inside diameter of the smaller end of the female taper at *E* from the opening (large end) of the female taper	5,21	5,26	5,31
Ø*H*	Major outside thread diameter (diameter at thread crest)	9,83	9,93	10,03
Ø*J*	Minor outside thread diameter (diameter at thread root)	8,00	8,10	8,20
(*L*)	Length of engagement (reference) (see Figure B.3)	(3,00)	(4,67)	(6,33)
M	Width of the thread profile at the crest (symmetrical with *N*)	0,80	0,90	1,00
N	Width of the thread profile at the root (symmetrical with *M*)	1,65	1,75	1,85
P (not illustrated)	Pitch of double-start, right-hand thread (reference 5 mm lead)	2,45	2,50	2,55
* *R*3	Length of clearance for male CONNECTOR collar and threads[a]	6,90	7,00 [b]	11,00 [b]
*T*3	Angle at end of female taper (degrees)	40°	45°	50°
Ø*U*	Inside diameter of the fluid lumen of the CONNECTOR	—	2,90	2,95
Ø*W*[b]	Diameter of the smallest cylinder that encompasses the outside surfaces of the external features at *R*3[c]	13,30	—	—
* *X*3	Chord length of thread major diameter (Ø*H*) at thread start	0,25	0,50	1,50
* *Y*	Chord length at extremity of thread in a plane at a right angle to axis of the CONNECTOR[d]	6,00	—	—
* *Z*3	Face angle at thread start (degrees)[e]	—	—	40°

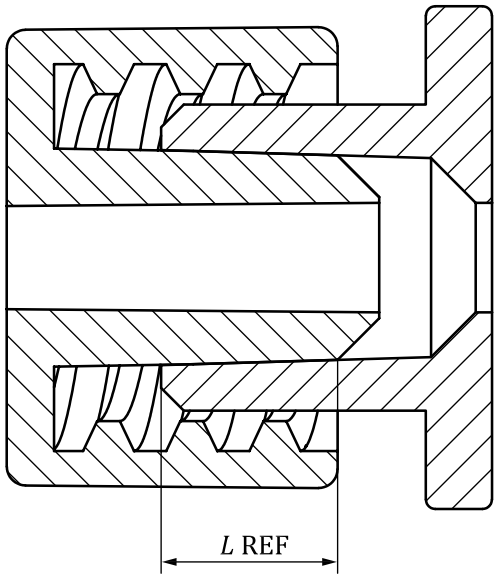
[a] The maximum thread revolution length is not specified but shall provide clearance for the thread of the male CONNECTOR.

[b] This dimension is only required where the female CONNECTOR is a source of fluid flow.

[c] This dimension may be achieved by either the CONNECTOR or the MEDICAL DEVICE which incorporates this CONNECTOR. Alternatively, NON-INTERCONNECTABLE characteristics may be demonstrated using ISO 80369-1:2010, Annex B.

[d] This definition allows full thread.

[e] Other geometries that begin and end at the limits of the specified angle line may be used.



NOTE Table B.1 and Table B.2 contain the dimension for Figure B.3.

Figure B.3 — E1 CONNECTOR assembly

Annex C
(normative)

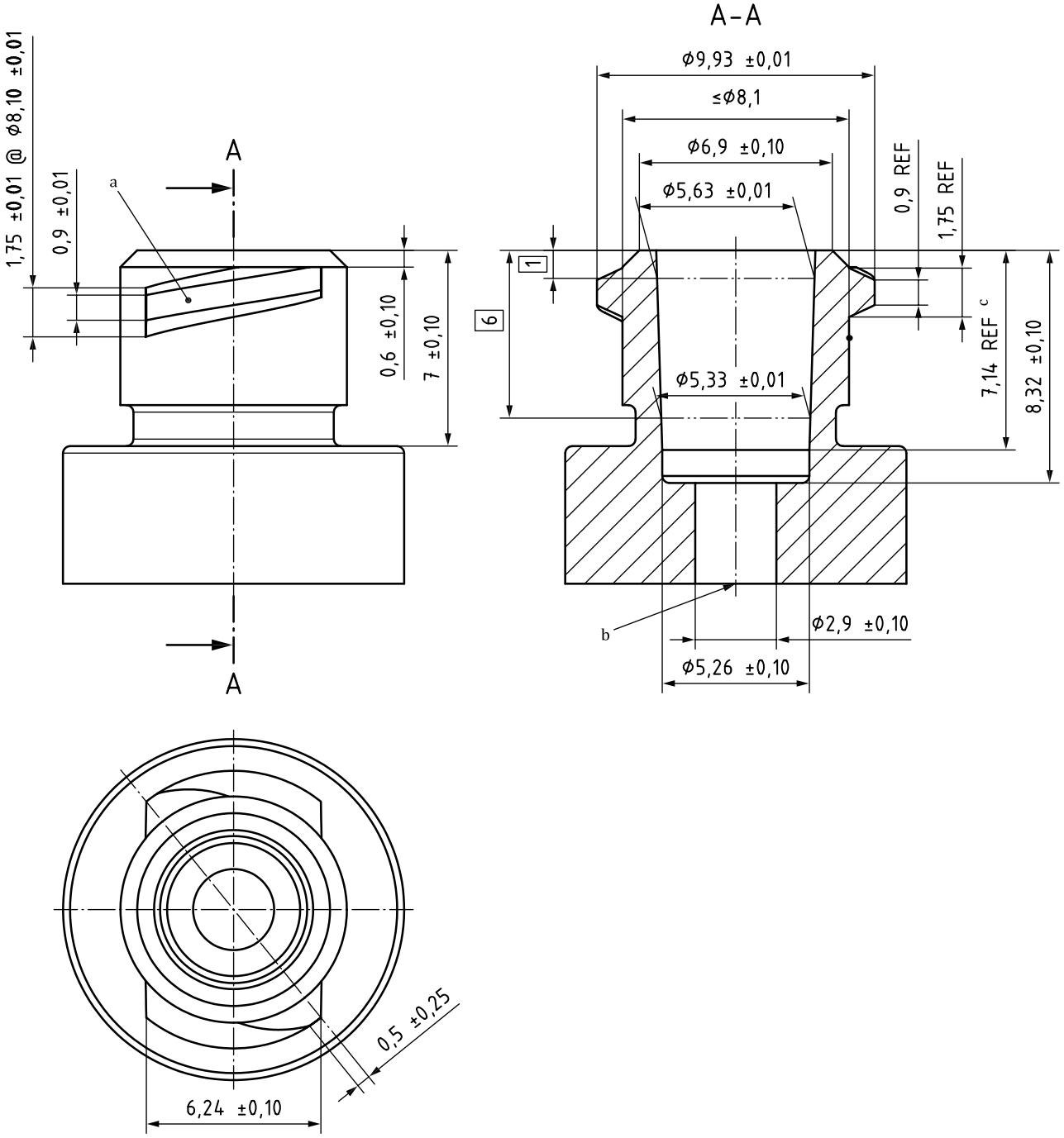
Reference CONNECTORS

C.1 General requirements for reference CONNECTORS

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

C.2 Reference CONNECTORS

Dimensions in millimetres unless otherwise indicated



Key

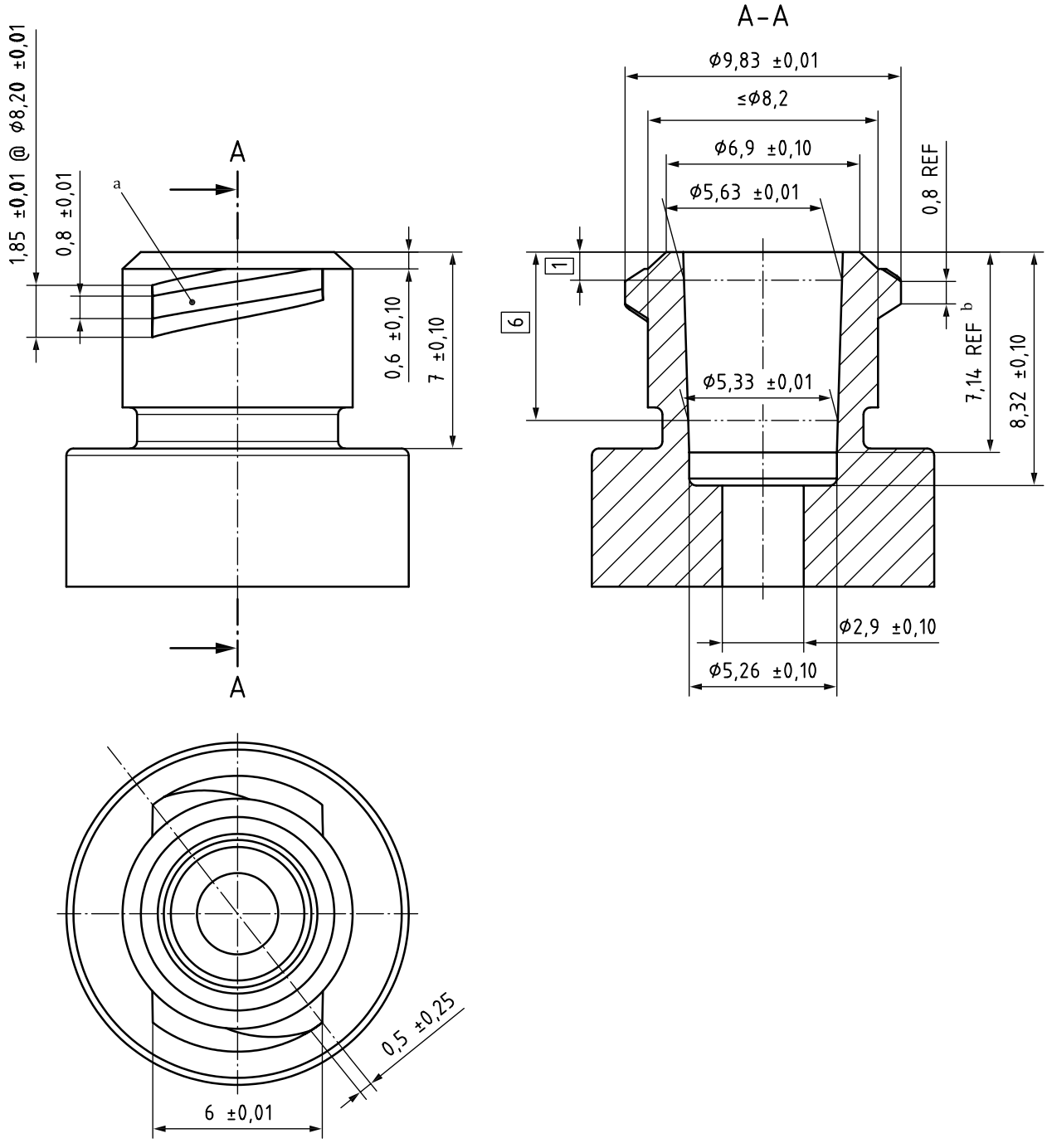
a 2,50 ± 0,05 thread pitch (5,0 thread lead).

b Fitting for leakage test required.

c Taper length.

Figure C.1 — Female reference CONNECTOR for testing male ENTERAL CONNECTOR for leakage, disconnection by unscrewing, separation from unscrewing, stress cracking, and NON-INTERCONNECTABLE characteristics

Dimensions in millimetres unless otherwise indicated



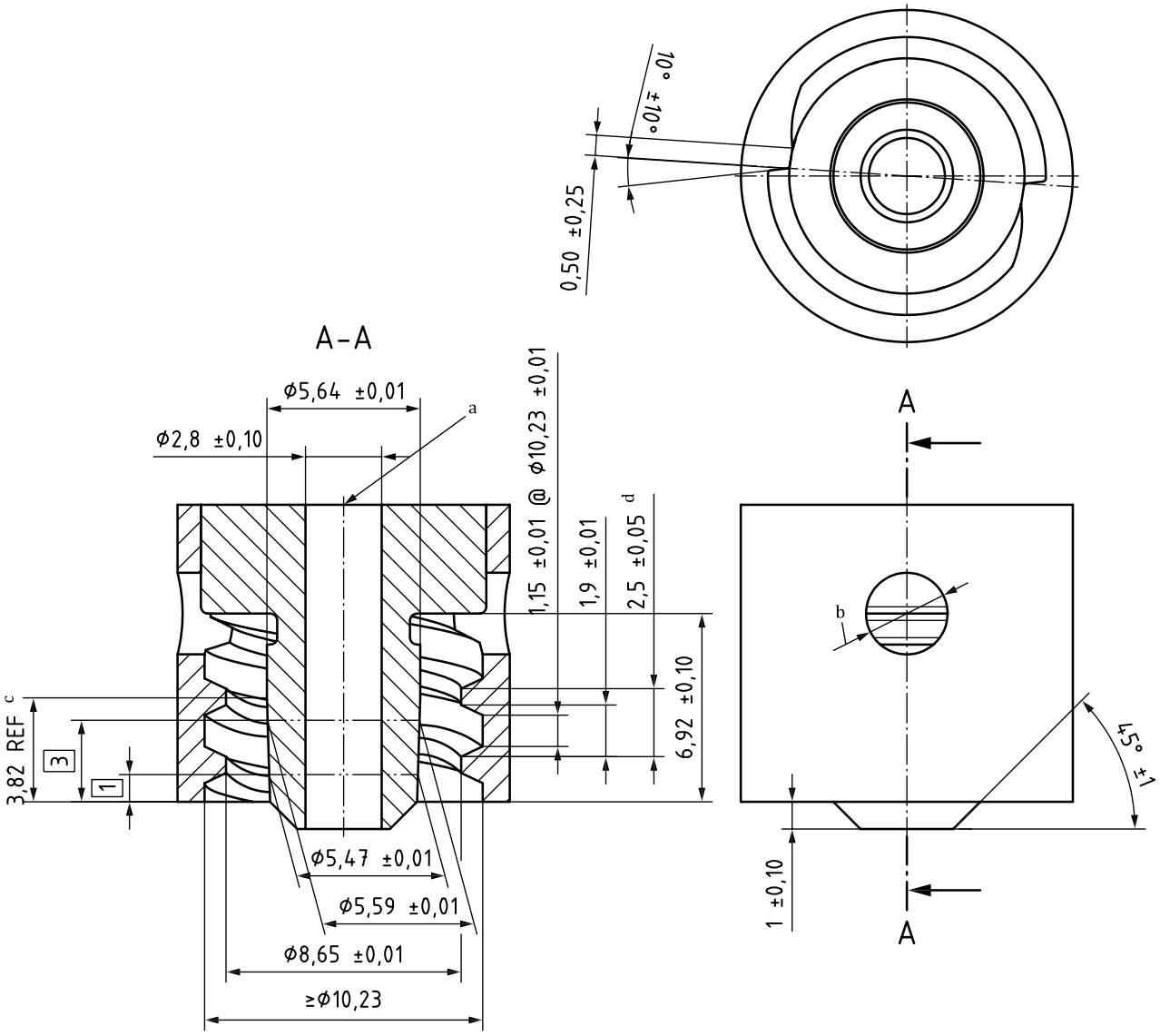
Key

a 2,50 ± 0,05 thread pitch (5,0 thread lead).

b Taper length.

Figure C.2 — Female reference CONNECTOR for testing male ENTERAL CONNECTOR for separation from axial load, resistance to overriding, and NON-INTERCONNECTABLE characteristics

Dimensions in millimetres unless otherwise indicated



Key

a Fitting for leakage test required.

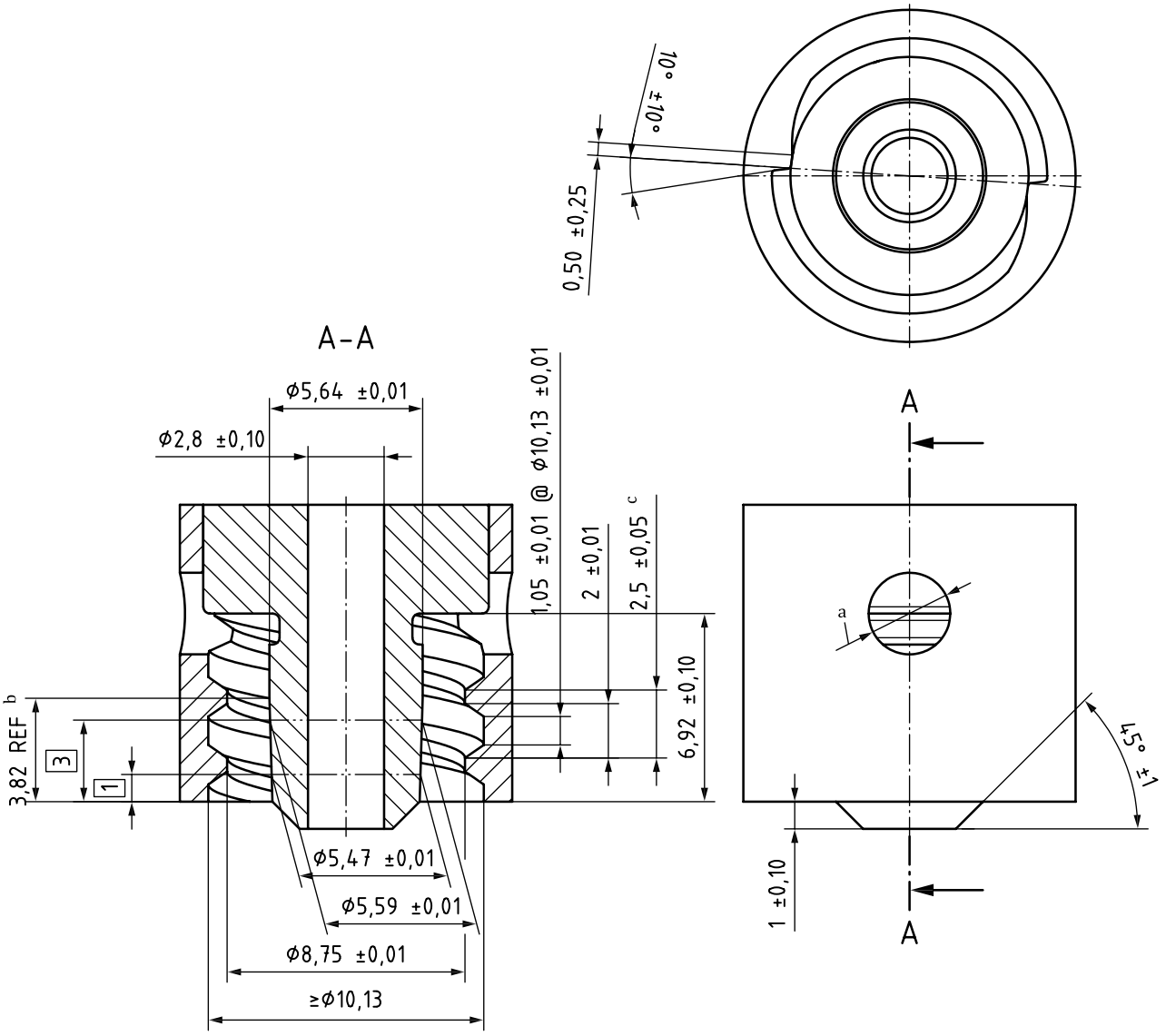
b Optional hole.

c Taper length.

d 5,0 thread lead.

Figure C.3 — Male reference CONNECTOR for testing female ENTERAL CONNECTOR for leakage, disconnection by unscrewing, separation from unscrewing, stress cracking, and NON-INTERCONNECTABLE characteristics

Dimensions in millimetres unless otherwise indicated



Key

a Optional hole.

b Taper length.

c 5,0 thread lead.

Figure C.4 — Male reference CONNECTOR for testing female ENTERAL CONNECTOR for separation from axial load, resistance to overriding, and NON-INTERCONNECTABLE characteristics

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 with ENTERAL APPLICATIONS. The table contains an assessment by the working group of the important attributes of MEDICAL DEVICES and ACCESSORIES as they relate to the intended CONNECTION. Each CONNECTION is assessed according to the following index of subgroups:

a) ENTERAL giving set, distal CONNECTIONS;

B) ENTERAL feeding sets (catheter) CONNECTIONS;

C) Syringe CONNECTIONS;

D) ACCESSORY CONNECTIONS;

E) ENTERAL drainage set CONNECTIONS.

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 giving set CONNECTIONS	0 to 3 000	300	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
ENTERAL feeding set (catheter) CONNECTIONS	0 to 3 000	300	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Syringe CONNECTIONS	0 to 3 000	300	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Accessory CONNECTIONS	0 to 3 000	300	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
ENTERAL drainage set CONNECTIONS	0 to 3 000	300	Yes	Yes	Yes	Yes	No	Yes	No	Yes

Annex E
(informative)

Summary of the usability requirements for SMALL-BORE 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 SMALL-BORE 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 MEDICAL DEVICE, ACCESSORY, PROCESS or service in accordance with the specifications, instructions and information provided by the MANUFACTURER.

USERS include the following:

a) PATIENTS, as the persons undergoing a medical, surgical, or dental procedure that are also expected to perform an intended action;

b) clinical USERS, as

   — physicians, physician's assistants, at all levels,

   — nurses, at all levels,

   — home-care providers, visiting nurses, and relatives,

   — pharmacists and 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 SMALL-BORE CONNECTORS for ENTERAL APPLICATIONS can differ by USER group and are comprised of the multitude of sub-APPLICATIONS of the CONNECTORS with different sub-specialities.

A summary of ENTERAL feeding (actual delivery of nutrients into the GI 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**
	Medical and surgical PATIENTS		**X**
Use environments	Medical and surgical wards		**X**
	Outpatient doctors' offices or clinics	**X**	**X**
	Emergency department		**X**
	Radiology		**X**
	Extended care facilities, including rehabilitation or 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**
	Adult medicine and surgery PATIENTS on wards		**X**
Use environments	Emergency department		**X**
	Interventional radiology		**X**
	Operating room area		**X**
	Extended care facilities including rehabilitation or 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**

A summary of decompression, suction of GI contents (removal of GI contents via suction, aspiration, or passive drainage) use scenarios by USER group is summarized in Table E.4.

Table E.4 — Use scenarios, decompression, and suction of GI content

	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**
	Adult medicine and surgery PATIENTS on wards		**X**

Table E.4 *(continued)*

	Use scenarios	PATIENTS/primary caregivers	Clinical USERS
Use environments	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**
	Home	**X**	**X**

A summary of delivery of radiologic contrast material (delivery of contrast material into the GI tract) use scenarios by USER group is summarized in Table E.5.

Table E.5 — Use scenarios, delivery of radiologic contrast material

	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**
	Adult medicine and surgery PATIENTS on wards		**X**
Use environments	Emergency department		**X**
	Interventional radiology		**X**
	Operating room area		**X**

E.3 Use environments

E.3.1 Facilities

Environments in which ENTERAL tubes are used include hospitals, surgical suites, PATIENT rooms, homes, ICUs, 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 in emergency medicine);

b) Body temperature, to 42 °C;

c) Hypothermia treatment, 10 °C;

d) ECMO, 10 °C to 43 °C (for hypo/normo/hyperthermia treatments);

e) 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 SMALL-BORE CONNECTORS:

a) proximity of liquids;

b) use of gloves;

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

d) duration, use-life (some tubes with PATIENT end CONNECTORS can be in place for more than 2 years);

e) low or variable light conditions;

f) ambient activity levels.

E.5 Generic USER needs

The following USER needs attributes are expected for ENTERAL SMALL-BORE CONNECTORS.

a) CONNECTORS should be easy to connect, disconnect, and manipulate, even with gloves. The CONNECTION must not require more force than the CONNECTION of LUER CONNECTORS (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. PATIENT end CONNECTIONS need to be durable, so that a secure fit is maintained over time.

b) CONNECTORS should have surfaces that are easy to keep clean (e.g. avoiding as much as possible areas where residual feed solution could collect 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 end of the feeding tube. 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. Required flow rate is under discussion.

g) The bore size also needs to be adequate to allow aspiration of gastric contents and passive drainage.

h) Preterm infants and sick newborns are probably the most important paediatric cohort of PATIENTS for whom ENTERAL tube feeding is used in combination with the use of intravenous, airway devices and ventilators on a daily basis. Therefore, CONNECTIONS in this PATIENT group are of ultimate importance.

   — The CONNECTOR needs to have external surfaces that are smooth in order not to hurt the fragile skin and to be small and lightweight to prevent bruising and dislocation.

   — Very small volumes (less than 0,1 ml) are sometimes administered and require precise dosage possibilities.

   — Gavage feeding is almost always milk (mostly human milk) and is sometimes administered by an open system with speed modulated by gravity.

   — CONNECTION needs to be secured with no RISK of disruption. Even a short interruption of feeding can cause hypoglycaemia.

i) The volume of the displacement when making a CONNECTION also matters. In a 500 g newborn infant, ENTERAL drugs are often prescribed in volumes as small as 0,1 ml or even 0,01 ml.

NOTE According to ISO 7886-1:1993, Table 1, for the smallest standard syringe, the tolerance on graduated capacity is ±(1,5 % of the nominal capacity + 2 % of the expelled volume).

j) It is important that education, training, and information be provided to all kinds of USERS, not just minimal pan-hospital MEDICAL DEVICE training. For example, USERS should be informed regarding management of CONNECTORS and giving sets to diminish the RISK of contamination.

k) Preferably, there should only be one type of ENTERAL CONNECTOR in a given locale (e.g. city) to ensure timely access in emergency or transport situations.

l) It is recommended that "devices" be labelled or coded in some way (e.g. with a symbol) to aid appropriate selection of ENTERAL equipment.

Annex F
(informative)

Summary of SMALL-BORE CONNECTOR criteria and requirements for ENTERAL APPLICATIONS

Table F.1 is a summary of the design criteria and requirements of the ENTERAL SMALL-BORE CONNECTOR.

Table F.1 — ENTERAL CONNECTOR-specific design criteria and requirements

	Criteria		Requirements	Remarks
1	**Fluid type**	a) Liquid b) Gas c) Both	c)	Accurately deliver fluid of 25 mPa·s to 150 mPa·s (25 cP to 150 cP).
2	**Operating pressure range**	maximum pressure minimum pressure subatmospheric? (yes/no)	Max. pressure, pump: 200 kPa Operating pressure: 0 kPa to 80 kPa Reservoir (gravity) pressure of 50 kPa Syringe (bolus) can differ	EN 1615 stipulates operating pressure of the pump and 50 kPa for CONNECTORS. ISO 594 stipulates 300 kPa to 330 kPa for 30 s.
3	**RATED pressure range**	minimum maximum	0 kPa to 300 kPa	ISO 594 stipulates 300 kPa to 330 kPa for 30 s
4	**Is there a need for a leak test?**	a)No b)Yes Reference for TEST METHOD	b)	ISO 594-2, 5.2 and 5.3
5	**RATED flow-rate range**	minimum maximum	Min: 0,1 ml/h Max:3 000 ml/hour water Bolus (plunger): 200 ml/min water, max. 3 000 ml/h 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	−40 °C 60 °C	
8	**Minimum range of CONNECTOR mating diameters**	minimum maximum	—	Incompatible with LUER CONNECTOR and other SMALL-BORE CONNECTORS of the ISO 80369- series.
9	**General layout**	a) Parallel-sided, O-ring seal b) Parallel-sided, other seal c) Conical d) Other (specify)	c) or d)	

Table F.1 *(continued)*

	Criteria		Requirements	Remarks
10	**Method of keying**	a) Collar b) Plug c) Other (specify)	none	Haptic features can be considered for inclusion.
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		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	EN 1615
18	**Construction materials** (excluding seals)	a) RIGID MATERIAL 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	d)	
21	**Stress-cracking resistance?**	a) No b) Yes Specify limits	b)	
22	**Externally, how is CONNECTOR to be distinguishable from LUER CONNECTOR?** (describe)		Shape and/or texture/ tactile.	
23	**Labelling/Symbols/ Marking?** (e.g. not for IV)	a) No 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) enteral mucosa	

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)	
27	**Decontamination needed?**	a) No, single use only b) Yes, cleaning and disinfection Indicate method c) Yes, cleaning and sterilization Indicate method	b) or c)	
28	**How is ISO 80369-2 incompatibility achieved?**	a) Dimensional b) Other Indicate method	a)	
29	**How is ISO 80369-3 incompatibility achieved?**	a) Dimensional b) Other Indicate method	This is the ENTERAL CONNECTOR.	
30	**How is ISO 80369-4 incompatibility achieved?**	a) Dimensional b) Other	Not yet defined.	
31	**How is ISO 80369-5 incompatibility achieved?**	a) Dimensional b) Other Indicate method	a)	
32	**How is ISO 80369-6 incompatibility achieved?**	a) Dimensional b) Other Indicate method	a)	N1 female to E1 female results in a leaky misconnection; see G.2.4.
33	**How is ISO 80369-7 incompatibility achieved?**	a) Dimensional b) Other Indicate method	a)	

Annex G
(informative)

Summary of assessment of the design of the CONNECTORS for ENTERAL APPLICATIONS

G.1 General

There are no known patents related to the CONNECTOR designs specified in this part of ISO 80369. The CONNECTOR depicted in Annex B uses a 6 % taper seal, with mating surface dimensions larger than the traditional LUER CONNECTOR. This design also incorporates other features to prevent this pair of CONNECTORS from either forming a fluid tight seal or being misconnected with other CONNECTORS defined in ISO 80369-1.

G.2 Summary of the engineering analysis of the design

G.2.1 NON-INTERCONNECTABLE analysis

A three-dimensional computer aided design (CAD) engineering analysis has been performed using computational analysis and 3D solid model constructs of all tolerances and material conditions (least, nominal, and maximum) for all CONNECTORS represented by the ISO 80369 series. The SMALL-BORE CONNECTORS specified in this part of ISO 80369 have been shown by engineering analysis to be NON-INTERCONNECTABLE with the other specified CONNECTORS of the ISO 80369 series with the exception of the following. Table G.1 summarizes the potential misconnections.

A Technical Report is planned to describe the PROCESS for the CAD engineering analysis more completely.

Table G.1 — Summary of possible misconnection from CAD analysis

E1	CONNECTOR of concern	Summary	Reference
male	N1 male	Physical testing per ISO 80369-1:2010, Annex B, results in no CONNECTION.	G.2.2
female	Luer slip connector female	Physical testing according ISO 80369-1:2010, Annex B, (except using all plastic parts) results in no CONNECTION.	G.2.3
female	N1 female	Physical testing according to ISO 80369-6:2015, Annex H, results in a leaky misconnection.	G.2.4
NOTE 1 N1 from ISO 80369-6. NOTE 2 LUER SLIP CONNECTOR from ISO 80369-7.			

G.2.2 E1 male to N1 male

Testing was performed according to the TEST METHOD of ISO 80369-1:2010, Annex B.

The test demonstrated that the CONNECTORS are NON-INTERCONNECTABLE.

G.2.3 E1 female to LUER SLIP CONNECTOR female

Testing was performed according to the TEST METHOD of ISO 80369-1:2010, Annex B, while substituting CONNECTORS of least material condition (LMC) and worstcase flexural modulus material (700 MPa to 720 MPa) for both the reference LUER SLIP CONNECTOR female, as specified in ISO 80369-7, and the E1

CONNECTOR being evaluated. The committee considers this modification of the TEST METHOD to be more conservative.

The test demonstrated that the CONNECTORS are NON-INTERCONNECTABLE.

G.2.4 E1 female to N1 female

In the engineering analysis, the sealing surface of female E1 CONNECTOR contacts the thread surfaces of the N1 female CONNECTOR, as specified in ISO 80369-6, in LMC conditions, and thereby these CONNECTORS will mutually fail the NON-INTERCONNECTABLE characteristics tests of ISO 80369-1:2010, Annex B.

Testing was performed according to the TEST METHOD of ISO 80369-6:2016, Annex H. Over 75 % of fluid intended to pass through the CONNECTION leaked.

The test demonstrated that the CONNECTORS are acceptable.

It is recommended that MANUFACTURERS use a material with the highest flexural modulus possible for the E1 female CONNECTOR for further RISK CONTROL.

G.3 Summary of the design VERIFICATION

This CONNECTOR design was selected based on the through bore similarity to currently marketed configurations and Newtonian fluid flow predictive evaluations through a range of orifice sizes smaller and larger than the 2,95 mm maximum diameter of the designated design. Flow studies have been conducted with E1 CONNECTORS (male and female) as specified in this part of ISO 80369 per the requirements of EN 1618:1997, Annex E using water, as specified, and commercial nutrition preparations. The E1 CONNECTOR produced flow rates with water in excess of 70 l/h and with formula in excess of 8,5 l/h. These flow rates meet or exceed the flow rate requirement of 3 l/h in Annex D.

The purpose of the performance testing protocol was to verify that the usage of the E1 SMALL-BORE CONNECTOR design can allow production of E1 CONNECTORS in compliance with the performance requirements defined in this part of ISO 80369 by applying the appropriate TEST METHODS defined in ISO 80369-20.

Because all of the tests are attribute tests (pass/fail), sample sizes can be determined from ISO 16269-6:2005, Annex F, for a one-sided distribution free statistical tolerance intervals. ISO 16269-6:2005, Table F.1, for 1 - α = 0,95 and P = 0,95, yields the required sample size was 59, which was rounded up to 60 for the sake of simplicity.

Since this protocol is intended to assess the capability of MANUFACTURERS to produce E1 CONNECTORS in compliance with the performance requirements defined of this part of ISO 80369 by applying the appropriate TEST METHODS defined in ISO 80369-20, the probability and confidence level are selected to be representative of the current acceptance criteria for common ENTERAL APPLICATIONS.

4.2 requires the tensile or flexural modulus of the material of the CONNECTOR to be greater than 700 MPa. In order to verify that the design of the ENTERAL SMALL-BORE CONNECTORS meets the functional requirements at the reasonable material conditions, the following materials were used for the indicated tests.

Polypropylene PP1 (760 MPa-tensile) or PP2 (700 MPa-tensile) for the following tests:

— fluid leakage by pressure decay TEST METHOD (6.1.2);

— fluid leakage by positive pressure liquid leakage TEST METHOD (6.1.3);

— resistance to separation from axial load (6.3);

— resistance to separation from unscrewing (6.4);

— resistance to overriding (6.5).

Styrene/acrylonitrile copolymer SAN (3 800 MPa) for the following tests:

— stress cracking (6.2);

— disconnection by unscrewing (6.6).

Conclusion:

The test results indicate the E1 design is compliant with the performance requirements specified in Clause 6 using the TEST METHODS defined in ISO 80369-20.

G.4 Summary of the design validation

G.4.1 General

A summative usability evaluation of the design specified in this part of ISO 80369 has been conducted with USERS representing intensive care unit (ICU) nurses, neonatal intensive care unit (NICU) nurses, and home caregivers.

Elements of usability standard IEC 62366:2007, including section D.5.13 were utilized in the development of the protocol. The home, ICU, and NICU critical care settings were simulated to complete this summative usability evaluation.

ENTERAL CONNECTOR systems are either used in a hospital or home/long term care (LTC) settings. Many hospital units, including the ICU, PICU, NICU, and the long term care facility, can be expected to have nurses interact with this type of ENTERAL CONNECTOR system multiple times daily on multiple PATIENTS. The home user group comprises USERS who use the CONNECTORS daily at home with a single PATIENT. For the summative usability evaluation, LTC USERS have been treated as the home user group category since they interact with CONNECTORS in a home environment.

The summative usability evaluation was designed to evaluate the following:

a) USERS do not attempt to connect male/female CONNECTOR from the ENTERAL CONNECTOR system to other ports coming out of the manikin's body.

b) USERS can successfully connect paired male/female ENTERAL CONNECTOR systems by twisting, or screwing, them into each other.

c) USERS can successfully administer enteral feeding or medication by having no leaks at the CONNECTION site due to participant error.

Since it is possible that nurses and home caregivers might receive little or no recent training on how to explicitly connect ENTERAL CONNECTOR systems, this summative evaluaton did not provide training or instructional materials in order to best simulate a worst case scenario. Moderators did not intervene at any point while participants were attempting tasks.

G.4.2 Test procedure

Each participant's session started with a brief introduction to the study and test setting. The moderator asked background questions about the USER's role and got additional information about experiences with ENTERAL medication/feeding administration.

The order of the tasks were counterbalanced and randomized so it was unlikely that multiple participants experienced the same sequence of tasks. This method reduced bias associated with the sequence in which the tasks were experienced by the participants.

Participants were instructed to verbally state when they were done with a task and were only asked follow up questions about their experience after the task was completed. USER-based evaluations (e.g. confidence to administer, ease-of-use, CONNECTION stability, and other subjective measures) were

asked to support root cause assessment of success/failure connection attempts, since the USER-based evaluations did not directly affect the overall success/fail criteria.

G.4.3 Test participants

53 USERS were recruited to represent a representative sample of potential USERS of the ENTERAL CONNECTOR systems in a clinical and home setting. All nurses had existing training with ENTERAL administration and all home USERS had experience with ENTERAL administration. Participants were categorized based on the environment in which they administered ENTERAL feeding medication:

— ICU nurses (n = 18);

— NICU nurses (n = 15);

— Home caregivers (n = 20).

These groups of caregivers represented a stratified sample of USERS in the United States. Previous research indicated that ICU, NICU, and home caregiver nurses are a reasonable representation of all intended USERS of ENTERAL CONNECTOR systems, including those outside the US. To ensure the testing reflected non-US practice as well as practice in the US, consultation was made in the protocol development, with members of the working group responsible for the usability testing who were experienced with non-US environments. The participants' average age was 43 years and ranged from 24 years to 61 years old.

Participant performance was measured along two dimensions:

a) Quantitative performance success and failure was scored for each of the three objectives:

   1) Locates paired male/female CONNECTORS to be used for ENTERAL administration

      — Success: Participant does not attempt to connect pump set/syringe to any tubing other than the ENTERAL feeding tube (NG or G tube).

      — Close Call: Failures avoided by vigilance on the part of the participant (i.e. participant begins to connect to the wrong port but corrects themselves before completing the task).

      — Failure: Any attempt to initially connect unpaired male/female parts of the ENTERAL CONNECTOR to other ports.

   2) Makes secure CONNECTION by fully twisting paired male/female parts together to lock CONNECTION

      — Success: Participant fully twists CONNECTORS to make a secure CONNECTION between the pump set/syringe and ENTERAL feeding tube (NG or G tube).

      — Close Call: Participant does not fully twist CONNECTORS at first, but realizes CONNECTION is not secure because CONNECTORS detach, become loose, or leaks.

      — Failure: Participant does not twist CONNECTORS to make secure CONNECTION, only pushes together.

   3) Administers ENTERAL feeding/medication

      — Success: Participant administers the entire ENTERAL medication or feeding as instructed, without leaks.

      — Failure: Participant does not administer the entire ENTERAL medication or feeding as instructed as a result of leaks due to participant error.

b) Qualitative:

   — Participant feedback and comments throughout the session;

— Usability issues observed;

— Root cause of any critical task failures;

— Post-task ease of use ratings.

G.4.4 Test results

ICU environment, 100 % success rate:

— Locates paired male/female CONNECTORS to be used for ENTERAL administration;

— Makes secure CONNECTION by fully twisting paired male/female parts to lock CONNECTION;

— Administers ENTERAL feeding/medication.

Implications for additional RISK CONTROL:

There were no close calls or failures in the ICU for the E1 CONNECTOR. Therefore, no additional RISK CONTROLS are required at this point in time.

NICU environment, 100 % success rate:

— Locates paired male/female CONNECTORS to be used for ENTERAL administration;

— Makes secure CONNECTION performance by fully twisting paired male/female parts to lock CONNECTION;

— Administers ENTERAL feeding/medication.

Implications for additional RISK CONTROL:

There were no close calls or failures in the NICU for the E1 CONNECTOR. Therefore, no additional RISK CONTROLS are required at this point in time.

Home environment, 100 % Success rate:

— Locates paired male/female CONNECTORS to be used for ENTERAL administration;

— Makes secure CONNECTION performance by fully twisting paired male/female parts to lock CONNECTION.

Home environment, 95 % Success rate:

— Administers ENTERAL feeding/medication.

ENTERAL administration in the home was successfully completed for the E1 CONNECTOR by 19 of 20 (95 %) participants. One participant who failed to fully administer the dose because of leaks did so because the G tube was not unclamped to allow the liquid to flow into the stomach.

Failed administration attempt for the E1 CONNECTOR in the home environment. Table G.1 summarizes the findings for the failed participant.

Table G.2 — Summary of findings for the failed participant

Participant number (P#)	Administration type	Reason(s) for failure	Root cause	Detailed explanations
56	Medication	Participant did not unclamp the G tube before starting the administration.	The failure was judged to be an artefact of the simulated use environment and inexperience with enteral medication administration.	Participant stated that they do not normally administer enteral medication as a caregiver. The participant was also hesitant about the task because they worried a mess would occur if the liquid was actually administered into the manikin.

G.4.5 Summative validation study conclusions

All participants were successfully able to locate paired male/female ENTERAL CONNECTOR systems for ENTERAL administration. The failed administration attempt was due to a use error but was not a critical failure.

G.5 Summary of the design review

The committee reviewed the assessment of the design of the E1 CONNECTORS based on the results reported in this Annex. ISO 80369-1:2010, Clause 7 gives the requirements for a CONNECTOR to be included as one of the CONNECTORS specified in ISO 80369-1:2010, Clause 5. Successful completion of requirements requires the combination of a material that is acceptably rigid with the design specified in Annex B.

In summary, the design review concludes there is significant objective engineering, technical, and simulated clinical evidence supporting the E1 CONNECTOR for the intended ENTERAL APPLICATION.

Annex H
(informative)

Reference to the essential principles

This part of ISO 80369 has been prepared to support the essential principles of safety and performance of SMALL-BORE CONNECTORS intended to be used for CONNECTIONS for ENTERAL APPLICATIONS of MEDICAL DEVICES and ACCESSORIES according to ISO/TR 16142. This part of ISO 80369 is intended to be acceptable for conformity assessment purposes.

Compliance with this part of ISO 80369 provides one means of demonstrating conformance with the specific essential principles of ISO/TR 16142. Other means are possible. Table H.1 maps the clauses and subclauses of this part of ISO 80369 with the essential principles of ISO/TR 16142.

Table H.1 — Correspondence between this part of ISO 80369 and the essential principles

Essential principle of ISO/TR 16142:2006	Corresponding clause(s)/sub-clause(s) of this part of ISO 80369	Qualifying remarks/Notes
A.1	—	Not applicable
A.2	—	Not applicable
A.3	—	Not applicable
A.4	—	Not applicable
A.5	—	Not applicable
A.6	—	Not applicable
A.7.1	—	Not applicable
A.7.2	—	Not applicable
A.7.3	—	Not applicable
A.7.4	—	Not applicable
A.7.5	Clause 4, Clause 5, Clause 6	—
A.7.6	Clause 4, Clause 5, Clause 6	—
A.8.1	—	Not applicable
A.8.1.1	—	Not applicable
A.8.1.2	—	Not applicable
A.8.2	—	Not applicable
A.8.3	—	Not applicable
A.8.4	—	Not applicable
A.8.5	—	Not applicable
A.8.6	—	Not applicable
A.9.1	Clause 4, Clause 5, Clause 6	—
A.9.2	—	Not applicable
A.9.3	—	Not applicable
A.10.1	—	Not applicable
A.10.2	—	Not applicable
A.10.3	—	Not applicable
A.11.1.1	—	Not applicable
A.11.2.1	—	Not applicable
A.11.2.2	—	Not applicable

Table H.1 *(continued)*

Essential principle of ISO/TR 16142:2006	Corresponding clause(s)/sub-clause(s) of this part of ISO 80369	Qualifying remarks/Notes
A.11.3.1	—	Not applicable
A.11.4.1	—	Not applicable
A.11.5.1	—	Not applicable
A.11.5.2	—	Not applicable
A.11.5.3	—	Not applicable
A.12.1	—	Not applicable
A.12.2	—	Not applicable
A.12.3	—	Not applicable
A.12.4	—	Not applicable
A.12.5	—	Not applicable
A.12.6	—	Not applicable
A.12.7.1	—	Not applicable
A.12.7.2	—	Not applicable
A.12.7.3	—	Not applicable
A.12.7.4	Clause 4, Clause 5, Clause 6	—
A.12.7.5	—	Not applicable
A.12.8.1	Clause 4, Clause 5, Clause 6	—
A.12.8.2	—	Not applicable
A.12.8.3	—	Not applicable
A.13.1	—	Not applicable
A.14.1	—	Not applicable

Annex I
(informative)

Terminology — Alphabetized index of defined terms

NOTE The ISO Online Browsing Platform (OBP) provides access to terms and definitions.[2)]

Term	Source
ACCESSORY	ISO 80369-1:2010, 3.1
APPLICATION	ISO 80369-1:2010, 3.2
BREATHING SYSTEM	ISO 80369-1:2010, 3.3
CONNECTION	ISO 80369-1:2010, 3.4
CONNECTOR	ISO 80369-1:2010, 3.5
ENTERAL	3.1
HARM	ISO 14971:2007, 2.2
INTENDED USE	ISO 14971:2007, 2.5
LUER CONNECTOR	ISO 80369-7:2015, 3.1
LUER SLIP CONNECTOR	ISO 80369-7:2015, 3.2
MANUFACTURER	ISO 14971:2007, 2.8
MEDICAL DEVICE	ISO 14971:2007, 2.9
NON-INTERCONNECTABLE	ISO 80369-1:2010, 3.6
NORMAL USE	3.2
PATIENT	ISO 80369-1:2010, 3.7
PROCEDURE	ISO 14971:2007, 2.12
PROCESS	ISO 14971:2007, 3.17
RATED	3.3
RESPONSIBLE ORGANIZATION	ISO 80369-1:2010, 3.8
RIGID MATERIAL	ISO 80369-1:2010, 3.9
RISK	ISO 14971:2007, 2.16
RISK ASSESSMENT	ISO 14971:2007, 2.18
RISK CONTROL	ISO 14971:2007, 2.19
SEMI-RIGID MATERIAL	ISO 80369-1:2010, 3.10
SMALL-BORE	ISO 80369-1:2010, 3.11
TEST METHOD	ISO 80369-20:2015, 3.1
TYPE TEST	ISO 80369-20:2015, 3.2
USER	3.4
USER PROFILE	3.5
VERIFICATION (VERIFIED)	ISO 14971:2007, 2.28

2) Available at https://www.iso.org/obp/ui/#home.

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3) Revises ISO 5356-1:2004.

4) Revises ISO 5356-2:2006.

5) Revises EN 13544-2:2002.

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