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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
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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·m³/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