
**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

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

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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](#).

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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.