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First edition  
2016-07-01

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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](http://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](http://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.

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## 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.

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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](#).