INTERNATIONAL STANDARD

ISO 80369-1

Second edition
2018-11

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

Part 1: General requirements

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

Partie 1: Exigences générales

Reference number
ISO 80369-1:2018(E)

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Published in Switzerland

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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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, in collaboration with IEC/TC 62, *Electrical equipment in medical practice,* Subcommittee SC D, *Electromedical equipment* and CEN/CENELEC TC 3/WG 2, *Small-bore connectors*.

This second edition cancels and replaces the first edition (ISO 80369-1:2010), which has been technically revised.

A list of all parts in the ISO 80369 series can be found on the ISO website.

The main changes compared to the previous edition are as follows:

— the normative references have been updated;

— the requirement for Alternative SMALL-BORE CONNECTORS, including disclosure and marking requirements have been updated;

— in Annex B, the TEST METHODS for demonstrating NON-INTERCONNECTABLE CHARACTERISTICS to reflect the testing used in the development of ISO 80369-2, ISO 80369-3, IEC 80369-5, ISO 80369-6 and ISO 80369-7 have been updated;

— Annex D has been created with the Assessment PROCEDURES SMALL-BORE CONNECTORS which replaces Clause 7 of the previous edition and contains a description of the computer aided design (CAD) analysis that was used in the evaluation of the NON-INTERCONNECTABLE characteristics.

A list of all parts in the ISO 80369 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

In the 1990s, concern grew regarding the proliferation of MEDICAL DEVICES fitted with Luer CONNECTORS as specified in ISO 80369-7 and the reports of PATIENT death or injury arising from misconnections that resulted in the inappropriate delivery of enteral solutions, intrathecal medication or compressed gases.

Concerns regarding the use of Luer CONNECTORS with enteral feeding tubes and gas sampling and gas delivery systems were raised with CEN/BT and the European Commission. In November 1997, the newly created CHeF steering group set up a Forum Task Group (FTG) to consider the problem.

The FTG produced CEN Report, CR 13825[12], in which they concluded that there is a problem arising from the use of a single CONNECTOR design to a number of incompatible APPLICATIONS. In a coronary care unit, there are as many as 40 Luer CONNECTORS on the MEDICAL DEVICES used with a single PATIENT. Therefore, it is not surprising that misconnections are made.

MEDICAL DEVICES have, for many years, followed the established principle of "safety under single fault conditions". Simply stated, this means that a single fault should not result in an unacceptable RISK. This principle is embodied in the requirements of numerous MEDICAL DEVICE standards[10]. Extending this principle to the use of Luer CONNECTORS, i.e. that misconnection should not result in an unacceptable RISK to a PATIENT, the FTG recommended that the Luer CONNECTOR should be restricted to MEDICAL DEVICES intended to be connected to the vascular system or a hypodermic syringe. In addition, new designs of SMALL-BORE CONNECTORS should be developed for other APPLICATIONS, and these should be NON-INTERCONNECTABLE with Luer CONNECTORS and each other.

ISO 16142-1 addresses this type of problem in Essential Principle B.1.2 (see Annex F):

— The solutions adopted by the manufacturer for the design and manufacture of the medical device should conform to safety principles, taking into account the generally acknowledged state of the art. When risk reduction is required the manufacturer should control the risks so that the residual risk associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed:

  a) identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse;

  b) eliminate risks as far as reasonably practicable through inherently safe design and manufacture;

  c) reduce as far as reasonably practicable the remaining risks by taking adequate protection measures, including alarms, or information for safety;

  d) inform users of any residual risk.

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. This will only be achieved through a long-term commitment involving industry, healthcare professionals, MEDICAL DEVICE purchasers and MEDICAL DEVICE regulatory authorities.

The ISO 80369 series has, wherever practicable, restricted the number of CONNECTORS for each APPLICATION to one, unless there is sufficient clinical or technical evidence to have more.

It is expected that particular MEDICAL DEVICE standards will reference the interface requirements from the appropriate parts of the ISO 80369 series.

This document contains the general requirements to ensure the prevention of misconnection between SMALL-BORE CONNECTORS used in different APPLICATIONS as well as defining those APPLICATIONS.

It specifies the general requirements and TEST METHODS for assessing the NON-INTERCONNECTABLE characteristics of SMALL-BORE CONNECTORS within the ISO 80369 series.

ISO 80369-20 specifies the TEST METHODS for assessing the basic performance requirements specified in ISO 80369-2 to ISO 80369-7 for SMALL-BORE CONNECTORS.

ISO 80369-2 to ISO 80369-7 specify the dimensional requirements for the interfaces of the CONNECTORS and the basic performance requirements for assessing the CONNECTION interconnectability of the CONNECTOR-mating halves.

The designs and dimensions of SMALL-BORE CONNECTORS specified in ISO 80369-2 to ISO 80369-7 have been successfully assessed according to the requirements of this document (i.e. have been proven to be acceptable with regard to the RISK of misconnection with the other CONNECTORS of this series).

Subsequent parts of this series are expected to include requirements with regard to the CONNECTORS used in different APPLICATION categories.

In this document, the following print types are used:

— requirements and definitions: roman type;

— informative material appearing outside of tables, such as notes, examples and references, and normative text of tables: in smaller type;

— terms defined in Clause 3 of this document or as noted: SMALL CAPITALS TYPE.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

— "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.

The attention of Member Bodies is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than three years from the date of publication for equipment newly designed and not earlier than five years from the date of publication for equipment already in production.

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

Part 1: General requirements

1 *Scope

This document specifies general requirements for SMALL-BORE CONNECTORS, which convey liquids or gases in healthcare APPLICATIONS. These SMALL-BORE CONNECTORS are used in MEDICAL DEVICES or ACCESSORIES intended for use with a PATIENT.

This document also specifies the healthcare fields in which these SMALL-BORE CONNECTORS are intended to be used.

These healthcare fields include, but are not limited to:

— BREATHING SYSTEMS and driving gases;

— enteral;

— limb cuff inflation;

— neuraxial;

— intravascular or hypodermic.

This document provides the methodology to assess NON-INTERCONNECTABLE characteristics of SMALL-BORE CONNECTORS based on their inherent design and dimensions in order to reduce the RISK of misconnections between MEDICAL DEVICES or between ACCESSORIES for different APPLICATIONS as specified in this document as well as those that will be developed under future parts of the ISO 80369 series.

This document does not specify requirements for the MEDICAL DEVICES or ACCESSORIES that use these SMALL-BORE CONNECTORS. Such requirements are given in particular International Standards for specific MEDICAL DEVICES or ACCESSORIES.

NOTE 1 Clause 7 allows for additional designs of SMALL-BORE CONNECTORS for new APPLICATIONS for inclusion in the ISO 80369 series.

NOTE 2 MANUFACTURERS are encouraged to incorporate the SMALL-BORE CONNECTORS specified in the ISO 80369 series into MEDICAL DEVICES, medical systems 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, the risks associated with changing to the new SMALL-BORE CONNECTORS as specified in the ISO 80369 series of standards will be considered.

NOTE 3 The CONNECTORS specified in the ISO 80369 series are intended for use only in their specified APPLICATION. Use of these CONNECTORS for other APPLICATIONS increases RISK that a hazardous misconnection could occur.

NOTE 4 MANUFACTURERS and RESPONSIBLE ORGANIZATIONS are encouraged to report their experience with the SMALL-BORE CONNECTORS specified in the ISO 80369 series to the Secretariat of ISO/TC 210 so that this feedback can be considered during the revision of the relevant part of the ISO 80369 series.

2 *Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 80369-3, *Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications*

IEC 80369-5, *Small-bore connectors for liquids and gases in healthcare applications — Part 5: Connectors for limb cuff inflation applications*

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

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*