SLOVENSKI STANDARD
oSIST prEN ISO 80369-1:2023

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Priključki z majhnim premerom za tekočine in pline za uporabo v zdravstvu - 1. del: Splošne zahteve (ISO/DIS 80369-1:2023)

Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements (ISO/DIS 80369-1:2023)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 1: Allgemeine Anforderungen (ISO/DIS 80369-1:2023)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 1: Exigences générales (ISO/DIS 80369-1:2023)

Ta slovenski standard je istoveten z: **prEN ISO 80369-1**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

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ISO/DIS 80369-1

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

Part 1:
General requirements

ICS: 11.040.20; 11.040.10

Member bodies are requested to consult relevant national interests in IEC/SC 62D before casting their ballot to the e-Balloting application.

This document is circulated as received from the committee secretariat.

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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 third edition cancels and replaces the second edition (ISO 80369-1:2018), which has been technically revised.

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

— the normative references have been updated;

— reformatted according to most recent Central Secretariat editing rules;

— added respiratory *applications*; and

— extended the use of the ISO 80369-7 *connector* to *medical devices* and *accessories* beyond intravascular and hypodermic *applications* where the *risk* is acceptable.

A list of all parts in the ISO and IEC 80369 series can be found on the ISO and IEC websites.

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 594 series and the reports of *patient* death or injury arising from *unintended connections* that resulted in the inappropriate delivery of fluids and gases via incorrect routes. In addition to clinical and workplace protocols and warnings, attention was turned to engineering solutions to reduce the probability of wrong route administration of liquids and 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[7], in which they concluded that there is a problem arising from the use of a single *connector* design to several different *applications*. In a coronary care unit, there were as many as 40 *Luer connectors* on the *medical devices* used with a single *patient* until the use of *connectors* defined in the ISO and IEC 80369 documents started to be established. Therefore, it is not surprising that *unintended connections* were 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[5]. Extending this principle to the use of *Luer connectors* (i.e., that an *unintended connection* 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, the FTG recommended that 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 16142-1:2016 addresses this type of problem in Essential Principle 2 of Table B.1:

> 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 *unintended connections* and potential for wrong route administration or to eliminate deliberate misuse. With these *application*-specific *connectors* now available, there is a much safer environment for *patients* and the potential of *unintended connections* is reduced with reduction of the *risk* of wrong route administration and thus improved *patient* safety. Introduction of *medical devices* and *accessories* utilizing these *small-bore connectors* is progressing albeit slowly.

The *risks* associated with *unintended connections* and subsequent wrong route administration of liquids and gasses cannot be fully assessed until these *small-bore connectors* are part of a *medical device* or *accessory*. Therefore, the intended *applications* specified are recommendations. It is expected that particular *medical device* standards will reference the *connectors* from the relevant parts of the ISO and IEC 80369 series if considered appropriate.

This document contains the general requirements to reduce *connections* between *small-bore connectors* used in different *applications* as well as specifying those *applications*.

It specifies the general requirements and *test methods* for assessing the *non-interconnectable* characteristics of *small-bore connectors* within the ISO and IEC 80369 series.

The *Luer connector* as originally defined in the withdrawn ISO 594 series has been widely used on many *medical devices* and *accessories* and in a wide range of clinical *applications* for many years. The clinical *applications* that present the highest *risk* to a *patient* from wrong route administration of liquids and gases have been identified and are those included in the *application* parts of the ISO and IEC 80369 series. ISO 80369-7, which replaces the ISO 594 series (i.e., the *Luer connector*), is intended for use with intravascular or hypodermic *applications.*

However, there are currently *medical devices* and *accessories* which incorporate a *Luer connector*, but do not fall into any of the *applications* specified by the ISO and IEC 80369 series. There are also some *medical devices* and *accessories* within the *applications* of the ISO and IEC 80369 series *applications* that incorporate a *Luer connector*. Those that present no unacceptable *risk* to the *patient* from an *unintended connection* to a *medical device* or *accessory* within intravascular or hypodermic *application* are suitable for consideration for the use of the *Luer connector* as specified in ISO 80369-7.

ISO 80369-20 specifies the common *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 specific performance requirements for assessing the 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).

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.

In this document the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— "can" is used to describe a possibility or capability.

Requirements in this document have been decomposed so that each requirement is uniquely delineated. This is done to support automated requirements tracking.

Small-bore connectors for liquids and gases in healthcare applications —Part 1: General requirements

1 Scope

NOTE 1 There is guidance or rationale for this Clause contained in Clause A.2.

This document specifies general requirements for *small-bore connectors* that form part of a *medical device* or *accessory* that conveys liquids or gases to a *patient*.

This document also identifies the *applications* for which these *small-bore connectors* are intended to be used, which include, but are not limited to:

— respiratory;

— enteral;

— limb cuff inflation;

— neural;

— intravascular or hypodermic.

This document provides the methodology to assess *non-interconnectable* characteristics of *small-bore connectors* based on their inherent design 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 might be developed under future parts of the ISO and IEC 80369 series.

This document specifies the *small-bore connector*-related interface requirements for the *medical devices* and *accessories* that use these *small-bore connectors*.

These interface requirements reduce the *risk* of wrong route administration of liquids or gases between the *medical device* or *accessory* by incorporating these *small-bore connectors* in different *applications*.

NOTE 2 6.1 allows for additional designs of *small-bore connectors* for inclusion in the ISO and IEC 80369 series.

NOTE 3 *Manufacturers* are encouraged to incorporate the *small-bore connectors* specified in the ISO and IEC 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 and IEC 80369 series of documents will be considered.

NOTE 4 *Manufacturers* and other entities including those accountable for the use of a *medical device* and the clinical incident monitoring are encouraged to report their experience with the *small-bore connectors* specified in the ISO and IEC 80369 series to the Committee Manager of ISO/TC 210 so that this feedback can be considered during the revision of the relevant part of the ISO and IEC 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 14971:2019, *Medical devices — Application of risk management to medical devices*

ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*

ISO 80369-2:—[1], *Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for respiratory applications*

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 neural applications*

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

IEC 62366-1:2015+AMD1:2020, *Medical devices — Part 1: Application of usability engineering to medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14971:2019 and IEC 62366-1:2015+AMD1:2020 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
accessory
additional part(s) for use with a *medical device* in order to:

— achieve the *intended use*;

— adapt it to some special use;

— facilitate its use;

— enhance its performance; or

— enable its functions to be integrated with those of other *medical devices*

[SOURCE: IEC 60601-1:2005, 3.3, modified — replaced “equipment” with “a *medical device*”.]

3.2
application
specific healthcare use

Note 1 to entry: Annex D lists examples of uses of the *applications* of *small-bore connectors.*

[1] Under preparation. Stage at the time of publication: ISO/FDIS 80369-2:2023.

3.3
connection
union or joining of two *connectors* (3.4)

3.4
connector
part of a *medical device*, consisting of one of two mating halves and designed to join a conduit to convey liquids or gases

3.5
contactable surface
any surface on a *connector* (3.4) that has an interaction potential in which physical contact occurs with any other surface on an opposing *connector*

Note 1 to entry: *Contactable surfaces* may include, but are not limited to, sealing surfaces as intended by design, crest geometry of external or internal threads, faces, shrouds, grips, etc. These are surfaces on a *connector* that can possibly interact with another *connector*.

3.6
information for safety
information provided to the *user* or responsible organization as a *risk control* measure

EXAMPLE 1 Warnings, precautions or contraindications.

EXAMPLE 2 *Instructions for the use* of a *medical device* or *accessory* to prevent use error or avoid a *hazardous situation*.

EXAMPLE 3 Explanation of a safety feature of a *medical device*.

Note 1 to entry: *Information for safety* may be found in any or all types of information supplied by the *manufacturer*.

Note 2 to entry: *Information for safety* can be located on the display of a *medical device*.

[SOURCE: ISO 20417:2021, 3.9]

3.7
instructions for use
IFU
portion of the accompanying information that is essential for the safe and effective use of a *medical device* or *accessory* (3.1) directed to the *user* of the *medical device*

Note 1 to entry: For the purposes of this document, a *user* can be either a lay *user* or professional *user* with relevant specialized training.

[SOURCE: ISO 20417:2021, 3.11, modified — deleted notes 2 to 5.]

3.8
interference test part
component that physically represents a *small-bore* (3.15) *connector* (3.4) or *connector* feature

Note 1 to entry: An *interference test part* is used to evaluate whether a *contactable surface* (3.5) can misconnect with the *small-bore connector* being evaluated.

Note 2 to entry: *Contactable surfaces* are identified during the dimensional analysis per B.2.

3.9
least material condition
LMC
condition in which a feature contains the least amount of material within the stated tolerance

EXAMPLES Maximum hole diameter, minimum shaft diameter.

3.10
Luer connector
small-bore (3.15) *connector* (3.4) that contains a conical mating surface with a 6 % (Luer) taper intended for use in intravascular or hypodermic *applications* (3.2) of *medical devices* and related *accessories* (3.1)

Note 1 to entry: A *Luer connector* can be either a Luer slip *connector* or a Luer lock *connector*.

[SOURCE: ISO 80369-7:2021, 3.2, modified — deleted note 2.]

3.11
marking
information, in text or graphical format, durably affixed, printed, etched (or equivalent) to a *medical device* or *accessory* (3.1)

Note 1 to entry: For the purposes of this document, the term *marked* is used to designate the corresponding act.

Note 2 to entry: For the purposes of this document, *marking* is different from 'direct *marking*' as commonly described in unique device identification (UDI) standards and regulations. A UDI 'direct *marking*' is a type of *marking*.

[SOURCE: ISO 20417:2021, 3.16, modified — deleted note 3.]

3.12
maximum material condition
MMC

condition in which a feature contains the maximum amount of material within the stated tolerance

EXAMPLE Minimum hole diameter, maximum shaft diameter.

3.13
misconnection
connection (3.3) between two *connectors* (3.4) of a different type

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.69]

3.14
non-interconnectable
having characteristics which incorporate geometries or other features that prevent different *connectors* (3.4) from making a *connection* (3.3)

3.15
patient
person undergoing a medical, surgical or dental *procedure*

[SOURCE: IEC 60601-1:2005+A1:2012, 3.76, modified — replaced "living being (person or animal)" with "person" and deleted the note.]

3.16
small-bore
inner-fluid pathway of a *connection* (3.3) with a diameter less than 8,5 mm

Note 1 to entry: For the purposes of this document, the 8,5 mm cone and socket of ISO 5356-1 is not considered a *small-bore connector*

3.17
test method
definitive *procedure* for evaluating *connectors* (3.4) that produces a test result

3.18
unintended connection
connection (3.3) between two *connectors* (3.4) of the same type for different use cases

4 *Small-bore connector non-interconnectable* requirement

NOTE 1 There is guidance or rationale for this Clause contained in Clause A.2.

Small-bore connectors of each *application* category specified in this document shall be *non-interconnectable* with any of the *small-bore connectors* of every other *application* category unless otherwise indicated within the ISO and IEC 80369 series.

Check conformity by confirming that *objective evidence* demonstrates that the acceptability criteria specified in Annex B are met.

The use of a *connector* specified by the ISO and IEC 80369 series is considered as *objective evidence* that the acceptability criteria specified in Annex B are met.

NOTE 2 For the purpose of this document, dimensional conformity and modulus of elasticity conformity with the requirements of the various *application* parts of the ISO and IEC 80369 series is considered sufficient *objective evidence* of *non-interconnectable* characteristics.

5 *Small-bore connectors* for clinical *applications*

NOTE 1 There is guidance or rationale for this Clause contained in Clause A.2.

NOTE 2 Annex D lists examples of the sort of *medical devices* or *accessories* for which the *small-bore connectors* within each *application* are intended.

5.1 *Small-bore connectors* for new clinical *applications*

Designs of *small-bore connectors* other than those specified in 5.2 to 5.6, for inclusion in the ISO and IEC 80369 series, and used in *medical devices* or *accessories* intended for use with a *patient*, shall meet the requirements of Annex C.

Check conformity by application of Annex C.

5.2 *Small-bore connectors* for respiratory *applications*

Small-bore connectors intended to be used for *connections* in the respiratory *application* shall conform with:

a) ISO 80369-2, unless the use of these *connectors* creates an unacceptable *risk* for a specific *medical device* or *accessory,* or

b) Clause 6.

Check conformity by inspection of the documentation demonstrating that the *small-bore connector* conforms to the requirements of ISO 80369-2 or, in case of alternative *connectors* as per Clause 6, by applying the performance tests of ISO 80369-2 using appropriate *reference connectors* for the alternative design.

5.3 *Small-bore connectors* for enteral *applications*

Small-bore connectors intended to be used for *connections* in the enteral *application* shall conform with:

a) ISO 80369-3, unless the use of these *connectors* creates an unacceptable *risk* for a specific *medical device* or *accessory,* or

b) Clause 6.

Check conformity by inspection of the documentation demonstrating that the *small-bore connector* conforms to the requirements of ISO 80369-3 or, in case of alternative *connectors* as per Clause 6, by applying the performance tests of ISO 80369-3 using appropriate *reference connectors* for the alternative design.

5.4 *Small-bore connectors* for limb cuff inflation *applications*

Small-bore connectors intended to be used for *connections* in limb cuff inflation *application* shall conform with:

a) IEC 80369-5, unless the use of these *connectors* creates an unacceptable *risk* for a specific *medical device* or *accessory,* or

b) Clause 6.

Check conformity by inspection of the documentation demonstrating that the *small-bore connector* conforms to the requirements of IEC 80369-5 or, in case of alternative *connectors* as per Clause 6, by applying the performance tests of IEC 80369-5 using appropriate *reference connectors* for the alternative design.

5.5 *Small-bore connectors* for neural *applications*

Small-bore connectors intended to be used for *connections* in neural *application* shall conform with:

a) ISO 80369-6, unless the use of these *connectors* creates an unacceptable *risk* for a specific *medical device* or *accessory,* or

b) Clause 6.

Check conformity by inspection of the documentation demonstrating that the *small-bore connector* conforms to the requirements of ISO 80369-6 or, in case of alternative *connectors* as per Clause 6, by applying the performance tests of ISO 80369-6 using appropriate reference *connectors* for the alternative design.

5.6 *Small-bore connectors* for intravascular and hypodermic *applications*

Small-bore connectors intended to be used for *connections* in intravascular or hypodermic *applications* shall conform with:

a) ISO 80369-7, unless the use of these *connectors* creates an unacceptable *risk* for a specific *medical device* or *accessory;* or

b) Clause 6.

Check conformity by inspection of the documentation demonstrating that the *small-bore connector* conforms to the requirements of ISO 80369-7 or, in case of alternative *connectors* as per Clause 6, by applying the performance tests acceptance criteria of ISO 80369-7 using appropriate *reference connectors* for the alternative design.

5.7 Other use cases utilizing an ISO 80369-7 *small-bore connector*

NOTE 1 There is guidance or rationale for this subclause contained in Clause A.2.