SLOVENSKI STANDARD
oSIST prEN ISO 80369-2:2021

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Priključki z majhnim premerom za tekočine in pline za uporabo v zdravstvu - 2. del: Priključki za respiratorno uporabo (ISO/DIS 80369-2:2021)

Small-bore connectors for liquids and gases in healthcare applications - Part 2: Connectors for respiratory applications (ISO/DIS 80369-2:2021)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 2: Verbindungsstücke für Atemsysteme und Antriebsgasanwendungen (ISO/DIS 80369-2:2021)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 2: Raccords destinés à des applications respiratoires (ISO/DIS 80369-2:2021)

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

Part 2:
Connectors for respiratory applications

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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. 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. 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

ISO 80369-2 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices* and IEC/TC 62, *Electrical equipment*, Subcommittee SC 62D, *Electrical equipment in medical practice*, in collaboration with the European Committee for Standardization (CEN) Technical Committee, CEN/CENELEC JTC3/WG 2, *Small-bore connectors*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This is the first edition of ISO 80369-2.

Introduction

This International Standard was developed because of several incidents, with catastrophic consequences, resultant from inappropriate medication, liquid nutritional formula or gas being administered via the incorrect route. Many incidents have been reported leading to international recognition of the importance of these issues, and a need has been identified to develop specific *connectors* for *medical devices* and their *accessories* used to deliver fluids in other *applications*.

The ISO 80369 series was developed to prevent misconnection between *small-bore connectors* used in different *applications*. Part 1 specifies the requirements necessary to verify the designs and dimensions 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.

Part 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 as well as performance of *small-bore connectors* intended for use as an ancillary port *connection* in a *breathing system* and respirable driving gases *applications*. The informative Annex D through Annex G describe the methods by which these designs have 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 International Standard are dimensionally incompatible with any of the other *connectors* for *applications* identified in the ISO 80369 series of documents for *small-bore connectors*, except as indicated in Annex G. If fitted to the relevant *medical devices* and *accessories*, these *connectors* should reduce the *risk* of gas, medication and liquid nutritional formula being delivered via an alternative route.

By conforming with the requirements of this document *manufacturers* of medical devices incorporating these respiratory *small-bore connectors* can presume conformance with the requirements of ISO 80369-1.

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: in smaller type. Normative text of tables is also in a smaller type.

— Terms defined in Clause 3 of this *document* or as noted: italics.

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 conformance with a requirement or a test is mandatory for conformance with this document;

— “should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;

— “may” is used to describe a permission (e.g. a permissible way to achieve conformance with a requirement or test);

— “can” is used to describe a possibility or capability; and

— “must” is used to express an external constraint.

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

Part 2: Connectors for respiratory applications

1 * Scope

This document specifies dimensions for two respiratory *small-bore connectors*. One (R1) for use on *medical devices* subjected to pressures up to 15 kPa such as a *breathing system,* the other (R2) for use on *medical devices* subjected to higher pressures between 15 kPa and 600 kPa such as oxygen therapy tubing.

This document also specifies the performance requirements used to verify the dimensions.

This document does not specify 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 document does not specify requirements for *connectors* for pressurizing and depressurizing the retention mechanism (e.g. balloon) used to hold invasive respiratory *medical devices* in place.

NOTE 1 *Manufacturers* are encouraged to incorporate the *small-bore connectors* specified in this part of ISO 80369 into *medical devices*, medical systems or *accessories* of *breathing systems* or respirable driving gas *applications* 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 this part of ISO 80369, will be included.

NOTE 2 ISO 80369-1:2018, Clause 7, specifies alternative methods of conformance with ISO 80369-1:2018, for *small-bore connectors* intended for use as an ancillary port *connection* in the *breathing system* or in the respirable driving gas *applications* of *medical devices* or *accessories*, which do not conform with this part of ISO 80369.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for the application 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.

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 Informative references are listed in the Bibliography.

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-3:2016, *Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications*

ISO 80369-7:2016, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ISO 80369-20:2015, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

3 Terms and definitions

For the purposes of this document, the terms and definitions specified in ISO 80369-1:2018, ISO 80369-7:2015, ISO 80369-20:2015, ISO 14971:2019 and the following apply. For convenience, the sources of all defined terms used in this document are given in Annex I.

3.1
AUXILIARY DIMENSION
dimensions derived from other dimensions given for information purposes only

[SOURCE: ISO 10209:2012[5], 4.2]

3.2
BREATHING SYSTEM
inspiratory and expiratory pathways through which gas flows at respiratory pressures and bounded by the port through which fresh gas enters, the *patient connection* port and the exhaust port

3.3
MEDICAL GAS PIPELINE SYSTEM
complete system which comprises a supply system, a monitoring and alarm system and a distribution system with terminal units at the points where medical gases or vacuum are required

[SOURCE: ISO 7396-1:2007 [3][1)], definition 3.36]

3.4
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 [6], definition 3.97, modified, replaced '*operator*' with '*user*'.]

3.5
RATED
<value> term referring to a value assigned by the *manufacturer* for a specified operating condition

[SOURCE: IEC 60601-1:2005 [6], definition 3.97]

3.6
USER
person interacting with (i.e. operating or handling) the *medical device*

Note 1 to entry: There can be more than one *user* of a *medical device*.

Note 2 to entry: Common *users* include clinicians, *patients*, cleaners, maintenance and service personnel.

[SOURCE: IEC 62366-1:2015 [9], definition 3.24]

1) Figures in square brackets refer to the Bibliography

3.7
USER PROFILE
summary of the mental, physical and demographic traits of an intended *user* group, as well as any special characteristics, such as occupational skills, job requirements and working conditions, which can have a bearing on design decisions

[SOURCE: IEC 62366-1:2015 [9], definition 3.29]

4 General requirements

4.1 General requirements for the respiratory *application*

Small-bore connectors made in conformance with this document conform with the requirements of ISO 80369-1:2018 unless otherwise indicated in this document.

The reference *connectors* for evaluation of the *non-interconnectable* characteristics are described in Annex C (Figures C.1, C.3, C.8, and C.10, as appropriate).

Where a *medical device* or *accessory* is designed to provide features of the respiratory *small-bore connector* of this document, those features shall be included in the *verification* to this document. When necessary, install the *small-bore connector* on the *medical device* or *accessory* to demonstrate conformance with this document.

NOTE 1 The summary of *medical devices* and their attributes with *connections* within this *application* is provided in informative Annex D.

NOTE 2 The summary of the usability requirements for *connectors* for this *application* is provided in informative Annex E.

NOTE 3 The summary of criteria and requirements for *connectors* for this *application* is provided in informative Annex F.

NOTE 4 The summary of assessment of the design of *connectors* for this *application* according to ISO 80369-1:2018, 6.1, is contained in informative Annex G.

NOTE 5 This document has been prepared to address the relevant essential principles of safety and performance of ISO 16142-1:2016[6] as indicated in Annex H.

NOTE 6 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745[13] as indicated in Annex I.

4.2 Material used for *small-bore connectors*

R1 and R2 *small-bore connectors* shall be made of materials that conform with ISO 80369-1:2018, Clause 4.

4.3 *Type tests*

Conformance with the requirements of this document shall be determined by *type tests*.

5 Dimensional requirements

5.1 R1 *small-bore connectors*

Small-bore connectors intended for use in the respiratory *application* at pressures less than 150 hPa (15 kPa) above ambient shall conform with the dimensions and tolerances as given in

— Figure B.1 and Table B.1 for the male R1 *connector.*

— Figure B.2 and Table B.2 for the female R2 *connector*.

Check conformance by confirming the relevant dimensions and tolerances specified in Annex B.

5.2 R2 *small-bore connectors*

Small-bore connectors intended to be used to convey air, oxygen or oxygen mixtures from one *medical device* or *accessory* to another in driving gas *applications* for respiratory use at pressures between 15 kPa and 600 kPa above ambient shall conform with the dimensions and tolerances given in

— Figure B.3 and Table B.3 for a male R2 *connector.*

— Figure B.4 and Table B.4 for a female R2 *connector*.

Check conformance by confirming the relevant dimensions and tolerances specified in Annex B.

6 Performance requirements

6.1 * Leakage by pressure decay

R1 and R2 *small-bore connectors* shall be evaluated for fluid leakage using the leakage by pressure decay *test method*. When tested over a hold period between 30 s and 35 s using air as the medium, the leakage flowrate of

— a R1 *small-bore connector* shall not exceed a leakage rate of 0,00025 Pa·m^3/s while being subjected to an applied pressure of between 12,5 kPa and 15,0 kPa.

— a R2 *small-bore connector* shall not exceed 0,005 Pa•m^3/s while being subjected to an applied pressure of between 1 000 kPa and 1 050 kPa.

Check for conformance by applying the tests of ISO 80369-20:2015, Annex B, while using the leakage reference *connector* specified in Annex C (Figures C.1, C.3, C.8, and C.10, as appropriate). A greater applied pressure or a longer hold period may be used.

6.2 Subatmospheric pressure air leakage

R1 and R2 *small-bore connectors* shall be evaluated for subatmospheric pressure air leakage. These *small-bore connectors* shall not exceed a leakage flowrate of more than

— 0,00005 Pa·m^3/s while being subjected to an applied subatmospheric pressure of between 3,0 kPa and 5,0 kPa over a hold period of between 25 s and 35 s for an R1 *connector.*

— 0,005 Pa·m^3/s while being subjected to an applied subatmospheric pressure of between 35,0 kPa and 45,0 kPa over a hold period of between 20 s and 30 s for a R2 *connector.*

Check conformance by applying the tests of ISO 80369-20:2015, Annex D, while using the leakage reference *connector* specified in Annex C (Figures C.1, C.3, C.8, and C.10, as appropriate). A greater applied subatmospheric pressure may be used.

6.3 Stress cracking

R1 and R2 *small-bore connectors* shall be evaluated for stress cracking. These *small-bore connectors* shall meet the requirements of 6.1 and 6.2 after being subjected to stresses of ISO 80369-20:2015, Annex E.

Check conformance by applying the tests of ISO 80369-20: 2015, Annex E, while using the stress cracking reference *connector* specified in Annex C (Figures C.1, C.3, C.8, and C.10, as appropriate).

6.4 Resistance to separation from axial load

R1 and R2 *small-bore connectors* shall be evaluated for separation from axial load. These *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.

Check conformance by applying the tests of ISO 80369-20:2015, Annex F, while using the separation from axial load reference *connector* specified in Annex C (Figures C.2, C.4, C.9, and C.11, as appropriate). A greater disconnection applied axial force or a longer hold period may be used.

6.5 Resistance to separation from unscrewing

R1 and R2 *small-bore connectors* shall be evaluated for separation from unscrewing. These *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 0,0198 N·m to 0,02 N·m.

Check conformance by applying the tests of ISO 80369-20:2015, Annex G, while using the separation from unscrewing reference *connector* specified in Annex C (Figures C.1, C.3, C.8, and C.10, as appropriate). A greater applied unscrewing torque or a longer hold period may be used.

6.6 Resistance to overriding

R1 and R2 *small-bore connectors* shall be evaluated for resistance to overriding. These *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 for a R1 *connector*.

— between 0,22 N·m to 0,25 N·m over a hold period between 5 s and 10 s for a R2 *connector*.

Check conformance by applying the tests of ISO 80369-20:2015, Annex H, while using the resistance to overriding reference *connector* specified in Annex C (Figures C.2, C.4, C.9, and C.11, as appropriate). A greater applied torque or a longer hold period may be used.

6.7 Disconnection by unscrewing

R1 and R2 *small-bore connectors* shall be evaluated for disconnection by unscrewing. These *small-bore connector* shall separate from the reference *connector* with an applied unscrewing torque of no greater than 0,35 N·m.

Check conformance by applying the tests of ISO 80369-20:2015, Annex I, while using the disconnection by unscrewing reference *connector* specified in Annex C (Figures C.1, C.3, C.8, and C.10, as appropriate).

Annex A
(informative)

Rationale and guidance

A.1 General guidance

This Annex provides a rationale for some requirements of ISO 80369-2, and is intended for those who are familiar with the subject of ISO 80369-2 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any revision of this document necessitated by those developments.

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 document 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*. 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 [10]. The *connectors* specified in this document are intended to be used on respiratory *medical devices*.

Manufacturers and *responsible organizations* are encouraged to report their experience with the *small-bore connectors* specified in this part of ISO 80369 to the Secretariat of ISO/TC 210, so that it can consider this feedback during the revision of the relevant part of this series of International Standards.

Subclause 6.1 Leakage by pressure decay

The test pressures chosen are the worst-case pressures that could be generated under a *single fault condition* for a *breathing system* for the R1 *connector* and for a *medical gas pipeline system* for the R2 *connector*.

Annex B
(normative)

Small-bore connectors for *breathing systems* and driving gases

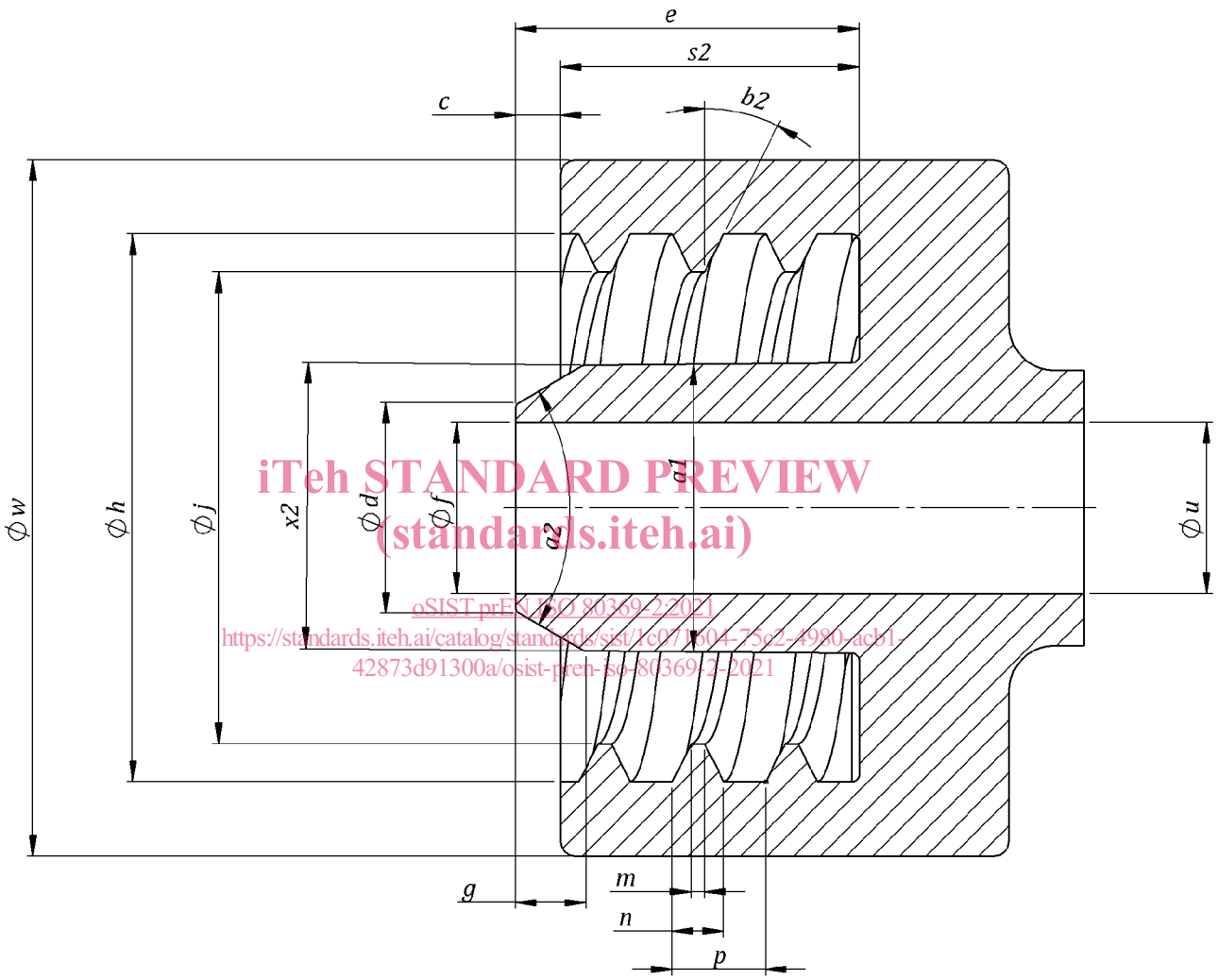

Table B.1 contains the dimensions for this figure. The male *connector* shows a permanently connected internally threaded lock fitting. A rotatable internally threaded lock fitting may be used.

Figure B.1 — Male R1 *small-bore connector*