



DPC: 23/30436367 DC

BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000

Fax: +44 (0)20 8996 7400

www.bsigroup.com

Date: 22 June 2023

Origin: European

Latest date for receipt of comments: 14 August 2023

Project No. 2021/00946

Responsible committee: CH/210 Quality management and corresponding general aspects for medical devices

Interested committees:

Title: Draft BS EN ISO 80369-1 Small-bore connectors for liquids and gases in healthcare applications. Part 1: General requirements.

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

WARNING: THIS IS A DRAFT AND MUST NOT BE REGARDED OR USED AS A BRITISH STANDARD. THIS DRAFT IS NOT CURRENT BEYOND 14 August 2023

This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

No copying is allowed, in any form, without prior written permission from BSI except as permitted under the Copyright, Designs and Patent Act 1988 or for circulation within a nominating organization for briefing purposes. Electronic circulation is limited to dissemination by e-mail within such an organization by committee members.

Further copies of this draft may be purchased from BSI Shop <http://shop.bsigroup.com> or from BSI Customer Services, Tel: +44(0) 20 8996 9001 or email cservices@bsigroup.com. British, International and foreign standards are also available from BSI Customer Services.

Information on the co-operating organizations represented on the committees referenced above may be obtained from <https://standardsdevelopment.bsigroup.com/>.

Responsible Committee Secretary: Mr Paul Lambert (BSI)

Direct tel:

E-mail: paul.lambert@bsigroup.com

Full document details: 23/30436367 DC

Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
------------------	------------------------

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

DRAFT INTERNATIONAL STANDARD

ISO/DIS 80369-1

ISO/TC 210

Secretariat: ANSI

Voting begins on:
2023-06-21

Voting terminates on:
2023-09-13

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.

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

ISO/CEN PARALLEL PROCESSING



Reference number
ISO/DIS 80369-1:2023(E)

AVA Documents
Document Sharing Hub
© ISO 2023



COPYRIGHT PROTECTED DOCUMENT

© ISO 2023

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Foreword	5
Introduction.....	6
1 Scope	8
2 Normative references	8
3 Terms and definitions.....	9
4 <i>Small-bore connector non-interconnectable</i> requirement	12
5 <i>Small-bore connectors for clinical applications</i>	12
5.1 <i>Small-bore connectors for new clinical applications</i>	12
5.2 <i>Small-bore connectors for respiratory applications</i>	12
5.3 <i>Small-bore connectors for enteral applications</i>	13
5.4 <i>Small-bore connectors for limb cuff inflation applications</i>	13
5.5 <i>Small-bore connectors for neural applications</i>	13
5.6 <i>Small-bore connectors for intravascular and hypodermic applications</i>	13
5.7 <i>Other use cases utilizing an ISO 80369-7 small-bore connector</i>	13
6 Alternative <i>small-bore connectors</i>.....	15
Annex A (informative) Rationale	16
Annex B (normative) <i>Process for demonstrating non-interconnectable</i> characteristics	21
Figure B.1 — Illustration of the <i>process</i> to evaluate the <i>non-interconnectable</i> characteristics	22
Figure B.2 — Example of typical fixed collar cone <i>connector</i> diameters to be evaluated	23
Figure B.3 — Example of typical full threaded socket <i>connector</i> diameters to be evaluated	24
Figure B.4 — Example of a typical rib diameter to be evaluated	24
Figure B.5 — Example of a typical <i>connector</i> with a lug to be evaluated.....	25
Figure B.6 — Example of a typical cylinder-to-cylinder interface to be evaluated	25
Figure B.7 — Example of a typical cylinder to full thread interface to be evaluated.....	26
Figure B.8 — Example of a typical cylinder to full thread interface to be evaluated (cross-section view)	26
Figure B.9 — Example of a typical cylinder to external lug interface to be evaluated	26
Figure B.10 — Example of a typical cylinder to external lug interface to be evaluated (cross-section view)	27
Annex C (normative) Assessment <i>procedures</i> for <i>small-bore connectors</i>	35
Annex D (informative) <i>Applications</i> of <i>small-bore connectors</i> and the relevant standard	38

33	Annex E (informative) Design assessment summary	40
34	Annex F (informative) Reference to the Essential Principles.....	43
35	Bibliography	50
36	Alphabetical index of defined terms.....	51

37

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.

223 **3.3**

224 **connection**

225 union or joining of two *connectors* (3.4)

226 **3.4**

227 **connector**

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

230 **3.5**

231 **contactable surface**

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

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

237 **3.6**

238 **information for safety**

239 information provided to the *user* or responsible organization as a *risk control* measure

240 EXAMPLE 1 Warnings, precautions or contraindications.

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

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

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

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

246 [SOURCE: ISO 20417:2021, 3.9]

247 **3.7**

248 **instructions for use**

249 **IFU**

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

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

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

255 **3.8**

256 **interference test part**

257 component that physically represents a *small-bore* (3.15) *connector* (3.4) or *connector* feature

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

260 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.

a) *Small-bore connectors*, intended to be used for *connections* other than those falling into the *applications* of 5.2, 5.3, 5.4, 5.5 and 5.6 of *medical devices* and *accessories* may conform with ISO 80369-7 under the following conditions, unless the use of these *connectors* creates an unacceptable *risk* for the specific *medical device* or *accessory*.

b) Such a *connector* shall conform with ISO 80369-7.

c) A *medical device* or *accessory* using an ISO 80369-7 *connector* for such use cases shall meet the following requirements:

1) The *risk* of *unintended connections* with any reasonably foreseeable *medical devices* or *accessories* using the ISO 80369-7 *connector* shall be:

i) evaluated using ISO 14971:2019; and

ii) determined to be an acceptable *risk*.

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

I) In determining acceptable *risk*, the *manufacturer* shall evaluate the *severity* of the potential *harm* associated with the potential *unintended connection* with flow in both directions of the *connection*.

2) Such a *medical device* or *accessory* shall be *marked* in accordance with ISO 20417:2021, 6.1.5.

3) If acceptable *risk* is achieved by providing *information for safety*, the *medical device* or *accessory* shall include in its *instructions for use* a statement to the effect that "As this [insert name of medical device or accessory here] uses an ISO 80369-7 small-bore connector for other than its intended application, there is a possibility that an inadvertent connection can occur between this [insert name of medical device or accessory here] and another medical device or accessory using this connector, which can result in a hazardous situation causing harm to the patient. Special measures need be taken by the user to mitigate these reasonably foreseeable risks."

4) It is recommended that the *manufacturer* of such a *medical device* or *accessory* that utilizes a *small-bore connector* of the ISO 80369-7 for other than its intended *application* notify the Committee Manager of ISO/TC 210² of their utilization.

i) The notification should include a description of:

I) the *connector* used;

II) the *medical device* or *accessory* using the *connector*;

III) the clinical *procedure*; and

IV) the fluid being used.

NOTE 3 This information will be used during the systematic review of this document.

Check conformity for a *medical device* or *accessory* using a *small-bore connector* of ISO 80369-7 for other than the intravascular and hypodermic *application* by:

- inspection of the *risk management file* of the *medical device* or *accessory* using the *connector* and confirming that the *risk* of any *unintended connection* is acceptable;
- inspection of the *marking*; and
- inspection of the *instructions for use*.

² Contact information is available on the ISO website at: <https://www.iso.org/committee/54892.html>.

6 Alternative *small-bore connectors*

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

a) Alternative designs of *small-bore connectors* to those specified in Clause 6 may be used in a *medical device* or *accessory*, and if used, they shall:

- 1) be evaluated according to Annex B for *non-interconnectable* characteristics, with the exception of a *connector* within the same *application* to which it is intended to connect;
- 2) not create an unacceptable *risk* for a specific *medical device* or *accessory*; and
- 3) be evaluated according to the engineering analysis of Annex C.3.

b) The *medical device* or *accessory*, which incorporates an alternative design *small-bore connector*, shall

- 1) be *marked* in accordance with ISO 20417:2021, 6.1.5.
- 2) if acceptable *risk* is achieved by providing *information for safety*, include in its *instructions for use* a statement to the effect that “As this [insert name of medical device or accessory here] uses an alternative small-bore connector design different from those specified in the ISO and IEC 80369 series, there is a possibility that an inadvertent connection can occur between this [insert name of medical device or accessory here] and a medical device or accessory using a different alternative small-bore connector or that compatibility with other alternative small-bore connectors might be impaired, which can result in a hazardous situation causing harm to the patient. Special measures need be taken by the user to mitigate these reasonably foreseeable risks.”

c) An alternative design *small-bore connector* that conforms with this clause:

- 1) may claim conformance with this document; but
- 2) shall not claim conformity with the other parts of the ISO and IEC 80369 series.

d) Generic claims of conformity to the ISO and IEC 80369 series shall not be made.

Check conformity by inspection of the *risk management file* of the *medical device* or *accessory* using the *connector* and confirming that the *risk* of any *unintended connection* is acceptable. Confirm conformity with Annex B and the specified portions of Annex C.