SLOVENSKI STANDARD
SIST EN 80369-5:2017

01-februar-2017

Priključki z majhnim premerom za tekočine in pline za uporabo v zdravstvu - 5. del: Priključki z raztegljivo manšeto za okončine

Small-bore connectors for liquids and gases in healthcare applications - Part 5: Connectors for limb cuff inflation applications

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 5: Verbindungsstücke für Anwendungen mit aufblasbaren Manschettensystemen für Gliedmaßen

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 5: Raccords destinés à des applications au gonflage de brassard

Ta slovenski standard je istoveten z: **EN 80369-5:2016**

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

SIST EN 80369-5:2017 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 80369-5

November 2016

ICS 11.040.20

English Version

Small-bore connectors for liquids and gases in healthcare applications - Part 5: Connectors for limb cuff inflation applications (IEC 80369-5:2016)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 5: Raccords destinés à des applications au gonflage de brassard (IEC 80369-5:2016)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 5: Verbindungsstücke für Anwendungen mit aufblasbaren Manschettensystemen für Gliedmaßen (IEC 80369-5:2016)

This European Standard was approved by CENELEC on 8 April 2016. CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN and CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

European foreword

The text of document 62D/1306/FDIS, future edition 1 of IEC 80369-5, prepared by SC 62D “Electromedical equipment” of IEC/TC 62 “Electrical equipment in medical practice”, ISO/TC 210 “Quality management and corresponding general aspects for medical devices” and CEN/CENELEC TC 3/WG 2 “Smallbore connectors”, was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 80369-5:2016.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2017-05-04
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2019-11-04

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 80369-5:2016 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

ISO 3040:2009	NOTE	Harmonized as EN ISO 3040:2012 [1] (not modified).
ISO 81060-1:2007	NOTE	Harmonized as EN ISO 81060-1:2012 (not modified).
IEC 60601-1-11:2015	NOTE	Harmonized as EN 60601-1-11:2015 (not modified).
IEC 60601-1-12:2014	NOTE	Harmonized as EN 60601-1-12:2015 (not modified).
IEC 62366-1:2015	NOTE	Harmonized as EN 62366-1:2015 (not modified).
IEC 80601-2-30:2009	NOTE	Harmonized as EN 80601-2-30:2010 (not modified).
IEC 80601-2-30:2009/A1:2013	NOTE	Harmonized as EN 80601-2-30:2010/A1:2015 (not modified).
ISO 80369-20:2015	NOTE	Harmonized as EN ISO 80369-20:2015 (not modified).
ISO 80369-6:2016	NOTE	Harmonized as EN ISO 80369-6:2016 (not modified).
ISO 80369-2 [2]	NOTE	Harmonized as EN ISO 80369-2 [2] (not modified).
ISO 80369-3:2016	NOTE	Harmonized as EN ISO 80369-3:2016 (not modified).

[1] Superseded by EN ISO 3040:2016 (ISO 3040:2016).

[2] At draft stage.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu

Publication	Year	Title	EN/HD	Year
-	-	Respiratory therapy equipment - Part 2: Tubing and connectors	EN 13544-2 +A1	2002 2009
ISO 5356-1	2004	Anaesthetic and respiratory equipment - Conical connectors - Part-1: Cones and sockets	EN ISO 5356-1	2004 [3)]
ISO 5356-1	2015	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets	EN ISO 5356-1	2015
ISO 5356-2	2006	Anaesthetic and respiratory equipment - Conical connectors - Part 2: Screw-threaded weight-bearing connectors	EN ISO 5356-2	2007 [4)]
ISO 5356-2	2012	Anaesthetic and respiratory equipment - Conical connectors - Part 2: Screw-threaded weight-bearing connectors	EN ISO 5356-2	2012
ISO 8185	2007	Respiratory tract humidifiers for medical use - Particular requirements for respiratory humidification systems	EN ISO 8185	2009
ISO 14971	2007	Medical devices - Application of risk management to medical devices	EN ISO 14971	2012
ISO 80369-1	2010	Small bore connectors for liquids and gases in healthcare applications - Part 1: General requirements	EN ISO 80369-1	2010
ASTM D638-14	-	Standard test method for tensile properties of plastics	-	-
ASTM D790-10	-	Standard test methods for flexural properties of unreinforced and reinforced plastics and electrical insulating materials	-	-

[3)] Superseded by EN ISO 5356-1:2015 (ISO 5356-1:2015).

[4)] Superseded by EN ISO 5356-2:2012 (ISO 5356-2:2012).

Annex ZZ
(informative)

Relationship between this European standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European standard has been prepared under a Commission's standardisation request M/023[1] to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZZ.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZZ is based on normative references according to Annex ZA of this document.

NOTE 4 When an Essential Requirement does not appear in Table ZZ.1, it means that it is not addressed by this European Standard.

Table ZZ.1 – Correspondence between this European standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
9.1	5, 6.2	ER 9.1 is met with respect to the connector dimensions and disconnection only.
12.7.4	6.3	ER 12.7.4 is met with respect to stress cracking only.

WARNING 1: Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2: Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

[1] Replace with 'M/023 concerning the development of European standards related to medical devices' or with 'M/295 concerning the development of European standards related to medical devices', or with the reference number and title of any other standardization request as relevant.

IEC 80369-5

Edition 1.0 2016-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

**Small-bore connectors for liquids and gases in healthcare applications –
Part 5: Connectors for limb cuff inflation applications**

**Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé –
Partie 5: Raccords destinés à des applications au gonflage de brassard**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.20

ISBN 978-2-8322-3211-8

CONTENTS

FOREWORD....4
INTRODUCTION....6
1 * Scope....7
2 Normative references....7
3 Terms and definitions....8
4 General requirements....9
4.1 General requirements for the limb cuff inflation APPLICATION....9
4.2 Materials used for SMALL-BORE CONNECTORS....9
4.3 TYPE TESTS....10
5 Dimensional requirements for sphygmomanometer and cuff SMALL-BORE CONNECTORS....10
5.1 * Requirements for adult or paediatric PATIENT SMALL-BORE CONNECTORS (S1)....10
5.2 Void....10
6 Performance requirements....10
6.1 Air leakage....10
6.2 * Resistance to separation from axial load....10
Annex A (informative) Rationale and guidance....11
A.1 General guidance....11
A.2 Rationale for particular clauses and subclauses....11
Annex B (normative) SMALL-BORE CONNECTORS for the limb cuff inflation APPLICATION....13
Annex C (normative) Reference CONNECTORS....17
C.1 General requirements for reference CONNECTORS....17
C.2 * Sphygmomanometer and cuff S1 reference CONNECTORS....17
Annex D (informative) Assessment of MEDICAL DEVICES and their attributes with CONNECTIONS within this APPLICATION....18
Annex E (informative) Summary of the usability requirements for SMALL-BORE CONNECTORS for limb cuff inflation APPLICATIONS....19
E.1 USER PROFILE....19
E.2 Use scenarios....19
E.3 Use environments and scenarios....20
E.4 Generic USER needs....20
Annex F (informative) Summary of SMALL-BORE CONNECTOR design requirements for limb cuff inflation APPLICATIONS....21
Annex G (informative) Summary of assessment of the design of the CONNECTORS for limb cuff inflation APPLICATION....29
G.1 General....29
G.2 Summary of the engineering analysis of the design....29
G.2.1 NON-INTERCONNECTABLE analysis....29
G.2.2 S1 male to N1 male....29
G.3 Summary of the design VERIFICATION....29
G.4 Summary of the design validation....30
G.5 Summary of the design review....30
Annex H (informative) Obsolete limb cuff inflation CONNECTOR....31
Annex I (informative) Air leakage by pressure decay TEST METHOD....34
I.1 Principle....34

I.2 * Test conditions 34
I.2.1 Test sample preconditioning 34
I.2.2 Environmental test conditions 34
I.3 Apparatus 34
I.4 PROCEDURE 34
I.5 Test report 35
Annex J (informative) Resistance to separation from axial load TEST METHOD 36
J.1 Principle 36
J.2 * Test conditions 36
J.2.1 Test sample preconditioning 36
J.2.2 Environmental test conditions 36
J.3 Apparatus 36
J.4 PROCEDURE 36
J.5 Test report 36
Annex K (informative) Reference to the essential principles 37
Index of defined terms 39
Bibliography 40

Figure B.1 – Male cuff S1 SMALL-BORE CONNECTOR 13
Figure B.2 – Female sphygmomanometer S1 SMALL-BORE CONNECTOR 15
Figure B.3 – Sphygmomanometer and cuff SMALL-BORE CONNECTOR (S1) assembly 15
Figure H.1 – Obsolete sphygmomanometer and cuff SMALL-BORE CONNECTOR 32

Table B.1 – Male cuff S1 SMALL-BORE CONNECTOR dimensions 14
Table B.2 – Female sphygmomanometer S1 SMALL-BORE CONNECTOR dimensions 16
Table E.1 – USER PROFILE 19
Table F.1 – Adult or paediatric PATIENT sphygmomanometer and cuff S1 CONNECTOR-specific design requirements *(1 of 4)* 21
Table F.2 – Neonatal sphygmomanometer and cuff CONNECTOR-specific design requirements *(1 of 4)* 25
Table G.1 – Summary of possible misconnection from CAD analysis 29
Table H.1 – Obsolete male sphygmomanometer and cuff SMALL-BORE CONNECTOR dimensions 33
Table H.2 – Obsolete female sphygmomanometer and cuff SMALL-BORE CONNECTOR dimensions 33
Table K.1 – Correspondence between this document and the essential principles *(1 of 2)* 37

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

SMALL-BORE CONNECTORS FOR LIQUIDS AND GASES IN HEALTHCARE APPLICATIONS –

Part 5: Connectors for limb cuff inflation applications

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 80369-5 has been prepared by a Joint Working Group of subcommittee 62D: Electromedical equipment of IEC technical committee 62: Electrical equipment in medical practice, ISO technical committee 210, Quality management and corresponding general aspects for medical devices and CEN/CENELEC TC3/WG 2, Small-bore connectors.

The text of this standard is based on the following documents:

FDIS	Report on voting
62D/1306/FDIS	62D/1329/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 23 P members out of 23 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

A list of all parts in the International Standard 80369 series, published under the general title *Small-bore connectors for liquids and gases in healthcare applications*, can be found on the IEC and ISO websites.

In this standard, 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 STANDARD OR AS NOTED IN THE INDEX OF DEFINED TERMS: SMALL CAPITALS.

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “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.

NOTE The attention of Member Bodies and National Committees 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 or IEC 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 committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

This International Standard was developed because of several incidents, with catastrophic consequences, resultant from inappropriate medication, liquid nutritional formula or air being administered intravenously. 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 International Standard 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. The other parts specify the designs of SMALL-BORE CONNECTORS for the various APPLICATIONS.

This part of International Standard 80369 specifies the design and the dimensions and drawings of SMALL-BORE CONNECTORS intended for use in limb cuff inflation APPLICATIONS. The informative Annex D through Annex G describe the methods by which this design has been assessed. Other parts of International Standard 80369 include requirements for SMALL-BORE CONNECTORS used in different APPLICATION categories.

CONNECTORS manufactured to the dimensions set out within this International Standard are therefore dimensionally incompatible with the SMALL-BORE CONNECTORS used in other APPLICATIONS specified by the standards in this series, unless otherwise indicated. If fitted to the relevant MEDICAL DEVICES and ACCESSORIES, these CONNECTORS should be able to prevent air being delivered intravenously. CONNECTORS manufactured to the dimensions specified in this standard are also NON-INTERCONNECTABLE with any of the other CONNECTORS identified in the International Standard 80369 series of standards for SMALL-BORE CONNECTORS, unless otherwise indicated.

SMALL-BORE CONNECTORS FOR LIQUIDS AND GASES IN HEALTHCARE APPLICATIONS –

Part 5: Connectors for limb cuff inflation applications

1 * Scope

This part of International Standard 80369 specifies dimensions and requirements for the design and functional performance of SMALL-BORE CONNECTORS intended to be used for CONNECTIONS in limb cuff inflation APPLICATIONS of MEDICAL DEVICES and ACCESSORIES. Limb cuff inflation APPLICATIONS include CONNECTIONS between a sphygmomanometer and its cuff. [3] [7] [1]

This part of International Standard 80369 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 part of International Standard 80369 does not specify requirements for pressurizing and depressurizing the retention mechanism (e.g. balloon) used to hold invasive MEDICAL DEVICES in place.

NOTE 1 MANUFACTURERS are encouraged to incorporate the SMALL-BORE CONNECTORS specified in this part of International Standard 80369 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, requirements for SMALL-BORE CONNECTORS, as specified in this part of International Standard 80369, will be included.

NOTE 2 The requirements for SMALL-BORE CONNECTORS intended to be used with neonatal PATIENTS to connect a cuff to a sphygmomanometer are intended to be added to this standard by an amendment or new edition. IEC 80601-2-30 [7] defines the age range for neonatal mode usage of sphygmomanometers.

NOTE 3 The requirements for SMALL-BORE CONNECTORS intended to be used to connect a tourniquet to its inflating equipment are intended to be added to this standard by an amendment or new edition.

NOTE 4 ISO 80369-1:2010, 5.8, specifies alternative methods of compliance with ISO 80369-1:2010, for SMALL-BORE CONNECTORS intended for limb cuff inflation APPLICATIONS of MEDICAL DEVICES or ACCESSORIES which do not comply 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 its application. 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 on page 40.

ISO 5356-1:2004, *Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets*

ISO 5356-1:2015[2], *Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets*

ISO 5356-2:2006[3], *Anaesthetic and respiratory equipment – Conical connectors – Part 2: Screw-threaded weight-bearing connectors*

---

[1] Figures in square brackets refer to the Bibliography.

[2] Both the current and previous versions of this standard are normatively referenced.

[3] Both the current and previous versions of this standard are normatively referenced.