

VÄIKESE AVAGA ÜHENDUSLIITMIKUD VEDELIKELE JA
GAASIDELE TERVISHOIU RAKENDUSTES. OSA 5:
ÜHENDUSLIITMIKUD JÄSEMETE MANSETTIDE
TÄITMISRAKENDUSTES

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 80369-5:2016 sisaldab Euroopa standardi EN 80369-5:2016 ingliskeelset teksti.	This Estonian standard EVS-EN 80369-5:2016 consists of the English text of the European standard EN 80369-5:2016.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 04.11.2016.	Date of Availability of the European standard is 04.11.2016.
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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 Manschetten systemen 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.

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

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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

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
-	-	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/023¹ 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.

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