

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



THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2016 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'IEC ou du Comité national de l'IEC du pays du demandeur. Si vous avez des questions sur le copyright de l'IEC ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de l'IEC de votre pays de résidence.

IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

IEC Catalogue - webstore.iec.ch/catalogue

The stand-alone application for consulting the entire bibliographical information on IEC International Standards, Technical Specifications, Technical Reports and other documents. Available for PC, Mac OS, Android Tablets and iPad.

IEC publications search - www.iec.ch/searchpub

The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,...). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and also once a month by email.

Electropedia - www.electropedia.org

The world's leading online dictionary of electronic and electrical terms containing more than 30 000 terms and definitions in English and French, with equivalent terms in 15 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary

More than 60 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

IEC Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: csc@iec.ch.

A propos de l'IEC

La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications IEC

Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Catalogue IEC - webstore.iec.ch/catalogue

Application autonome pour consulter tous les renseignements bibliographiques sur les Normes internationales, Spécifications techniques, Rapports techniques et autres documents de l'IEC. Disponible pour PC, Mac OS, tablettes Android et iPad.

Recherche de publications IEC - www.iec.ch/searchpub

La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études,...). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished

Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et aussi une fois par mois par email.

Electropedia - www.electropedia.org

Le premier dictionnaire en ligne de termes électroniques et électriques. Il contient plus de 30 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans 15 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

Glossaire IEC - std.iec.ch/glossary

Plus de 60 000 entrées terminologiques électrotechniques, en anglais et en français, extraites des articles Termes et Définitions des publications IEC parues depuis 2002. Plus certaines entrées antérieures extraites des publications des CE 37, 77, 86 et CISPR de l'IEC.

Service Clients - webstore.iec.ch/csc

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: csc@iec.ch.



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

**Warning! Make sure that you obtained this publication from an authorized distributor.
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.**

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 5356-1:2015², *Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets*

ISO 5356-2:2006³, *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.