

# 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 Varembé  
CH-1211 Geneva 20  
Switzerland

Tel.: +41 22 919 02 11  
Fax: +41 22 919 03 00  
[info@iec.ch](mailto:info@iec.ch)  
[www.iec.ch](http://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](http://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](http://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](http://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](http://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](http://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](http://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](mailto: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](http://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](http://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](http://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](http://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](http://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](http://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](mailto:csc@iec.ch).

# 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**

## 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.