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Small-bore connectors for liquids and gases in healthcare applications —

Part 7: Connectors for intravascular or hypodermic applications

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé —

Partie 7: Connecteurs pour les applications intravasculaires ou hypodermiques



Reference number
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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

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Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 General requirements	3
4.1 General requirements for <i>Luer connectors</i>	3
4.2 Type tests	3
5 Dimensional requirements for <i>Luer connectors</i>	3
6 Performance requirements	4
6.1 Fluid leakage	4
6.1.1 Fluid leakage requirement	4
6.1.2 Leakage by pressure decay	4
6.1.3 Positive pressure liquid leakage	4
6.2 Sub-atmospheric pressure air leakage	4
6.3 Stress cracking	5
6.4 Resistance to separation from axial load	5
6.5 Resistance to separation from unscrewing	5
6.6 Resistance to overriding	5
Annex A (informative) Rationale and guidance	6
Annex B (normative) <i>Luer connectors</i>	10
Annex C (normative) Reference connectors	25
Annex D (informative) Assessment of <i>medical devices</i> and their attributes with <i>connections</i> within this application	32
Annex E (informative) Summary of the usability requirements for <i>Luer connectors</i> for intravascular or hypodermic applications	34
Annex F (informative) Summary of <i>Luer connector</i> design requirements for intravascular or hypodermic applications	38
Annex G (informative) Summary of assessment of the design of the <i>Luer connector</i> for intravascular or hypodermic applications	41
Annex H (informative) Reference to the essential principles	44
Annex I (informative) Reference to the general safety and performance requirements	45
Annex J (informative) Terminology — Alphabetized index of defined terms	46
Bibliography	47

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*, and IEC/SC62D, *Electromedical equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee, CEN/CENELEC JTC3/WG 2, *Small-bore connectors*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 80369-7:2016), which has been technically revised.

The main changes compared to the previous edition are as follows:

- Tolerances of several reference *connector* dimensions are increased to facilitate easier manufacturing and certification. Most of the affected tolerances are for features that do not contact the test *connector* and therefore do not affect the test results. The angle tolerance for the bearing side of the threads do contact the *connector* under test but the change in the tolerance is considered likely have minimal to no effect on test outcomes.
- Some requirements for *Luer connectors* have been separated for *semi-rigid materials* and *rigid materials* to better ensure compatibility at the extreme of the design space. Definitions of *semi-rigid material* and *rigid material* have been added.
- The distance from the tip of the *connector* to the bottom of the first complete thread profile of the internal thread (*t* dimension) has been made an *auxiliary dimension* due to the difficulty in its measurement. The functional impact of the dimension is evaluated with the resistance to separation (from axial load) functional test.
- The N1 and N2 dimensions of the female *Luer lock connector* variant A (with lugs at right angle to axis) have been changed to allow measurement from the open end of the *connector*, to better ensure compatibility at the extreme of the design space.

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.

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Introduction

This document was developed because of several incidents, with catastrophic consequences, resulting 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 ISO 80369 series was developed to prevent misconnection between *small-bore connectors* used in different *applications*. ISO 80369-1 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.

This document specifies the design and the dimensions and the drawings of *small-bore connectors* intended to be used as conical fittings with a 6 % (Luer) taper for *connections* in intravascular or hypodermic *applications*. [Annex D](#) to [Annex G](#) describe the methods by which this design has been assessed. Other parts of ISO 80369 include requirements for *small-bore connectors* used in different *application* categories.

Connectors manufactured to the dimensions set out within this document are dimensionally incompatible with any of the other *connectors* for *applications* identified in the ISO 80369 series of documents for *small-bore connectors*, except as indicated in [Annex G](#). If fitted to the relevant *medical devices* and *accessories*, these *connectors* should reduce the *risk* of air, non-vascular medication and liquid nutritional formula being delivered through an alternative route, such as intravenously or through an airway device.

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” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.