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# American National Standard



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## ANSI/AAMI/ ISO 80369-7: 2016

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Small-bore connectors  
for liquids and gases in  
healthcare applications—  
Part 7: Connectors for  
intravascular or hypodermic  
applications

## Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.


In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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American National Standard

ANSI/AAMI/ISO 80369-7:2016



**Small-bore connectors for liquids and gases in  
healthcare applications—Part 7: Connectors for  
intravascular or hypodermic applications**

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Approved 2 September 2016 by  
**Association for the Advancement of Medical Instrumentation**

Approved 27 September 2016 by  
**American National Standards Institute**

**Abstract:** Specifies dimensions and requirements for the design and functional performance of small-bore connectors intended to be used for connectors in intravascular applications or hypodermic connections in hypodermic applications of medical devices and accessories.

## AAMI Standard

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AAMI  
4301 N. Fairfax Drive, Suite 301  
Arlington, VA 22203-1633  
[www.aami.org](http://www.aami.org)

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International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

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## Committee representation

### Association for the Advancement of Medical Instrumentation

#### Quality Management and Corresponding General Aspects for Medical Devices Committee

The publication of AAMI/ISO 80369-5 as a new American National Standard was initiated by the AAMI Quality Management and Corresponding General Aspects for Medical Devices Committee, which also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the AAMI Small Bore Connectors Committee, chaired by Scott Colburn of FDA and Brad Noe of Becton Dickinson & Co. played an active part in developing ISO 80369-7.

At the time this document was published, the **AAMI Quality Management and Corresponding General Aspects for Medical Devices Committee** had the following members:

*Cochairs:* Scott A. Colburn, MS, BSN, RN  
Charles B. Sidebottom, PE

*Members:* Jon Cammack, AstraZeneca/MedImmune  
Scott A. Colburn, MS, BSN, RN, FDA/CDRH  
Jeffrey L. Eggleston, MS PE, Covidien  
Sunny Gill, Combination Product Partners  
Laila Gurney, MS RAC, GE Healthcare  
Rajeswari R. Itharaju, Covidien  
Mizanu Kebede, Halyard Health  
Ed R. Kimmelman, BME JD, Kimmelman Consultancy  
Kristi M. Kistner, RAC ASQ CBA, Amgen Inc  
Dan Laelle, Nonin Medical Inc  
David G. Osborn, Philips Electronics North America  
Christine Park, Christine Park & Associates  
Brodie Pedersen, Logic PD  
Luan M. Pandy, Medtronic Inc WHO Campus  
Dan Reid, Omnex Engineering and Management  
Charles B. Sidebottom, PE, PPO Standards LLC  
Mike Silvestri, Terumo Americas Corporate  
Chandresh Thakur, CareFusion  
Al Van Houdt, Spacelabs Medical Inc  
John Williams, Baxter Healthcare Corporation  
Dadi Zhong, Chongqing University

*Alternates:* Ujjal Chakravarty, Halyard Health  
David J. Geraghty, Spacelabs Medical Inc  
Robert RabeH Hijazi, MS MHA CBET, St Louis VA Medical Center - John Cochran Division  
Mike Hudon, Philips Electronics North America  
Chad Kymal, Omnex Engineering Management  
Robert Sestrack, GE Healthcare

#### Small-bore Connectors Committee

At the time this document was published, the **AAMI Small-bore Connectors Committee** had the following members:

*Cochairs:* Scott A. Colburn, MS, BSN, RN  
Brad Noe

*Members:* Mark S. Adams, MBA PMP, Boston Scientific Corporation  
Keith Anderson, Smiths-Medical  
Jim Brown, Colder Products Company  
James Brugger, BSME MEEM, NxStage Medical Inc

Edwin L. Burnard, B Braun of America Inc  
Scott A. Colburn, MS, BSN, RN, FDA/CDRH  
Conor Curtin, Fresenius Medical Care  
Michael Dennis, Abbvie  
Loretta Dorn, Baxter Healthcare Corporation  
Bruce A. Friedman, D.Eng, GE Healthcare  
Jason Glithero, CR Bard  
Cathie Gosnell, RN MS MBA, Premier Healthcare Alliance  
Krisanne Graves  
Stephanne Hale, RN BSN MBA MHA, Novation LLC  
Tom Hancock, Global Enteral Device Supplier Association  
Trevor C. Huang, PhD MBA, Medtronic Inc WHQ Campus  
Michael B. Jaffe, PhD, Cardiorespiratory Consulting LLC  
Rory Jaffe, MD, California Hospital Patient Safety Organization (CHPSO)  
David W. Johnson, Halyard Health  
Crystal Koelper, Corpak MedSystems  
Tony Lair, NeoMed Inc  
Michael W. Maryan, Cook Inc  
Ravi Narayanan, Value Plastics Inc  
Brad Noe, Becton Dickinson & Company  
David G. Osborn, Philips Electronics North America  
Tricia Leilani Otstot, RN  
Shailendra Parihar, Ph.D., Johnson & Johnson  
James H. Philip, CCE, Brigham & Womens Hospital  
David Quinn, Welch Allyn Inc  
Ben Rush, Hospira Worldwide Inc  
Wayne Schuessler, Covidien  
Paul R. Smith, Terumo BCT  
Michael Turturro, PhD, Medline Industries Inc  
Olliver Wallnewitz, Draeger Medical Systems Inc

*Alternates:*

Brian Cassidy, Terumo BCT  
Jean E. Daavettila, Nestle HealthCare Nutrition Inc  
Rick Dodd, GE Healthcare  
Doug Garrity, Boston Scientific Corporation  
Weston Harding, Becton Dickinson & Company  
Eric R. Hudson, Medline Industries Inc  
Lynn E. Jensen, Fresenius Medical Care  
Steven C. Jepson, Baxter Healthcare Corporation  
Kent Lurvey, Baxter Healthcare Corporation  
John R. Miskovic, Hospira Worldwide Inc  
Charles C. Monroe, Philips Electronics North America  
Golfredo Murillo, Halyard Health  
Tony Sacchetti, Covidien  
Pamela D. Scott, FDA/CDRH  
Nityanand Shetty, Spacelabs Medical Inc  
Charles B. Sidebottom, PE, PPO Standards LLC  
Roxanne M. Smarszcz, RN MSN, Abbott Laboratories  
Kyle Steele, Nordson Medical

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NOTE—Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

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## Background of AAMI/ISO 80369-7:2016

As indicated in the foreword to the main body of this document (page viii), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard, which was developed by a joint ISO and International Electrotechnical Commission (IEC) working group, ISO/TC 210-IEC/SC 62D/JWG4, Small-bore connectors.

U.S. participation in ISO/TC 210-IEC/SC 62D/JWG4 is organized through the U.S. Technical Advisory Group to ISO/TC 210-IEC/SC 62D/JWG4, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the standard. “Should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the standard. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

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NOTE Users of this standard are advised that this document is an AAMI identical adoption of an ISO document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g. colour instead of color)
- Use of SI units (e.g. metres instead of feet, Celsius instead of Fahrenheit, etc.)
- Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15)

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This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision. The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633.

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NOTE—Beginning with the ISO foreword on page viii, this American National Standard is identical to the Corrected version of ISO 80369-7 published on 12-1-2016.

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## 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](http://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](http://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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following: <https://www.iso.org/foreword-supplementary-information.html>.

The committee responsible for this document is ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and IEC/SC62D, *Electromedical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This first edition of ISO 80369-7 cancels and replaces ISO 594-1:1986 and ISO 594-2:1998, clauses, subclauses, tables, figures, and annexes of which have been consolidated and technically revised.

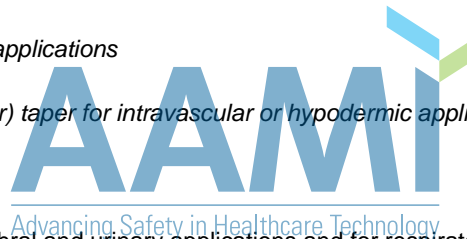
This part of ISO 80369 contains the following major technical revisions to ISO 594-1 and ISO 594-2.

- a) New terms and definitions have been added to this part of ISO 80369 to more clearly define the various types of LUER CONNECTORS included in the scope of this part of ISO 80369. This part of ISO 80369 more broadly describes the requirements for the CONNECTORS used for intravascular or hypodermic APPLICATIONS, unlike ISO 594-1 and ISO 594-2 that are replaced by this part of ISO 80369, which only described the requirements for the fittings (intended CONNECTION surfaces) of these CONNECTORS. This distinction is important to define here because the previous International Standards do not contain the terms CONNECTOR or CONNECTION and ISO 80369- series does not use the term fitting.
- b) Requirements for certain dimensions not previously identified in ISO 594-1 and ISO 594-2 are added to this part of ISO 80369 to reduce the RISK of misconnections between MEDICAL DEVICES or ACCESSORIES for different APPLICATIONS with the SMALL-BORE CONNECTORS that are being developed under other parts of the ISO 80369- series. These new dimensions were selected to represent the current design and dimensions of LUER CONNECTORS in clinical use at the time this part of ISO 80369 was developed. The term "6 % (Luer) taper" used throughout the previous standards has also been clarified to the more commonly used equivalent specified diameters separated by a specified distance on a common axis.

- c) Requirements for gauging of LUER CONNECTORS made from SEMI-RIGID MATERIALS using plug and ring test gauges have been replaced by dimensional requirements, which are more precise and essential for reducing the RISK of misconnection with the other CONNECTORS identified in ISO 80369-1.
- d) Separate requirements for LUER CONNECTORS made from SEMI-RIGID MATERIALS and RIGID MATERIALS have been eliminated and combined as one common set of dimensions and requirements. This consolidation of requirements was made to further reduce the RISK of misconnection with other SMALL-BORE CONNECTORS.

ISO 80369 consists of the following parts, under the general title *Small-bore connectors for liquids and gases in healthcare applications*:

- *Part 1: General requirements*
- *Part 3: Connectors for enteral applications*
- *Part 5: Connectors for limb cuff inflation applications*
- *Part 6: Connectors for neuraxial applications*
- *Part 7: Connectors with 6 % (Luer) taper for intravascular or hypodermic applications*
- *Part 20: Common test methods*



Additional parts on connectors for urethral and urinary applications and for respiratory applications are planned.

This corrected version of ISO 80369-7:2016 incorporates the following corrections:

- in the Scope, NOTE 1 has been removed and the other notes renumbered accordingly;
- in the second paragraph of 6.6, the reference to the annex has been changed;
- the lower-case greek letter " $\beta$ " has been changed into a capital greek letter " $B$ " in the notes of Tables B.5 and B.6;
- the representation of the angle  $B$  has been updated in Figure B.7;
- values and angles have been corrected in Figures C.1, C.2, C.3, C.4 and C.6.

## Introduction

This part of ISO 80369 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.

ISO 80369-20 contains the common TEST METHODS to support the performance requirements for SMALL-BORE CONNECTORS.

This part of ISO 80369 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 part of ISO 80369 are dimensionally incompatible with any of the other CONNECTORS for APPLICATIONS identified in the ISO 80369- series of standards 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 part of ISO 80369, 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 or as noted: SMALL CAPITALS.

In this part of ISO 80369, 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 part of ISO 80369 conform to usage described in the ISO/IEC Directives, Part 2, Annex H. For the purposes of this part of ISO 80369, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this part of ISO 80369;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this part of ISO 80369;
- “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.

# Small-bore connectors for liquids and gases in healthcare applications—Part 7: Connectors with 6 % (Luer) taper for intravascular or hypodermic applications

## 1 \* Scope

This part of ISO 80369 specifies dimensions and requirements for the design and functional performance of SMALL-BORE CONNECTORS intended to be used for CONNECTIONS in intravascular APPLICATIONS or hypodermic CONNECTIONS in hypodermic APPLICATIONS of MEDICAL DEVICES and ACCESSORIES.

**EXAMPLES** Hypodermic syringes and needles or intravascular (IV) cannulae with male and female LUER SLIP CONNECTORS and LUER LOCK CONNECTORS.

**NOTE 1** The LUER CONNECTOR was originally designed for use at pressures up to 300 kPa.

This part of ISO 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 ISO 80369 does not specify requirements for the following SMALL-BORE CONNECTORS, which are specified in other International Standards:

- haemodialyser, haemodiafilter and haemofilter blood compartment ports (ISO 8637 and applicable portion of ISO 8638 referencing blood compartment ports);
- haemodialysis, haemodiafiltration and haemofiltration equipment CONNECTORS (ISO 8637);
- infusion system closure piercing CONNECTORS (ISO 8536-4).

**NOTE 2** MANUFACTURERS are encouraged to incorporate the SMALL-BORE CONNECTORS specified in this part of ISO 80369 into MEDICAL DEVICES 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 ISO 80369, will be included.

**NOTE 3** ISO 80369-1:2010, 5.8, specifies alternative methods of compliance with ISO 80369-1:2010, for SMALL-BORE CONNECTORS intended for use with intravascular APPLICATIONS or hypodermic APPLICATION 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.

ISO 14971:2007, *Medical devices—Application of risk management to medical devices*

ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications—Part 1: General requirements*