

This is a preview of "ANSI/AAMI/ISO 80369-...". Click here to purchase the full version from the ANSI store.

# American National Standard



PREVIEW COPY

## ANSI/AAMI/ ISO 80369-3: 2016

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.

For a complete copy of this AAMI document, contact AAMI at +1-977-249-8226 or visit [www.aami.org](http://www.aami.org).

Small-bore connectors  
for liquids and gases in  
healthcare applications—  
Part 3: Connectors for  
enteral 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.

### INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

American National Standard

ANSI/AAMI/ISO 80369-3:2016



**Small-bore connectors for liquids and gases in  
healthcare applications—Part 3: Connectors for  
enteral applications**

**PREVIEW COPY**

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.

For a complete copy of this AAMI document, contact AAMI at +1-977-249-8226 or visit [www.aami.org](http://www.aami.org).

Approved 5 June 2016 by  
**AAMI**

Approved 3 August 2016 by  
**American National Standards Institute**

**Abstract:** Specifies the dimensions and requirements for the design and functional performance of SMALL-BORE CONNECTORS intended to be used for CONNECTIONS ON ENTERAL MEDICAL DEVICES and ACCESSORIES.

## AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

**CAUTION NOTICE:** This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than five years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI.

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are voluntary, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.



## PREVIEW COPY

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.

*Published by*

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

For a complete copy of this AAMI document, contact AAMI at  
+1-977-249-8226 or visit [www.aami.org](http://www.aami.org).

© 2016 by the Association for the Advancement of Medical Instrumentation

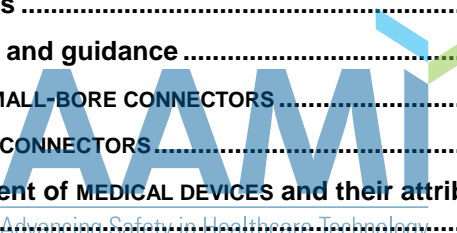
All Rights Reserved

This publication is subject to copyright claims of ISO and AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this document should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, complete the reprint request form at [www.aami.org](http://www.aami.org) or contact AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633. Phone: +1-703-525-4890; Fax: +1-703-276-0793.

Printed in the United States of America

**ISBN 1-57020-620-1**

<b>Contents</b>	<b>Page</b>
<b>Glossary of equivalent standards .....</b>	<b>iv</b>
<b>Committee representation.....</b>	<b>v</b>
<b>Background on ANSI/AAMI adoption of ISO 80369-3:2016.....</b>	<b>vii</b>
<b>Foreword .....</b>	<b>viii</b>
<b>Introduction .....</b>	<b>ix</b>
<b>1 * Scope .....</b>	<b>1</b>
<b>2 Normative references .....</b>	<b>1</b>
<b>3 Terms and definitions.....</b>	<b>2</b>
<b>4 General requirements.....</b>	<b>3</b>
<b>5 Dimensional requirements for ENTERAL SMALL-BORE CONNECTORS.....</b>	<b>4</b>
<b>6 Performance requirements .....</b>	<b>4</b>
<b>Annex A (informative) Rationale and guidance .....</b>	<b>6</b>
<b>Annex B (normative) ENTERAL SMALL-BORE CONNECTORS.....</b>	<b>10</b>
<b>Annex C (normative) Reference CONNECTORS.....</b>	<b>15</b>
<b>Annex D (informative) Assessment of MEDICAL DEVICES and their attributes with CONNECTIONS within this APPLICATION.....</b>	<b>20</b>
<b>Annex E (informative) Summary of the usability requirements for SMALL-BORE CONNECTORS for ENTERAL applications.....</b>	<b>21</b>
<b>Annex F (informative) Summary of SMALL-BORE CONNECTOR criteria and requirements for ENTERAL APPLICATIONS .....</b>	<b>26</b>
<b>Annex G (informative) Summary of assessment of the design of the CONNECTORS for ENTERAL APPLICATIONS.....</b>	<b>29</b>
<b>Annex H (informative) Reference to the essential principles.....</b>	<b>35</b>
<b>Annex I (informative) Terminology—Alphabetized index of defined terms.....</b>	<b>37</b>
<b>Bibliography .....</b>	<b>38</b>



**PREVIEW COPY**

This preview is for informational purposes only. It is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-977-249-8226 or visit [www.aami.org](http://www.aami.org).

## Glossary of equivalent standards

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.

[www.aami.org/standards/glossary.pdf](http://www.aami.org/standards/glossary.pdf)



## PREVIEW COPY

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.

For a complete copy of this AAMI document, contact AAMI at +1-977-249-8226 or visit [www.aami.org](http://www.aami.org).

## Committee representation

### Association for the Advancement of Medical Instrumentation

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

The publication of AAMI/ISO 80369-3 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 (U.S. Sub-TAG for ISO/TC 210/JWG 04), chaired by Scott Colburn of FDA and Brad Noe of Becton Dickinson & Co. played an active part in developing ISO 80369-3.

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, FDA/CDRH  
Charles B. Sidebottom, PE, PPO Standards LLC

*Members:* Jon Cammack, AstraZeneca/MedImmune  
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  
Luann M. Pendy, Medtronic Inc WHQ Campus  
Dan Reid, Omnex Engineering and Management  
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 Sestrick, 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, FDA/CDRH  
Brad Noe, Becton Dickinson & Company

*Members:* Mark S. Adams, MBA PMP, Boston Scientific Corporation  
Keith Anderson, Smiths-Medical  
Steve J. Bernard, Nestle HealthCare Nutrition Inc  
Jim Brown, Colder Products Company  
James Brugger, BSME MEEM, NxStage Medical Inc  
Edwin L. Burnard, B Braun of America Inc  
David Carr, ASQ CQA CMI, Teleflex Medical

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  
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

Advancing Safety in Healthcare Technology

*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

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. For a complete copy of this AAMI document, contact AAMI at 1-800-577-2158 or visit [www.aami.org](http://www.aami.org).

---

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.

---

**Acknowledgments**

The committee gratefully acknowledges Nathan Griffith, Halyard Health; John Miskovic, Hospira; Kyle Steele, Nordson Medical; Robert Virag, TRIFID Medical Medical Group LLC and especially Weston Harding, Becton Dickinson, for their contributions as CAD (computer-aided design) experts to the development of this standard. Their extraordinary commitment of time and effort attests to their dedication to patient safety and is greatly appreciated.



## Background on ANSI/AAMI adoption of ISO 80369-3:2016

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. sub-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.

This standard replaces AAMI/CN3, Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications.

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.

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.

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.

For a complete copy of this AAMI document, contact AAMI at +1-977-249-8226 or visit [www.aami.org](http://www.aami.org).

## 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 URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and IEC/SC 62D, *Electromedical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

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 2: *Connectors for breathing systems and driving gases applications*
- 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*

An additional part on connectors for urethral and urinary applications is planned.

## Introduction

This part of ISO 80369 was developed because of several incidents, with catastrophic consequences, resulting from firstly, the administration of inappropriate medication into the alimentary canal and secondly, from ENTERAL solutions being administered via incorrect routes, including intravenously and into the airway. Many incidents were reported leading to international recognition of the importance of these issues, and a need was identified to develop specific CONNECTORS for MEDICAL DEVICES and their ACCESSORIES used to deliver feed via the ENTERAL route.

The ISO 80369 series has been developed to prevent misconnection between SMALL-BORE CONNECTORS used in different APPLICATIONS. ISO 80369-1 specifies the requirements necessary to verify the designs 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, the dimensions, and the drawings of SMALL-BORE CONNECTORS intended to be used in ENTERAL 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 for SMALL-BORE CONNECTORS, except as indicated in G.2. If fitted to the relevant MEDICAL DEVICES and ACCESSORIES, these CONNECTORS are to reduce the RISK of medication and liquid nutritional formula intended for ENTERAL administration from being delivered via an alternative route, such as intravenously or via an airway device.

During the development of this International Standard, the committee decided to cover the whole ENTERAL system but to have a separate International Standard for reservoir CONNECTORS. ISO 18250-3 specifies the requirements for ENTERAL reservoir CONNECTORS. This part of ISO 80369 includes the interface dimensions for SMALL-BORE CONNECTORS for access ports and PATIENT interfaces on ENTERAL feeding sets and ENTERAL syringes.

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 International Standard conform to usage described in 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, and
- “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.



## PREVIEW COPY

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.

For a complete copy of this AAMI document, contact AAMI at +1-977-249-8226 or visit [www.aami.org](http://www.aami.org).

# Small-bore connectors for liquids and gases in healthcare applications—Part 3: Connectors for enteral applications

## 1 \* Scope

This part of ISO 80369 specifies the dimensions and requirements for the design and functional performance of SMALL-BORE CONNECTORS intended to be used for CONNECTIONS on ENTERAL MEDICAL DEVICES and ACCESSORIES.

NOTE 1 ENTERAL MEDICAL DEVICES include ENTERAL feeding sets, ENTERAL drainage sets, ENTERAL syringes, and PATIENT interface devices including access ports.

This part of ISO 80369 does not specify the dimensions and 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 SMALL-BORE CONNECTORS that are used for the following:

- gastric suction-only MEDICAL DEVICES;
- oral-only MEDICAL DEVICES;

EXAMPLE An oral tip syringe that is not intended to connect to another MEDICAL DEVICE. It is intended to administer directly to the PATIENT'S mouth.

- pressurizing and depressurizing the retention mechanism (e.g. balloon) used to hold invasive ENTERAL MEDICAL DEVICES in place;
- MEDICAL DEVICES for rectal drainage, rectal administration of medicines or fluid, and any other rectal access MEDICAL DEVICE;
- gastrointestinal endoscopy equipment;
- skin level gastrostomy MEDICAL DEVICES.

NOTE 2 MANUFACTURERS are encouraged to incorporate the SMALL-BORE CONNECTORS specified in this part of ISO 80369 into ENTERAL 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.

## 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*