Provisional American National Standard **AAMI/CN3(PS):2014**

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

Approved 2 December 2014 by
Association for the Advancement of Medical Instrumentation

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

This is a provisional standard. The text in this document reproduced from ISO/DIS 80369-3 is from a draft ISO standard that is subject to change without notice.

Published by

Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633
www.aami.org

Printed in the United States of America

ISBN 1-57020-563-9

Contents

Page

Committee representation

Association for the Advancement of Medical Instrumentation

Quality Management and Corresponding General Aspects for Medical Devices Committee

The publication of AAMI/CN3(PS) as a new provisional 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 the Draft International Standard 80369-3.2, upon which this Provisional American National Standard is based.
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:
Jeffrey L. Eggleston, MS PE, Covidien
Mizanu Kebede, Kimberly-Clark Corporation
Ed R. Kimmelman, BME, JD, Kimmelman Consultancy
Kristi M. Kistner, RAC ASQ CBA, Amgen Inc
Dan Labelle, Nonin Medical Inc
Sherry M. Leichtweis, Abbott Laboratories
Emmanuel O. Nyakako, Zimmer Inc
David G. Osborn, Philips Electronics North America
Robert Sestrick, GE Healthcare
Mike Silvestri, Terumo Americas Corporate
Al Van Houdt, Spacelabs Medical Inc

Alternates:
Ujjal Chakravartty, Kimberly-Clark Corporation
Richard Gardner, GE Healthcare
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
Luann M. Pendy, Medtronic Inc VHQ Campus
Kimberly A. Trautman, FDA/CDRH

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:
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
Richard Chan, CCP, North Shore University Hospital
Conor Curtin, Fresenius Medical Care
Jim Dahl, Spacelabs Medical Inc
Michael Dennis, Abbvie
Bruce A Friedman, D.Eng, GE Healthcare
Carrie L. Gavriloff, MSN RN Ed, Akron Childrens Hospital
J. C. Gerancher, III, MD, Wake Forest University Baptist Medical Center

Cathie Gosnell, RN MS MBA, Premier Healthcare Alliance
Krisanne Graves
Peggi Guenter, PhD RN CNSN, American Society for Parenteral and Enteral Nutrition
Stephanne Hale, RN BSN MBA MHA, Novation LLC
Tom Hancock, Global Enternal Device Supplies Association
Brian K. Heston, Zimmer Inc
Trevor C. Huang, PhD MBA, Medtronic Inc WHQ Campus
Rory Jaffe, MD, California Hospital Patient Safety Organization (CHPSO)
Steven C. Jepson, Baxter Healthcare Corporation
David W. Johnson, Kimberly-Clark Corporation
Crystal Koelper, Corpak MedSystems
John J. Kropczynski, Jr., BS MBA, Abbott Laboratories
Tony Lair, NeoMed Inc
Lee Leichter, P/L Biomedical
Michael W. Maryan, Cook Inc
Ravi Narayanan, Value Plastics Inc
William O'Neill, Smiths Medical
David G. Osborn, Philips Electronics North America
Tricia Leilani Otstot, RN
Shailendra Parihar, PhD, Johnson & Johnson
James H. Philip, CCE, Brigham & Womens Hospital
David Quinn, Welch Allyn Inc
Glenda S. Rodgers, RNC, Heartland Regional Medical Center
Ben Rush, Hospira Worldwide Inc
Wayne Schuessler, Covidien
Debora Simmons, RN MSN CCRN, University of Texas MD Anderson Cancer Center
Courtney Smith, Blue Water Consulting
Paul R. Smith, Terumo BCT
William A. Tait, Cuffco LLC
Michael Turturro, PhD, Medline Industries Inc
Timothy W. Vanderveen, MS, PharmD, CareFusion
Torge Wall, Draeger Medical Systems Inc
Stanley W. Weitzner, MD, Duke University Medical Center

Alternates:
Mary Ann Allen, Children's Hospital of Akron
Brian Cassidy, Terumo BCT
Rick Dodd, GE Healthcare
Eric R. Hudson, Medline Industries Inc
Lynn E. Jensen, Fresenius Medical Care
Kent Lurvey, Baxter Healthcare Corporation
John R. Miskevic, Hospira Worldwide Inc
Charles C. Monroe, Philips Electronics North America
John Rotella, Kimberly-Clark Corporation
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, Value Plastics Inc
Olliver Wallnewitz, Draeger Medical Systems Inc
Yan Yevmenenko, Becton Dickinson & Company

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.

Background of AAMI/CN3(PS):2014

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 198/WG 2, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.

This is a provisional standard. It is being published because it is urgently needed in the United States to promote patient safety. The text in this document reproduced from ISO/DIS 80369-3.2 is from a draft ISO standard that is subject to change without notice. The text in this document, therefore, might not reflect the final text of ISO 80369-3 upon publication.

Once the final version of ISO 80369-3 is approved by ISO, this provisional standard will be replaced by a parallel adoption of ISO 80369-3. The text of the parallel adoption shall be aligned to the text of the ISO standard during the parallel approval process.

If ISO 80369-3 is not approved, AAMI will withdraw this provisional standard.

Purchasers of this provisional standard will receive a PDF copy of ANSI/AAMI/ISO 80369-3, presuming it is approved, at no additional cost, when it is published.

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.

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the fact 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.

ISO 80369-3 was prepared by a Joint Working Group of Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, IEC/TC 62, *Electrical equipment*, Subcommittee SC 62D, *Electrical equipment in medical practice* and CEN/CENELEC TC3/WG 2, *Small-bore connectors.*

This is the first edition of ISO 80369-3.

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* (this standard)

— *Part 4: Connectors for urethral and urinary applications*[1)]

— *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*

In this standard, the following print types are used:

1) Planned but not yet begun as of the date of publication.

— 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: SMALL CAPS

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.

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 for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

Introduction

This International Standard was developed because of several incidents, with catastrophic consequences, resultant from firstly, the administration of inappropriate medication into the alimentary canal and secondly, from ENTERAL solutions 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 feed via the ENTERAL route.

The ISO 80369 series ISO 80369 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 ISO 80369 specifies the design and the dimensions and drawings of SMALL-BORE CONNECTORS intended to be used in ENTERAL APPLICATIONS. The informative Annex D through 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 International Standard are therefore dimensionally incompatible with Luer CONNECTORS and if fitted to the relevant MEDICAL DEVICES and ACCESSORIES, these CONNECTORS should be able to prevent medication and liquid nutritional formula intended for ENTERAL administration from 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 ISO 80369 series of standards for SMALL-BORE CONNECTORS.

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

Provisional American National Standard **AAMI/CN3(PS):2014**

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 on ENTERAL MEDICAL DEVICES and ACCESSORIES.

NOTE 1 ENTERAL MEDICAL DEVICES include ENTERAL feeding 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, which are used for:

— gastric suction only MEDICAL DEVICES;

— oral only MEDICAL DEVICES;

— pressurizing and depressurizing inflation cuffs used to hold invasive ENTERAL MEDICAL DEVICES in place (ISO 80369-7);

— skin level gastrostomy MEDICAL DEVICES; and

— accessing ENTERAL feeding reservoirs (ISO 18250-3).

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 referenced documents, in whole or in part, are normatively referenced in this document and are indispensable for the application of this document. 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 39.

ISO 5356-1:2004, *Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and socket*

ISO 5356-2:2012, *Anaesthetic and respiratory equipment -- Conical connectors -- Part 2: Screw-threaded weight-bearing connectors*

ISO 8185:2007, *Respiratory tract humidifiers for medical use -- Particular requirements for respiratory humidification systems*