American National Standard

AAMI/ CN6:2015

Small-bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications

AAMI
Advancing Safety in Healthcare Technology

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*.

Small-bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications

Approved 16 October 2015 by
Association for the Advancement of Medical Instrumentation

Abstract: Specifies requirements for SMALL-BORE CONNECTORS intended to be used for CONNECTIONS in neuraxial APPLICATIONS. Neuraxial APPLICATIONS involve the use of MEDICAL DEVICES intended to administer medications to neuraxial sites, wound infiltration anaesthesia delivery, and other regional anaesthesia procedures or to monitor or remove cerebro-spinal fluid for therapeutic or diagnostic purposes.

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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

Committee representation

Association for the Advancement of Medical Instrumentation
Quality Management and Corresponding General Aspects for Medical Devices Committee

The publication of AAMI/CN6 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 80369-6, 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:

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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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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 Provisional American National Standard. Their extraordinary commitment of time and effort attests to their dedication to patient safety and is greatly appreciated.

Background of AAMI/CN6 (PS)

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 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 80369-6 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 80369-6 upon publication.

Once the final version of ISO 80369-6 is approved by ISO, this provisional standard will be replaced by a parallel adoption of ISO 80369-6. The text of the parallel adoption shall be aligned to the text of the ISO standard during the parallel approval process.

If ISO 80369-6 is not approved, AAMI will withdraw this provisional standard.

Purchasers of this provisional standard will receive a copy of ANSI/AAMI/ISO 80369-6, 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.

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. 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. 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

ISO 80369-6 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, *Quality management and corresponding general aspects for medical devices*, WG 2, *Small-bore connectors*.

This is the first edition of ISO 80369-6.

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

— *Part 5: Connectors for limb cuff inflation applications*

— *Part 6: Connectors for neuraxial applications* (this standard)

— *Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications*

— *Part 20: Common test methods*

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

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: 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.

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 inappropriate medication, liquid nutritional formula or air being administered neuraxially. 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. 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.

This part of ISO 80369 specifies the design and the dimensions and drawings of SMALL-BORE CONNECTORS intended to be used in neuraxial 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.

There is international evidence that 'wrong-route' medication errors with neuraxial MEDICAL DEVICES have caused deaths and severe HARM. There are reports of non-epidural medications being administered into the epidural space and local anaesthetic solutions intended for epidural administration being administered by the intravenous route. [1][10][15][16] [20] [2] There is also a report where an anaesthetic agent for intravenous use was administered into the cerebrospinal fluid via an external ventricular drain [12]and earlier reports of antibiotics being inappropriately administered by this route.

In July 2007 the World Health Organisation's World Alliance For Patient Safety issued Alert 115 describing four incidents in different countries in which vincristine had been accidentally administered by the intrathecal route instead of intravenous route, as intended. [24] The Alert indicated that, since 1968, this same error had been reported 55 times from a variety of institutional settings.

These incidents occurred despite repeated warnings of the RISK and the introduction of extensive labeling requirements and recommendations, intended to standardize practice and reduce RISKS.

Other health organisations around the world have also issued detailed guidance to minimize the RISK of these 'wrong-route' errors. [21][16][22][10]

Nevertheless, reports of fatal incidents following the administration of vinca alkaloids continue to be reported internationally. [23] In 2009, the Food and Drug Administration in the USA issued a Medical Devices Calendar, which included an example of a case study of a neuraxial misconnection. [13]

CONNECTORS manufactured to the dimensions set out within this International Standard 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.2. 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 via an alternative route, such as neuraxially, intravenously or via an airway device.

[2] Figures in square brackets refer to the Bibliography.

Small-bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications

1 * Scope

This part of ISO 80369 specifies requirements for SMALL-BORE CONNECTORS intended to be used for CONNECTIONS in neuraxial APPLICATIONS. Neuraxial APPLICATIONS involve the use of MEDICAL DEVICES intended to administer medications to neuraxial sites, wound infiltration anaesthesia delivery, and other regional anaesthesia procedures or to monitor or remove cerebro-spinal fluid for therapeutic or diagnostic purposes.

NOTE 1 Sites for the neuraxial APPLICATION include the spine, intrathecal or subarachnoid space, ventricles of the brain and the epi-, extra-, or peri-dural space. Neuraxial APPLICATION anaesthetics can be administered regionally affecting a large part of the body, such as a limb, and include plexus blocks, such as the branchial plexus blocks or single nerve blocks. Neuraxial APPLICATION procedures include continuous infusion of wounds with local anaesthetic agents.

NOTE 2 For the purposes of this standard, local anaesthesia injected hypodermically is not considered a neuraxial APPLICATION.

EXAMPLES Intended administration includes intrathecal chemotherapy, local anaesthetics, radiological contrast agents, antibiotics, analgesics

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

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.

NOTE 3 MANUFACTURERS are encouraged to incorporate the SMALL-BORE CONNECTORS specified in this part of ISO 80369 into MEDICAL DEVICES, medical systems 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 this part of ISO 80369, will be included. Furthermore it is recognized that standards need to be developed for many MEDICAL DEVICES used for neuraxial APPLICATIONS.

NOTE 4 ISO 80369-1:2010, 5.8, specifies alternative methods of compliance with ISO 80369-1:2010, for SMALL-BORE CONNECTORS intended for use with NEURAXIAL APPLICATION MEDICAL DEVICES or ACCESSORIES, which do not comply with this part of ISO 80369.

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 50.

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