Provisional American National Standard **AAMI/CN20(PS):2014**

Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods

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Association for the Advancement of Medical Instrumentation

Abstract: Specifies the TEST METHODS to support the functional requirements for SMALL-BORE CONNECTORS intended to be used for CONNECTIONS of MEDICAL DEVICES and related ACCESSORIES.

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Association for the Advancement of Medical Instrumentation

Quality Management and Corresponding General Aspects for Medical Devices Committee

The publication of AAMI/CN20(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 Final Draft International Standard 80369-20, upon which this Provisional American National Standard is based.

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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.

Background of AAMI/CN20(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 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/FDIS 80369-20 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 80369-20 upon publication.

Once the final version of ISO 80369-20 is approved by ISO, this provisional standard will be replaced by a parallel adoption of ISO 80369-20. The text of the parallel adoption shall be aligned to the text of the ISO standard during the parallel approval process.

If ISO 80369-20 is not approved, AAMI will withdraw this provisional standard.

Purchasers of this provisional standard will receive a PDF copy of ANSI/AAMI/ISO 80369-20, 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 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.

ISO 80369-20 was prepared jointly by Technical Committees 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.

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*

— *Part 7: Connectors for intravascular or hyopdermic applications*

— *Part 20: Common test methods* (this standard)

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.

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

— TERMS DEFINED IN ISO 80369-1 AND CLAUSE 3 OF THIS STANDARD: 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 following paragraph is directed to authorities with jurisdiction and is not intended to address clinical implementation:

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 committee 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 part of ISO 80369 includes common TEST METHODS for evaluating the functional performance of the SMALL-BORE CONNECTORS of this series.

During the development of the ISO 80369 series it became evident that many of the TEST METHODS were very similar for each of the APPLICATIONS. It was therefore decided to standardize all the TEST METHODS into a separate part of the series to prevent unnecessary duplication and minor differences. It is also recognized that not all CONNECTORS can be evaluated using each TEST METHOD in this part. The TEST METHODS applicable to each CONNECTOR are specified in the respective part of the ISO 80369 series.

Provisional American National Standard **AAMI/CN20(PS):2014**

Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods

1 * Scope

This part of ISO 80369 specifies the TEST METHODS to support the functional requirements for SMALL-BORE CONNECTORS intended to be used for CONNECTIONS of MEDICAL DEVICES and related ACCESSORIES.

This part of ISO 80369 does not specify the functional 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.

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 29.

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

3 Terms and definitions

For the purposes of this document, the terms and definitions specified in ISO 80369-1:2010 and ISO 14971:2007 and the following apply. For convenience, the sources of all defined terms used in this document are given in the index at the end of this document.

3.1
TEST METHOD
definitive PROCEDURE for evaluating CONNECTORS that produces a test result

3.2
TYPE TEST
test on a representative sample with the objective of determining if the CONNECTOR, as designed and manufactured, can meet the requirements of this standard

Note 1 to entry: More than one set of representative samples can be required, e.g. testing the SMALL-BORE CONNECTORS produced in each cavity of a multi-cavity mould.

[SOURCE: IEC 60601-1:2005, definition 3.135 modified: deleted ‘of the equipment’ and replaced ‘equipment’ with ‘CONNECTOR’.]