DRAFT INTERNATIONAL STANDARD

ISO/DIS 80369-6

ISO/TC **210**

Secretariat: **ANSI**

Voting begins on:
2014-09-25

Voting terminates on:
2015-02-25

Small bore connectors for liquids and gases in healthcare applications —

Part 6:
Connectors for neuraxial applications

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé —

Partie 6: Raccords destinés à des applications neuraxiales

ICS: 11.040.25

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Reference number
ISO/DIS 80369-6:2014(E)

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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.

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/IEC 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) D, *Electrical equipment in medical practice* and CEN/CENELEC TC3/WG 2, *Small-bore connectors*.

This is the first edition of ISO 80369-6.

ISO/IEC 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*

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 CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR 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

The standards in this series were developed to prevent misconnection between SMALL-BORE CONNECTORS used in different APPLICATIONS. Part 1 of the series documents the necessary measures and PROCEDURES to prevent misconnection and defines the APPLICATIONS. Part 20 contains the common TEST METHODS to support the functional requirements for SMALL-BORE CONNECTORS. The other parts specify the designs of SMALL-BORE CONNECTORS for each APPLICATION.

This part of ISO 80369 includes the dimensions and drawings of CONNECTORS intended to be used in neuraxial APPLICATIONS. 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][6][11][12][12][16] There is also a report where an anaesthetic agent for intravenous use was administered into the cerebrospinal fluid via an external ventricular drain [7] 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. [20] The Alert indicated that, since 1968, this same error had been reported 55 times from a variety of institutional settings.

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

Other health organisations around the world have also issued detailed guidance to minimise the RISK of these 'wrong-route' errors. [17][12][18][6]

Nevertheless, reports of fatal incidents following the administration of vinca alkaloids continue to be reported internationally. [19] 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. [9]

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 recognised that standards need to be developed for many MEDICAL DEVICES used for neuraxial APPLICATIONS.

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 43.

ISO 10933-1:2009, *Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process*

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

ISO 80369-3:— [2], *Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications*

ISO 80369-5:— [3], *Small-bore connectors for liquids and gases in healthcare applications — Part 5: Connectors for limb cuff inflation applications*

ISO 80369-7:— [4], *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications*

ISO 80369-20:— [5], *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

ASTM D638-10, *Standard test method for tensile properties of plastics*

ASTM D790-10, *Standard test methods for flexural properties of unreinforced and reinforced plastics and electrical insulating materials*

3 Terms and definitions

For the purpose of this document, the terms and definitions specified in ISO 80369-1 ISO 80369-20:—, ISO 14971:2007 and the following apply. For convenience, the sources of all defined terms used in this document are given in the Index on page 45.

3.1
LOCK CONNECTOR
CONNECTOR with a locking mechanism

3.2
NORMAL USE
operation, including routine inspection and adjustments by any USER, and stand-by, according to the instructions for use

NOTE 1 to entry: NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, service, transport, etc. as well.

[SOURCE: IEC 60601-1:2005+A1:2012, definition 3.97, modified, replaced 'OPERATOR' with 'USER'.]

3.3
RATED
<value> term referring to a value assigned by the MANUFACTURER for a specified operating condition

[SOURCE: IEC 60601-1:2005, definition 3.97]

3.4
SLIP CONNECTOR
CONNECTOR without a locking mechanism

2) To be published.

3) To be published.

4) To be published.

5) To be published.

3.5
USER
person using, i.e. operating or handling, the MEDICAL DEVICE

NOTE 1 to entry: This includes, but is not limited to, cleaners, maintainers and installers.

NOTE 2 to entry: PATIENTS or other laypersons can be USERS.

[SOURCE: ISO 62366:2007, definition 3.23]

3.6
USER PROFILE
summary of the mental, physical and demographic traits of an intended USER population, as well as any special characteristics that can have a bearing on design decisions, such as occupational skills and job requirements

[SOURCE: ISO 62366:2007, definition 3.25]

4 General requirements

4.1 General requirements for the neuraxial APPLICATION

SMALL-BORE CONNECTORS of MEDICAL DEVICES or ACCESSORIES intended for use in neuraxial APPLICATIONS specified in this standard comply with the general requirements of ISO 80369-1:2010 except as follows.

Because the following CONNECTORS are inadequately specified, SMALL-BORE CONNECTORS for use in neuraxial APPLICATIONS should not, but may connect with:

— the cones and sockets of ISO 5356-1:2004 and ISO 5356-2:2006;

— the temperature sensor CONNECTOR and mating ports specified in Annex DD of ISO 8185:2007; and

— the nipples of EN 13544-2:2002,

The reference CONNECTORS for evaluation of the NON-INTERCONNECTABLE characteristics are described in Annex C.

The tests of Annex H shall replace ISO 80369-1:2010, Annex B.

NOTE 1 ISO 80369-6, Annex H, describes a deviation to the physical test NON-INTERCONNECTABLE characteristics of ISO 80369-1, Annex B. A rationale for the deviation is provided in Annex A. For neuraxial SMALL-BORE CONNECTORS, ISO 80369-6, Annex H, supersedes ISO 80369-1 Annex B.

Where the design of the SMALL-BORE CONNECTORS of this standard, relies on dimensions or features of the MEDICAL DEVICE or ACCESSORY to ensure NON-INTERCONNECTABLE characteristics, the MANUFACTURER shall verify the NON-INTERCONNECTABLE characteristics. Check compliance by application of the tests of Annex H. When necessary, the SMALL-BORE CONNECTOR may be installed on the MEDICAL DEVICE or ACCESSORY to demonstrate compliance with the NON-INTERCONNECTABLE requirements of Annex H.

NOTE 2 MEDICAL DEVICES using the SMALL-BORE CONNECTORS of this standard that do not rely on the dimensions or features of the MEDICAL DEVICE or ACCESSORY to ensure NON-INTERCONNECTABLE characteristics are presumed to comply with the NON-INTERCONNECTABLE characteristics test requirements of this standard by virtue of testing used to create and validate this standard.

NOTE 3 The summary of MEDICAL DEVICES and their attributes with CONNECTIONS within this APPLICATION is provided in informative Annex D.

NOTE 4 The summary of the usability requirements for CONNECTORS for this APPLICATION is provided in informative Annex E.

NOTE 5 The summary of criteria and requirements for CONNECTORS for this APPLICATION is provided in informative Annex F.

NOTE 6 The summary of assessment of the design of CONNECTORS for this APPLICATION according to ISO 80369-1:2010, Clause 7, is contained in informative Annex G.

4.2 Material used for SMALL-BORE CONNECTORS

In addition to the requirements of ISO 80369-1:2010, Clause 4, SMALL-BORE CONNECTORS of MEDICAL DEVICES or ACCESSORIES shall be made of materials with a modulus of elasticity either in flexure or in tension greater than 950 MPa.

Check compliance by application of the tests of ASTM D638 or ASTM D790.

4.3 Compatibility

4.3.1 Compatibility with substances used

The material from which the SMALL-BORE CONNECTOR of MEDICAL DEVICES or ACCESSORIES is made shall be compatible with the substances intended to be passed through the CONNECTOR.

Check compliance by inspection of the RISK MANAGEMENT FILE.

4.3.2 Biocompatibility

The SMALL-BORE CONNECTOR of MEDICAL DEVICES or ACCESSORIES shall be evaluated to the requirements of ISO 10933-1:2009.

Check compliance by application of ISO 10933:2009.

5 Dimensional requirements for SMALL-BORE CONNECTORS for neuraxial APPLICATIONS

SMALL-BORE CONNECTORS intended to be used in the neuraxial APPLICATION shall comply with the relevant dimensions and tolerances as given in

— Figure B.1 and Table B.1 for a male SLIP CONNECTOR (N1).

— Figure B.2 and Table B.2 for a male LOCK CONNECTOR (N2).

— Figure B.3 and Table B.3 for a male LOCK CONNECTOR with rotatable collar (N2).

— Figure B.4 and Table B.4 for a female CONNECTOR with swept threads (N2).

— Figure B.5 and Table B.5 for a female CONNECTOR with lugs (N2).

NOTE ISO 80369-1, 5.8, specifies alternative methods of compliance with the ISO 80369 (series), for SMALL-BORE CONNECTORS intended for use in the neuraxial APPLICATION, which do not comply with this International Standard.

Check compliance by verifying the relevant dimensions and tolerances specified in Annex B.

The dimensions of male and female CONNECTORS made of RIGID and SEMI-RIGID MATERIALS shall comply with the relevant dimensional values given in Annex B.

6 Performance requirements

6.1 General performance requirements

The tests described within this International Standard are TYPE TESTS.

6.2 Fluid leakage

6.2.1 Fluid leakage requirement

Neuraxial SMALL-BORE CONNECTORS shall either be evaluated for leakage using the leakage by pressure decay TEST METHOD or be evaluated for leakage using the positive pressure liquid leakage TEST METHOD.

6.2.2 Leakage by pressure decay

Neuraxial SMALL-BORE CONNECTORS evaluated for fluid leakage performance with the leakage by pressure decay TEST METHOD shall not leak by more than 0,005 Pa· m^3/s while being subjected to an applied pressure of between 300 kPa and 330 kPa over a hold period between 15 s and 20 s using air as the medium. MANUFACTURERS may use a greater applied pressure or longer hold period.

Check compliance by applying the tests of ISO 80369-20:—, Annex B, while using the leakage reference CONNECTOR specified in Annex C.

6.2.3 Positive pressure liquid leakage

Neuraxial SMALL-BORE CONNECTORS evaluated for fluid leakage performance with the positive pressure liquid leakage TEST METHOD shall show no signs of leakage, sufficient to form a falling drop of water, over a hold period of 30 s to 35 s while being subjected to an applied pressure of between 300 kPa and 330 kPa. MANUFACTURERS may use a greater applied pressure or a longer hold period.

Check compliance by applying the tests of ISO 80369-20:—, Annex C, while using the leakage reference CONNECTOR specified in Annex C.

6.3 Subatmospheric-pressure air leakage

Neuraxial SMALL-BORE CONNECTORS evaluated for subatmospheric pressure air leakage. Neuraxial SMALL-BORE CONNECTORS shall not leak by more than 0,005 Pa·m^3/s while being subjected to an applied subatmospheric pressure of between 80,0 kPa and 88,0 kPa over a hold period of between 15 s and 20 s. MANUFACTURERS may use a greater applied subatmospheric pressure.

Check compliance by applying the tests of ISO 80369-20:—, Annex D, while using the stress cracking reference CONNECTOR specified in Annex C.

6.4 Stress cracking

Neuraxial SMALL-BORE CONNECTORS evaluated for stress cracking. Neuraxial SMALL-BORE CONNECTORS shall meet the requirements of 6.2.1 after being subjected to stresses of ISO 80369-20:—, Annex E.

Check compliance by applying the tests of ISO 80369-20:—, Annex E, while using the stress cracking reference CONNECTOR specified in Annex C.

6.5 Resistance to separation from axial load

Neuraxial SMALL-BORE CONNECTORS shall be evaluated for separation from axial load. Neuraxial SMALL-BORE CONNECTORS shall not separate from the reference CONNECTOR over a hold period between 10 s and 15 s while being subjected to a disconnection applied axial force between:

a) 23 N and 25 N for a SLIP CONNECTOR; and

b) 32 N and 35 N for a LOCK CONNECTOR.

MANUFACTURERS may use a greater disconnection applied axial force or a longer hold period.

Check compliance by applying the tests of ISO 80369-20:—, Annex F, while using the separation from axial load reference CONNECTOR specified in Annex C.

6.6 Resistance to separation from unscrewing

LOCK CONNECTORS shall be evaluated for separation from unscrewing. A LOCK CONNECTOR shall not separate from the reference CONNECTOR for a hold period between 10 s and 15 s while being subjected to an unscrewing torque of between 0,0198 N· m to 0,02 N· m. MANUFACTURERS may use a greater applied unscrewing torque or a longer hold period.

Check compliance by applying the tests of ISO 80369-20:—, Annex G, while using the separation from axial load reference CONNECTOR specified in Annex C.

6.7 Resistance to overriding

Neuraxial SMALL-BORE CONNECTORS shall be evaluated for resistance to overriding. Neuraxial SMALL-BORE CONNECTORS shall not override the threads or lugs of the reference CONNECTOR while being subjected to an applied torque of between 0,15 N· m to 0,17 N· m over a hold period between 5 s and 10 s. MANUFACTURERS may use a greater applied torque or a longer hold period.

Check compliance by applying the tests of ISO 80369-20:—, Annex H, while using the separation from axial load reference CONNECTOR specified in Annex C.

Annex A

(informative)

Rationale and guidance

A.1 General guidance

This Annex provides a rationale for some requirements of ISO 80369-6, and is intended for those who are familiar with the subject of ISO 80369-6 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this part of ISO 80369 necessitated by those developments.

A.2 Rationale for particular clauses and subclauses

The clauses and subclauses in this Annex have been numbered to correspond to the numbering of the clauses and subclauses of this document to which they refer. The numbering is, therefore, not consecutive.

Subclause 1 – Scope

In 2000, a Task Group of the European standards organisation CEN proposed a strategy to reduce incidents of accidental misconnection of PATIENT therapy lines by the use of a series of NON-INTERCONNECTABLE CONNECTORS, differentiated by design, for use in different medical applications. The strategy reserves the use of Luer CONNECTORS solely for use in MEDICAL DEVICES used to access the vascular system or for hypodermic syringes so that they can achieve their intended function. [5] The CONNECTORS .of this standard are reserved for neuraxial APPLICATIONS.

MANUFACTURERS and RESPONSIBLE ORGANIZATIONS are encouraged to report their experience with the SMALL-BORE CONNECTORS specified in this part of ISO 80369 to the Secretariat of ISO TC 210, so that it can consider this feedback during the revision of the relevant part of this series of International Standards.

Annex B

Dimension '*K*' & '*k*' are defined to ensure an understanding by MANUFACTURERS of the extent of the CONNECTOR. Failure to comply with these minimum dimensions could result in the inability to properly connect to neuraxial CONNECTORS produced by other MANUFACTURERS. The Figure A.1 and Figure A.2 illustrates this concern.

All surface finishes of parts of these CONNECTORS which do not form part of the mating surfaces should be constructed so as to avoid the possibility of any another CONNECTOR, which could be present in the clinical environment, from being able to form a fluid-tight CONNECTION to the CONNECTORS specified within this standard. This ensures that attempts made to connect any other CONNECTOR (not complying with this part of ISO 80369) to one specified within this standard results in fluid leakage and the failure to establish a fluid-tight path into the CONNECTORS specified within this standard.

Annex B defines a maximum internal diameter of the male CONNECTOR, to prevent inadvertent male-to-male connectivity between the CONNECTORS defined within this standard and any other standardised SMALL-BORE CONNECTORS used in healthcare APPLICATIONS.