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INTERNATIONAL ELECTROTECHNICAL COMMISSION • МЕЖДУНАРОДНАЯ ЭЛЕКТРОТЕХНИЧЕСКАЯ КОММИСИЯ • COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

Small-bore connectors for liquids and gases in healthcare applications —

Part 3:
Connectors for enteral applications

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

Partie 3: Raccords destinés à des applications entérales

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.

This draft is submitted to a parallel enquiry in ISO and a CDV vote in the IEC.

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.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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 fact that some of the elements of this document are 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 Project Group 3 of Technical Committee ISO/TC 210/ IEC62D Joint Working Group 4 *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:

— Requirements and definitions: roman type.

— *Test specifications: italic 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] To be developed

— TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR 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

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 ENTERAL APPLICATIONS. Other parts of ISO 80369 include requirements for SMALL-BORE CONNECTORS used in different APPLICATION categories.

This International Standard was developed as a result 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.

CONNECTORS manufactured to the dimensions set out within this International Standard are dimensionally incompatible with Luer CONNECTORS and if fitted to the relevant MEDICAL DEVICES, 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.

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

1 Scope

This part of ISO 80369 specifies requirements for SMALL-BORE CONNECTORS intended to be used as CONNECTIONS in ENTERAL APPLICATIONS of MEDICAL DEVICES and ACCESSORIES intended for use with a PATIENT.

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

NOTE 1 ENTERAL MEDICAL DEVICES include ENTERAL feeding sets and PATIENT interface devices and include 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 CONNECTORS which are used for:

- gastric suction only MEDICAL DEVICES;
- oral only MEDICAL DEVICES;
- pressurizing and depressurizing inflation cuffs used to hold invasive MEDICAL DEVICES in place (ISO 80369-7);
- skin level gastrostomy MEDICAL DEVICES; and
- accessing ENTERAL feeding reservoirs (ISO 18250).

NOTE 2 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 ISO 80369, will be included.

2 Normative references

The following referenced documents are indispensable for the application of this document. The way in which these referenced documents are cited in normative requirements determines the extent (in whole, or in part) to which they apply. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 80369-20: —[1], *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*

[1] To be published

3 Terms and definitions

For the purposes of this document, the terms and definitions specified in ISO 80369-1:2010, ISO 80369-20: –, ISO 14971:2007, IEC 62366:2007 and the following apply. For convenience, the sources of all defined terms used in this document are given in the index on page 40.

3.1
ENTERAL
administration or removal of fluid (liquid or gas) to or from the gastrointestinal tract

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
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]

3.5
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 requirement

4.1 General requirements for ENTERAL SMALL-BORE CONNECTORS

SMALL-BORE CONNECTORS of MEDICAL DEVICES or ACCESSORIES intended for use in ENTERAL APPLICATIONS shall comply with ISO 80369-1:2010 unless otherwise indicated in this standard.

SMALL-BORE CONNECTORS for use in ENTERAL APPLICATIONS 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

241
242 – the nipples of EN 13544-2:2002
243
244 because these CONNECTORS are inadequately specified.
245
246 The reference CONNECTOR for evaluation of the NON-INTERCONNECTABLE characteristics is described in Annex
247 C.
248
249 Check compliance by applying the tests of ISO 80369-1:2010, 5.1, 5.7, 5.8 and Annex B. When necessary,
250 the SMALL-BORE CONNECTOR may be installed on the MEDICAL DEVICE or ACCESSORY to demonstrate compliance
251 with the NON-INTERCONNECTABLE characteristics test requirements of ISO 80369-1:2010, Annex B.
252

253 NOTE 1 The summary of MEDICAL DEVICES and their attributes with CONNECTIONS within this APPLICATION is provided in
254 informative Annex D.

255 NOTE 2 The summary of the usability requirements ENTERAL SMALL-BORE CONNECTORS is provided in informative Annex E.

256 NOTE 3 The summary of ENTERAL SMALL-BORE CONNECTORS criteria and requirements is provided in informative Annex F.

257 NOTE 4 The summary of assessment of the design of ENTERAL SMALL-BORE CONNECTORS according to ISO 80369-1:2010,
258 Clause 7, is contained in informative Annex G.

259 4.2 Security of CONNECTION

260 SMALL-BORE CONNECTORS for ENTERAL APPLICATIONS shall have a means to prevent inadvertent disconnection.
261
262 Check compliance by inspection.
263

264 4.3 * Direction of fluid flow

265 SMALL-BORE CONNECTORS for the ENTERAL APPLICATION shall be deployed such that the delivery of ENTERAL
266 nutrition fluid from the source to the PATIENT is in the female to male direction. ENTERAL feeding sets and
267 extension sets should not contain any in-line female administration ports or connect to the PATIENT using a
268 male terminal CONNECTOR.
269
270 Check compliance by inspection.
271

272 4.4 Material used for SMALL-BORE CONNECTORS

273 In addition to the requirements of ISO 80369-1:2010, Clause 4, ENTERAL SMALL-BORE CONNECTORS of MEDICAL
274 DEVICES or ACCESSORIES shall be made of materials with a modulus of elasticity either in flexure or in tension
275 greater than 700 MPa.
276
277 Check compliance by applying the tests of ASTM D638 or ASTM D790 at 23 °C ± 2 °C and 50 % ± 5 % relative
278 humidity.
279

280 5 Dimensional requirements for ENTERAL SMALL-BORE CONNECTORS

281 SMALL-BORE CONNECTORS for the ENTERAL APPLICATION shall comply with the relevant dimensions and
282 tolerances as given in
283
284 – Figure B.1 and Table B.1 for a male CONNECTOR
285
286 – Figure B.2 and Table B.2 for a female CONNECTOR.
287

NOTE ISO 80369-1, 5.8, specifies alternative methods of compliance with the ISO 80369 (series), for SMALL-BORE CONNECTORS intended to for use with ENTERAL APPLICATIONS MEDICAL DEVICES or ACCESSORIES, which do not comply with this International Standard.

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

6 Performance requirements

6.1 * General performance requirements

The tests described in this International Standard are TYPE TESTS. TYPE TESTS are performed on representative samples of the SMALL-BORE CONNECTOR being evaluated.

NOTE 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.

6.2 Fluid leakage

6.2.1 Fluid leakage requirement

ENTERAL SMALL-BORE CONNECTORS shall either be evaluated for leakage by the pressure decay TEST METHOD or be evaluated for leakage by the falling drop positive pressure decay TEST METHOD.

6.2.2 Fluid leakage by pressure decay

ENTERAL SMALL-BORE CONNECTORS evaluated for fluid leakage performance with the pressure decay TEST METHOD shall not leak by more than 0,005 Pa·m3 /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 water as the medium. MANUFACTURERS may use a greater applied pressure.

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 Falling drop positive pressure liquid leakage

ENTERAL SMALL-BORE CONNECTORS evaluated for fluid leakage performance with the falling drop 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 Stress cracking

ENTERAL SMALL-BORE CONNECTORS shall be evaluated for stress cracking. ENTERAL 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.

6.4 Resistance to separation from axial load

ENTERAL SMALL-BORE CONNECTORS shall be evaluated for separation from axial load. ENTERAL 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 32 N and 35 N. MANUFACTURERS may use a greater disconnection applied axial force or a longer hold period.