INTERNATIONAL STANDARD

ISO 80369-1

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

Part 1: General requirements

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

Partie 1: Exigences générales

Reference number
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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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 80369-1 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 TC 3/WG 2, *Small-bore connectors*.

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*

The following parts are under preparation:

— *Part 2: Connectors for breathing systems and driving gases applications*

— *Part 3: Connectors for enteral applications*

— *Part 4: Connectors for urethral and urinary applications*

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

— *Part 6: Connectors for neuraxial applications*

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

Introduction

In the 1990s concern grew regarding the proliferation of MEDICAL DEVICES fitted with Luer CONNECTORS and the reports of PATIENT death or injury arising from misconnections that resulted in the inappropriate delivery of enteral solutions, intrathecal medication or compressed gases.

Concerns regarding the use of Luer CONNECTORS with enteral feeding tubes and gas sampling and gas delivery systems were raised with CEN/BT and the European Commission. In November 1997 the newly created CHeF steering group set up a Forum Task Group (FTG) to consider the problem.

The FTG produced CEN Report CR 13825, in which they concluded that there is a problem arising from the use of a single CONNECTOR design to a number of incompatible APPLICATIONS. In a coronary care unit there are as many as 40 Luer CONNECTORS on the MEDICAL DEVICES used with a single PATIENT. Therefore it is not surprising that misconnections are made.

MEDICAL DEVICES have for many years followed the established principle of "safety under single fault conditions". Simply stated this means that a single fault should not result in an unacceptable RISK. This principle is embodied in the requirements of numerous MEDICAL DEVICE standards. Extending this principle to the application of Luer CONNECTORS, i.e. that misconnection should not result in an unacceptable RISK to a PATIENT, the FTG recommended that the Luer CONNECTOR should be restricted to MEDICAL DEVICES intended to be connected to the vascular system or a hypodermic syringe. In addition, new designs of SMALL-BORE CONNECTORS should be developed for other APPLICATIONS and these should be NON-INTERCONNECTABLE with Luer CONNECTORS and each other.

ISO/TR 16142:2006 addresses this type of problem in Essential Principle A.1.2:

> The solutions adopted by the manufacturer for the design and construction of the devices should conform to safety principles, taking into account the generally acknowledged state of the art.
>
> In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order:
>
> — identify hazards and the associated risks arising from the intended use and foreseeable misuse;
>
> — eliminate or reduce risks as far as possible (inherently safe design and construction);

It is understood that SMALL-BORE CONNECTOR systems cannot be designed to overcome all chances of misconnection or to eliminate deliberate misuse. However, a number of steps that would improve the current situation and lead to greater PATIENT safety can be taken. This will only be achieved through a long-term commitment involving industry, healthcare professionals, MEDICAL DEVICE purchasers and MEDICAL DEVICE regulatory authorities.

This is the first edition of ISO 80369-1 and it cancels and replaces EN 15546-1:2008 which has been editorially revised.

Part 1 of this International Standard and its parts are intended to be the reference documents in which the necessary measures and PROCEDURES to prevent misconnection between SMALL-BORE CONNECTORS used in different APPLICATIONS and designs of SMALL-BORE CONNECTORS for APPLICATIONS are listed. The JWG of ISO/TC 210 – IEC 62D and CEN/CENELEC TC 3/WG 2 is developing this series of standards in such a way that ISO 80369-1 includes general requirements to prevent misconnections between SMALL-BORE CONNECTORS used in different APPLICATIONS.

This part 1 of this International Standard contains general requirements to ensure the prevention of misconnection between SMALL-BORE CONNECTORS used in different APPLICATIONS. Subsequent parts of this series of standards are expected to include requirements with regard to the CONNECTORS used in different APPLICATION categories.

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 THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

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 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.

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

Part 1:
General requirements

1 Scope

This part of ISO 80369 specifies general requirements for SMALL-BORE CONNECTORS, which convey liquids or gases in healthcare APPLICATIONS. These SMALL-BORE CONNECTORS are used in MEDICAL DEVICES or ACCESSORIES intended for use with a PATIENT.

This International Standard also specifies the healthcare fields in which these SMALL-BORE CONNECTORS are intended to be used.

These healthcare fields of use include, but are not limited to, APPLICATIONS for:

— BREATHING SYSTEMS and driving gases,

— enteral and gastric,

— urethral and urinary,

— limb cuff inflation,

— neuraxial devices, and

— intravascular or hypodermic.

SMALL-BORE CONNECTORS as specified in this International Standard are NON-INTERCONNECTABLE 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.

This International Standard provides the methodology to assess NON-INTERCONNECTABLE characteristics of SMALL-BORE CONNECTORS based on their inherent design and dimensions in order to reduce the RISK of misconnections between MEDICAL DEVICES or between ACCESSORIES for different APPLICATIONS and to reduce the RISK of misconnections between MEDICAL DEVICES with 6 % Luer CONNECTORS, and all other non-Luer CONNECTORS that will be developed under future parts of this series of standards.

It does not specify requirements for the MEDICAL DEVICES or ACCESSORIES that use these SMALL-BORE CONNECTORS. Such requirements are given in particular International Standards for specific MEDICAL DEVICES or ACCESSORIES.

NOTE 1 It is intended that new designs of SMALL-BORE CONNECTORS will be included in this series of standards after they have been assessed according to the PROCEDURE given in Clause 6.

NOTE 2 MANUFACTURERS are encouraged to incorporate the SMALL-BORE CONNECTORS specified in this series of standards 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 the series of standards will be included.

NOTE 3 MANUFACTURERS and RESPONSIBLE ORGANIZATIONS are encouraged to report their experience with the SMALL-BORE CONNECTORS specified in this series of standards to the Secretariat of ISO/TC 210 to consider this feedback during the revision of the relevant part of this series of standards.

2 Normative references

The following referenced documents 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.

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

ISO 5356-2:2006, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

EN 13544-2:2002, *Respiratory therapy equipment — Part 2: Tubing and connectors*

IEC 62366:2007, *Medical devices — Application of usability engineering to medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions specified in 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 an index on page 17.

3.1
ACCESSORY
additional part(s) for use with MEDICAL DEVICE in order to:

— achieve the INTENDED USE,

— adapt it to some special use,

— facilitate its use,

— enhance its performance, or

— enable its functions to be integrated with those of other MEDICAL DEVICES

[Modified from IEC 60601-1:2005, definition 3.3]

3.2
APPLICATION
specific healthcare field in which a SMALL-BORE CONNECTOR is intended to be used

NOTE Annex C lists SMALL-BORE CONNECTOR APPLICATIONS.

3.3
BREATHING SYSTEM
inspiratory and expiratory pathways through which gas flows at respiratory pressures and bounded by the port through which fresh gas enters, the PATIENT CONNECTION port and the exhaust port

3.4
CONNECTION
union or joining of mating halves of a CONNECTOR

3.5
CONNECTOR
mechanical device, consisting of one of two mating halves and designed to join a conduit to convey liquids or gases

3.6
NON-INTERCONNECTABLE
having characteristics which incorporate geometries or other characteristics that prevent different CONNECTORS from being connected

3.7
PATIENT
person undergoing a medical, surgical or dental PROCEDURE

[Modified from IEC 60601-1:2005, definition 3.76]

3.8
RESPONSIBLE ORGANIZATION
entity accountable for the use and maintenance of a MEDICAL DEVICE

NOTE 1 The accountable entity can be, for example, a hospital, an individual clinician or a layperson. In home use applications, the PATIENT, USER and RESPONSIBLE ORGANIZATION can be one and the same person.

NOTE 2 Education and training is included in "use."

[Modified from IEC 60601-1:2005, definition 3.101]

3.9
RIGID MATERIAL
material with a modulus of elasticity either in flexure or in tension greater than 35 000 kg/cm^2 (3 433 MPa)

3.10
SEMI-RIGID MATERIAL
material with a modulus of elasticity either in flexure or in tension, between 700 kg/cm^2 and 35 000 kg/cm^2 (69 MPa and 3 433 MPa)

3.11
SMALL-BORE
inner-fluid pathway of a CONNECTION with a diameter less than 8,5 mm

NOTE For the purposes of this standard, the 8,5 mm cone and socket of ISO 5356-1 is not considered a SMALL-BORE CONNECTOR.

4 Materials used for SMALL-BORE CONNECTORS

A SMALL-BORE CONNECTOR shall be made of RIGID MATERIAL or SEMI-RIGID MATERIAL.

Check compliance by application of the tests of ASTM D747 or ASTM D790 at (23 ± 2) °C and (50 ± 5) % relative humidity.

5 Requirements for SMALL-BORE CONNECTORS for specific APPLICATIONS

5.1 SMALL-BORE CONNECTOR incompatibility

SMALL-BORE CONNECTORS of each APPLICATION category specified in this International Standard shall be NON-INTERCONNECTABLE with any of the SMALL-BORE CONNECTORS of every other APPLICATION category for RISKS to be acceptable, unless otherwise indicated.

SMALL-BORE CONNECTORS for APPLICATION categories specified in this International Standard shall be NON-INTERCONNECTABLE with:

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

— the nipples of EN 13544-2:2002;

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

unless otherwise indicated.

Check compliance by confirming that OBJECTIVE EVIDENCE verifies that RISKS have been reduced to acceptable levels for the acceptability criteria specified in Annex B and other acceptability criteria established by the MANUFACTURER for NON-INTERCONNECTABLE characteristics. Verify that the SMALL-BORE CONNECTOR is NON-INTERCONNECTABLE.

5.2 BREATHING SYSTEMS and driving gases APPLICATIONS

SMALL-BORE CONNECTORS intended to be used either as an ancillary port CONNECTION in a BREATHING SYSTEM or a respirable driving gas APPLICATION of MEDICAL DEVICES and ACCESSORIES shall comply with ISO 80369-2:—, unless the use of these CONNECTORS creates an unacceptable RISK for a specific MEDICAL DEVICE, or shall comply with 5.8.

Check compliance by inspection of the RISK MANAGEMENT FILE for a specific MEDICAL DEVICE or application of the tests of ISO 80369-2:—. See also 5.8 for alternative methods of compliance.

5.3 Enteral and gastric APPLICATIONS

SMALL-BORE CONNECTORS intended to be used for CONNECTIONS in enteral and gastric APPLICATIONS shall comply with ISO 80369-3:—, unless the use of these CONNECTORS creates an unacceptable RISK for a specific MEDICAL DEVICE or shall comply with 5.8.

Check compliance by inspection of the RISK MANAGEMENT FILE for a specific MEDICAL DEVICE or application of the tests of ISO 80369-3:—. See also 5.8 for alternative methods of compliance.

5.4 Urethral and urinary APPLICATIONS

SMALL-BORE CONNECTORS intended to be used for CONNECTIONS in urethral and urinary APPLICATIONS shall comply with ISO 80369-4:— or 5.8, unless the use of these CONNECTORS creates an unacceptable RISK for a specific MEDICAL DEVICE or shall comply with 5.8.

Check compliance by inspection of the RISK MANAGEMENT FILE for a specific MEDICAL DEVICE or application of the tests of ISO 80369-4:—. See also 5.8 for alternative methods of compliance.

5.5 Limb cuff inflation APPLICATIONS

SMALL-BORE CONNECTORS intended to be used for CONNECTIONS in limb cuff inflation APPLICATIONS shall comply with ISO 80369-5:—, unless the use of these CONNECTORS creates an unacceptable RISK for a specific MEDICAL DEVICE or shall comply with 5.8.

Check compliance by inspection of the RISK MANAGEMENT FILE for a specific MEDICAL DEVICE or application of the tests of ISO 80369-5:—. See also 5.8 for alternative methods of compliance.

5.6 Neuraxial APPLICATIONS

SMALL-BORE CONNECTORS intended to be used for CONNECTIONS in neuraxial APPLICATIONS shall comply with ISO 80369-6:—, unless the use of these CONNECTORS creates an unacceptable RISK for a specific MEDICAL DEVICE or shall comply with 5.8.

Check compliance by inspection of the RISK MANAGEMENT FILE for a specific MEDICAL DEVICE or application of the tests of ISO 80369-6:—. See also 5.8 for alternative methods of compliance.

5.7 Intravascular or hypodermic APPLICATIONS

SMALL-BORE CONNECTORS intended to be used for CONNECTIONS in intravascular or hypodermic APPLICATIONS shall comply with ISO 80369-7:—, unless the use of these CONNECTORS creates an unacceptable RISK for a specific MEDICAL DEVICE or shall comply with 5.8.

NOTE Upon its publication, ISO 80369-7:— will replace ISO 594-1:1986 and ISO 594-2:1998.

Check compliance by inspection of the RISK MANAGEMENT FILE for a specific MEDICAL DEVICE or application of the tests of ISO 80369-7:—. See also 5.8 for alternative methods of compliance.

5.8 Alternative SMALL-BORE CONNECTORS

Alternative designs of SMALL-BORE CONNECTORS to those specified in 5.2 to 5.7 may be used in a MEDICAL DEVICE or ACCESSORY, and if used, they shall:

a) be NON-INTERCONNECTABLE with the CONNECTORS specified in 5.2 through 5.7, inclusive;

b) not create an unacceptable RISK for a specific MEDICAL DEVICE or ACCESSORY;

c) be evaluated according to Annex B; and

d) comply with Clause 4.

Check compliance by confirming that OBJECTIVE EVIDENCE verifies that RISKS have been reduced to acceptable levels for the acceptability criteria specified in Annex B and other acceptability criteria established by the MANUFACTURER for NON-INTERCONNECTABLE characteristics for the MEDICAL DEVICE or ACCESSORY.

6 Additional SMALL-BORE CONNECTOR APPLICATIONS

Alternative designs of SMALL-BORE CONNECTORS to those specified in 5.2 to 5.7, which convey liquids or gases, and which are used in MEDICAL DEVICES and ACCESSORIES intended for use with a PATIENT for other APPLICATIONS, may be used, and if used, they shall:

a) be NON-INTERCONNECTABLE with the CONNECTORS specified in 5.2 through 5.7, inclusive;

b) not create an unacceptable RISK for a specific MEDICAL DEVICE or ACCESSORY; and

c) be evaluated according to Annex B.

Check compliance by confirming that OBJECTIVE EVIDENCE verifies that RISKS have been reduced to acceptable levels for the acceptability criteria specified in Annex B and other acceptability criteria established by the MANUFACTURER for NON-INTERCONNECTABLE characteristics.

7 PROCEDURE to assess a proposed new design of SMALL-BORE CONNECTOR for inclusion in this series of standards

7.1 General

Working groups or individuals, including MANUFACTURERS, wishing to include a new design of a SMALL-BORE CONNECTOR into this family of International Standards, should make this request to ISO/TC 210 according to the PROCEDURE set out in this clause. ISO/TC 210 shall consider this request and shall determine which relevant part of this series of standards should be amended or revised, in accordance with ISO and IEC PROCEDURES.

Groups or individuals submitting a design shall verify that there are no outstanding intellectual property right issues or, as appropriate, shall declare that they are prepared to license relevant patents, both granted and pending, which are necessary to manufacture and sell MEDICAL DEVICES that include the submitted design. Groups or individuals holding patents hereby shall also declare that they are aware of the rules governing inclusion of patented items in International Standards as described in the appropriate ISO PROCEDURES and that they are willing to negotiate licenses with an unlimited number of applicants throughout the world under reasonable and non-discriminatory terms and conditions that are demonstrably free of any unfair competition.

7.2 Proposal initiation

Groups or individuals submitting a new SMALL-BORE CONNECTOR design shall submit to ISO/TC 210 a concept proposal identifying the targeted APPLICATION category. ISO/TC 210, or a designated working group, shall evaluate the submitted proposal.

The submitter shall develop the design proposal and shall maintain and supply RECORDS for the evaluation. The design proposal shall include:

a) a justification for the proposal that includes a description of any CONNECTIONS of concern, which need to become NON-INTERCONNECTABLE, literature reviews, adverse event information and/or complaint analysis;

b) design requirements that include USER PROFILES, according to IEC 62366:2007, use environments, USABILITY goals, according to IEC 62366:2007, functional requirements suitable to maintain clinical performance necessary to achieve freedom from unacceptable RISK, requirements suitable to maintain NON-INTERCONNECTABLE characteristics, RISK ANALYSIS and results, according to ISO 14971:2007, if any, from previous similar designs;

c) design specifications, including a USABILITY specification, according to IEC 62366:2007, which satisfy all aspects of design requirements; it shall include objective evidence that risks have been reduced to acceptable levels, according to ISO 14971:2007, for the acceptability criteria specified in Annex B; and

d) a completed summary of SMALL-BORE CONNECTOR criteria and requirements for the proposed SMALL-BORE CONNECTOR design.

7.3 PROCEDURE to assess acceptability and NON-INTERCONNECTABLE characteristics

7.3.1 Design

The submitter shall conduct an engineering analysis of the design of the proposed SMALL-BORE CONNECTOR using the design details in this series of standards. This evaluation can include, but is not limited to, minimum and maximum tolerance stack up assessments that compare the proposed design with other existing or proposed designs of SMALL-BORE CONNECTORS in this series. Computer-assisted design (CAD) drawing evaluations or other appropriate design feasibility assessment tools may be utilized.

7.3.2 Design realization

The submitter shall produce test samples and carry out testing, as described in 7.3.3 and 7.3.4, to verify that design requirements and design specifications are met. This PROCESS may be iterative.

7.3.3 Design VERIFICATION

The submitter shall verify the design as follows:

a) Select an independent party to carry out design review and VERIFICATION testing.

b) Conduct dimensional analyses, physical testing and MEDICAL DEVICE category-specific performance testing on sample sizes sufficient to allow statistical analysis of test results. The tests shall verify that dimensions meet specification and NON-INTERCONNECTABLE characteristics with other SMALL-BORE CONNECTORS in this series, and that physical performance properties and MEDICAL DEVICE performance requirements are met. It shall include OBJECTIVE EVIDENCE that RISKS have been reduced to acceptable levels, according to ISO 14971:2007, for the acceptability criteria specified in Annex B and other acceptability criteria established for NON-INTERCONNECTABLE characteristics.

c) The potential for misuse, aging and disinfection/sterilization shall be considered.

d) Evidence of design acceptance by clinical USERS of a potential target MEDICAL DEVICE shall be provided.

VERIFICATION reports summarizing the above testing shall be prepared and submitted for consideration to the technical committee or a designated working group. These reports shall include VERIFICATION results for each identified design requirement and each element of the design specification.

7.3.4 Design validation

After design VERIFICATION, the submitter shall conduct a design validation assessment. Validation shall assess the acceptability of production quality SMALL-BORE CONNECTORS in the intended APPLICATION and MEDICAL DEVICE with a population of USERS in the clinical or simulated environment. The validation shall assess the NON-INTERCONNECTABLE characteristics of the SMALL-BORE CONNECTOR with the SMALL-BORE CONNECTORS of the other APPLICATIONS as specified in Clause 5. Conclusions shall be statistically based and demonstrate that performance objectives have been met.

The design validation shall also include a USABILITY validation according to IEC 62366:2007, 5.9.

7.4 Design review

ISO/TC 210, or a designated working group, shall assign a group with specific technical expertise in the targeted APPLICATION and MEDICAL DEVICE(S) that are affected, to assess the design and submitted information resulting from 7.3, and prepare a report to ISO/TC 210 giving its conclusions.

ISO/TC 210 shall decide on the suitability of the proposed SMALL-BORE CONNECTOR for inclusion in this series of standards for the intended APPLICATION.

7.5 Subsequent parts of this series of standards

If the proposed SMALL-BORE CONNECTOR is suitable for inclusion in this series of standards, ISO/TC 210, or a designated working group, shall assign the proposal to the relevant working group, which shall initiate the appropriate steps to include the new design by amendment, revision or creation of the relevant part of this series of standards.

A summary of the data and reports (see 7.3) shall be prepared as an informative annex to be included as a rationale in the preparation of the subsequent Standard.

Annex A
(informative)

Rationale

This Annex provides rationale for the important requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for its proper application. Furthermore, as clinical practice and technology change, it is believed that rationale for the present requirements will facilitate any revision of this document necessitated by those developments.

The clauses in this annex have been so numbered to correspond to the clauses in this International Standard to which they refer. The numbering is, therefore, not consecutive.

Clause 1 Scope

Advances in modern medicine have led to a significant rise in the number of MEDICAL DEVICES attached to PATIENTS. Many of these devices fall into the categories of monitoring devices, diagnostic devices and drug delivery devices.

Such MEDICAL DEVICES perform a variety of similar, but not interchangeable, functions. Examples include: intravenous fluid delivery, enteral feeding, respiratory gas sampling, non-invasive blood pressure measurement and injection of intrathecal medication. Despite the varied nature of the functions performed, many of these MEDICAL DEVICES use a universal system of SMALL-BORE CONNECTORS based on the 6 % Luer tapered CONNECTOR as specified in ISO 594-1:1996 and ISO 594-2:1998.

The universal nature of the CONNECTORS used, and the proximity of several different CONNECTORS around a single PATIENT, makes accidental misconnections inevitable. The consequences of such misconnections vary but a significant number are actually or potentially fatal.

Serious and usually fatal misconnections include intravenous injection of air, intravenous injection of enteral feeds and intrathecal injection of vincristine. Less disastrous misconnections such as enteral administration of intravenous fluids might not directly HARM the PATIENT but cause a failure of the intended administration.

Introducing a series of NON-INTERCONNECTABLE, SMALL-BORE CONNECTORS for MEDICAL DEVICES will help to reduce the likelihood of misconnections and lead to a direct improvement in PATIENT safety. Any such series also includes the 6 % Luer which is restricted to CONNECTIONS in vascular APPLICATIONS or with CONNECTIONS to a hypodermic syringe.

CEN BT TF 123 carried out an extensive RISK ANALYSIS of possible misconnections that might result when the same CONNECTOR is used in different APPLICATIONS. Reducing the identified unacceptable RISKS is the basis of this series of standards.

Clause 4 Materials used for SMALL-BORE CONNECTORS

Introducing a series of NON-INTERCONNECTABLE, SMALL-BORE CONNECTORS for MEDICAL DEVICES made from RIGID MATERIAL or SEMI-RIGID MATERIAL will help to reduce the incidence of misconnections and lead to a direct improvement in PATIENT safety. RIGID MATERIALS or SEMI-RIGID MATERIALS have been specified to eliminate the possibility of forcing a fit between incompatible SMALL-BORE CONNECTORS made from flexible materials.

It is understood that SMALL-BORE CONNECTOR systems cannot be designed to overcome all chances of misconnection or to eliminate deliberate misuse. For example, the possibility of the misconnection of a SMALL-BORE CONNECTOR to a specialized PATIENT-access port can still exist. Specialized PATIENT-access ports often require the use of flexible materials which are intended to permit access by a range of MEDICAL DEVICES or ACCESSORIES, such as, endoscopes, bronchoscopes, and surgical instruments. These access ports can permit interconnection with some SMALL-BORE CONNECTORS. The RISKS associated with the use of these specialized

PATIENT-access ports are not addressed by this standard. MANUFACTURERS of MEDICAL DEVICES or ACCESSORIES and the committees responsible for the development of standards for MEDICAL DEVICES or ACCESSORIES that incorporate these specialized PATIENT-access ports will need to assess these RISKS.

Clause 5 Requirements for SMALL-BORE CONNECTORS for specific APPLICATIONS

National regulatory bodies, hospital accreditation organizations, and independent public health organizations recognize misconnections as a persistent problem with potentially lethal consequences. Warnings have been issued and strategies offered for healthcare organizations to reduce RISKS and MANUFACTURERS to redesign CONNECTORS to prevent misconnections. The ability of CONNECTORS used to interconnect is identified as a root cause of misconnections.

CEN Report CR 13825 identifies possible misconnections among MEDICAL DEVICE functions involving the conveyance of a gas or liquid for the different APPLICATION categories and classifies each according to the SEVERITY of the HARM that can occur. The report confirms that the APPLICATION categories specified in this standard are incompatible i.e., misconnections among these APPLICATION categories can cause serious injury or death.

The committee reviewed this material and agreed that these APPLICATION categories were the highest areas of RISK to public health from MEDICAL DEVICE misconnection if a misconnection were to occur. This determination comes from years of adverse event reports, literature reviews and research on MEDICAL DEVICE misconnection. It is noted that the identified APPLICATION categories do not encompass all medical areas to which MEDICAL DEVICES are intended to be used and therefore all potential areas of misconnection might not be addressed by this document. It is intended that the APPLICATION categories in this clause represent a majority of MEDICAL DEVICES containing SMALL-BORE CONNECTORS and therefore the use of these SMALL-BORE CONNECTORS will bring the RISK of misconnection to an acceptable level.

This clause provides the requirements for SMALL-BORE CONNECTORS based upon these APPLICATION categories. Minimal requirements including verifiable acceptability criteria are established to reduce the RISK of misconnection. The purpose is to make the RISK of misconnection acceptably low by ensuring that halves of incompatible CONNECTORS are NON-INTERCONNECTABLE. OBJECTIVE EVIDENCE is required that the criteria are met for the RISK of misconnection for these criteria to be acceptable.

The requirements are not comprehensive. Additional requirements and criteria for other NON-INTERCONNECTABLE characteristics can be needed to reduce the RISK of incompatible misconnections to acceptable levels. This circumstance is acknowledged in the standard by requiring that all RISK acceptability criteria applicable to NON-INTERCONNECTABLE characteristics be met.

Subclause 5.8 Alternative SMALL-BORE CONNECTORS

As it is not the intent of this standard to prevent the use of alternative designs (proprietary SMALL-BORE CONNECTORS) within an identified APPLICATION category, this subclause provides the requirements for such designs to ensure that their use provides the same level of safety in the market without introducing additional RISK. As the approach of this subclause does not include inspection of the RISK MANAGEMENT FILE by the committee, but rather the use of force functions as described in Annex B to address NON-INTERCONNECTABILITY, it is expected that each MANUFACTURER intending to use a proprietary SMALL-BORE CONNECTOR not in this standard shall establish, validate and maintain their RISK MANAGEMENT FILE to ensure the clinical safety of their SMALL-BORE CONNECTOR.

Clause 6 Additional SMALL-BORE CONNECTOR APPLICATIONS

This clause provides the requirements for a new SMALL-BORE CONNECTOR design for an APPLICATION not identified in clause 5. The purpose of this clause is to allow the inclusion of other APPLICATIONS not identified in this standard for inclusion to this series of standards.

Subclause 7.2 Proposal initiation

The proposal serves two interrelated purposes. One provides justification for a new APPLICATION category and the other introduces a design for a new SMALL-BORE CONNECTOR for that category. ISO/TC 210 evaluates the

proposal to determine if a new APPLICATION category is needed and that necessary requirements for the new SMALL-BORE CONNECTOR for that category have been identified.

The need for a new APPLICATION category can arise by the introduction of a MEDICAL DEVICE for a new medical APPLICATION or changing conveyance requirements for MEDICAL DEVICES within an existing APPLICATION category. However, safety is always an important consideration in justifying that need. Thus, justification for a new medical APPLICATION involving conveyance of a gas or liquid is based on analytical results establishing the need to prevent CONNECTIONS with the other APPLICATION categories. Those safety concerns are based in large part on the SEVERITY of the HARM that can occur with misconnections. Thus, the justification involving changing requirements is based upon RISK ANALYSIS, adverse events, reported complaints, and other relevant safety issues.

Safety requirements are also important for a new SMALL-BORE CONNECTOR. The RISK of misconnection for a proposed new SMALL-BORE CONNECTOR is required to be acceptable. New SMALL-BORE CONNECTORS are designed to be NON-INTERCONNECTABLE between MEDICAL DEVICES or between ACCESSORIES for the different APPLICATION categories. However, since NON-INTERCONNECTABLE characteristics alone cannot eliminate misconnections, the use of identified HAZARDS and HAZARDOUS SITUATIONS to establish safety-related USABILITY goals is also needed to reduce RISKS for the new SMALL-BORE CONNECTOR to an acceptable level. Thus, OBJECTIVE EVIDENCE is required verifying that acceptability criteria are met and validation is required to assess the acceptability of NON-INTERCONNECTABLE characteristics under clinical or simulated use conditions.

NON-INTERCONNECTABLE CONNECTORS are expected to easily fall apart after a USER attempts to assemble them and to prevent the perception that a secure CONNECTION has been made. The very low force of separation of 0,02 N (2 g) was chosen as the lowest haptic detection threshold of secure CONNECTION that can be easily measured. No additional leak testing is proposed, because a leaking CONNECTION that appears to be a secure CONNECTION when first assembled is considered by the committee to be an unacceptable RISK.

EXAMPLES RISK of infection, embolism, or hypoxia.

Annex B
(normative)

Mechanical tests for verifying NON-INTERCONNECTABLE characteristics

This Annex specifies the criteria and test methods to be used to obtain OBJECTIVE EVIDENCE to demonstrate NON-INTERCONNECTABLE characteristics between a SMALL-BORE CONNECTOR being evaluated and the other CONNECTORS likely to be found in the environment around the PATIENT. There can and will be other CONNECTOR-specific acceptability criteria necessary for NON-INTERCONNECTABLE characteristics such as specific dimensional or rigidity requirements. They are not addressed in this Annex. However, VERIFICATION that such other acceptability criteria are met, are required for all such criteria. The test methods used should be appropriate for those acceptability criteria.

A NON-INTERCONNECTABLE SMALL-BORE CONNECTOR shall not appear to provide a secure CONNECTION when forcefully assembled to any surface of the components of, and shall easily disengage from each of the following:

— each SMALL-BORE CONNECTOR of every other APPLICATION category specified in this International Standard and its parts;

— the nipples of EN 13544-2:2002; and

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

For the purposes of this test, the CONNECTORS above other than the SMALL-BORE CONNECTOR being evaluated, shall be made of RIGID MATERIAL using nominal dimensions or may be REFERENCE CONNECTORS as specified in other parts of this standard.

Check compliance with the following test.

a) Condition the CONNECTORS to be assembled at 23 °C ± 2 °C and a relative humidity of 50 % ±5 % for not less than 1 h.

b) Assemble the SMALL-BORE CONNECTOR to the test CONNECTOR by applying an axial force at a rate of approximately 10 N/s that does not visibly damage either CONNECTOR, not exceeding 70 N and a torque not exceeding 0,12 Nm to a limit of no more than 90°. Rotate threaded CONNECTORS in a clockwise manner. Hold the maximum assembly force for no less than 10 s.

c) After 10 s of engagement, without activation of any latch or disengagement mechanism, apply an axial force of separation to the assembled CONNECTORS to a maximum 0,02 N (2 g). Verify the assembled CONNECTORS disengage.

d) If applicable, for threaded CONNECTORS, repeat a) to c) by assembling the CONNECTORS in a counter-clockwise manner in b).

e) Repeat a) to d) for every potential assembly surface.

NOTE Potential assembly surfaces include any CONNECTION of inside and outside surfaces or inside or outside diameters on either CONNECTOR which can interconnect and provide the appearance of a secure CONNECTION.

Annex C
(informative)

APPLICATIONS of SMALL-BORE CONNECTORS

Table C.1 summarizes the categories of APPLICATION of SMALL-BORE CONNECTORS.

Table C.1 — APPLICATIONS of SMALL-BORE CONNECTORS

APPLICATION category	Specific use	Examples of MEDICAL devices	SMALL-BORE CONNECTOR specification
BREATHING SYSTEMS and driving gases	Ancillary port CONNECTIONS that operate at BREATHING SYSTEM pressures	gas sampling lines for respiratory gas monitoring lines for BREATHING SYSTEM pressure measurement line to control expiratory valve in the BREATHING SYSTEM lines to BREATHING SYSTEM from nebuliser	ISO 80369-2
	CONNECTIONS for respirable driving gas at pressures greater than BREATHING SYSTEM pressures	driving gas to a nebuliser	ISO 80369-2
Limb cuff inflation	CONNECTIONS for inflation of sphygmomanometer cuffs	tubing CONNECTORS for neonatal sphygmomanometers	ISO 80369-5
		tubing CONNECTORS for 1-hose paediatric/adult sphygmomanometers	ISO 80369-5
		tubing CONNECTORS for 2-hose paediatric/adult sphygmomanometers	ISO 80369-5
	CONNECTIONS for inflation of tourniquets	tubing CONNECTORS for tourniquet devices	ISO 80369-5
Enteral and gastric	CONNECTIONS for access to the oesophagus or stomach	enteral feeding sets (nutrition) gravity plus pumped feed connecting sets medication ports (Y-ports, T-sets) enteral tubes nasal, gastric, duodental, jejunal percutaneous (PEG, PEJ, buttons) enteral Pouches syringes for feeding and enteral medication administration	ISO 80369-3

Table C.1 (*continued*)

APPLICATION category	Specific use	Examples of MEDICAL devices	SMALL-BORE CONNECTOR specification
Neuraxial	CONNECTIONS for access to nerves or the nervous system	epi(peri)dural and intrathecal (spinal) needles and catheters caudal needles (adult and paediatric) introducer needles, drawing up needles, other needles (e.g. other nerve blocks) epidural/spinal catheters inline filters syringes (2-100 ml) neuraxial extension sets neuraxial infusion pump sets loss of resistance syringes intracranial pressure monitor	ISO 80369-6
Urethral/urinary	CONNECTIONS for access to the urinary tract	urinary catheters ureteric catheters urine collecting system tubing	ISO 80369-4
Intravascular or hypodermic	CONNECTIONS for access to arterial and venous vascular systems CONNECTIONS for subcutaneous, intra-muscular and intraperitoneal injections and infiltrations MEDICAL DEVICES intended to connect to syringes	venous access port central venous catheter arterial pressure lines diagnostic catheter extracorporeal devices	ISO 80369-7 NOTE Upon its publication, ISO 80369-7:— will replace ISO 594-1:1986 and ISO 594-2:1998.