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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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.