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Medical devices — Connectors for reservoir delivery systems for healthcare applications —

Part 6: Neural applications

Dispositifs médicaux — Connecteurs pour systèmes de livraison de réservoir pour des applications de soins de santé — Partie 6: Applications neurales

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

A list of all parts in the ISO 18250 series can be found on the ISO website.

In this document, the following print types are used:

— requirements and definitions: roman type;

— informative material appearing outside of tables, such as notes, examples and references: smaller type;

— TERMS DEFINED IN THIS DOCUMENT: SMALL CAPS;

— *compliance requirements: italic type.*

In this document, 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 document conform to usage described in the ISO/IEC Directives, Part 2, Annex H. For the purposes of this document, the auxiliary verb:

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this document;

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

— “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.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

During the development of the ISO 80369 series of standards for small-bore connectors for liquids and gases in healthcare applications it became evident that the risk of misconnections was not limited to the patient access connectors and that the connectors used at the reservoir end of the systems were also a potential high risk for misconnection. For many reasons these reservoir connectors did not fit well within the scope of ISO 80369 so it was decided to develop a separate series of standards specifically for these reservoir connectors. The 18250 series takes into account the risks of misconnections between the reservoir connectors of different applications including the existing standardized IV spike specified in ISO 8536-4 and ISO 1135-4.

NOTE Manufacturers are encouraged to incorporate the connectors specified in this document into medical devices, even if not currently required by the particular device standard. It is expected that when the particular device standards are revised, requirements for connectors with the dimensions, as specified within this document, will be included.

Medical devices — Connectors for reservoir delivery systems for healthcare applications —

Part 6: Neural applications

1 *Scope

This document specifies the connectors recommended for the outlet ports of neural reservoirs and inlet ports of neural giving sets.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 18250-1, *Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 1: General requirements and common test methods*

ISO 80369-6, *Small bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18250-1 and ISO 80369-6 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 *Neural reservoir outlet port connector

4.1 The connector at the outlet port of a neural reservoir shall be a male, N2, neuraxial lock connector complying with ISO 80369-6.

4.2 The connector should be non-user-detachable from the reservoir.

5 *Neural giving set inlet port connector

5.1 The connector at the inlet port of a neural giving set shall be a female, N2, neuraxial, lock connector complying with ISO 80369-6.

5.2 The connector should be non-user-detachable from the giving set.

NOTE See Annex A for a rationale.

Annex A
(informative)

Rationale

A.1 Scope

The word neural has been used as a more generic term as neuraxial only relates to the central nervous system and not the peripheral nervous system.

This document does not specify how this outlet port connector is attached to the reservoir, neither does it concern itself with any other reservoir ports necessary to make the reservoir work, e.g. air inlets, nor does it specify how the reservoir is sealed to prevent ingress of contaminants. These requirements are left to the manufacturers as they do not affect the misconnection of the reservoir outlet with a giving set of another application.

A.2 Clause 4 and Clause 5

The ISO 80369-6 connector has been specified as it has been through a rigorous regime of testing both for its performance characteristics and its suitability for use following extensive usability testing. It was therefore considered unnecessary to reinvent another connector for the reservoir end of the system.

"The ISO 80369-6 connectors were further analysed for misconnection per the requirements of ISO 18250-1. The results of that analysis are captured in Annex B with a corresponding assessment of the probability of misconnection and a statement mitigating the risk. Conformance to ISO 18250-1 can therefore be demonstrated.

Annex B
(informative)

Summary of design history of connectors for neural reservoirs

B.1 Summary of the engineering analysis of the design

See ISO 80369-6:2016, G.1.

B.2 CAD process

A three dimensional CAD analysis was conducted to verify the requirements of ISO 18250-1:2018, 5.1. The connectors defined in this document were compared to the connectors of the other application parts of ISO 18250 series and to those defined surfaces of both ISO 17256 and ISO/IEC 80601-2-74.

The process of making this comparison included modelling all of the connectors in 3-Dimensional CAD software. Each connector had multiple configurations created including the Least Material Condition (LMC), the nominal, and the Maximum Material Condition (MMC). The models of these three configurations were superimposed on each other to create a graphical representation of the geometrical bounds of each connector type.

Those superimposed models were then compared one connector after the next to check for areas of unintended interconnectability (i.e. an engineering assessment of whether or not the connection, anywhere within the allowable tolerances for dimensions on either part, would fail the requirements of ISO 18250-1:2018, Annex B). A further assessment was then rendered regarding the likelihood of establishing liquid flow between any unintended connections.

The residual concerns (where a connection could be established and liquid flow is likely) are summarized in the tables below for each connector pair.