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Medical devices — Non-electrically driven portable infusion devices

Dispositifs médicaux — Diffuseurs portables de médicaments, non mus électriquement

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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 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 28620:2010), which has been technically revised. The main changes compared with the previous edition are as follows:

— the Scope has been amended to explicitly cover neuraxial and intravascular or hypodermic applications;

— the requirements on components and their fittings have been aligned with the appropriate parts of the ISO 80369 series, i.e. ISO 80369-1, ISO 80369-6 and ISO 80369-7;

— the requirements on filter and tubing have been updated;

— a test method for the efficiency of the fluid filter has been added;

— Table 1, which gives information to be provided by the manufacturer, has been updated.

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.

Medical devices — Non-electrically driven portable infusion devices

1 Scope

This document specifies essential requirements and related test methods for non-electrically driven portable infusion devices, thereafter called "device".

It is applicable to devices designed for continuous (fixed or adjustable) flow and/or for bolus neuraxial and intravascular or hypodermic applications.

NOTE 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.

These devices can be used in health care and non-health care settings. They can be applied or administered by health care professionals or by the intended patient.

These devices can be pre-filled by the manufacturer or filled before use by a health care professional or the intended patient.

This document does not apply to

— electrically driven or electrically controlled infusion pumps that are covered by IEC 60601-2-24,

— devices for single patient use intended to deliver discrete volumes (bolus) of medicinal product that are covered by the ISO 11608 series,

— implantable devices,

— enteral devices,

— transdermal delivery devices, and

— devices where the energy for infusion is not provided by the device or through active intervention by the patient (e.g. devices only powered by gravity).

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 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

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

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

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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/

3.1
bolus
discrete volume of solution that is delivered in a short time

3.2
bolus refill time
time required to refill the emptied bolus device to the bolus volume

3.3
nominal bolus refill time
bolus refill time (3.2) indicated by marking on the device or its packaging

3.4
filling volume
nominal volume (3.10) plus *residual volume* (3.5)

3.5
residual volume
volume remaining in the device and applicable components after the completion of infusion

3.6
instantaneous flow rate
ratio between a volume administered and the time necessary to administer it

Note 1 to entry: It is expressed in millilitres per hour (ml/h).

3.7
mean flow rate
ratio between the *nominal volume* (3.10) and the actual time for administration

Note 1 to entry: It is expressed in millilitres per hour (ml/h).

3.8
nominal time
time for administering the *nominal volume* (3.10)

3.9
nominal flow rate
ratio between the *nominal volume* (3.10) and *nominal time* (3.8)

Note 1 to entry: It is expressed in millilitres per hour (ml/h).

3.10
nominal volume
volume indicated by marking on the device or its packaging

3.11
nominal bolus volume
bolus volume indicated by marking on the device or its packaging