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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

3.12
device
portable infusion device
equipment intended for the controlled infusion of liquids into the patient and intended to be carried or worn by the patient

3.13
protective packaging
configuration of materials designed to prevent damage to the *sterile barrier system* (3.14) and its contents from the time of their assembly until the point of use

[SOURCE: ISO 11139:2018, 3.219]

3.14
sterile barrier system
minimum package that prevents the ingress of microorganisms and allows aseptic presentation of the product at the point of use

4 General requirements

4.1 Components

The device shall contain the following components:

— means to convert non-electric energy into fluid flow;

— a flow restrictor;

— a reservoir designed to contain the solution to be administered;

— a particulate matter filter in the fluid path.

NOTE 1 These components can be integrated or delivered separately.

The device may also contain one or more of the following components (non-exhaustive list):

— a system to adjust the flow rate;

— a filling port preferably with check valve;

NOTE 2 The filling port is intended for use in the pharmacy during filling only and can be a Luer type female geometry in accordance with ISO 80369-7.

— a lock connector at the distal end of the tubing conforming to ISO 80369-6 or ISO 80369-7, as appropriate for the intended application;

— a clamp to stop the flow if necessary;

— a sterility protector, e.g. Luer cap, at the distal end of the tubing and of the filling site;

— a system to administer a bolus with a means for controlling the maximum amount of solution infused over time;

— a protective element of the reservoir, preventing the drug solution from flowing out should the reservoir break or leak (which can be necessary to fulfil the leakage test in 6.4 and 6.5);

— a means of indicating the end of infusion;

NOTE 3 This can be achieved by a visual, audible or other indication.

— administration tubing;

— an air-eliminating feature.

4.2 Materials

The materials used in the manufacture of the parts that come in contact with the drug solution shall have undergone a biological evaluation in accordance with ISO 10993-1.

4.3 Design and characteristics

4.3.1 General

The device shall be designed to deliver according to its nominal flow rate (see 5.1).

4.3.2 Fittings

If applicable, the fitting at the filling port shall be a female lock connector conforming to ISO 80369-6 or ISO 80369-7.

If fittings at the distal end of the tubing are used, they shall be male lock connectors conforming to ISO 80369-6 or ISO 80369-7, as appropriate for the intended application.

All device fittings designed to be connected to other medical devices or accessories shall conform to ISO 80369-1, ISO 80369-6 or ISO 80369-7, as appropriate for the intended application.

4.3.3 Filter

The system shall include a particulate matter filter on the fluid path of the solution.

When tested in accordance with 6.9, the retention of latex particles on the filter shall be not less than 80 %.

4.3.4 Tubing

If the device is designed with tubing, it can be fixed or removable. If the tubing is removable, the connection system to the device shall use a lock connector when tested in accordance with 6.6.

The junction between the reservoir and the tubing shall resist a static traction of 15 N for 15 s.

4.3.5 Reservoir

All elements of the device designed to receive the drug shall constitute a closed, water-tight system. This requirement shall be verified by tests in accordance with 6.3, 6.4, 6.5 and 6.6.

If necessary, a redundant mechanism of the reservoir shall be available, minimizing the risk of leakage of the solution from the reservoir.

The reservoir of the device shall be designed so as to allow a visual inspection of the solution.

4.4 Sterility and non-pyrogenicity

All parts of the device in contact with the drug solution shall have been subjected to a validated sterilization process, shall be delivered sterile and non-pyrogenic, and shall be for single use only.

5 Operating requirements

5.1 Flow rate

Each nominal flow rate of the device shall be checked using control solutions at a given temperature. The nominal flow rate, the control solutions and the temperatures shall be specified in the instructions for use accompanying the device [see Clause 8 c) and g)].

The mean flow rate shall have a tolerance of ±15 % compared to the nominal flow rate. The adjustable flow rate shall have a tolerance of ±20 %. At least 80 % of the nominal volume shall be delivered at an instantaneous flow rate within ±50 % of the nominal flow rate. These requirements shall be verified using the test methods described in Clause 6.

NOTE The instantaneous flow rate can deviate by more than 50 % of the nominal flow rate if the device is exposed to external pressure.

5.2 Bolus, if applicable

The bolus volume shall be not more than 115 % of the nominal bolus volume (see 6.7).

When the bolus device is activated after the nominal bolus refill time, the bolus volume shall be in the range of 50 % to 115 % of the nominal bolus volume.

When the bolus device is activated one or more times prior to the nominal refill time (see 6.8), the accumulated bolus volume shall not be more than 150 % of the nominal bolus volume.

6 Test methods

6.1 Test conditions

6.1.1 General

Except for particular indications, the following provisions are common and applicable before each test.

6.1.2 Apparatus and reagents

6.1.2.1 Needles, with sizes recommended by the manufacturer or, in the absence thereof, needles with a minimum inner diameter of 1,2 mm.

6.1.2.2 Control solutions, as recommended by the manufacturer and listed in the accompanying documents (see Clause 8).

6.1.3 Operating conditions

Prepare the device according to the instructions for use and accompanying documents [see Clause 8 c)] so that the solution can be administered.

Fill the reservoir to the filling volume or as specified by the manufacturer.

Perform the tests at the conditions as specified by the manufacturer or, if not specified, at a temperature of (23 ± 2) °C at (50 ± 5) % relative humidity, with an ambient pressure between 86 kPa and 106 kPa, and with the reservoir and the distal outlet at the same head height.

NOTE Ambient pressure limits can be ignored in tests not affected by atmospheric pressure.