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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.

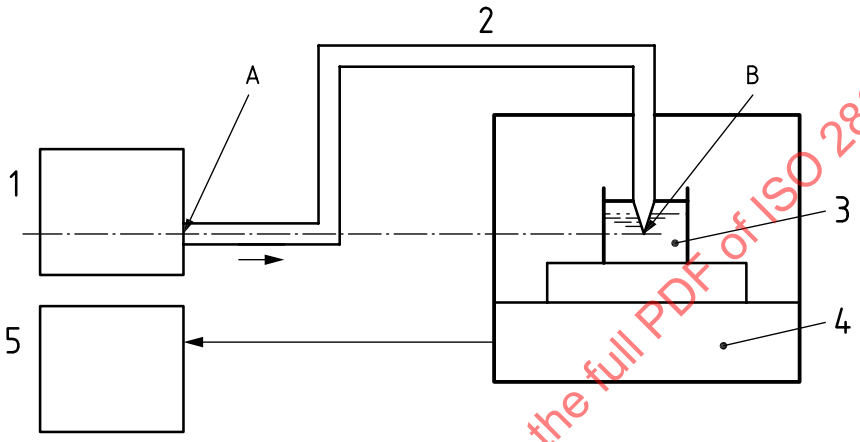
6.2 Determination of the flow rate

6.2.1 Principle

The purpose of this test is to confirm that the difference between the mean flow rate, the instantaneous flow rates and the nominal flow rate remains within the tolerances defined in Clause 5 during the entire administration time of the solution.

6.2.2 Apparatus

The apparatus consists of the elements shown in Figure 1. A and B shall be positioned at the same level unless otherwise specified by the manufacturer.



Key

A centre of the outlet channel of the reservoir
B distal end of the needle
1 device to be tested
2 additional components (administration tubing, needle, etc.) required by the manufacturer
3 anti-evaporation fluid container
4 electronic scale with appropriate accuracy
5 data processing system

Figure 1 — Apparatus for determining the flow rate (schematic)

The temperature conditions for the test shall be controlled by placing the entire device or the flow restrictor within the controlled temperature environment in 6.1.3 or as specified by the manufacturer.

The distal end of the needle shall be at the same level of the centre of the outlet channel of the reservoir unless otherwise specified by the manufacturer.

6.2.3 Procedure

Perform the test with a zero counter-pressure or with the counter-pressure indicated by the manufacturer.

At time $t = 0$, start the flow.

NOTE Before starting the flow, stabilization can be required following a recommendation by the manufacturer.

Take measurements in accordance with 6.2.4.2 until the solution initially present in the device is totally delivered.

6.2.4 Expression of results

6.2.4.1 Mean flow rate

The mean flow rate, Q_m, is determined by measuring the time, t, necessary for the device to deliver the majority of the nominal volume, V_N, of solution. This volume can be determined by the mass of the solution delivered divided by its density. See Formula (1):

$$Q_m = \frac{V'}{t} \tag{1}$$

where $V' = 0{,}75 \cdot V_N$.

6.2.4.2 Instantaneous flow rates

The instantaneous flow rates, Q_i, are determined by the volume of the solution, V_n, delivered by the device during regular time intervals, t_n, with t_n being 1 % of the nominal time. See Formula (2):

$$Q_i = \frac{V_n}{t_n} \tag{2}$$

6.2.4.3 Processing of the results

Plot the curves Q_m and Q_i, $= f(t)$ allowing the respective fluctuations of the mean flow rate to be calculated, as well as the instantaneous flow rates on both sides of the characteristic straight line of the nominal flow rate, Q_N, provided by the manufacturer.

Thus, determine the correlation between the differences of the measured value of the mean flow rate of the nominal flow rate and the various measured values of the instantaneous flow rates of the nominal flow rate based on the requirements in Clause 5.

6.3 Resistance to pressure

Apply, perpendicularly to the device reservoir along its longest axis, a force of 150 N, for 5 s, using an adapted assembly with two hard parallel plates capable of covering the entire device reservoir. The manufacturer shall identify the most critical orientation and perform tests in this orientation.

At the end of the test, after the pressure is removed, the device shall conform to the flow rate test in 6.2 and the water-tightness test described in 6.5.

6.4 Drop test method

Let the device, filled with a dyed solution to nominal volume, fall twice from a height of 1 m, unless otherwise specified by the manufacturer, over a thick hardwood board (e.g. > 600 kg/m^3). Position the device once on its axis, then once perpendicular to its axis. The manufacturer shall identify the most critical orientation and perform tests in this orientation.

NOTE A suitable solution is one containing Patent Blue V (see Reference [16])[1)] 20 mg/l.

At the end of this test, the device shall conform to the water-tightness test described in 6.5.

1) E 131 PATENT BLUE V; Definition: Patent Blue V consists essentially of the calcium or sodium compound of [4-(α-(4-diethylaminophenyl)-5-hydroxy-2,4-disulfophenyl-methylidene)2,5-cyclohexadien-1-ylidene] diethylammonium hydroxide inner salt and subsidiary colouring matters together with sodium chloride and/or sodium sulfate and/or calcium sulfate as the principal uncoloured components. The potassium salt is also permitted; Class: Triarylmethane. Colour Index No: 42051. Einecs: 222-573-8.

6.5 Water-tightness of the components of the device

Other methods equivalent to the method described below can be used.

Fill the device with a dyed solution to nominal volume. After the drop test, immerse the device for 5 min in a container of water. For this test method, each manufacturer shall perform a test method validation to ensure the test parameters are suitable for this specific device.

NOTE A suitable solution is one containing Patent Blue V (see Reference [16])[1)] 20 mg/l.

If applicable, an air filter should be sealed or kept out of the water.

Under the test conditions described above, the device shall remain water-tight and the solution in the container shall not become coloured.

6.6 Resistance to traction of the entire device

Apply a force of 15 N for 15 s between each of the ends of the device.

At the end of this test, the device shall not show deterioration liable to affect the performance as specified in Clause 5 and shall pass the water-tightness test described in 6.5.

6.7 Bolus volume

6.7.1 Prepare the device in accordance with 6.1.3.

6.7.2 Allow sufficient time to fill the reservoir by doubling the nominal refill time. For example, if the device refill time is 60 min, allow a minimum of 120 min to fill the bolus reservoir.

6.7.3 Activate the bolus device according to the manufacturer's instructions and measure the volume delivered.

6.7.4 Repeat the readings two additional times with the same device. Calculate the average of the three volume measurements.

6.8 Refill time

6.8.1 Prepare the device in accordance with 6.1.3.

6.8.2 Activate the bolus device and allow the bolus device to empty completely.

6.8.3 Test 1: After the nominal bolus refill time, activate the bolus device again. Measure the volume delivered.

6.8.4 Test 2: After 50 % of the nominal bolus refill time, activate the bolus device again. Measure the volume delivered.

6.8.5 Repeat the readings for both tests two additional times with the same device.

6.8.6 Calculate the average of the three volume measures for both tests.

6.8.7 The average bolus volumes shall be in the range of 50 % to 115 % of the nominal bolus volume for the first test, and less than 75 % of the nominal bolus volume for the second test.

EXAMPLE If the nominal bolus volume is 5 ml, the result of the second test cannot be more than 3,75 ml.

6.9 Test for efficiency of the fluid filter

6.9.1 Preparation of the test fluid

For the test liquid, use an aqueous suspension of latex particles with a diameter of (20 ± 1) µm and a concentration of approximately 1 000 particles per 100 ml.

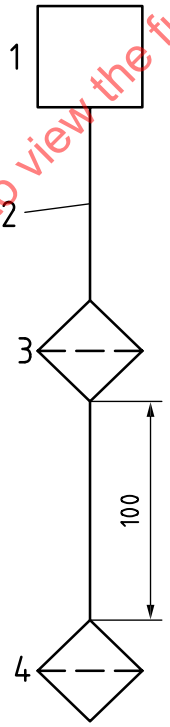
6.9.2 Procedure

Assemble the fluid filter and position it so that it is equivalent to that of one actually used in a suitable test apparatus in accordance with Figure 2. Cut the tubing of the device to approximately 100 mm below the fluid filter.

Flush the fluid filter with 5 ml of the test fluid from the storage bottle and discard the filtrate. Pass 100 ml of the test fluid through the fluid filter and collect the effluent under a vacuum after passing it through a black gridded membrane filter with a pore size of 5 µm to 8 µm and 47 mm diameter. Mount the membrane with any retained latex particles on a suitable microscope slide or holder and count the latex particles in a minimum of 50 % of the grid squares under a magnification of × 50 to × 100. Disregard any particles that are obviously non-latex.

All procedures involved in this test should be conducted in a clean environment and, if possible, under a laminar flow.

Dimensions in millimetres



Key

1	storage bottle	3	fluid filter
2	transfer tube	4	membrane filter

Figure 2 — Example apparatus setup for testing the efficiency of the fluid filter (schematic)

6.9.3 Expression of results

The retention rate of the filter, expressed as a percentage, is given by Formula (3):

$$\left(1-\frac{n_1}{n_0}\right)\times 100 \tag{3}$$

where

n_1 is the number of particles retained on the black gridded membrane filter;

n_0 is the number of particles in the test fluid used.

7 Information to be listed on packaging and/or product

The information given in Table 1 shall be on the device, sterile barrier system and/or protective packaging, as indicated.

Table 1 — Information to be listed on the device, sterile barrier system and/or protective packaging

Information	Device	Sterile barrier system	Protective packaging
Nominal flow rate in millilitres per hour (ml/h)	x	x	
Nominal filling volume in millilitres (ml)	x	x	
Legible warning or symbol concerning compliance with use instructions		x	
If bolus is provided, bolus volume		x	
Commercial reference (model number)		x	x
Name and address of manufacturer		x	x
Designation “Sterile”[a]		x	x
Sterilization method		x	x
Lot number		x	x
Expiration date (year – month)[b]		x	x
Designation “Disposable device”, if appropriate, or corresponding symbol[b]		x	x
Special storage and/or handling conditions if appropriate (e.g. temperature, humidity, pressure)		x	
Appropriate warning statement for application type, e.g. not for IV use (for neuraxial devices)		x	x

[a] See, for example, EN 556-1 or ANSI/AAMI ST67.

[b] Shall be in accordance with ISO 15223-1.

x Indicates that the information shall be included.