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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.

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 28620 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

Medical devices — Non-electrically driven portable infusion devices

1 Scope

This International Standard specifies essential requirements and related test methods for non-electrically driven portable infusion devices[1)]. It applies to devices designed for continuous (fixed or adjustable) flow and/or for bolus application.

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 International Standard does not apply to

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

— implantable devices;

— enteral feeding pumps;

— transdermal delivery devices;

— 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 referenced documents are indispensable for the application 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 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 10993 (all parts), *Biological evaluation of medical devices*

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

1) Thereafter called “device”.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
bolus
discrete volume of solution which 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 indicated by marking on the device or its packaging

3.4
filling volume
nominal volume plus residual volume

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

3.6
instantaneous flow rate
ratio, in millilitres per hour (ml/h), between a volume administered and the time necessary to administer it

3.7
mean flow rate
ratio, in millilitres per hour (ml/h), between the nominal volume and the actual time for administration

3.8
nominal time
operating time for administering the nominal volume

3.9
nominal flow rate
ratio, in millilitres per hour (ml/h), between the nominal volume and nominal time

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
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 and its contents from the time of their assembly until the point of use

[ISO 11607-1:2006, definition 3.13]

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

[ISO 11607-1:2006, definition 3.22]

4 General requirements

4.1 Components

The device shall contain the following components:

— an energy source (other than battery);

— 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 separately delivered.

The device may also contain one or more of the following components (not an exhaustive list):

— a system to adjust the flow rate;

— a filling port preferably with check valve;

— a 6 % (Luer) conical locking connector at the distal end of the tubing;

— 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 (that may be necessary to fulfill the leakage test in 6.4 and 6.5);

— a means of indicating the end of infusion;

NOTE 2 This can be achieved by visual, sound 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 according to the pertinent parts of ISO 10993.

4.3 Design and characteristics

4.3.1 General

All elements of the device designed to receive the drug shall constitute a closed, water-tight system. This requirement shall be verified by the 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.

4.3.2 Fittings

If fittings at the distal end of the tubing are used they shall be interlocking male fittings.

If applicable, the fitting at the filling port shall be an interlocking female fitting.

All device fittings designed to be connected to other medical devices or to accessories shall comply with ISO 594-1 and ISO 594-2.

4.3.3 Filter

The system shall include a particulate matter filter on the fluid path of the solution. Its pore size shall be less than or equal to 15 µm.

4.3.4 Tubing

If the device is designed with tubing it may be fixed or removable. If the tubing is removable, the connection system to the device shall use an interlocking fitting. The junction between the reservoir and the tubing shall resist a static traction of 15 N for 15 s.

4.3.5 Reservoir

The reservoir of the device shall be designed so as to allow 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 and be delivered sterile and non-pyrogenic, and be for single use only.

5 Operating requirements

5.1 Accuracy of the device

5.1.1 Flow rate

Each nominal flow rate of the device shall be calibrated using control solutions at a given temperature. The nominal flow rate as well as the control solutions and the temperatures shall be specified in the instructions for use accompanying the device [see 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.

5.1.2 Bolus, if applicable

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

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

Activating the bolus device one or more times prior to the nominal refill time shall not result in an accumulated bolus volume of more than 150 % of the nominal bolus volume, applying the test method described in 6.8.

6 Test methods

6.1 General test conditions

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

6.1.1 Apparatus and reagents

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

6.1.1.2 Control solutions, recommended by the manufacturer and listed in the accompanying documents [see 8 c)].

6.1.2 Operating conditions

Prepare the device according to the instructions for use and accompanying documents [see 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 ambient pressure between 86 kPa and 106 kPa with the reservoir and the distal outlet at the same head height.

6.1.3 Expression of results

6.1.3.1 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 weight of the solution delivered divided by its density.

$$Q_m = V'/T \tag{1}$$

where

$$V' = 0{,}75 \cdot V_N \tag{2}$$

6.1.3.2 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.

$$Q_i = V_n/T_n \tag{3}$$

6.1.3.3 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 between 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 5.1.

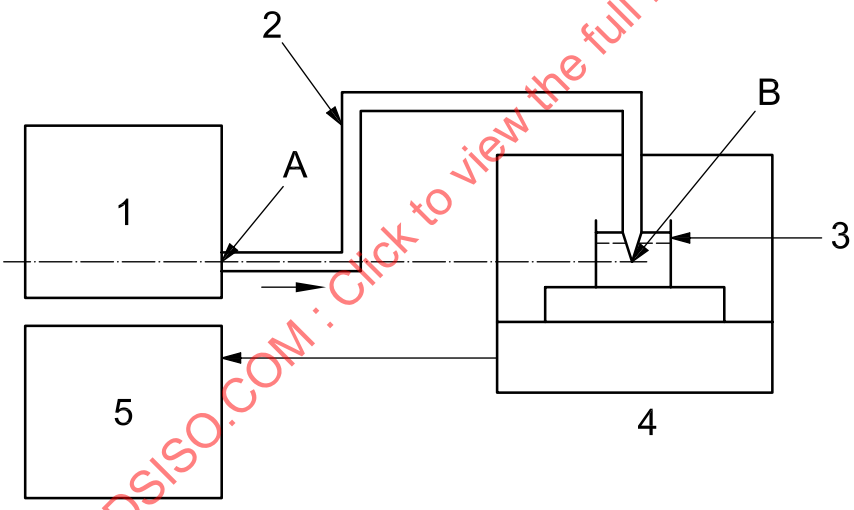
6.2 Determination of the flow rate

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 5.1 during the entire administration time of the solution.

6.2.2 Apparatus

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



Key

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 — Diagrammatic representation of the apparatus used for the determination of the flow rate

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

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

6.2.3 Procedure

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

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

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

Take measurements in accordance with 6.1.3.2 until the solution initially present in the device is totally delivered.

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 that has two hard parallel plates capable of covering the entire device reservoir.

At the end of the test after the pressure is removed, the device shall comply with the flow rate test in 6.2 and with the leak-proof 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 one meter, unless otherwise specified by the manufacturer, over a thick hardwood board (for example > 600 kg/m^3), positioning the device once on its axis, then once perpendicular to its axis.

NOTE A suitable solution is one containing Patent Blue V[2] 2 mg/100 ml.

At the end of this test the device shall comply with the leak-proof test described in 6.5.

6.5 Water-tightness of the components of the device

Other methods equivalent to that described below can be used.

Fill the device with dyed solution to nominal volume and after the drop test, immerse the device for 5 min in a container of water.

NOTE A suitable solution is one containing Patent Blue V[2] 2 mgl/100 ml.

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

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

2) See Commission Directive 2008/128/EC[15].
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

6.6 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 5.1 and shall pass the leak-proof test described in 6.5.

6.7 Bolus volume

6.7.1 Prepare the device according to 6.1.2.

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 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 6.1.2.

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 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 should be no more than 3,75 ml.

7 Information to be listed on packaging and/or product

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