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МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Infusion equipment for medical use —

Part 4:
Infusion sets for single use

Matériel de perfusion à usage médical —

Partie 4: Appareils pour perfusion non réutilisables

Reference number
ISO 8536-4 : 1987 (E)

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 8536-4 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use.*

ISO 8536-4 is a revision, in part, of ISO 1135: 1977; this first edition of ISO 8536-4 together with the other parts of ISO 8536 and ISO 1135 will cancel and replace ISO 1135: 1977.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

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Infusion equipment for medical use —

Part 4:
Infusion sets for single use

1 Scope and field of application

This part of ISO 8536 specifies requirements for types of single-use infusion sets for medical use in order to ensure compatibility of use with containers for infusion solutions and intravenous equipment.

The materials and components of the sets are validated by various test methods (type tests) and, in addition, tests are performed for the release of lots of finished sets (lot tests).

The manufacturer shall select appropriate test methods to comply with the requirements laid down in this part of ISO 8536.

Secondary aims of this part of ISO 8536 are to provide

a) specifications relating to the quality and performance of materials used in infusion sets;

b) a unified presentation of terms and designations for infusion sets.

In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this part of ISO 8536.

This part of ISO 8536 specifies requirements applicable to sterilized infusion sets intended for single use.

2 References

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 a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings.* 1)

ISO 3696, *Water for analytical laboratory use — Specifications and test methods.*

3 General requirements

3.1 Components for use with infusion containers

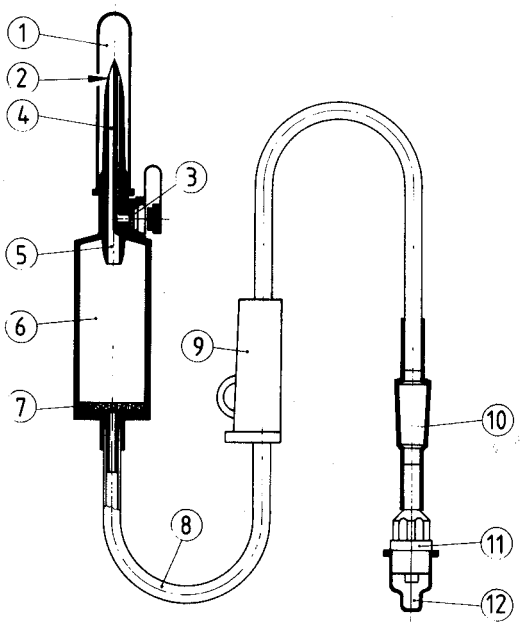
3.1.1 The infusion set shall consist of the components as illustrated in figures 1 and 2.

3.1.2 Infusion sets as illustrated in figure 2 shall be used for collapsible plastics containers.

3.1.3 Infusion sets with separate air-inlet device or a device as illustrated in figure 1 shall be used for rigid bottles.

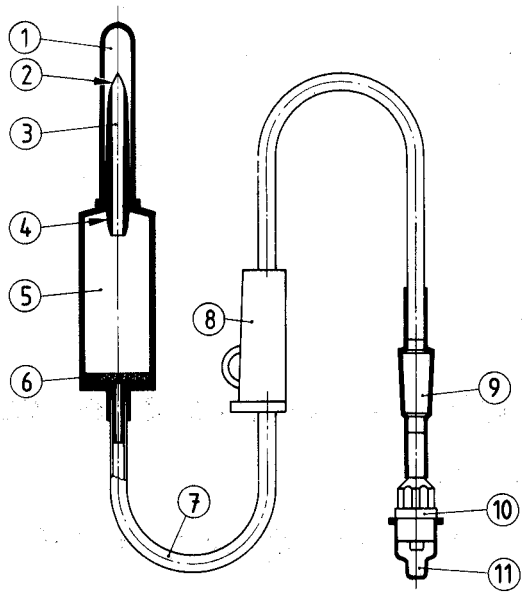
NOTE — Figures 1 and 2 illustrate examples of configurations of typical infusion sets but they do not form part of the requirements for infusion sets for single use as laid down in this part of ISO 8536.

1) At present at the stage of draft.



1 Protective cap of the closure-piercing device
2 Closure-piercing device
3 Air inlet with air filter and closure[1)]
4 Fluid channel
5 Drip tube
6 Drip chamber
7 Fluid filter[2)]
8 Tubing
9 Flow regulator
10 Injection site
11 Male fitting
12 Protective cap of the male fitting

Figure 1 — Example of a typical vented infusion set



1 Protective cap of the closure-piercing device
2 Closure-piercing device
3 Fluid channel
4 Drip tube
5 Drip chamber
6 Fluid filter
7 Tubing
8 Flow regulator
9 Injection site
10 Male fitting
11 Protective cap of the male fitting

Figure 2 — Example of a typical non-vented infusion set

1) Closure of air inlet is optional.

2) The fluid filter may be positioned at other sites, for example preferably near the patient access.

3.2 Sterilization

The set shall be sterile in its unit container. Evidence of the effectiveness of the sterilization process used shall be provided.

3.3 Maintenance of sterility

The set shall be provided with protective caps designed to maintain sterility of the internal parts of the set until the set is used.

3.4 Designation example

3.4.1 Designation example of an infusion set (IS) with an integral air-inlet device complying with the requirements laid down in this part of ISO 8536:

Infusion set ISO 8536-4 IS-V

3.4.2 Designation example of an infusion set (IS) with separate air-inlet device (NV) complying with the requirements laid down in this part of ISO 8536:

Infusion set ISO 8536-4 IS-NV

4 Materials

The materials from which the infusion set is made shall not have undesirable effects on the infusion solution passing through the set under ordinary conditions of use. They shall not produce any general toxic effects or any local reaction on the recipient of the infusion solution.

Appropriate type tests for assessing biological compatibility are given in annex E.

5 Physical requirements

5.1 Integrity

The infusion set, when tested in accordance with annex A, shall show no signs of air leakage.

5.2 Connection between the male fitting, injection site and tubing

The connection between the male fitting, the injection site and the tubing shall withstand a static tensile force of 15 N for 15 s.

5.3 Closure-piercing device

The dimensions of the closure-piercing device shall conform with the dimensions shown in figure 3.

Dimensions in millimetres

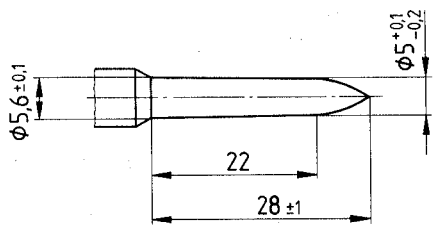


Figure 3 — Dimensions for the closure-piercing device

5.4 Air-inlet device

5.4.1 The air-inlet device shall be provided with a filter designed to prevent the ingress of micro-organisms into the container into which the device is to be inserted.

5.4.2 The air-inlet device may be separate from or integral with the closure-piercing device.

5.4.3 When an air-inlet device is inserted into a rigid infusion container, the air admitted into the container shall not become entrained in the liquid outflow.

5.5 Air filter

The air filter shall be so made that all air entering the rigid container passes through it and that the flow of fluid is not significantly reduced.

5.6 Tubing

5.6.1 The tubing, made of suitable material, shall be transparent or sufficiently translucent for the passage of bubbles of air to be readily detected.

5.6.2 The tubing shall have an internal diameter of not less than 2,7 mm. The tubing length distal to the drip chamber shall be not less than 1 500 mm in length. The tubing shall be flexible and shall not have any kinks.

5.7 Fluid filter

The infusion set shall be provided with a fluid filter which can be visibly observed.

When tested in accordance with annex B, the amount of latex particles retained on the filter shall be not less than 80 %.

NOTES

1 The filter should preferably be positioned between the male fitting and the injection site near the patient access.

2 A fluid filter in general use has an aperture size of 15 µm.

5.8 Drip chamber and drip tube

The drip chamber shall assist the procedure of priming and permit continuous observation of the fall of drops. The liquid shall enter the drip chamber through a tube which projects into the chamber. There shall be a distance of not less than 40 mm between the end of the drip tube and the outlet of the chamber or a distance of not less than 20 mm between the drip tube and filter. The wall of the drip chamber shall not be closer than 5 mm to the end of the drip tube. The drip tube shall be such that 20 drops of distilled water at 20 °C and at a flow rate of 50 ± 5 drops/min deliver 1 ± 0,1 ml (1 ± 0,1 g).

5.9 Flow regulator

5.9.1 The flow regulator shall adjust the flow of the infusion solution between zero and the maximum.

5.9.2 The flow regulator shall be capable of continuous use throughout an infusion without damaging the tubing. There shall be no deleterious reaction between the flow regulator and the tubing when stored in contact.

5.10 Flow rate of infusion fluid

The complete infusion set shall deliver not less than 1 000 ml of a sodium chloride solution [$\varrho(NaCl) = 9$ g/l] in 10 min under a static head of 1 m.

5.11 Injection site

There shall be a self-sealing injection port or other equivalent means near the distal end. Self-sealing injection ports shall reseal under normal working pressure after being perforated by a needle 0,6 mm in diameter.

NOTE — The injection site should be located near the male fitting.

When tested in accordance with annex C, there shall be no signs of air leakage.

5.12 Male fitting

The distal end of the tubing shall terminate in a male fitting having a cone with a 6 % taper conforming with ISO 594-1 or ISO 594-2.

When tested in accordance with ISO 594-1 or ISO 594-2 using a female reference fitting, there shall be no signs of air leakage.

5.13 Protective caps

The protective caps at the end of the infusion set shall be maintain the sterility of the closure-piercing device, the male fitting and the interior of the infusion set. They shall be secure but easily removable.

6 Chemical requirements

6.1 Reducing (oxidizable) matter

When tested in accordance with clause D.2, the total amount of potassium permanganate solution, $c(KMnO_4) = 0{,}002$ mol/l, used shall not exceed 2,0 ml.

6.2 Metal ions

The extract shall not contain in total more than 1 µg/ml (1 ppm) of barium, chromium, copper, lead and tin, and not more than 0,1 µg/l (0,1 ppm) of cadmium, when determined by atomic absorption spectroscopy (AAS) or equivalent method.

When tested in accordance with clause D.3, the colour produced in the test solution shall not exceed that of the standard matching solution containing $\varrho(Pb^{2+}) = 1$ µg/ml.

6.3 Titration acidity or alkalinity

When tested in accordance with clause D.4, not more than 1 ml of either standard volumetric solution shall be required for the indicator to change to the colour grey.

6.4 Residue on evaporation

When tested in accordance with clause D.5, the total amount of dry residue shall not exceed 5 mg.

6.5 Absorbance

When tested in accordance with clause D.6, the extract solution S_1 shall not show absorbance greater than 0,1 (optical density).

7 Biological requirements

The infusion set shall not release any substances which may adversely affect the therapeutic effectiveness of the infusion, including those substances which may exhibit toxic, pyrogenic, bacteriostatic, bactericidal or haemolytic reactions.

7.1 Requirements for type test

The type test shall be established and assessed by an expert (or experts) in the infusion field and on toxicology of plastics material. It shall cover the following elements:

a) General biocompatibility of the plastics material of the set.

Materials shall be assessed for biocompatibility by carrying out suitable tests for those properties detailed in clause E.2 and the results of the tests shall indicate freedom from toxicity.

NOTE — In many countries there are national pharmacopoeias, governmental regulations or standards detailing suitable tests for assessing biocompatibility. However, if no such regulations are provided, the test methods specified in the table should be used.

b) Compatibility of the infusion set with the process of manufacture and sterilization.

The process of manufacture and sterilization, and the prolonged contact with the infusion fluid shall not alter properties of the plastics material and of the set itself.

c) Compatibility of the plastics material of the set with the infusion fluid.

Absence of migration after sterilization and prolonged contact of the constituents of the plastics material shall not alter the properties of the infusion fluid or cause any toxicological risk for the patient.

d) Biocompatibility of the plastics set with the infusion fluid.

7.2 Requirements for lot test

7.2.1 Sterility

The infusion set shall be assessed for sterility using a suitable test (guidance on testing for sterility is given in annex E) and the results shall indicate that the infusion set is sterile.

7.2.2 Pyrogens

The infusion set supplied shall be assessed for freedom from pyrogens using a suitable test (guidance on testing for pyrogens is given in annex E) and the results shall indicate that the set is free from pyrogenicity.

8 Marking and labelling

8.1 Unit container

The unit container of each infusion set for single use shall be marked with the following information:

a) a description of the contents, in words and/or pictorially;

b) indications that the infusion set is sterile, free from pyrogens and for single use only;

c) instructions for the use of the infusion set, including a warning note about checking that seals are intact and about detached protective caps;

d) a warning: "NOT TO BE USED FOR BLOOD OR BLOOD COMPONENTS";[1]

e) the nominal dimension of an intravenous needle, if included;

f) the year and month of sterilization, where applicable, and the date of expiry, where applicable;

g) the lot (batch) designation;

h) the manufacturer's and/or supplier's name and address;

i) a statement that 20 drops of distilled water delivered by the drip tube are equivalent to 1 ± 0,1 ml (1 ± 0,1 g);

j) a statement to the effect that the infusion set shall be destroyed after use.

8.2 Shelf or multi-unit container

Shelf or multi-unit containers shall be marked with the following information:

a) a description of the contents, in words and/or pictorially;

b) the number of infusion sets;

c) instructions for use in each shelf container, or on the unit container;

d) the word "STERILE" in prominent lettering (see note in 9.1);

NOTE — This may form part of the description listed under a) above.

e) the manufacturer's or supplier's name;

f) the lot (batch) designation;

g) the year and month of sterilization, where applicable, and the date of expiry, where applicable;

h) the recommended storage conditions, if any.

8.3 Outer or transit container[2]

Outer or transit containers shall be marked with the following information:

a) the manufacturer's or supplier's name and address;

b) a description of the contents, in words and/or pictorially;

c) the number of infusion sets;

d) the lot (batch) designation;

e) the year and month of sterilization, where applicable, and the date of expiry where applicable;

f) the recommended storage conditions, if any.

9 Packaging

9.1 The infusion set shall be individually packed so that the set remains sterile during storage.

The unit container shall be sealed in such a manner that it cannot be opened and closed again without it being obvious that the container has been opened.

NOTE — If, in special cases, only the interior of the set is required to be sterile, a statement to this effect should be clearly marked on the shelf or multi-unit container.

9.2 The sets shall be packed and sterilized in such a way that there are no flattened portions or kinks when they are ready for use.

1) If required by the national authority.

2) Is not intended to be the final shipping container.