INTERNATIONAL STANDARD

ISO 8536-4

Second edition
1998-02-15

Infusion equipment for medical use —

Part 4:
Infusion sets for single use, gravity feed

Matériel de perfusion à usage médical —

Partie 4: Appareils de perfusion non réutilisables, à alimentation par gravité

Reference number
ISO 8536-4:1998(E)

Contents

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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.

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.

In the field of information technology, ISO and IEC have established a joint technical committee, ISO/IEC JTC 1. Draft International Standards adopted by the joint technical committee are circulated to national bodies for voting. Publication as an International Standard requires approval by at least 75 % of the national bodies casting a vote.

International Standard ISO 8536-4 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and*

This second edition cancels and replaces the first edition (ISO 8536-4:1987), which has been technically revised.

ISO 8536 consists of the following parts, under the general title *Infusion equipment for medical use:*

— *Part 1: Infusion glass bottles*

— *Part 2: Closures for infusion bottles*

— *Part 3: Aluminium caps for infusion bottles*

— *Part 4: Infusion sets for single use, gravity feed*

— *Part 5: Burette type infusion sets*

— *Part 6: Freeze-drying closures for infusion bottles*

— *Part 7: Caps made of aluminium-plastics combinations for infusion bottles.*

Annexes A, B, C, D, E and F form an integral part of this part of ISO 8536. Annexes G, H and J are for information only.

Infusion equipment for medical use —

Part 4:
Infusion sets for single use, gravity feed

1 Scope

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

Secondary aims of this part of ISO 8536 are to provide guidance on specifications relating to the quality and performance of materials used in infusion sets and to present designations for infusion set components.

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

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 8536. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 8536 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements.*

ISO 594-2:1991, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings.*

ISO 3696:1986, *Water for analytical laboratory use — Specification and test methods.*

ISO 7864:1993, *Sterile hypodermic needles for single use.*

ISO 14644-1:—[1)], *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness.*

EN 980, *Graphical symbols for use in labelling of medical devices.*

US Federal Standard 209 E, *Airborne particulate cleanliness classes in cleanrooms and clean zones.*

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1) To be published.

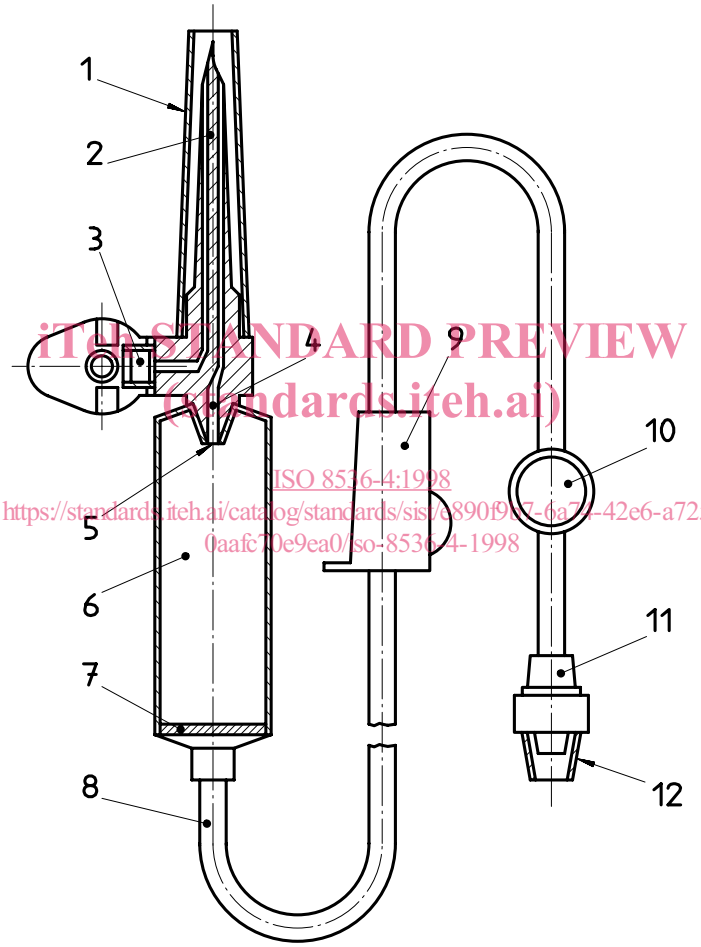
3 General requirements

3.1 The nomenclature to be used for components of infusion sets and of a separate air-inlet device is given in figures 1, 2 and 3.

NOTE Figures 1, 2 and 3 illustrate examples of the configuration of infusion sets and air-inlet devices; other configurations may be used provided they lead to the same results.

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

3.3 Infusion sets as illustrated in figure 2 used with separate air-inlet devices as illustrated in figure 3, or infusion sets as illustrated in figure 1 shall be used for rigid containers.



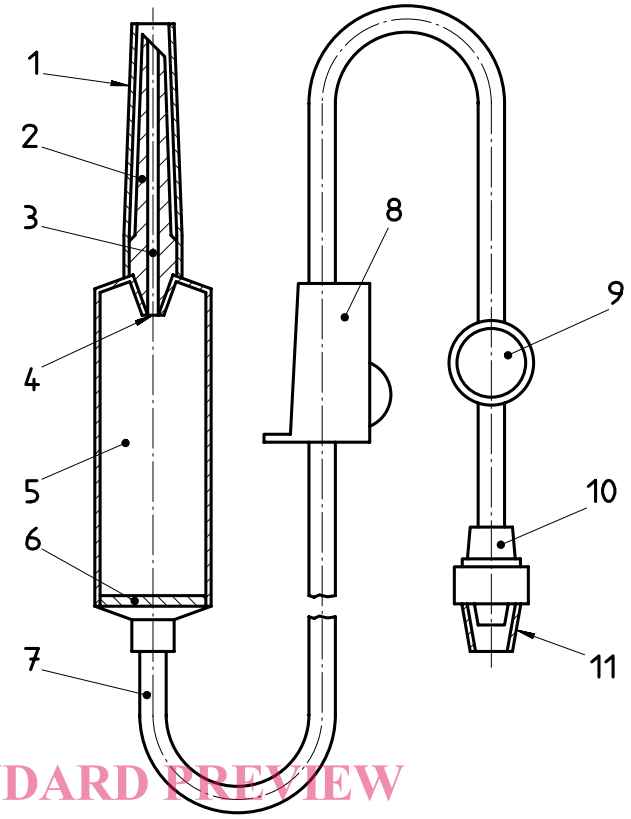
Key

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

* Closure of air inlet is optional.

** The fluid filter may be positioned at other sites, for example preferably near the patient access. Generally the fluid filter used has a nominal pore size of 15 µm.

*** Injection site is optional.

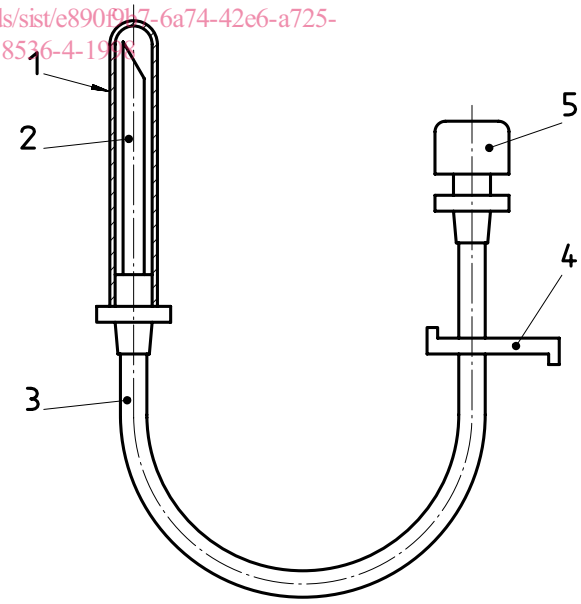


Key

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 conical fitting
11 Protective cap of male conical fitting

* The fluid filter may be positioned at other sites, for example preferably near the patient access. Generally the fluid filter used has a nominal pore size of 15 µm.
** Injection site is optional.

Figure 2 — Example of a non-vented infusion set



Key

1 Protective cap
2 Closure-piercing device or needle
3 Tubing
4 Clamp*
5 Air-inlet with air filter

* Other designs are acceptable if the same safety aspects are ensured.

Figure 3 — Example of an air-inlet device

3.4 The infusion set shall be provided with protective caps to maintain sterility of the internal parts of the set until the set is used. The air-inlet device shall be provided with a protective cap over the closure-piercing device or needle.

4 Designation

4.1 Infusion set

Infusion sets complying with the requirements specified in this part of ISO 8536 shall be designated by the descriptor words, followed by a reference to this part of ISO 8536, followed by the letters IS, followed by the letter V for a vented infusion set or NV for a non-vented infusion set:

EXAMPLES

Infusion set ISO 8536-4 - IS - V

Infusion set ISO 8536-4 - IS - NV

4.2 Air-inlet device

Air-inlet devices complying with the requirements specified in this part of ISO 8536 shall be designated by the descriptor words, followed by a reference to this part of ISO 8536, followed by the letters AD.

EXAMPLE

Air-inlet device ISO 8536-4 - AD

5 Materials

The materials from which the infusion set and its components as given in clause 3 are manufactured shall comply with the requirements as specified in clause 6. Where components of the infusion set come into contact with solutions, the materials additionally shall comply with the requirements as specified in clauses 7 and 8.

6 Physical requirements

6.1 Particulate contamination

The infusion sets shall be manufactured under conditions that minimize particulate contamination.

Determination of visible particles shall be carried out as given in annex F or by using an equivalent procedure.

6.2 Integrity

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

6.3 Connections between components

Any connections between fluid path components of the infusion set, excluding protective caps, shall withstand a static tensile force of not less than 15 N for 15 s.

6.4 Closure-piercing device

The dimensions of the closure-piercing device shall conform with the dimensions shown in figure 4.

The closure-piercing device shall be capable of piercing and penetrating the closure of a fluid container without prepiercing. No coring should occur during this procedure.

Dimensions in millimetres

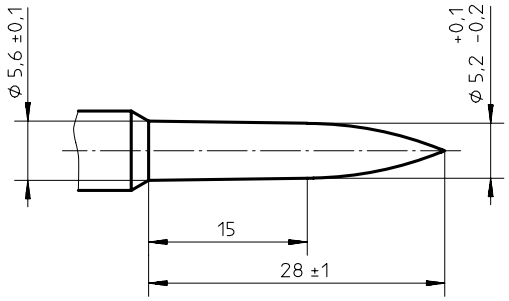


Figure 4 —Dimensions of the closure-piercing device

6.5 Air-inlet device

The air-inlet device shall conform with clauses 3.2 and 8.2.

The air-inlet device shall be provided with an air filter to prevent the ingress of microorganisms into the container into which the device is to be inserted.

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

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

The air filter shall be fitted so that all air entering the rigid container passes through it and that the flow of fluid is not reduced by more than 20 % of that from a freely ventilated container when tested in accordance with annex B.

6.6 Tubing

The tubing, made of flexible material, shall be transparent or sufficiently translucent so that the interface of air and water during the passage of air bubbles can be observed with normal or corrected vision.

The tubing length distal to the drip chamber shall be not less than 1 500 mm in length, including the injection site, when provided, and the male conical fitting.

6.7 Fluid filter

The infusion set shall be provided with a fluid filter.

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

6.8 Drip chamber and drip tube

The drip chamber shall 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 the fluid 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 or 60 drops of distilled water at 23 °C ± 2 °C and at a flowrate of 50 drops/min ± 10 drops/min deliver a volume of 1 ml ± 0,1 ml (1 g ± 0,1 g).

NOTE The drip chamber should permit and facilitate the procedure of priming.

6.9 Flow regulator

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

NOTE The flow regulator should be capable of continuous use throughout an infusion without the tubing being damaged. There should be no deleterious reaction between the flow regulator and the tubing when stored in such a manner that there is contact.

6.10 Flowrate of infusion fluid

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

6.11 Injection site

When provided, the self-sealing injection site shall reseal when tested in accordance with annex D and there shall be no leakage of more than one falling drop of water.

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

6.12 Male conical fitting

The distal end of the tubing shall terminate in a male conical fitting in accordance with ISO 594-1 or ISO 594-2.

6.13 Protective caps

The protective caps at the end of the infusion set shall maintain the sterility of the closure-piercing device, the male conical fitting and the interior of the infusion set.

NOTE Protective caps should be secure but easily removable.

7 Chemical requirements

7.1 Reducing (oxidizable) matter

When tested in accordance with clause E.2, the total amount of potassium permanganate solution used [$c(\text{KMnO}_4) = 0{,}002$ mol/l] shall not exceed 2,0 ml.

7.2 Metal ions

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

When tested in accordance with clause E.3, the intensity of the colour produced in the test solution shall not exceed that of the standard matching solution with a mass concentration $\rho(\text{Pb}^{2+}) = 1$ µg/ml.

7.3 Titration acidity or alkalinity

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

7.4 Residue on evaporation

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

7.5 UV absorption of extract solution

When tested in accordance with clause E.6, the extract solution S_1 shall not show absorption greater than 0,1.

8 Biological requirements

8.1 General

The infusion set shall not release any substances which may adversely affect the patient (see annex H).

8.2 Sterility

The infusion set and/or the air-inlet device in its unit container shall have been subjected to a validated sterilization process (see annex J).

8.3 Pyrogenicity

The infusion set and/or the air-inlet device shall be assessed for freedom from pyrogens using a suitable test, and the results shall indicate that the infusion set is free from pyrogenicity. Guidance on testing for pyrogenicity is given in annex G.

8.4 Haemolysis

The infusion set shall be assessed for freedom from haemolytic constituents and the result shall indicate that the infusion set is free from haemolytic reactions.

Guidance on testing for haemolytic constituents is given in ISO 10993-4.

8.5 Toxicity

Materials shall be assessed for toxicity by carrying out suitable tests, and the results of the tests shall indicate freedom from toxicity. Guidance on testing for toxicity is given in ISO 10993-1.

9 Labelling

9.1 Unit container

The unit container shall be labelled with the following minimum information:

a) a textual description of the contents, including the words “Gravity feed only”;

b) indication that the infusion set is sterile, using the graphical symbol given in EN 980;