
**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*

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ISO 8536-4:2010

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

This fifth edition cancels and replaces the fourth edition (ISO 8536-4:2007), of which it constitutes a minor revision. In detail, 7.1 was more clarified in alignment with B.2, and A.2.2 was changed in order to go back with the leakage test pressure to 20 kPa and to restrict the leakage test for $(40 \pm 1) ^\circ\text{C}$.

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 infusion sets for single use, gravity feed*
- *Part 6: Freeze drying closures for infusion bottles*
- *Part 7: Caps made of aluminium-plastics combinations for infusion bottles*
- *Part 8: Infusion equipment for use with pressure infusion apparatus*
- *Part 9: Fluid lines for use with pressure infusion equipment*
- *Part 10: Accessories for fluid lines for use with pressure infusion equipment*
- *Part 11: Infusion filters for use with pressure infusion equipment*
- *Part 12: Check valves*

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.

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2 Normative references (standards.iteh.ai)

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 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 7864, *Sterile hypodermic needles for single use*

ISO 14644-1, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness¹⁾*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements²⁾*

3 General requirements

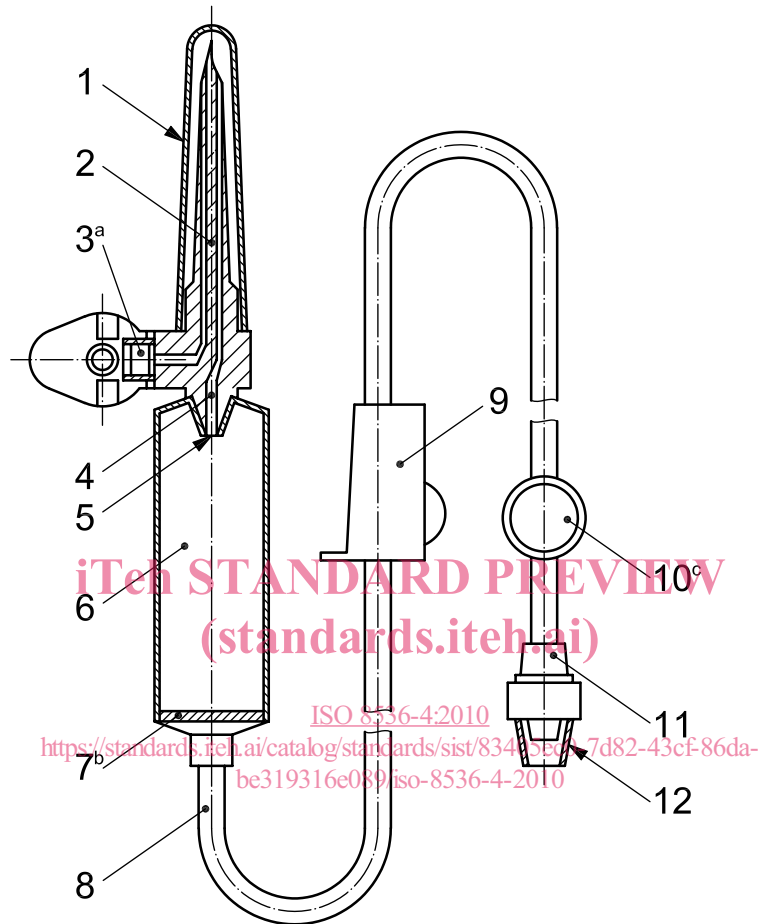
3.1 The nomenclature to be used for components of infusion sets and of a separate air-inlet device is given in Figures 1, 2 and 3. These figures illustrate examples of the configuration of infusion sets and air-inlet devices; other configurations may be used provided they lead to the same results. Infusion sets as illustrated in Figure 2 should only be used for collapsible plastic containers. Infusion sets as illustrated in Figure 2 used

1) Under preparation. (Revision of ISO 14644-1:1999)

2) To be published. (Revision of ISO 15223-1:2007)

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

3.2 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.



Key

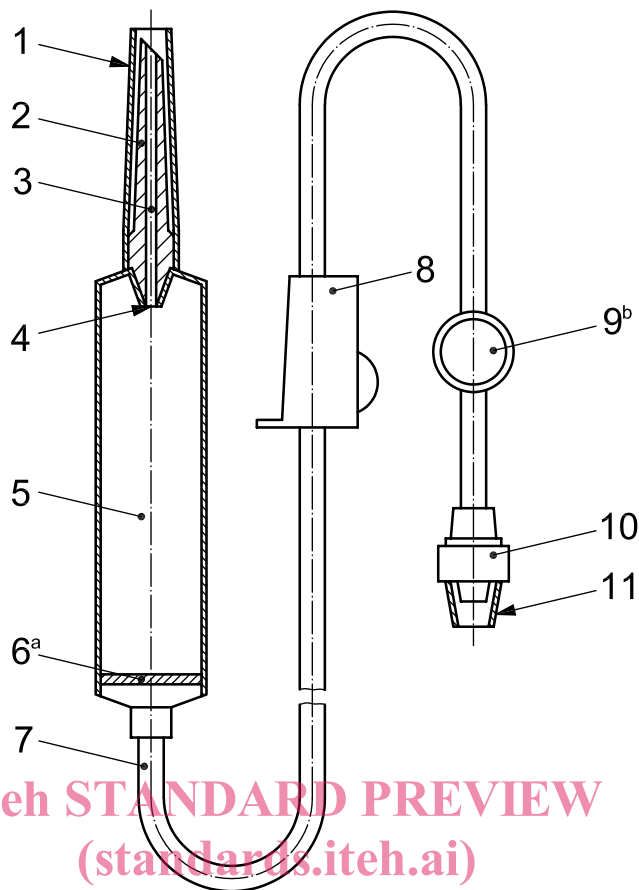
- | | |
|---|---|
| 1 protective cap of closure-piercing device | 7 fluid filter |
| 2 closure-piercing device | 8 tubing |
| 3 air inlet with air filter and closure | 9 flow regulator |
| 4 fluid channel | 10 injection site |
| 5 drip tube | 11 male conical fitting |
| 6 drip chamber | 12 protective cap of male conical fitting |

a Closure of the air inlet is optional.

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

c The injection site is optional.

Figure 1 — Example of a vented infusion set



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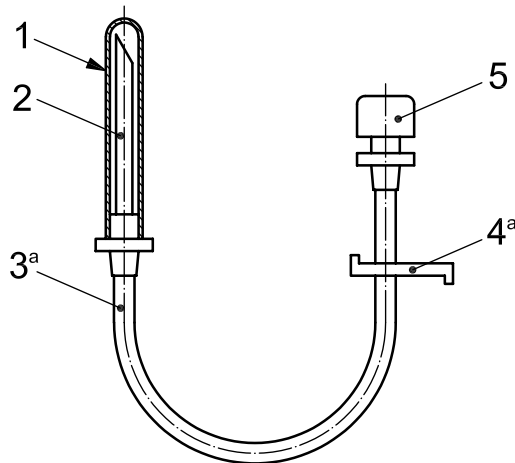
Key

- | | |
|---|---|
| 1 protective cap of closure-piercing device | 7 tubing |
| 2 closure-piercing device | 8 flow regulator |
| 3 fluid channel | 9 injection site |
| 4 drip tube | 10 male conical fitting |
| 5 drip chamber | 11 protective cap of the male conical fitting |
| 6 fluid filter | |

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

^b The injection site is optional.

Figure 2 — Example of a non-vented infusion set



Key

- | | |
|-------------------------------------|-----------------------------|
| 1 protective cap | 4 clamp |
| 2 closure-piercing device or needle | 5 air-inlet with air filter |
| 3 tubing | |

^a Other designs are acceptable if the same safety aspects are ensured.

Figure 3 — Example of an air-inlet device
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4 Designation

4.1 Infusion set

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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 G:

Infusion set ISO 8536-4 - IS - G

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 IS, followed by the letters AD:

Air-inlet device ISO 8536-4 - IS - AD

5 Materials

The materials from which the infusion set and its components are manufactured (as described in Clause 3) shall comply with the requirements specified in Clause 6. Where components of the infusion set come into contact with solutions, the materials shall also comply with the requirements 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. All parts shall be smooth and clean at the fluid pathway surfaces. When tested as specified in A.1, the number of particles shall not exceed the contamination index limit.

6.2 Leakage

The infusion set, when tested in accordance with A.2, shall show no signs of air leakage.

6.3 Tensile strength

When tested as specified in A.3, 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 to the dimensions shown in Figure 4.

NOTE The dimension of 15 mm in Figure 4 is a reference measurement. The cross-section of the piercing device at this site is a circle.

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

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Dimensions in millimetres

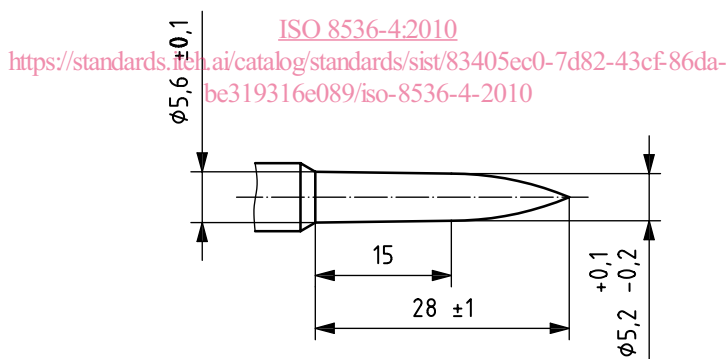


Figure 4 — Dimensions of the closure-piercing device

6.5 Air-inlet device

The air-inlet device shall conform to 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 such that all air entering the rigid container passes through it, and such that the flow of fluid is not reduced by more than 20 % of that from a freely ventilated container when tested in accordance with A.4.

6.6 Tubing

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

The tubing from the distal end 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 A.5, 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 that 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 ± 2) °C at a flow rate of (50 ± 10) drops/min deliver a volume of $(1 \pm 0,1)$ ml or a mass of $(1 \pm 0,1)$ g. The drip chamber should permit and facilitate the priming procedure.

6.9 Flow regulator

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The flow regulator shall adjust the flow of the infusion solution between zero and the maximum. 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 they are stored in such a way that there is contact.

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6.10 Flow rate of infusion fluid

The infusion set shall deliver not less than 1 000 ml of a sodium chloride solution [mass concentration $\rho(\text{NaCl}) = 9 \text{ g/l}$] 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 A.6, and there shall be no leakage of more than one falling drop of water. 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. Luer lock fittings in accordance with ISO 594-2 should preferably be used.

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. Protective caps should be secure but easily removable.

7 Chemical requirements

7.1 Reducing (oxidizable) matter

When tested in accordance with B.2, the difference of volume of $\text{Na}_2\text{S}_2\text{O}_3$ solution [$c(\text{Na}_2\text{S}_2\text{O}_3) = 0,005 \text{ mol/l}$] for the extract solution S_1 and of volume of $\text{Na}_2\text{S}_2\text{O}_3$ solution for blank solution S_0 shall not exceed 2,0 ml.

7.2 Metal ions

The extract shall not contain in total more than 1 $\mu\text{g/ml}$ of barium, chromium, copper, lead and tin, and not more than 0,1 $\mu\text{g/ml}$ of cadmium, when determined by atomic absorption spectroscopy (AAS) or an equivalent method.

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

7.3 Titration acidity or alkalinity

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

7.5 UV absorption of extract solution

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

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8 Biological requirements

8.1 General

The infusion set shall be assessed for biological compatibility according to the guidelines given in C.2.

8.2 Sterility

The infusion set or the air-inlet device, or both, in its unit container shall have been subjected to a validated sterilization process (see ISO 11135, ISO 11137 and ISO 17665).

8.3 Pyrogenicity

The infusion set and/or the air-inlet device shall be assessed for freedom from pyrogens by using a suitable test, and the results shall indicate that the infusion set is free from pyrogens. Guidance on testing for pyrogenicity is given in C.1.

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.