INTERNATIONAL STANDARD

ISO 8536-4

Sixth edition
2019-09

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
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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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 sixth edition cancels and replaces the fifth edition (ISO 8536-4:2010), which has been technically revised. It also incorporates the Amendment ISO 8536-4:2010/Amd.1:2013.

The main changes compared to the previous edition are as follows:

— Clause 5 'Designation' now refers to Clause 10 'Labelling';

— the physical requirements – especially regarding stand-alone air-inlet devices – have been further clarified;

— Clause 10 'Labelling' has been updated;

— test for leakage in A.3 has been updated;

— determination of flow rate in A.5 has been totally reviewed;

— normative references in Clause 2 and the Bibliography have been updated.

A list of all parts in the ISO 8536 series can be found on the ISO website.

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.

Infusion equipment for medical use —

Part 4:
Infusion sets for single use, gravity feed

1 Scope

This document 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 document 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.

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

ISO 7864, *Sterile hypodermic needles for single use — Requirements and test methods*

ISO 8536-13, *Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact*

ISO 8536-14, *Infusion equipment for medical use — Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact*

ISO 14644-1, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*

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

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

3 Terms and definitions

No terms and definitions are listed in this document.

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

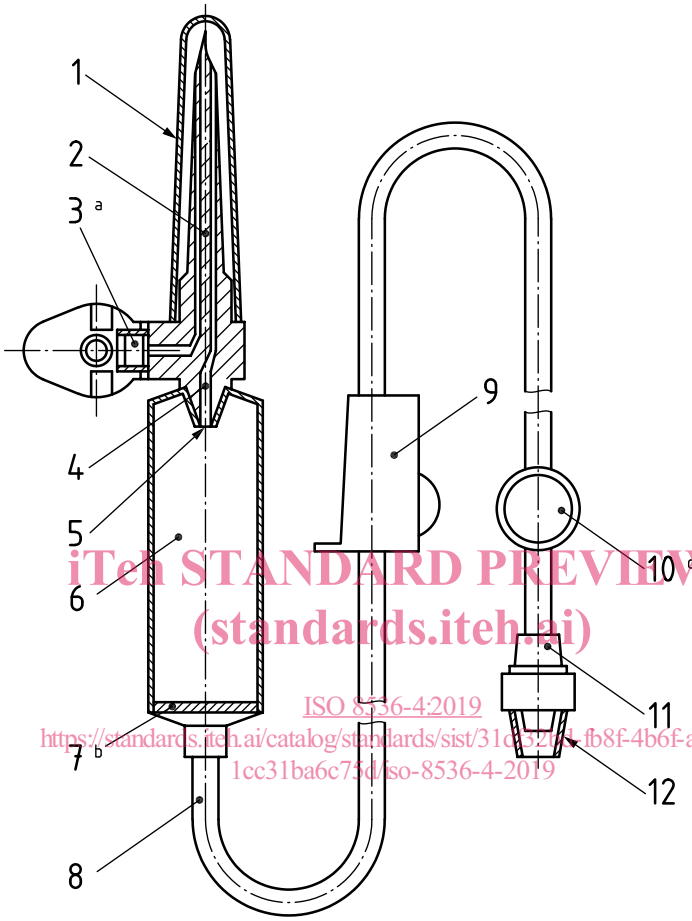
— IEC Electropedia: available at http://www.electropedia.org/

4 General requirements

4.1 The nomenclature to be used for components of infusion sets and of a stand-alone 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 with stand-alone air-inlet devices as illustrated in Figure 3, or infusion sets as illustrated in Figure 1, shall be used for rigid containers.

4.2 The infusion set shall be provided with protective caps. The air-inlet device shall be provided with a protective cap over the closure-piercing device or needle (see Figure 3).



Key

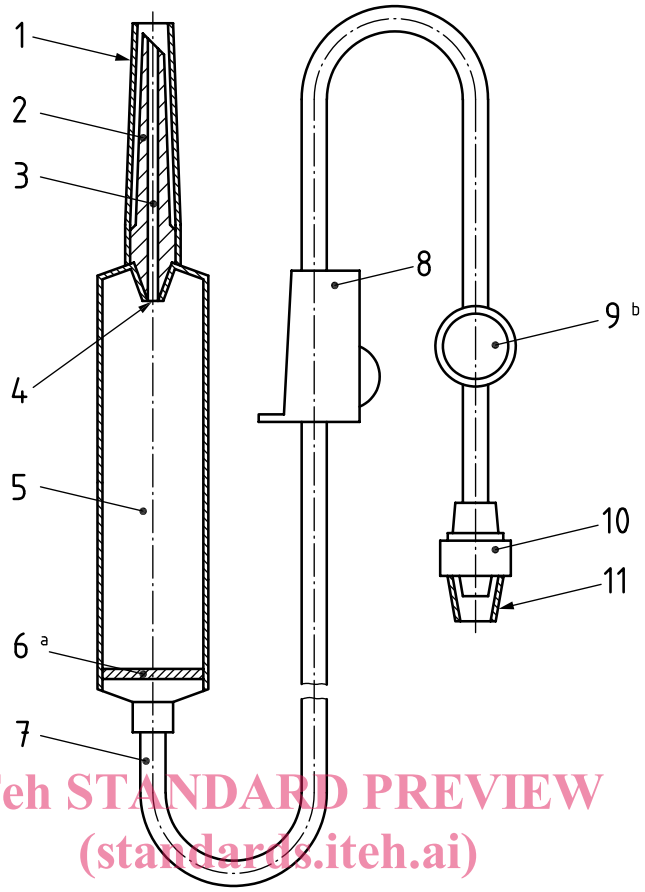
1 protective cap of closure-piercing device
2 closure-piercing device
3 integral air-inlet with air filter and closure
4 fluid channel
5 drip tube
6 drip chamber
7 fluid filter
8 tubing
9 flow regulator
10 injection site
11 male conical fitting
12 protective cap of male conical fitting

a Closure of the air-inlet is optional.

b The fluid filter may be positioned at other sites, preferably near the patient access.

c The injection site is optional.

Figure 1 — Example of a vented infusion set



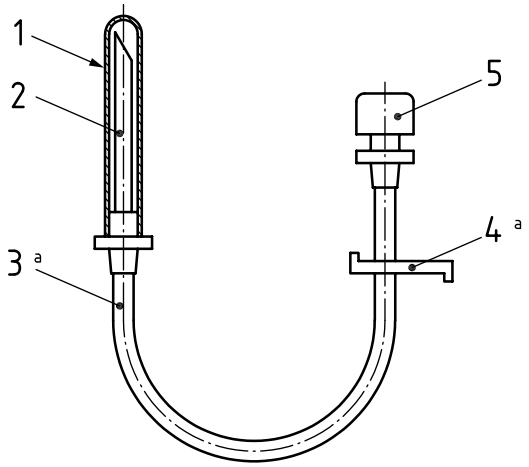
Key

1 protective cap of 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 the male conical fitting

[a] The fluid filter may be positioned at other sites, preferably near the patient access.

[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 a stand-alone air-inlet device

5 Designation

Designation shall follow label requirements according to Clause 10.

6 Materials

The materials from which the infusion set, its components and the stand-alone air-inlet device are manufactured (as described in Clause 4) shall comply with the requirements specified in Clause 7. Where components of the infusion set come into contact with solutions, the materials shall also comply with the requirements specified in Clauses 8 and 9.

7 Physical requirements

7.1 Particulate contamination

The infusion set and stand-alone air-inlet device 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.2, the number of particles shall not exceed the contamination index limit.

7.2 Leakage

The infusion set, when tested in accordance with A.3, shall show no signs of air leakage.

7.3 Tensile strength

When tested as specified in A.4, the infusion set, excluding protective caps, shall withstand a static tensile force of not less than 15 N for 15 s.

7.4 Closure-piercing device

The dimensions of the closure-piercing device shall conform to the dimensions shown in Figure 4. The cross-section of the closure-piercing device over the length of 15 mm shall be a circle.

NOTE The dimension of 15 mm in Figure 4 is a reference measurement.

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.

Dimensions in millimetres

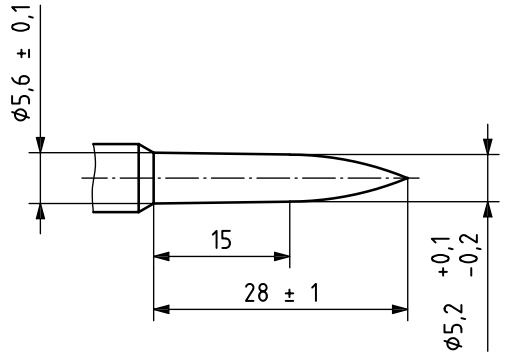


Figure 4 — Dimensions of the closure-piercing device

7.5 Air-inlet device

The air-inlet device can be an integral part of the infusion set (Figure 1) or a stand-alone device (Figure 3).

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.

When the air-inlet device is in use the air admitted into the container shall not become entrained in the liquid-entry of the closure-piercing device.

The air filter and the design of the air-inlet device shall be 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.5.2 and A.5.3.

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

7.6 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.

7.7 Fluid filter

The infusion set shall be provided with a fluid filter.

When tested in accordance with A.6, the retention of latex particles on the filter shall be not less than 80 %.

7.8 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 and 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. Depending on the design, the drip tube shall be such that 20 drops or 60 drops of distilled water at (23 ± 2) °C at a flow rate of (50 ± 10) drops/min deliver a volume of (1 ± 0,1) ml or a mass of (1 ± 0,1) g. The drip chamber should permit and facilitate the priming procedure.

7.9 Flow regulator

The flow regulator shall be in accordance with ISO 8536-13 or ISO 8536-14.

7.10 Flow rate of infusion set

The infusion set without the use of an air-inlet device shall deliver not less than 1 000 ml of a sodium chloride solution [concentration of NaCl = 9 g/l] in 10 min for a drip tube that delivers 1 ml with 20 drops. Testing shall be done in accordance with A.5.1.

7.11 Injection site

When provided, the self-sealing injection site shall reseal when tested in accordance with A.7, and there shall be no leakage of water. The injection site should be located near the male conical fitting.

7.12 Male conical fitting

The distal end of the tubing shall terminate in a male conical fitting in accordance with ISO 80369-7.

7.13 Protective caps

The protective caps shall cover the respective surfaces of the infusion equipment to prevent contamination from surrounding environment, to avoid stick injuries and packaging damages. Protective caps should be secure but easily removable.

8 Chemical requirements

8.1 Reducing (oxidizable) matter

When tested in accordance with B.2, the difference of volume of $Na_2S_2O_3$ solution [concentration of $Na_2S_2O_3$ = 0,005 mol/l] for the extract solution S_1 and of volume of $Na_2S_2O_3$ solution for blank solution S_0 shall not exceed 2,0 ml.

8.2 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 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 concentration of Pb^{2+} = 1 µg/ml.

8.3 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.

8.4 Residue on evaporation

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

8.5 UV absorption of extract solution

When tested in accordance with B.6, the extract solution S_1 shall be $S(\lambda) < 0{,}1$ with λ in the range from 250 nm to 320 nm.

9 Biological requirements

9.1 General

The infusion set and the stand-alone air-inlet device shall be assessed for biological compatibility according to the guidelines given in C.2.

9.2 Sterility

The infusion set and the stand-alone air-inlet device in its unit container shall have been subjected to a validated sterilization process, e.g. ISO 11135, ISO 11137-1, ISO 11137-2 and ISO 17665.

9.3 Pyrogenicity

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

9.4 Haemolysis

The infusion set shall be assessed for freedom from haemolytic constituents. The test result shall indicate that the infusion set is free from haemolytic reactions. Guidance on testing for haemolytic constituents is given in ISO 10993-4.

9.5 Toxicity

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

10 Labelling

10.1 General

The labelling shall include the requirements as specified in 10.2 and 10.3. If graphical symbols are used, then refer to ISO 15223-1.

NOTE The presence of substances of interest can be indicated by using symbol 2725 of ISO 7000 by replacing the "XXX" by the abbreviation of the substance. The absence of substances of interest can be indicated by crossing the respective symbol.

10.2 Unit container

The unit container shall be labelled at least with the following information:

a) the name and address of the manufacturer;

b) a description of the contents;