INTERNATIONAL STANDARD

ISO 1135-4

Second edition
1998-03-15

Transfusion equipment for medical use —

Part 4:
Transfusion sets for single use

Matériel de transfusion à usage médical —

Partie 4: Appareils de transfusion non réutilisables

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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.

International Standard ISO 1135-4 was prepared by ISO/TC 76, *Transfusion, infusion and injection equipment for medical use*.

This second edition cancels and replaces the first edition (ISO 1135-4:1987), which has been technically revised.

ISO 1135 consists of the following parts, under the general title *Transfusion equipment for medical use*:

— *Part 1: Glass transfusion bottles, closures and caps*

— *Part 3: Blood-taking sets*

— *Part 4: Transfusion sets for single use.*

Annexes A, B, C, D, E and F form an integral part of this part of ISO 1135. Annexes G, H and J are for information only.

Transfusion equipment for medical use —

Part 4:
Transfusion sets for single use

1 Scope

This part of ISO 1135 specifies requirements for single-use transfusion sets for medical use in order to ensure their compatibility with containers for blood and blood components as well as with intravenous equipment.

This part of ISO 1135 also specifies requirements for air-inlet devices for use with rigid containers for blood and blood components.

Secondary aims of this part of ISO 1135 are to provide guidance on specifications relating to the quality and performance of materials used in transfusion sets and to present designations for transfusion set components.

In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this part of ISO 1135.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 1135. 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 1135 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 3696:1987, *Water for analytical laboratory use — Specification and test methods*.

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

ISO 10993-1:—[1)], *Biological evaluation of medical devices — Part 1: Guidance on selection of tests.*

ISO 10993-4:1992, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood.*

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1) To be published. (Revision of ISO 10993-1:1992)

ISO 14644-1:—[2], *Clean rooms and associated controlled environments — Part 1: Classification of air cleanliness.*

ISO/TR 15223:—[2], *Medical devices — Symbols to be used with labels, labelling and information to be supplied.*

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

3 General requirements

3.1 Nomenclature for components of the transfusion set

The nomenclature for components of transfusion sets is given in figure 1. An air-inlet device as shown in figure 2 is required for use with rigid containers for blood and blood components.

NOTE — Figure 1 illustrates an example of a transfusion set. Figure 2 illustrates a separate air-inlet device. Figures 1 and 2 do not form part of the requirements for transfusion sets for single use as specified in this part of ISO 1135.

3.2 Maintenance of sterility

The transfusion 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.

3.3 Designation

3.3.1 Transfusion set

An example of the designation of a transfusion set complying with the requirements of this part of ISO 1135 is as follows:

Transfusion set ISO 1135-4 TS

3.3.2 Air-inlet device

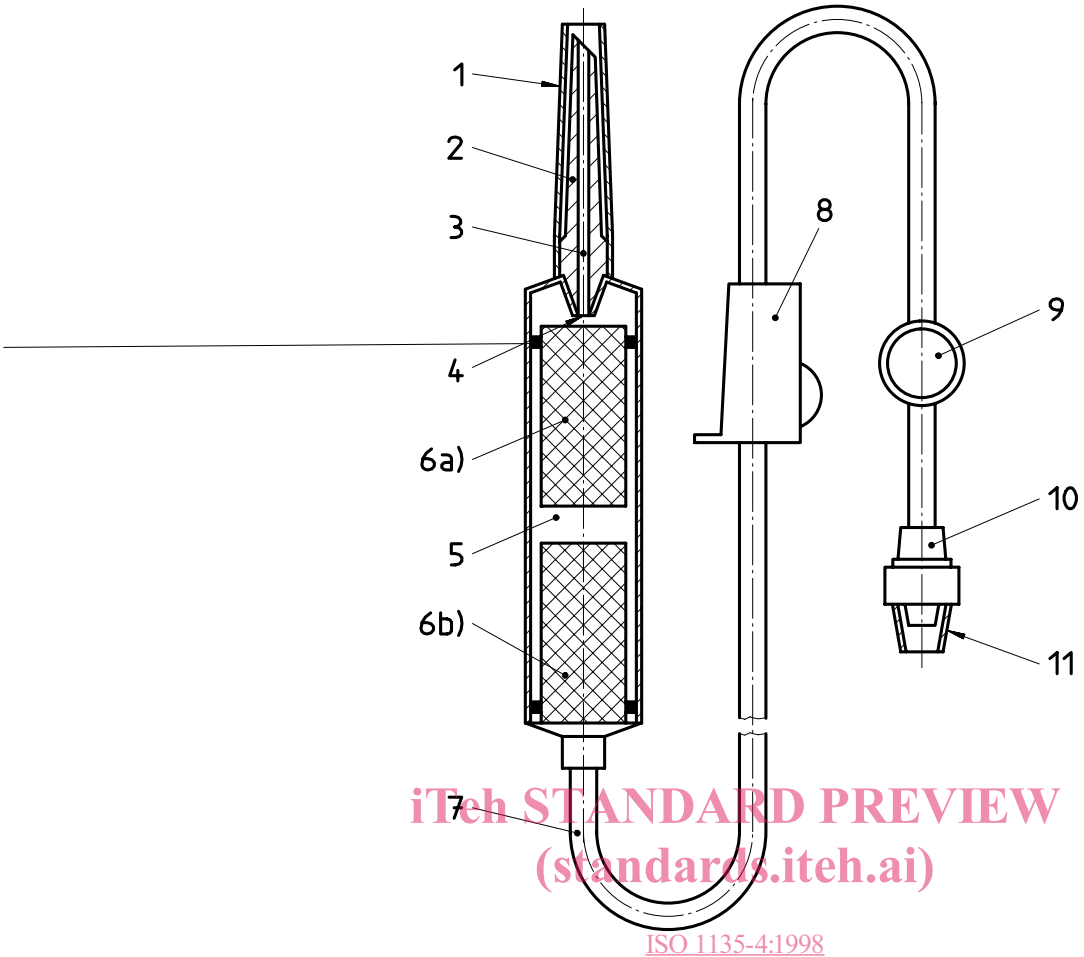
An example of the designation of an air-inlet device complying with the requirements of this part of ISO 1135 is as follows:

Air-inlet device ISO 1135-4 AD

4 Materials

The materials from which the transfusion set and its components as given in clause 3 are manufactured shall comply with the requirements specified in clause 5. Where components of the transfusion set come into contact with blood and blood components, they shall additionally comply with the requirements specified in clauses 6 and 7.

[2] To be published.

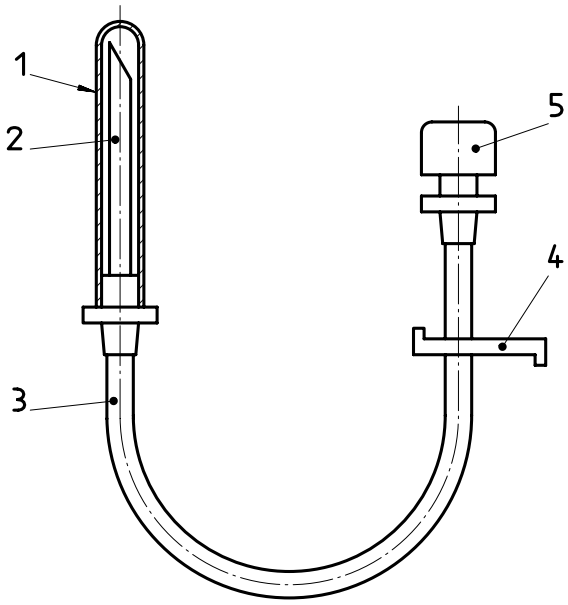


Key

1 Protective cap of the closure-piercing device
2 Closure-piercing device
3 Fluid channel
4 Drip tube
5 Drip chamber
6 Filter for blood and blood components [1)2)]
7 Tubing
8 Flow regulator
9 Injection site [3)]
10 Male conical fitting
11 Protective cap of the male conical fitting

1) Other designs are acceptable if the same safety aspects are ensured.
2) a) or b) indicates alternative locations of the filter for blood and blood components.
3) Injection site is optional.

Figure 1 — Example of a transfusion set



Key

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

1) Other designs are acceptable if the same safety aspects are ensured.

Figure 2 — Example of an air-inlet device

5 Physical requirements

5.1 Particulate contamination

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

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

5.2 Integrity

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

5.3 Connections between components

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

5.4 Closure-piercing device

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

Dimensions in millimetres

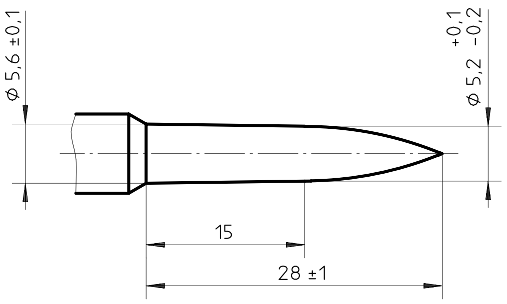


Figure 3 — Dimension of the closure-piercing device

5.4.2 The closure-piercing device, and the air-inlet device if used, shall be capable of piercing and penetrating the closure of a container for blood and blood components without prepiercing. No coring should occur during this procedure.

5.5 Air-inlet device

5.5.1 The air-inlet device shall also conform with 3.2 and 7.2.

5.5.2 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.

5.5.3 The air-inlet device shall be separate from the closure-piercing device.

5.5.4 If the end of the air-inlet device is connected to an air filter by means of flexible tubing, the tubing shall be not less than 250 mm in length.

5.5.5 The air filter shall be fitted in such a manner 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.

5.6 Tubing

5.6.1 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-to-normal vision.

5.6.2 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.

5.7 Filter for blood and blood components

5.8 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 filter for blood and blood components. 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 23 °C ± 2 °C and at a flowrate of 50 drops/min ± 10 drops/min deliver 1 ml ± 0,1 ml (1 g ± 0,1 g).

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

5.9 Flow regulator

The flow regulator shall adjust the flow of the blood and blood components between zero and maximum.

NOTE — The flow regulator should be capable of continuous use throughout a transfusion 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.

5.10 Flowrate of blood and blood components

The transfusion set shall deliver not less than 1 000 ml of blood at 23 °C ± 2 °C in 30 min under a static head of 1 m. The transfusion set shall also deliver not less than 500 ml of blood in 2 min under a pressure of 30 kPa above atmospheric pressure.

The blood shall be collected into a suitable anticoagulant solution and stored for not less than 2 weeks, and be free of large clots.

5.11 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.

5.12 Male conical fitting

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

5.13 Protective caps

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

NOTE — Protective caps should be secure but easily removable.

6 Chemical requirements

6.1 Reducing (oxidizable) matter

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

6.3 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.

6.4 Residue on evaporation

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

6.5 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.

7 Biological requirements

7.1 General

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

7.2 Sterility

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

7.3 Pyrogenicity

The transfusion 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 transfusion set is free from pyrogenicity. Guidance on testing for pyrogenicity is given in annex G.

7.4 Haemolysis

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

7.5 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.

8 Labelling

8.1 Unit container

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

a) a textual description of the contents;

b) indication that the transfusion set is sterile, using the graphical symbol given in ISO/TR 15223;

c) that the transfusion set is free from pyrogens;

d) that the transfusion set and/or the air-inlet device is for single use only, or equivalent wording;

NOTE — The graphical symbol for "DO NOT RE-USE" according to ISO 7000 No. 1051 may additionally be given.