INTERNATIONAL STANDARD

ISO 1135-4

Third edition
2004-07-15

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

Reference number
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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 1135-4 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This third edition cancels and replaces the second edition (ISO 1135-4:1998), which has been technically revised.

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

— *Part 3: Blood-taking set*

— *Part 4: Transfusion sets for single use*

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

ISO 594-2:1998, *Conical fittings with 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*

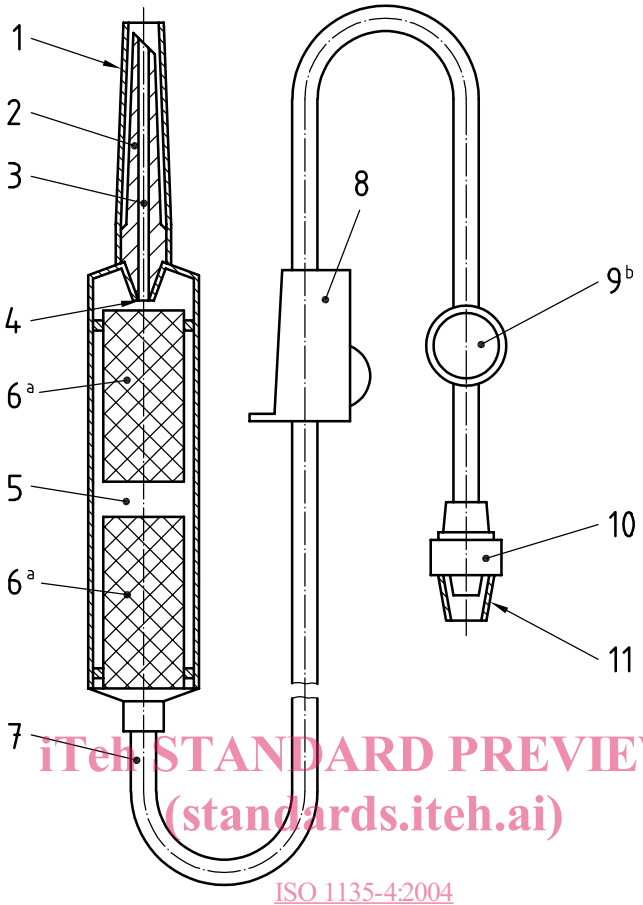
ISO 14644-1:1999, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness*

ISO 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

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.



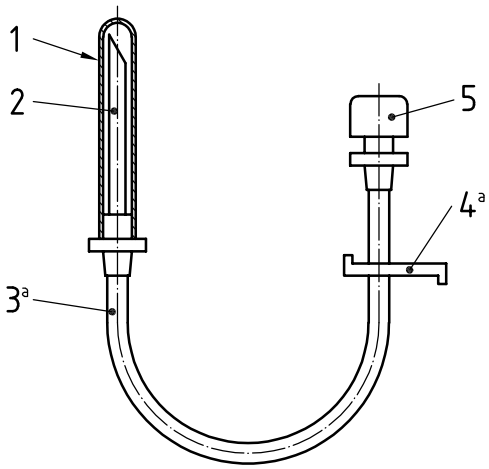
Key

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
7 tubing
8 flow regulator
9 injection site
10 male conical fitting
11 protective cap of the male conical fitting

[a] Indicates alternative locations of the filter for blood and blood components. Other designs are acceptable if the same safety aspects are ensured.

[b] Injection site is optional.

Figure 1 — Example of a transfusion set



Key

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

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

Figure 2 — Example of an air-inlet device

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 air-inlet device as given in Clause 3 are manufactured shall comply with the requirements specified in Clause 5. If 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.

5 Physical requirements

5.1 Particulate contamination

The transfusion 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 detected shall not exceed the contamination index.

5.2 Leakage

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

5.3 Tensile strength

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.

NOTE The dimension of 15 mm in Figure 3 is a reference measurement. The cross-section of the piercing device at this site is a circle.

Dimensions in millimetres

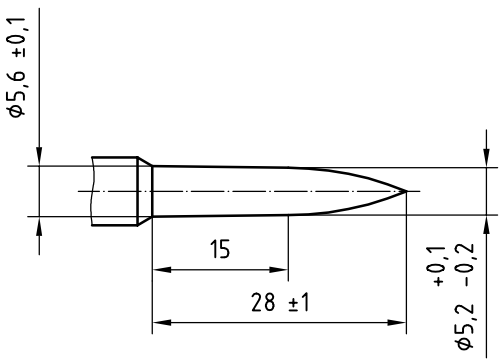


Figure 3 — Dimensions of the closure-piercing device

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 pre-piercing. No coring should occur during this procedure.

5.5 Air-inlet device

5.5.1 The air-inlet device shall also conform with 3.3 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 A.3.

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 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.

5.7 Filter for blood and blood components

The transfusion set shall be provided with a filter for blood and blood components. The filter shall have uniform pores and shall cover a total area of not less than 10 cm^2. When tested in accordance with Annex A, A.4, the mass of solid material retained on the filter shall be not less than 80 % (mass fraction) of that retained on the reference filter.

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 ± 2) °C and at a flow rate of (50 ± 10) drops/min deliver (1 ± 0,1) ml [(1 ± 0,1) g].

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.

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 Flow rate of blood and blood components

The transfusion set shall deliver not less than 1 000 ml of blood at (23 ± 2) °C in 30 min with a pressure difference of 10 kPa. 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.