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Transfusion equipment for medical use — Part 4: Transfusion sets for single use, gravity feed

Matériel de transfusion à usage médical —

Partie 4: Appareils de transfusion non réutilisables à alimentation par gravité

[Revision of five edition (ISO 1135-4:2012)]

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ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

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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, and blood processing equipment for medical and pharmaceutical use*.

This sixth edition of ISO 1135-4 together with ISO 1135-5, first edition, cancels and replaces the fifth edition (ISO 1135-4:2012), of which the scope has been restricted to gravity feed and the whole document aligned accordingly. Transfusion sets for single use used in conjunction with pressure infusion apparatus are now covered by ISO 1135-5.

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, gravity feed*
- *Part 5: Transfusion sets for single use with pressure infusion apparatus*

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Transfusion equipment for medical use — Part 4: Transfusion sets for single use, gravity feed

1 Scope

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

Gravity feed is here defined as unassisted gravity or positive pressure up to 30 kPa. However sets with an elastomeric buffer (optional) are only rated to 20 kPa.

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, to present designations for transfusion set components and to ensure the compatibility of sets with a range of cellular and plasma blood 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*¹⁾

ISO 594-2:1998, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*¹⁾

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 3826-1:2013, *Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 7864, *Sterile hypodermic needles for single use*

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

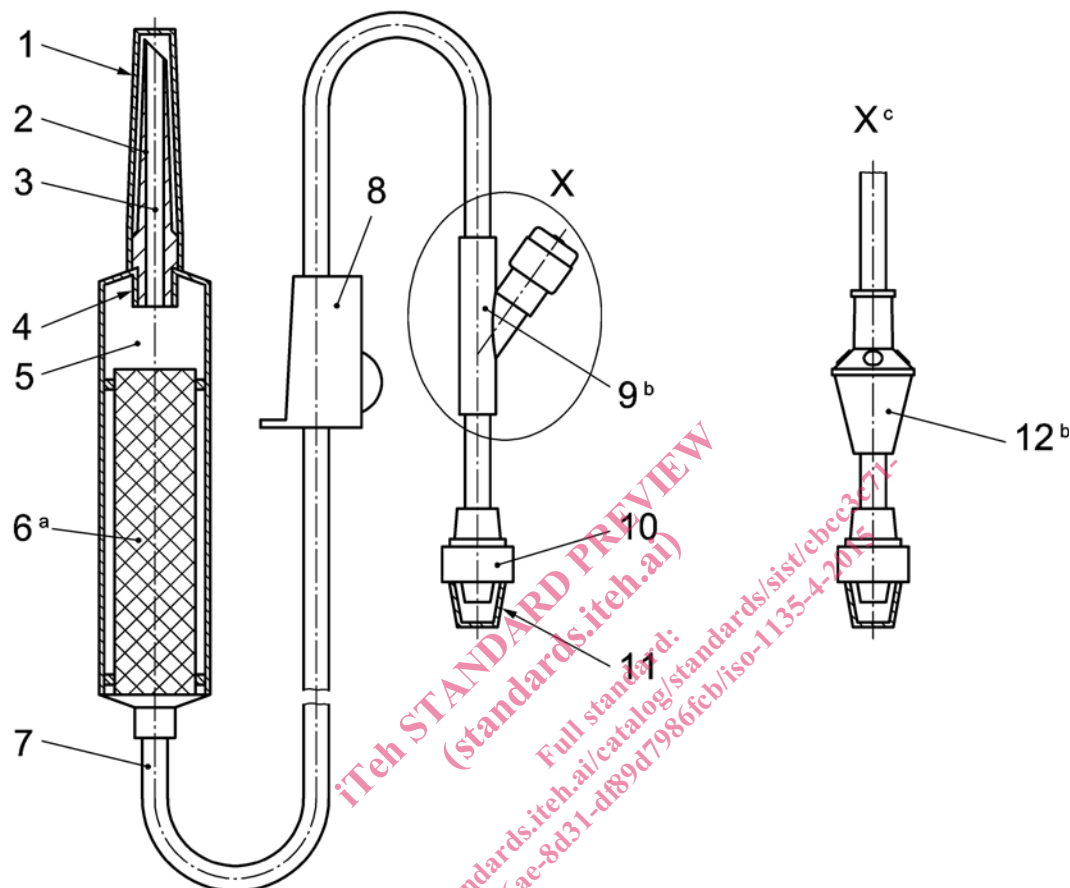
ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

1) Will be replaced by ISO 80369-7.

3 General requirements

3.1 Nomenclature for components of the transfusion set

The nomenclature for components of transfusion sets is given in Figure 1.



Key

- | | |
|---|---|
| 1 protective cap of the 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 filter for blood and blood components | 12 elastomeric buffer |

^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 and elastomeric buffer are optional.

^c Optional design.

Figure 1 — Example of a transfusion set

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.

3.3 Designation

A transfusion set complying with the requirements of this part of ISO 1135 is designated as follows:

Transfusion set ISO 1135-4

4 Materials

The materials from which the transfusion sets 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 limit.

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 to the dimensions shown in Figure 2.

NOTE The dimension of 15 mm in Figure 2 is a reference measurement. The cross-section of the piercing device at this site is a circle.

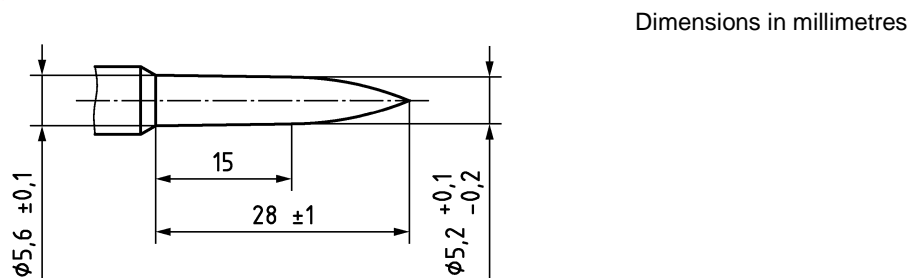


Figure 2 — Dimensions of the closure-piercing device

5.4.2 The closure-piercing device 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.

NOTE 1 A carefully controlled surface treatment of the closure-piercing device (e.g. siliconization) is recommended to facilitate its insertion into the blood bag port. The same effect may be achieved by a careful selection of material for the closure-piercing device. Typical results including test equipment for penetration forces between spikes and blood bag ports have been published. See References [11] and [12].

NOTE 2 A central closure-piercing device tip is preferred to an asymmetric design in order to aid its insertion.

5.4.3 When inserted into a blood bag port conforming to ISO 3826-1, the closure-piercing device shall resist a pull force of 15 N for 15 s.

5.4.4 When tested in accordance with ISO 3826-1:2013, 5.3, the connection between the closure-piercing device and the blood bag port shall show no evidence of leakage.

5.5 Tubing

5.5.1 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.

5.5.2 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.

5.6 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 cm². When tested in accordance with A.3, the mass of solid material retained on the filter shall be not less than 80 % (mass fraction) of that retained on the reference filter.

If the filter has a confirmed thread diameter of $(100 \pm 10) \mu\text{m}$ and a pore size of $(200 \pm 20) \mu\text{m}$, with a single warp and a single weft, a filtration performance test can be exempted.

Pore size measurement can be performed by microscopic inspection.

5.7 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 $(23 \pm 2) ^\circ\text{C}$ and at a flow rate of (50 ± 10) drops/min deliver $(1 \pm 0,1)$ ml $[(1 \pm 0,1) \text{ g}]$.

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

5.8 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.

5.9 Flow rate of blood and blood components

The transfusion set shall deliver not less than 1 000 ml of blood at $(23 \pm 2) ^\circ\text{C}$ 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.