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МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Transfusion equipment for medical use —

Part 4:
Transfusion sets for single use

Matériel de transfusion à usage médical —

Partie 4: Appareils pour transfusion non réutilisables

Reference number
ISO 1135-4: 1987 (E)

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

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

ISO 1135-4 is a revision, in part, of ISO 1135: 1977; this first edition of ISO 1135-4 together with the other parts of ISO 1135 and ISO 8536 will cancel and replace ISO 1135: 1977.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

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Transfusion equipment for medical use —

Part 4:
Transfusion sets for single use

1 Scope and field of application

This part of ISO 1135 specifies requirements for types of single-use transfusion sets for medical use in order to ensure compatibility of use with containers for blood and blood components and intravenous catheters and cannulas.

The materials and components of the sets are validated by various test methods (type tests) and, in addition, tests are performed for the release of lots of finished sets (lot tests).

The manufacturer shall select appropriate test methods to comply with the requirements laid down in this part of ISO 1135.

Secondary aims of this part of ISO 1135 are to provide

a) specifications relating to the quality and performance of materials used in transfusion sets;

b) a unified presentation of terms and designations for transfusion sets.

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

This part of ISO 1135 specifies requirements applicable to sterilized transfusion sets intended for single use and for a single patient only.

2 References

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 a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings.* [1)]

ISO 3696, *Water for analytical laboratory use — Specifications and test methods.*

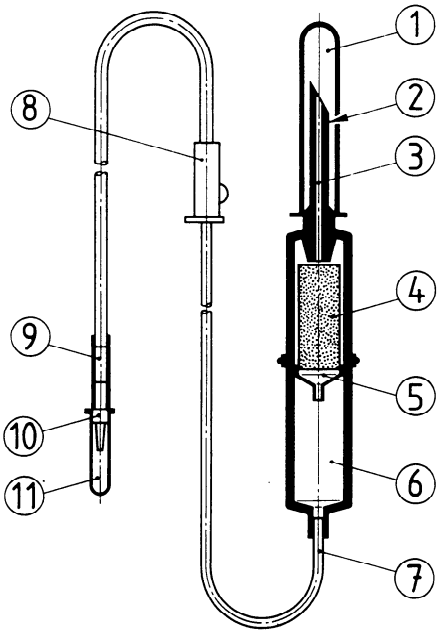
3 General requirements

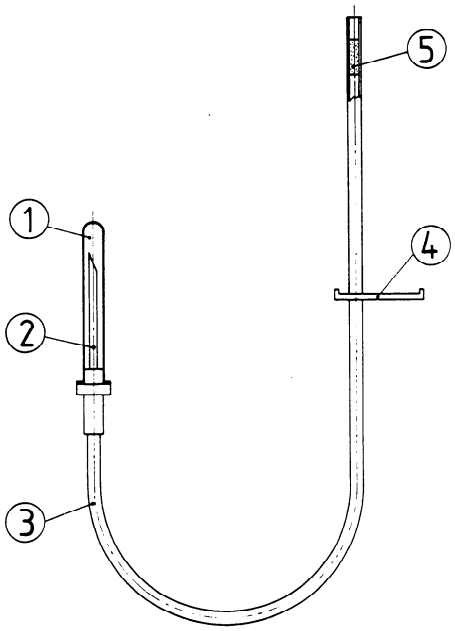
3.1 Components for use with blood containers

The transfusion set shall consist of the components as illustrated in figure 1. An air-inlet device as illustrated in figure 2 is required for use with rigid containers.

NOTE — Figures 1 and 2 illustrate examples of configurations of typical transfusion sets but they do not form part of the requirements for transfusion sets for single use as laid down in this part of ISO 1135.

1) At present at the stage of draft.





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

Figure 1 — Example of a typical transfusion set

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

Figure 2 — Example of a typical air-inlet device

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

2) Optional

3.2 Sterilization

The set shall be sterile in its unit container. Evidence of the effectiveness of the sterilization process used shall be provided.

3.3 Maintenance of sterility

The set shall be provided with protective caps designed to maintain sterility of the internal parts of the set until the set is used.

3.4 Designation examples

3.4.1 Transfusion set

Designation example of a transfusion set (TS) complying with the requirements laid down in this part of ISO 1135:

Transfusion set ISO 1135-4 TS

3.4.2 Air-inlet device

Designation example of an air-inlet device (AD) complying with the requirements laid down in this part of ISO 1135:

Air-inlet ISO 1135-4 AD

4 Materials

The materials from which the transfusion set is made shall not have undesirable effects on the blood passing through the set under ordinary conditions of use, or on the fluids used in connection with the blood. They shall not produce any general toxic effects or any local reaction on the recipient of the blood.

Appropriate type tests for assessing biological compatibility are given in annex E.

5 Physical requirements

5.1 Integrity

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

5.2 Connection between the male fitting, injection site and tubing

The connection between the male fitting, injection site and the tubing shall withstand a static tensile force of 15 N for 15 s.

5.3 Closure-piercing device

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

Dimensions in millimetres

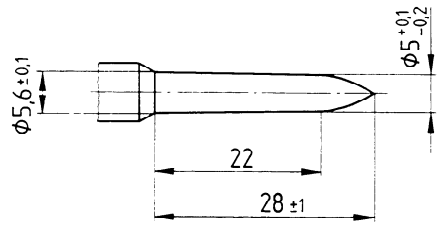


Figure 3 — Dimensions for the closure-piercing device

5.4 Air-inlet device

5.4.1 The air-inlet device shall be provided with a filter designed to prevent the ingress of micro-organisms into the container into which the device is to be inserted.

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

5.4.3 When an air-inlet device is inserted into a rigid transfusion container, the air admitted into the container shall not become entrained in the liquid outflow.

5.4.4 If the end of the air-inlet device is connected to an air filter by means of flexible tubing, the tubing shall have an internal diameter not less than 2,7 mm and shall be not less than 250 mm in length.

5.4.5 If the air-inlet device incorporates a length of flexible tubing, means for fixing the filter above the level of the fluid shall be provided.

5.5 Air filter

The air filter shall be so made that all air entering the bottle passes through it and that the flow of fluid is not significantly reduced.

5.6 Tubing

5.6.1 The tubing, made of suitable material, shall be transparent or sufficiently translucent for the passage of bubbles of air to be readily detected.

5.6.2 The tubing shall have an internal diameter of not less than 2,7 mm. The tubing length distal to the drip chamber shall be not less than 1 500 mm in length. The tubing shall be flexible and shall not have any kinks.

5.7 Filter for blood and blood derivates

The transfusion set shall be provided with a filter. The filter shall have uniform apertures covering a total area of not less than 10 cm^2. When tested in accordance with annex B, the dry residue retained on the filter shall be not less than 80 % (m/m) of the residue retained on the reference filter.

5.8 Drip chamber and drip tube

The drip chamber shall assist the procedure of priming and 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 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 at 20 °C and at a flow rate of 50 ± 5 drops/min deliver 1 ± 0,1 ml (1 ± 0,1 g).

5.9 Flow regulator

5.9.1 The flow regulator shall adjust the flow of the transfusion fluid between zero and the maximum.

5.9.2 The flow regulator shall be capable of continuous use throughout a transfusion without damaging the tubing. There shall be no deleterious reaction between the flow regulator and the tubing when stored in contact.

5.10 Flow rate of blood

The complete transfusion set shall deliver not less than 1 000 ml of whole blood in 30 min under a static head of 1 m. The blood shall have been collected into a suitable anticoagulant solution, be stored for not less than 2 weeks and be free of large clots.

The set shall also deliver 500 ml of blood in 2 min under a pressure of 100 kPa (1 bar) above the atmospheric pressure.

5.11 Injection site

There shall be a self-sealing injection port or other equivalent means near the distal end. Self-sealing injection ports shall reseal under normal working pressure after being perforated by a needle 0,6 mm in diameter.

NOTE — The injection site should be located near the male fitting.

When tested in accordance with annex C, there shall be no signs of air leakage.

5.12 Male fitting

The distal end of the tubing shall terminate in a male fitting having a cone with a 6 % taper conforming with ISO 594-1 or ISO 594-2.

When tested in accordance with ISO 594-1 or ISO 594-2 using a female reference fitting, there shall be no signs of air leakage.

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 fitting and the interior of the transfusion set. They shall be secure but easily removable.

6 Chemical requirements

6.1 Reducing (oxidizable) matter

When tested in accordance with clause D.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 (1 ppm) of barium, chromium, copper, lead and tin, and not more than 0,1 µg/l (0,1 ppm) of cadmium, when determined by atomic absorption spectroscopy (AAS) or equivalent method.

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

6.3 Titration acidity or alkalinity

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

6.5 Absorbance

When tested in accordance with clause D.6, the extract solution S_1 shall not show absorbance greater than 0,1 (optical density).

7 Biological requirements

The transfusion set shall not release any substances which may adversely affect the therapeutic effectiveness of the blood or the blood components, including those substances which may exhibit toxic, pyrogenic, bacteriostatic, bactericidal or haemolytic reactions.

7.1 Requirements for type test

The type test shall be established and assessed by an expert (or experts) in the transfusion field and on toxicology of plastics material. It shall cover the following elements:

a) General biocompatibility of the plastics material of the set.

Materials shall be assessed for biocompatibility by carrying out suitable tests for those properties detailed in clause E.2 and the results of the tests shall indicate freedom from toxicity.

NOTE — In many countries there are national pharmacopoeias, governmental regulations or standards detailing suitable tests for assessing biocompatibility. However, if no such regulations are provided, the test methods specified in the table should be used.

b) Compatibility of the transfusion set with the process of manufacture and sterilization.

The process of manufacture and sterilization, and the prolonged contact with the blood or blood components shall not alter properties of the plastics material and of the set itself.

c) Compatibility of the plastics material of the set with blood and blood components.

Absence of migration after sterilization and prolonged contact of the constituents of the plastics material shall not alter the properties of the blood or blood components or cause any toxicological risk for the patient.

d) Biocompatibility of the plastics set with the cellular elements of the blood or blood components.

7.2 Requirements for lot test

7.2.1 Sterility

The transfusion set shall be assessed for sterility using a suitable test (guidance on testing for sterility is given in annex E) and the results shall indicate that the transfusion set is sterile.

7.2.2 Pyrogens

The transfusion set supplied shall be assessed for freedom from pyrogens using a suitable test (guidance on testing for pyrogens is given in annex E) and the results shall indicate that the transfusion set is free from pyrogenicity.

8 Marking and labelling

8.1 Unit container

The unit container of each transfusion set for single use shall be marked with the following information:

a) a description of the contents, in words and/or pictorially;

b) indications that the transfusion set is sterile, free from pyrogens and for single use only;

c) instructions for the use of the transfusion set, including a warning note about checking that seals are intact and about detached protective caps;

d) the nominal dimension of an intravenous needle, if included;

e) the year and month of sterilization, where applicable, and the date of expiry, where applicable;

f) the lot (batch) designation;

g) the manufacturer's and/or supplier's name and address;

h) a statement that 20 drops of distilled water delivered by the drip tube are equivalent to 1 ± 0,1 ml (1 ± 0,1 g);

i) a statement to the effect that the transfusion set shall be destroyed after use.

8.2 Shelf or multi-unit container

Shelf or multi-unit containers shall be marked with the following information:

a) a description of the contents, in words and/or pictorially;

b) the number of transfusion sets;

c) instructions for use in each shelf container, or on the unit container;

d) the word "STERILE" in prominent lettering (see note in 9.1);

NOTE — This may form part of the description listed under a) above.

e) the manufacturer's or supplier's name;

f) the lot (batch) designation;

g) the year and month of sterilization, where applicable, and the date of expiry, where applicable;

h) the recommended storage conditions, if any.

8.3 Outer or transit container [1)]

Outer or transit containers shall be marked with the following information:

a) the manufacturer's or supplier's name and address;

b) a description of the contents, in words and/or pictorially;

c) the number of transfusion sets;

d) the lot (batch) designation;

e) the year and month of sterilization, where applicable, and the date of expiry where applicable;

f) the recommended storage conditions, if any.

9 Packaging

9.1 The transfusion sets shall be individually packed so that the set remains sterile during storage.

The unit container shall be sealed in such a manner that it cannot be opened and closed again without it being obvious that the container has been opened.

NOTE — If, in special cases, only the interior of the set is required to be sterile, a statement to this effect should be clearly marked on the shelf or multi-unit container.

9.2 The sets shall be packed and sterilized in such a way that there are no flattened portions or kinks when they are ready for use.

1) Is not intended to be the final shipping container.