International Standard 1135/3

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION•МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ•ORGANISATION INTERNATIONALE DE NORMALISATION

Transfusion equipment for medical use — Part 3: Blood-taking set

Matériel de transfusion à usage médical — Partie 3: Nécessaires pour prélèvement sanguin

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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.

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 1135/3 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use.*

ISO 1135/3 is a revision, in part, of 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 3: Blood-taking set

1 Scope and field of application

This part of ISO 1135 specifies requirements for types of blood-taking sets for medical use in order to ensure functional interchangeability of transfusion equipment.

The materials and the 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 equipment;

b) a unified presentation of terms and designations for such equipment.

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 blood-taking sets intended for single use and for a single donor only.

2 References

ISO 1773, *Laboratory glassware — Boiling flasks (narrow-necked).*

ISO 3696, *Water for laboratory use — Specifications and test methods.* [1]

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

3 General requirements

3.1 Types of sets

The blood-taking set shall consist of the blood-taking assembly and the air-outlet assembly, which may be separate or combined.

A diagram of a typical blood-taking set is illustrated in the figure.

3.2 Blood-taking assembly

The blood-taking assembly shall consist of a needle for vein puncture (the blood-taking needle) and of a needle (the bottle needle) to be inserted through one of the specified areas provided on the bottle closure. Each needle is connected to one end of a length of tubing.

3.3 Air-outlet assembly

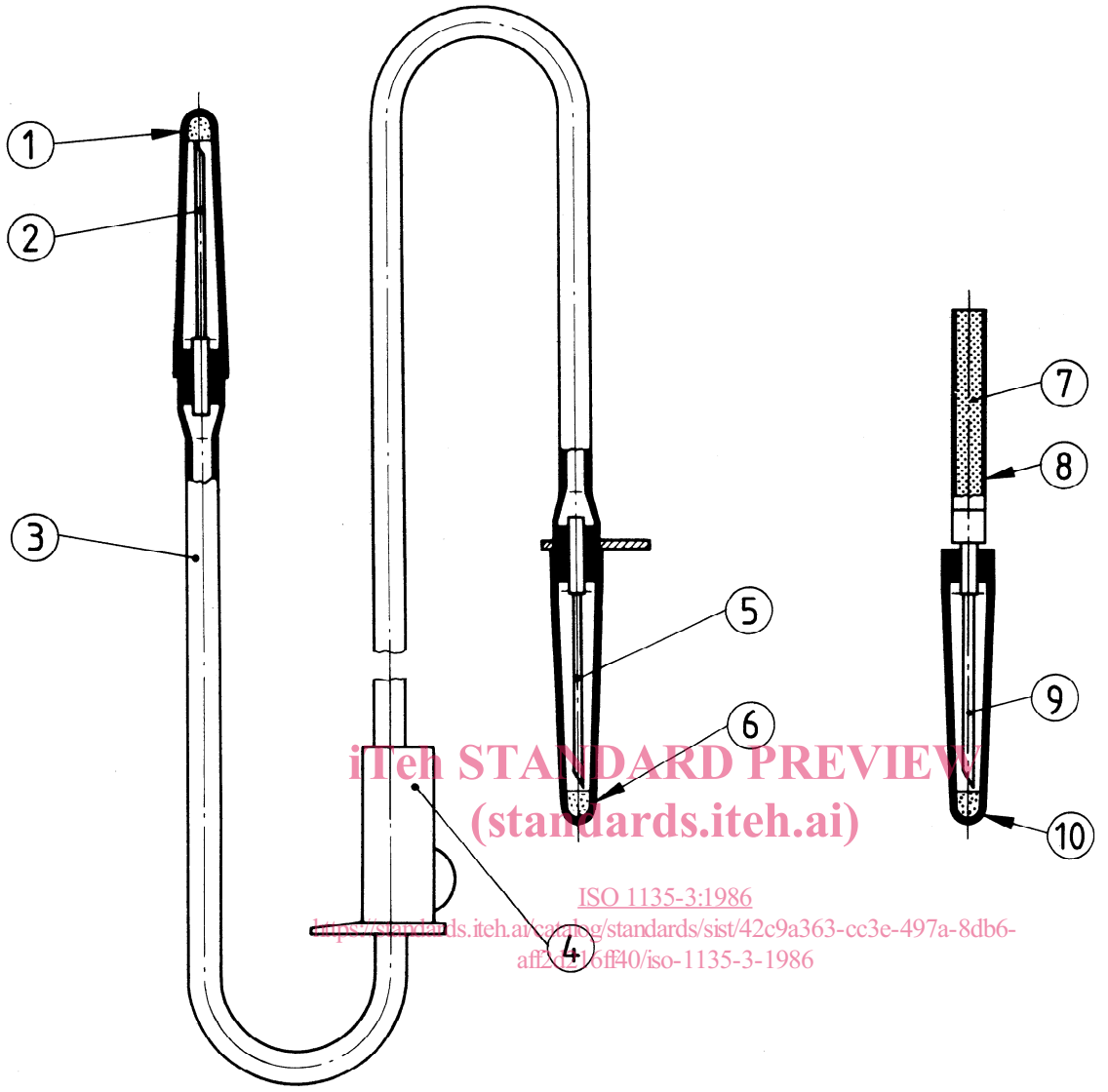
The air-outlet assembly shall consist of an air filter housing with air filter combined with a needle (the air-outlet needle) for piercing the specified area provided on the bottle closure.

The filter shall be capable of preventing microbial ingress.

3.4 Sterilization

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

1) At present at the stage of draft.



1. Protective cap
2. Bottle needle
3. Tubing
4. Flow regulator [1)]
5. Blood-taking needle
6. Protective cap

a) Blood-taking assembly

7. Air filter
8. Air filter housing
9. Air-outlet needle
10. Protective cap

b) Air-outlet assembly

NOTE — The figure illustrates an example of the configuration of a typical blood-taking set but it does not form part of the requirements for blood-taking sets as laid down in this part of ISO 1135.

Figure — Blood-taking set

1) Optional

3.5 Maintenance of sterility

The set shall be provided with protective caps designed to maintain sterility of the internal surface of the set and the internal and external surfaces of the needles until the set is used.

3.6 Designation examples

3.6.1 Designation example of a blood-taking set (TK) with a separate air-outlet assembly (S) complying with the requirements laid down in this part of ISO 1135:

Blood-taking set ISO 1135/3 - TK - S

3.6.2 Designation example of a blood-taking set (TK) with a combined air-outlet assembly (C) complying with the requirements laid down in this part of ISO 1135:

Blood-taking set ISO 1135/3 - TK - C

4 Materials

The materials from which the blood-taking 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 C.

5 Physical requirements

5.1 Integrity

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

5.2 Connection between the needle hub and tubing

The connection of the needle hub and the tubing shall withstand a static tensile force of 20 N for 15 s.

5.3 Bottle needle

5.3.1 The bottle needle shall not be less than 35 mm in length. The external diameter shall not be less than 1,8 mm and the internal diameter shall not be less than 70 % of the external diameter.

5.3.2 The internal and external surfaces of the needle tube shall be clean and smooth.

5.3.3 The joint between the needle tube and the needle hub shall withstand a static tensile force or compressive force of 90 N for 15 s along the longitudinal axis.

5.3.4 The bottle needle shall be designed in accordance with ISO 7864 in order to minimize the number of rubber particles when the closure is pierced.

5.4 Air-outlet needle

The air-outlet needle shall have an internal diameter not less than 0,7 mm, an external diameter not greater than 1,9 mm and a needle not exceeding 25 mm in length.

5.5 Blood-taking needle

5.5.1 The blood-taking needle shall not be less than 35 mm in length. The external diameter shall not be greater than 2 mm and the internal diameter shall not be less than 70 % of the external diameter.

5.5.2 The internal and external surface of the needle tube shall be clean and smooth. The bevel of the needle shall be sharp and free from ridges, burrs and barbs.

5.5.3 The joint between the needle tube and the needle hub shall withstand a static tensile force or compressive force of 20 N for 15 s along the longitudinal axis.

5.6 Tubing

The tubing shall have an internal diameter of not less than 2,7 mm. It shall not be less than 600 mm in length. The tubing shall be flexible and shall not have any kinks.

5.7 Flow regulator

5.7.1 The flow regulator shall be capable of adjusting the flow of the blood between zero and the maximum.

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

6 Chemical requirements

6.1 Reducing (oxidizable) matter

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

6.5 Absorbance

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

7 Biological requirements

The blood-taking 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 C.2 and the results of the tests shall indicate freedom from toxicity.

NOTE — In many countries there are national pharmacopeias, 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 blood-taking 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 blood-taking set shall be assessed for sterility using a suitable test (guidance on testing for sterility is given in annex C) and the results shall indicate that the blood-taking set is sterile.

7.2.2 Pyrogens

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

8 Marking and labelling

8.1 Unit container

The unit container of a blood-taking 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 blood-taking set is sterile, free from pyrogens and for single use only;

c) instructions for the use of the blood-taking set, including a warning note about detached protective caps;

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

e) the lot (batch) number;

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

g) a statement to the effect that the blood-taking set shall be destroyed after use;

h) the recommended storage conditions, if any.

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 blood-taking sets;

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

d) the word "STERILE" in prominent lettering;

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

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

f) the lot (batch) number;

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

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 blood-taking sets;

d) the lot (batch) number;

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 blood-taking sets shall be individually packed so that the sets remain sterile during storage.

9.2 The blood-taking sets shall be packed and sterilized so that there are no flattened portions or kinks when they are is ready for use.