INTERNATIONAL STANDARD 1135

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

Transfusion equipment for medical use

Matériel de transfusion à usage médical

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FOREWORD

ISO (the International Organization for Standardization) is a worldwide federation of national standards institutes (ISO member bodies). The work of developing International Standards is carried out through ISO technical committees. Every member body interested in a subject for which a technical committee has been set up 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.

Prior to 1972, the results of the work of the technical committees were published as ISO Recommendations; these documents are in the process of being transformed into International Standards. As part of this process, Technical Committee ISO/TC 76, *Transfusion equipment for medical use*, has reviewed ISO Recommendation R 1135-1969 and found it technically suitable for transformation. International Standard ISO 1135 therefore replaces ISO Recommendation R 1135-1969, to which it is technically identical.

ISO Recommendation R 1135 had been approved by the member bodies of the following countries :

Australia	India	Norway
Austria	Ireland	South Africa, Rep. of
Canada	Israel	Spain
Chile	Italy	Sweden
Denmark	Korea, Rep. of	United Kingdom
Germany	Netherlands	
Greece	New Zealand	

The member body of France had also approved parts I (excluding clause 5.4.1), II and III of the draft, but had disapproved part IV as it was not in favour of having sets for repeated use.

The member body of Japan had opposed the approval of the draft mainly because the capacity of the glass bottle described in part I and the diameter of the blood-taking needle described in part II were considered too large for use for the population of Japan.

The member body of the following country disapproved the transformation of the Recommendation into an International Standard :

Germany

Printed in Switzerland

Transfusion equipment for medical use

0 INTRODUCTION

It is recognized that some countries may not wish to include in their national standards all the types of equipment covered by this International Standard. It is hoped that countries which at present employ forms of equipment that would not satisfy the criterion of interchangeability, as between different countries, will abandon these as soon as possible.

In a number of countries the only giving sets prescribed in national standards are of the single-use type. It is recognized that this type is to be preferred but, in order to assist countries that are not able to insist that only single-use sets should be permitted, a specification for giving sets for repeated use is also included in this International Standard.

The primary purpose of this International Standard is to specify such requirements, for types of transfusion equipment for medical use, as will ensure functional interchangeability of the equipment irrespective of the country of origin.

Subsidiary purposes of this International Standard are to provide

a) specifications for quality and performance of materials used in transfusion equipment;

b) unification of terms and designations for such equipment.

1 SCOPE AND FIELD OF APPLICATION

This International Standard specifies requirements for transfusion equipment, as follows :

Section one : Glass bottle, means of suspension and closure.

Section two : Taking sets for blood.

Section three : Giving sets for single use with blood and blood derivatives.

Section four : Giving sets for single use with medical fluids other than blood and blood derivatives.

Section five : Giving sets for repeated use with blood and blood derivatives.

Section six : Giving sets for repeated use with medical fluids other than blood and blood derivatives.

Diagrammatic illustrations of taking and giving sets are also included. In addition, certain test methods are given in annexes, as follows :

Annex A : Test for thermal shock resistance of glass bottle.

Annex B : Test for efficiency of filter.

Annex C : Limit test for pyrogens.

Annex D : Tests for toxicity.

Annex E : Tests for sterility.

NOTE — The term "transfusion equipment for medical use" connotes equipment which is used to transfuse human blood and its derivatives or other infusion fluids, but does not include syringes for injection and special mechanical devices. Section one is concerned with glass bottles intended primarily for use with blood and blood derivatives.

2 REFERENCES

ISO/R 594, *Conical fittings for syringes, needles and other medical equipment — Definition and dimensional characteristics for conical fittings with a* 6 % *and a* 10 % *taper.*

ISO/R 596, *Hypodermic needles.*

ISO/R 718, *Methods for thermal shock tests on laboratory glassware.*

ISO 3825, *Glass transfusion bottles for medical use — Chemical resistance.*

ISO 3826, *Plastics, collapsible containers for blood and blood components.*[1]

1) At present at the stage of draft.

SECTION ONE

GLASS BOTTLE, MEANS OF SUSPENSION AND CLOSURE[1]

3 GLASS BOTTLE

3.1 General

The glass bottle shall be transparent and substantially colourless. It shall not yield, under normal conditions of use, substances having undesirable effects upon the contents or harmful effects on the patient receiving the contents.[2]

3.2 Thermal resistance

The bottle shall withstand the temperatures encountered during normal conditions of use, including :

3.2.1 *Sterilization* of the empty bottle by autoclaving in saturated steam at temperatures up to 134 °C.

3.2.2 *Heating* of the empty bottle in air to 250 °C.

3.2.3 *Cooling* of the bottle, filled to 70 % of its graduated capacity and closed under normal conditions of use, by immersion in a mixture of solid carbon dioxide and acetone.

3.3 Thermal shock resistance

Transfusion bottles shall not break, crack or chip when subjected to a thermal shock resistance test at a temperature difference agreed between the purchaser and the vendor, but not less than 40 °C. The test shall be conducted in accordance with the procedure described in annex A.

3.4 Resistance to internal pressure

The bottle when completely filled with water shall withstand an internal gauge pressure of not less than the following :

1 030 kPa[3] for bottles with a 22,5 mm neck;

860 kPa for bottles with 30 mm neck.

The test pressure shall be reached in not more than 5 s and maintained for 1 min.

3.5 Mechanical strength

The bottle, charged with water to the total graduated capacity and itself immersed in water up to the 500 ml mark, in a suitable centrifuge cup, shall withstand centrifuging, such as to produce an acceleration equivalent to 2 000 times that due to gravity in the plane of the base of the bottle, for at least 30 min.

3.6 External form of neck

The transfusion bottle may be provided with a screw thread on the neck. Whether or not there is a screw thread, the neck shall be provided with a bead which will permit the fitting of a cap to act either as the main closure or as an additional closure when the neck has a screw thread. If a screw thread is used,[4] the overall diameter should preferably be less than that of the bead to facilitate the fitting of an additional closure. The dimensions of the bead shall be as shown in figure 1 a) or 1 b), according to the neck diameter.

3.7 Graduation marks

There shall be two moulded scales marked at 100 ml intervals; if desired, the intermediate 50 ml intervals may also be marked. At least the 100 ml graduation marks shall be numbered. One scale serves for the collection of fluid, the numbers being upright when the container stands on its base; the other scale serves for the delivery of fluid, the numbers being upright when the container is inverted. The marks shall not project more than 1 mm from the surface of the cylindrical portion of the bottle.

3.8 Internal neck diameter

The nominal internal diameter of the neck shall be either

a) 22,5 mm, or

b) 30 mm

1) See ISO 3826 for specifications for plastics containers for blood.

2) For tests for chemical resistance, see ISO 3825.

3) 1 kPa = 1 kN/m^2

4) Screw threads for glass containers and closures are being studied, and any recommendations will be taken into consideration when available.

3.9 Overall dimensions and graduated capacity

The overall dimensions and graduated capacity shall comply with the appropriate requirements of the following table, according to the internal diameter of the bottle used.

TABLE — **Dimensions and graduated capacity of the transfusion bottle**

Internal neck diameter	mm	22,5 ± 0,7	30 ± 0,4
Graduated capacity	ml	500 (see note 3)	500
Overall height, max.	mm	220	153
Overall diameter, max.	mm	80	91,5
Projection of graduation marks, max.	mm	1	1

NOTES

1 The requirements given in this table specify the leading dimensions of well established types of bottle. It is recommended that one or other of the specified sizes should be adopted on a national basis by countries where transfusion services using glass containers are to be organized.

2 The tolerance on the internal neck diameter shall hold in all parts of the neck in contact with the closure.

3 The bottle may be marked additionally at the 540 ml level, if required.

4 MARKING

Marks enabling the manufacturer, the mould number and the month and year of manufacture to be identified shall be moulded on the base of the bottle.

5 MEANS OF SUSPENSION

Means of suspending the bottle securely in an inverted position shall be provided.

6 CLOSURE

6.1 Design

The design of the closure and the material from which it is made shall be such that the closure is easy to clean and makes an airtight seal when fitted to the bottle concerned. The closure shall have an overall height between the limits 15 and 20 mm, and the thickness of the flange shall be not less than 4 mm. The thickness of the piercing areas (see 6.2) shall be not less than 5 mm except for one or both of the areas marked "2" which may have a small circular portion having a thickness of 3 mm. If an internal air tube is fitted, it shall be attached to the closure under one of the areas marked "2".

6.2 Marking

The upper surface of the rubber closure shall be marked for piercing at four different areas. Two diagonally opposite areas shall be marked with the numeral 1 for the collection of fluid, and two diagonally opposite areas shall be marked with the numeral 2 for the delivery of fluid.

6.3 Material

The closure shall be made of self-sealing elastomeric material such that, having been aged for 168 h at 70 °C and then fitted to a transfusion bottle, it will withstand a temperature of − 79 °C and the temperatures encountered during sterilization by autoclaving in saturated steam at 121 ± 1 °C for 1 h, without impairment of its function under conditions of normal use. The material before ageing shall have a hardness of 40 to 50 IRHD.[1)]

The closure, under normal conditions of use, shall not produce undesirable effects upon the contents of the bottle or harmful effects upon the patient receiving the contents.

6.4 Sealing test

6.4.1 The design and material of the closure shall be such that, after ageing for 168 h at 70 °C and sterilizing (see 6.3), the closure is capable of maintaining airtightness of the container at room temperature at a pressure of 27 kPa (200 mmHg) below the prevailing atmospheric pressure for 72 h, after each piercing area 1 has been pierced with a non-coring needle of 2,4 mm external diameter and the needle has been left in the closure for 10 min and then withdrawn. This requirement test is deemed to be satisfied if any change in absolute pressure is within the limits 0 to + 1,3 kPa (10 mmHg).

NOTE — This test will reveal closures which are grossly unsatisfactory. Some failures in the test are also found with batches of closures which prove satisfactory in use, but the maximum percentage of failures that can be accepted has not yet been determined.

6.4.2 The closure shall not show any signs of leakage when the bottle is inverted immediately after it has been filled with fluid through a taking set, the piercing needles have been withdrawn and the surface of the closure has been wiped clean.

NOTE — Closures which pass the above tests will not necessarily prevent bacteria from reaching the interior of a container. The risk of bacterial contamination should be avoided by taking other suitable precautions.

7 BOTTLE CAP

The bottle cap shall be made of aluminium alloy or other suitable material, the thickness and design being such that it will withstand the conditions of normal use without being deformed. It shall be provided with a suitable aperture or apertures for use with taking and giving sets, and shall be so designed that it retains, and prevents distortion of, the closure during normal use.

1) International rubber hardness degrees (ISO 48).

SECTION TWO

TAKING SETS FOR BLOOD

8 GENERAL REQUIREMENTS

8.1 Types of sets

Blood-taking sets may be either for repeated use or for single use (disposable). Alternatively some components may be disposable (for example tubing) and some components re-usable (for example needles). Any component of the equipment that is intended to be re-used shall be so designed that it can be cleaned.

Each taking set shall consist of the blood-collection assembly and the air-outlet assembly, which may be separate or combined. A diagram of a typical taking set is shown in figure 2.

8.2 Blood-collection assembly

The blood-collection assembly shall consist of a needle for vein puncture (the blood-taking needle), connected by a length of tubing to a needle (the bottle needle) to be inserted through one of the areas marked "1" on the bottle closure (see 6.2). The overall length of this assembly should be such as is convenient for the particular method of collection used, but the tubing shall be not less 600 mm long.

8.3 Air-outlet assembly

The air-outlet assembly shall consist of tubing carrying an air filter made of non-absorbent material and fitted to a needle (the air-outlet needle) for piercing the other area marked "1" on the bottle closure (see 6.2).

8.4 Sterilization

It shall be possible to sterilize the assembled complete set, by autoclaving or some other method, without causing any loosening of joints or any important alteration in the shape of the set or in the consistency of the materials used. When sets are supplied sterile, the maker shall be able to produce evidence, acceptable to the user, of the efficacy of the actual process of sterilization used.

Positive controls to check the efficacy of sterilization shall be included with each batch submitted to sterilization and, if required, samples of the sets should be tested for sterility (see annex E).

8.5 Maintenance of sterility

The set shall be so packed that the needles and the interior of the set remain sterile during storage.

NOTE — The conditions and duration of storage will govern how this requirement is to be interpreted between purchaser and vendor.

Sets shall be packed and sterilized in such a way that there are no flattened portions or kinks when the equipment is ready for use.

If the set is to be packed and distributed in such a way that the external surface may not remain sterile, all the extremities of the set shall be provided with protectors designed to maintain sterility of the internal parts of the set and the needles until the set is used. The protectors shall be easily removable.

8.6 Pilot tubes

Means shall be available for collecting and retaining samples of the donor's blood without entering the bottle, and maintaining their unmistakable identity until the blood in the bottle has been used.

9 MATERIALS

9.1 The materials from which the equipment is made shall not have undesirable effects upon 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 on the recipient of the blood, or any local reaction (see annex D).

9.2 Samples of the sterilized assembled sets shall satisfy tests for pyrogens and toxicity (see annexes C and D). The method of sampling shall be based on statistical practice.

10 TUBING

The tubing used shall comply with such requirements of clause 20 as are appropriate. The use of opaque rubber tubing necessitates the introduction of a window in the blood collection assembly, about 5 to 8 cm from the blood-taking needle. No window is necessary with translucent tubing.

11 NEEDLES

11.1 The tubing mounts of needles shall either comply with the requirements of clause 32, for use with re-usable tubing, or be specially designed for single use or repeated use with disposable tubing.

NOTE — As far as the bottle needle is concerned, the use of a retaining ring to ensure a leak-proof joint between disposable tubing and needle hub may be necessary.

11.2 The relative lengths and method of insertion of the bottle needle and air-outlet needle shall be such that the point of the bottle needle projects well below and clear of the point of the air-outlet needle, to avoid entry of blood into the air-outlet assembly and possible soiling of the filter.

11.3 Dimensions

With the exception of the dimensions given below, all needles shall comply with the requirements of clause 22.

11.3.1 *Blood-taking needle*

The needle tubing of needles for repeated use shall be not less than 40 mm in length. Disposable needles shall have a needle length (as specified in ISO/R 596) of not less than 35 mm. The nominal external diameter of the needle tubing shall be 1,9 mm. The needle shall not be fitted with a stilette.

11.3.2 *Bottle needle*

The needle shall be not less than 35 mm in length. The bore of the bottle needle shall be not less than, and preferably slightly greater than, that of the blood-taking needle. A needle tubing of nominal external diameter 2,1 mm is recommended, but in no circumstances shall the diameter exceed 2,4 mm in view of the self-sealing property required of the bottle closure (see 6.4.2).

11.3.3 *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 length not exceeding 25 mm. The needle shall be fitted with a stilette, preferably in such a manner that it has to be removed before blood enters the bottle.

12 LEAKAGE TESTS

12.1 The sterilized set of equipment completely assembled, with one end closed, shall not leak under an internal air pressure of 158 kPa (1 185 mmHg) absolute, when immersed in water at 20 to 30 °C for 2 min.

12.2 The sterilized set of equipment evacuated to an internal pressure of 10 kPa (75 mmHg) absolute shall, with the ends closed, maintain this pressure with an increase of not more than 3,3 kPa (25 mmHg) for 1 h when the set is in air under normal atmospheric conditions.

NOTE — An apparatus suitable for this test is shown in figure 3.

13 MARKING

13.1 The container of each set, or of sets, of equipment for single use shall show the following information :

13.1.1 Description and diagram of contents.

13.1.2 Instructions for use, including warning notes about inspection for integrity of the seals used to maintain sterility.

13.1.3 The year and month of sterilization and a batch number which will permit all details of materials, manufacture and sterilization to be determined.

13.1.4 The manufacturer's name and address.

13.2 If the external surfaces of the set are not sterile, a statement to this effect shall be exhibited boldly on the outside of the container.

SECTION THREE

GIVING SETS FOR SINGLE USE WITH BLOOD AND BLOOD DERIVATIVES

14 GENERAL DESCRIPTION

14.1 Components

The set shall consist of

1) a closure-piercing device, a filter, a drip counter, a length of tubing with a flow regulator and, if desired, a device for the injection of drugs or other solutions, a needle adaptor and a giving needle assembly;

2) an air-inlet device connected to a length of flexible tubing which incorporates an air filter. A diagram showing these components is given in figure 4.

14.2 Sterilization

The set shall have been sterilized by autoclaving or some other method, and the maker shall be able to produce evidence, acceptable to the user, of the efficacy of the process of sterilization actually used.

Positive controls to check the efficacy of sterilization shall be included in each batch submitted to sterilization and, if required, samples of the sets should be tested for sterility (see annex E).

14.3 Maintenance of sterility

The set shall be so packed that the needles and the interior of the set remain sterile during storage.

NOTE – The conditions and duration of storage will govern how this requirement is to be interpreted between purchaser and vendor.

All extremities of the set shall be provided with protectors designed to maintain sterility of the needles and internal parts of the set until the set is used. The protectors shall be easily removable.

Sets of equipment which are required to be stored for long periods of time shall be packed in airtight and moisture-proof containers. Sets shall be packed and sterilized in such a way that there are no flattened portions or kinks when the equipment is ready for use.

15 MATERIALS

15.1 The materials from which the equipment is made shall not have undesirable effects upon the blood passing through the set under ordinary conditions of use, or produce any general toxic effects on the recipient or any local reaction (see annex D).

15.2 Samples of the sterilized assembled sets shall satisfy tests for pyrogens and toxicity (see annexes C and D). The method of sampling shall be based on statistical practice.

16 CLOSURE-PIERCING AND AIR-INLET DEVICES

16.1 General

The air-inlet device may be separate from, or composite with, the closure-piercing device.

NOTE – A composite closure-piercing device may not be suitable for use with collapsible plastics blood containers.

The closure-piercing device and the air-inlet device shall be capable of piercing the bottle closure without pre-piercing and of forming a fluid-tight seal with it.

16.2 Closure-piercing device

The bore of the closure-piercing device shall have a cross-sectional area of not less than 5 mm^2. The extent to which the closure-piercing device can be inserted through the closure shall be restricted by means of a flange and the device shall project from the lowest part of the closure, with the bottle upright, to a distance of 15 to 20 mm.

16.3 Air-inlet assembly

The bore of the air-inlet device shall have a cross-sectional area of not less than 0,44 mm^2. If the air-inlet device is separate from the closure-piercing device, its length shall be such that it extends at least 25 mm beyond the end of the closure-piercing device when fitted in position. If the air-inlet device is composite with the closure-piercing device, the air-inlet device shall extend at least 13 mm beyond the opening of the closure-piercing device (see figure 4). If desired, an internal air tube may be used.

The end of the air-inlet device shall be connected to an air filter by means of flexible tubing not less than 3 mm internal diameter and not less than 25 cm length, or shall incorporate an air filter.

17 AIR FILTER

The distal end of the air filter shall be fitted with a conical socket. The air filter shall be so made that all air entering the bottle passes through it and that the flow of fluid is not reduced significantly. Cotton wool or other material used for this purpose shall be non-absorbent. If the air-inlet assembly incorporates a length of flexible tubing, means of fixing the filter above the level of the fluid shall be provided.

The use of bottles having an internal air tube is not excluded.

18 FILTER FOR TRANSFUSION FLUID

18.1 General

It is essential that the equipment be provided with a filter and drip chamber, which may be separate or combined and shall be transparent; both may be compressible.

18.2 Filter

The filter shall be made from smooth, non-wettable material and shall be not less than 80 % as efficient as the reference filter specified in annex B. The efficiency of the filter material may be tested by the method described in annex B.

19 DRIP CHAMBER AND COUNTER

The drip chamber shall be designed so as to permit continuous observation of the fall of the drops. The position of the drip tube in the chamber shall be such that it cannot produce a continuous flow down the walls and that the minimal height of free fall of the drops is 20 mm.

NOTE – One form of drip chamber is specified in more detail in clause 35.

20 TUBING

The tubing, made of suitable flexible material, shall be transparent or sufficiently translucent for the passage of bubbles of air to be readily detected. This tubing shall have a cross-section such that it can carry a flow greater than that of the whole apparatus and a length such that the total length of the complete equipment as issued for use is not less than 1 700 mm and the free length of

tubing is not less than 1 500 mm. At the distal end there shall be a short additional length of tubing which is capable of reclosing under normal working pressure after being perforated by a needle of 0,6 mm diameter. Alternatively, other means should be provided at the distal end for the injection of drugs or other solutions into the lumen of the tubing.

The distal end of the tubing shall terminate in a cone.

If self-sealing tubing or other device is used for injection purposes, it shall satisfy the following test :

Insert short pieces of the transparent transfusion tubing into the open ends of the self-sealing device and sterilize the assembly under exactly the same conditions as are intended for sterilization of the set. The sterilized assembly shall withstand ageing in air at 70 °C for 168 h, without impairment of its function under normal conditions of use. Any change in colour of the device or of the transfusion tubing shall be disregarded.

Rubber parts shall not be sterilized by dry heat.

21 FLOW REGULATOR

The flow regulator shall be capable of stopping the flow of the transfusion fluid completely and controlling the flow as required. It should preferably be at the distal end of the set.

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

22 GIVING NEEDLE ASSEMBLY

Each set shall be provided with an intravenous needle or a giving needle assembly, suitably packed in a container which can be readily opened manually and which affords protection against contamination and damage.

The giving needle for insertion in the recipient's vein shall be 35 to 40 mm long, shall have an internal diameter of not less than 1,016 mm and shall be suitably sharpened. The internal diameter shall be not less than 70 % of the external diameter of the needle. The bore shall be of uniform circular cross-section and the internal surface shall be smooth. The butt of the delivery needle may be extended by means of flexible tubing of 4 cm length which shall terminate with an adaptor having a conical socket. If a needle alone is supplied, this shall have a conical socket.

NOTE – In this International Standard the term "cone" is used for the part of a conical joint that is inserted, and the term "socket" for the part into which the cone is inserted. The basic dimensions of conical fittings with 6/100 taper are given in ISO/R 594.

23 LEAKAGE TESTS

23.1 The sterilized set of equipment completely assembled, with one end closed, shall not leak under an internal air pressure of 158 kPa (1 185 mmHg) absolute, when immersed in water at 20 to 30 °C for at least 2 min.

23.2 The sterilized set of equipment evacuated to an internal pressure of 10 kPa (75 mmHg) absolute shall, with the ends closed, maintain this pressure with an increase of not more than 3,3 kPa (25 mmHg) for 1 h when the set is in air under normal atmospheric conditions.

NOTE – An apparatus suitable for this test is shown in figure 3.

24 PERFORMANCE

The complete set of equipment shall be capable of delivering not less than 1 000 ml of blood (which has been collected in acid citrate dextrose, and stored for not less than 2 weeks and is free of large clots) in 30 min under a static head of 1 m and with the giving needle (see clause 22) in position but not inserted in a vein.

In emergencies it may be necessary for the flow of blood to be assisted. The set shall therefore be capable of delivering 500 ml in 2 min under a pressure of 133 kPa (1 000 mmHg) absolute and with the giving needle (see clause 22) in position but not inserted in a vein.

25 MARKING

25.1 The container of each set of equipment shall show the following information :

25.1.1 Description and diagram of contents.

25.1.2 Complete instructions on the use of the set of equipment, including warning notes about inspection for integrity of the seals used to maintain sterility and about the maximum size of needle to be used for the injection of drugs or other solutions.

25.1.3 The year and month of sterilization.

25.1.4 A batch number which will permit all details of materials, manufacture and sterilization to be determined.

25.1.5 Drip-tube delivery, in terms of number of drops of distilled water per millilitre.

25.1.6 The manufacturer's name and address.

25.2 If the external surfaces of the set are not sterile, a statement to this effect shall be exhibited boldly on the outside of the container.

SECTION FOUR

GIVING SETS FOR SINGLE USE WITH MEDICAL FLUIDS OTHER THAN BLOOD DERIVATIVES

26 GENERAL REQUIREMENTS

The set of equipment shall satisfy the requirements of clauses 14 to 23 and of clause 25, except that a filter as mentioned in clause 14 and described in clause 18 need not be provided if a safety filter (see clause 27) is incorporated in the set.

27 SAFETY FILTER

If the set does not include a filter as specified in clause 18, it shall be provided with a coarse filter having a mesh aperture 1,00 to 1,25 mm square and an area not less than that of the cross-section of the drip-chamber inlet or outlet.

NOTE — The purpose of the safety filter is to prevent the passage of clots or large particles, in the event of the set being used *in error* to administer blood or blood derivatives.

SECTION FIVE

GIVING SETS FOR REPEATED USE WITH BLOOD AND BLOOD DERIVATIVES[1)]

28 GENERAL DESCRIPTION

28.1 Components

The set shall consist of

1) a closure-piercing device, a filter, a drip counter, a length of tubing with a flow regulator and, if desired, a device for the injection of drugs and other solutions, a needle adaptor and a giving needle assembly;

2) a separate air-inlet device connected to a length of flexible tubing which incorporates an air filter.

All the components shall be so designed that the set can be completely dismantled for cleaning. A diagram of a typical giving set is shown in figure 4.

28.2 Sterilization

It shall be possible to sterilize the assembled complete set, by autoclaving or some other method, without causing any loosening of joints or any important alteration in the shape of the set, or in the consistency of the materials used. When sets are supplied sterile, the maker shall be able to produce evidence, acceptable to the user, of the efficacy of the actual process of sterilization used.

Positive controls to check the efficacy of sterilization shall be included in each load and, if required, samples of the sets shall be tested for sterility, as outlined in annex E.

28.3 Maintenance of sterility

The set shall be so packed that the needles and the interior of the set remain sterile during storage.

NOTE — The conditions and duration of storage will govern how this requirement is to be interpreted between purchaser and vendor.

Sets shall be packed and sterilized in such a way that there are no flattened portions or kinks when the equipment is ready for use.

If the set is to be packed and distributed in such a way that the external surface may not remain sterile, all the extremities of the set shall be provided with protectors designed to maintain sterility of the needles and internal parts of the set until the set is used. The protectors shall be easily removable.

29 MATERIALS

29.1 The materials from which the equipment is made shall not have undesirable effects upon the blood or the fluid passing through the set under ordinary conditions of use, or general toxic effects on the recipient, and shall not cause any local reaction (see annex D).

29.2 Samples of the sterilized assembled sets shall satisfy tests for pyrogens and toxicity (see annexes C and D). The method of sampling shall be based on statistical practice.

1) This section may be disregarded by countries wishing to include only single-use sets in their national standards.

30 CLOSURE-PIERCING DEVICE AND AIR-INLET ASSEMBLY

30.1 General

The closure-piercing device and the air-inlet assembly shall be capable of piercing the bottle closure without pre-piercing, and of forming a fluid-tight seal with it.

30.2 Closure-piercing device

The closure-piercing device shall satisfy the following requirements :

a) the length shall be not less than 35 mm;

b) the maximum external diameter shall be 4 mm; the bore shall have a cross-sectional area of not less than 5 mm^2; the inner surface shall be smooth and continuous;

c) the tubing mount shall comply with the requirements of clause 32;

d) the closure-piercing device shall be so designed that it can be properly cleaned.

30.3 Air-inlet assembly

The length of the air-inlet assembly shall be such that it extends at least 25 mm beyond the end of the closure-piercing device fitted in position. The bore shall have a cross-sectional area of not less than 0,44 mm^2. If desired, an internal air tube may be used.

The end of the air-inlet assembly shall be connected to an air filter by means of flexible tubing of such a length that the filter can be fixed above the level of the fluid.

31 MOUNTS OF NEEDLES OR PIERCING DEVICES

The mounts of needles and piercing devices shall carry a standard conical socket.

NOTE – In this International Standard the term "cone" is used for the part of a conical joint that is inserted, and the term "socket" for the part into which the cone is inserted. The basic dimensions of conical fittings with 6/100 taper are given in ISO/R 594.

32 TUBING MOUNTS

Tubing mounts of needles or adaptors shall be so shaped as to allow manual application of tubing to form a firm airtight joint, without causing splitting of the tube during sterilization.

NOTE – A mount approximately 10 mm long and 6,5 mm in external diameter at the maximum diameter of the olive-shaped portion, with a cylindrical free end of 4 mm external diameter, has been found satisfactory for rubber tubing.

33 AIR FILTER

The air filter shall be so made that all air entering the bottle passes through it and the flow of fluid is not significantly reduced. Cotton wool or other material used for this purpose shall be non-absorbent. Means of fixing the filter of the air-inlet assembly above the level of the fluid shall be provided.

The use of bottles having an internal tube is not excluded.

34 FILTER FOR TRANSFUSION FLUID

34.1 General

It is essential that the equipment be provided with a filter and drip chamber. These may be separate or combined but the drip chamber shall be transparent. They shall be capable of being easily cleaned and shall be provided with tubing mounts complying with the requirements of clause 32.

34.2 Filter

The filter shall be made from smooth, non-wettable material and shall be not less than 80 % as efficient as the reference filter specified in annex B. The efficiency of the filter material may be determined by the method described in annex B.

35 DRIP CHAMBER AND COUNTER

The fluid shall enter the drip chamber through a tube which shall project for a short distance into the chamber. There shall be a clear space of not less than 40 mm between the end of the drip tube and the outlet of the chamber. 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 so designed that 15 to 20 drops are equivalent to 1 ml when distilled water is used.

36 TUBING

The tubing shall be made from natural rubber or other acceptable material. It shall have a cross-section such that it can carry a flow greater than that of the whole apparatus and a length such that the total length of the complete equipment as issued for use is not less than 1 700 mm and the free length of tubing is not less than 1 500 mm. At least a portion of this tubing, at the distal end, shall be capable of reclosing, under the normal working pressure, after being perforated by a needle of 0,6 mm diameter. Alternatively, other means shall be provided at the distal end for the injection of drugs or other solutions into the lumen of the tubing. The distal end shall terminate in a cone.

37 FLOW REGULATOR

The flow regulator shall be capable of stopping the flow of the transfusion fluid completely and controlling the flow as required. It shall preferably be at the distal end of the set.

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