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ISO RECOMMENDATION

R 1135

TRANSFUSION EQUIPMENT FOR MEDICAL USE

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BRIEF HISTORY

The ISO Recommendation R 1135, *Transfusion equipment for medical use,* was drawn up by Technical Committee ISO/TC 76, *Transfusion equipment for medical use,* the Secretariat of which is held by the British Standards Institution (BSI).

Work on this question led to the adoption of Draft ISO Recommendation No. 1221, which was circulated to all the ISO Member Bodies for enquiry in April 1967. It was approved, subject to a few modifications of an editorial nature, by the following Member Bodies :

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 also approved Parts I (excluding clause 5.4.1), II and III of the Draft, but disapproved Part IV as it was not in favour of having sets for repeated use.

The Member Body of Japan 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.

This Draft ISO Recommendation was then submitted by correspondence to the ISO Council which decided, in November 1969, to accept it as an ISO RECOMMENDATION.

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TRANSFUSION EQUIPMENT FOR MEDICAL USE

INTRODUCTION

It is recognized that some countries may not wish to include in their national standards all the types of equipment covered by this ISO Recommendation. 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 ISO Recommendation.

The primary purpose of this ISO Recommendation 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 ISO Recommendation 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

This ISO Recommendation gives requirements for transfusion equipment, as follows :

Part I – Glass bottle, means of suspension and closure.

Part II – Taking sets for blood.

Part III – Giving sets for single use :

A – Giving sets for use with blood and blood derivatives.

B – Giving sets for use with medical fluids other than blood and blood derivatives.

Part IV – Giving sets for repeated use :

A – Giving sets for use with blood and blood derivatives.

B – Giving sets for use with medical fluids other than blood and blood derivatives.

Diagrammatic illustrations of taking and giving sets are also included.

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. Part I of this ISO Recommendation is concerned with glass bottles intended primarily for use with blood and blood derivatives.

PART I

GLASS BOTTLE, MEANS OF SUSPENSION AND CLOSURE*

2. GLASS BOTTLE

2.1 General

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

2.2 Thermal resistance

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

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

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

2.2.3 *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.

2.3 Thermal shock resistance

Transfusion bottles should 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 should be conducted in accordance with the procedure described in Annex A.

2.4 Resistance to internal pressure

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

10.3 bar (10.5 kgf/cm^2) for bottles with a 22.5 mm neck;
8.6 bar (8.8 kgf/cm^2) for bottles with a 30 mm neck.

The test pressure should be reached in not more than 5 seconds and maintained for 1 minute.

2.5 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, should withstand centrifuging, such as to produce an acceleration equivalent to 2000 times that due to gravity in the plane of the base of the bottle, for at least 30 minutes.

2.6 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 should 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,*** 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 should be as shown in Figure 1 (*a*) or 1 (*b*), according to the neck diameter.

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* A specification for plastics containers for blood is being prepared.

** Tests for chemical resistance are under consideration.

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

2.7 Graduation marks

There should 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 should 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 should not project more than 1 mm from the surface of the cylindrical portion of the bottle.

2.8 Internal neck diameter

The nominal internal diameter of the neck should be either

(*a*) 22.5 mm, or

(*b*) 30 mm

2.9 Overall dimensions and graduated capacity

The overall dimensions and graduated capacity should comply with the appropriate requirements of Table 1, according to the internal neck diameter of the bottle used.

TABLE 1 – **Dimensions and graduated capacity of the transfusion bottle**

Internal neck diameter	22.5 ± 0.7 mm	30 ± 0.4 mm
Graduated capacity	500 ml (see Note 3)	500 ml
Overall height	220 mm (maximum)	153 mm (maximum)
Overall diameter	80 mm (maximum)	91.5 mm (maximum)
Projection of graduation marks	1 mm (maximum)	1 mm (maximum)

NOTES

1. The requirements given in Table 1 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 should 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.

3. MARKING

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

4. MEANS OF SUSPENSION

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

5. CLOSURE

5.1 Design

The design of the closure and the material from which it is made should be such that the closure is easy to clean and makes an airtight seal when fitted to the bottle concerned. The closure should have an overall height between the limits 15 and 20 mm, and the thickness of the flange should be not less than 4 mm. The thickness of the piercing areas (see clause 5.2) should 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 should be attached to the closure under one of the areas marked "2".

5.2 Marking

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

5.3 Material

The closure should be made of self-sealing elastomeric material such that, having been aged for 168 hours 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 hour, without impairment of its function under conditions of normal use. The material before ageing should have a hardness of 40 to 50 international rubber hardness degrees.

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

5.4 Sealing test

5.4.1 The design and material of the closure should be such that, after ageing for 168 hours at 70 °C and sterilizing (see clause 5.3), the closure is capable of maintaining airtightness of the container at room temperature at a pressure of 270 mbar (200 mmHg) below the prevailing atmospheric pressure for 72 hours, 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 minutes and then withdrawn. This requirement test is deemed to be satisfied if any change in absolute pressure is within the limits 0 to + 13 mbar (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.

5.4.2 The closure should 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.

6. BOTTLE CAP

The bottle cap should 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 should be provided with a suitable aperture or apertures for use with taking and giving sets, and should be so designed that it retains, and prevents distortion of, the closure during normal use.

PART II

TAKING SETS FOR BLOOD

7. GENERAL REQUIREMENTS

7.1 Types of sets

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

Each taking set should 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.

7.2 Blood-collection assembly

The blood-collection assembly should 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 clause 5.2). The overall length of this assembly should be such as is convenient for the particular method of collection used, but the tubing should be not less than 600 mm long.

7.3 Air-outlet assembly

The air-outlet assembly should 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 clause 5.2).

7.4 Sterilization

It should be possible to sterilize the assembled complete set, by auto-claving 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 should 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 should be included with each batch submitted to sterilization and, if required, samples of the sets should be tested for sterility (see Annex E).

7.5 Maintenance of sterility

The set should 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 should 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 should 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 should be easily removable.

7.6 Pilot tubes

Means should 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.

8. MATERIALS

8.1 The materials from which the equipment is made should 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 should not produce any general toxic effects on the recipient of the blood, or any local reaction (see Annex D).

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

9. TUBING

The tubing used should comply with such requirements of section 19 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.

10. NEEDLES

10.1 The tubing mounts of needles should either comply with the requirements of section 31, for use with re-usable tubing, or be specially designed for single use or for 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.

10.2 The relative lengths and method of insertion of the bottle needle and air-outlet needle should 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.

10.3 Dimensions

With the exception of the dimensions given below, all needles should comply with the requirements of section 21.

10.3.1 *Blood-taking needle.* The needle tubing of needles for repeated use should be not less than 40 mm in length. Disposable needles should have a needle length (as defined in ISO Recommendation R 596, *Hypodermic needles*) of not less than 35 mm. The nominal external diameter of the needle tubing should be 1.9 mm. The needle should not be fitted with a stilette.

10.3.2 *Bottle needle.* The needle should be not less than 35 mm in length. The bore of the bottle needle should 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 should the diameter exceed 2.4 mm in view of the self-sealing property required of the bottle closure (see clause 5.4.2).

10.3.3 *Air-outlet needle.* The air-outlet needle should 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 should be fitted with a stilette, preferably in such a manner that it has to be removed before blood enters the bottle.

11. LEAKAGE TESTS

11.1 The sterilized set of equipment completely assembled, with one end closed, should not leak under an interior air pressure of 1580 mbar (1185 mmHg) absolute, when immersed in water at 20 to 30 °C for 2 minutes.

11.2 The sterilized set of equipment evacuated to an interior pressure of 100 mbar (75 mmHg) absolute should, with the ends closed, maintain this pressure with an increase of not more than 33 mbar (25 mmHg) during 1 hour when the set is in air under normal atmospheric conditions.

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

12. MARKING

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

12.1.1 Description and diagram of contents.

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

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

12.1.4 The manufacturer's name and address.

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

PART III

GIVING SETS FOR SINGLE USE

III A. GIVING SETS FOR USE WITH BLOOD AND BLOOD DERIVATIVES

13. GENERAL DESCRIPTION

13.1 Components

The set should 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.

13.2 Sterilization

The set should have been sterilized by autoclaving or some other method, and the maker should 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 should be included in each batch submitted to sterilization and, if required, samples of the sets should be tested for sterility (see Annex E).

13.3 Maintenenace of sterility

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

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

14. MATERIALS

14.1 The materials from which the equipment is made should 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).

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

15. CLOSURE-PIERCING AND AIR-INLET DEVICES

15.1 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 should be capable of piercing the bottle closure without pre-piercing and of forming a fluid-tight seal with it.

15.2 Closure-piercing device

The bore of the closure-piercing device should 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 should be restricted by means of a flange and the device should project from the lowest part of the closure, with the bottle upright, to a distance of 15 to 20 mm.

15.3 Air-inlet assembly

The bore of the air-inlet device should 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 should be such 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 should extend at least 13 mm beyond the opening of the closure-piercing device (see Fig. 4). If desired, an internal air tube may be used.

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

16. AIR FILTER

The distal end of the air filter should be fitted with a conical socket. The air filter should 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 should 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 should be provided.

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

17. FILTER FOR TRANSFUSION FLUID

17.1 General

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

17.2 Filter

The filter should be made from smooth, non-wettable material and should 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.

18. DRIP CHAMBER AND COUNTER

The drip chamber should be designed so as to permit continuous observation of the fall of the drops. The position of the drip tube in the chamber should 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 section 34.

19. TUBING

The tubing made of suitable flexible material should be transparent or sufficiently translucent for the passage of bubbles of air to be readily detected. This tubing should 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 1700 mm and the free length of tubing is not less than 1500 mm. At the distal end there should 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 should terminate in a cone.

If self-sealing tubing or other device is used for injection purposes, it should 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 should withstand ageing in air at 70 °C for 168 hours, without impairment of its function under normal conditions of use. Any change in colour of the device or of the transfusion tubing should be disregarded.

Rubber parts should not be sterilized by dry heat.

20. FLOW REGULATOR

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

21. GIVING NEEDLE ASSEMBLY

Each set should 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 should be 35 to 40 mm long, should have an internal diameter of not less than 1.016 mm and should be suitably sharpened. The internal diameter should be not less than 70 % of the external diameter of the needle. The bore should be of uniform circular cross-section and the internal surface should be smooth. The butt of the delivery needle may be extended by means of flexible tubing of 4 cm length which should terminate with an adaptor having a conical socket. If a needle alone is supplied, this should have a conical socket.

NOTES

1. In this ISO Recommendation 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.
2. The basic dimensions of conical fittings with 6/100 taper (see ISO Recommendation 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*) are as follows :

Minimum diameter of end of cone (reference diameter)	3.925 mm
Maximum diameter of end of cone	3.970 mm
Minimum diameter at opening of socket	4.270 mm
Maximum diameter at opening of socket	4.315 mm
Minimum length of cone	7.500 mm
Depth of socket	$7.500\ ^{0}_{+\,1.000}$ mm

22. LEAKAGE TESTS

22.1 The sterilized set of equipment completely assembled, with one end closed, should not leak under an interior air pressure of 1580 mbar (1185 mmHg) absolute, when immersed in water at 20 to 30 °C for at least 2 minutes.

22.2 The sterilized set of equipment evacuated to an interior pressure of 100 mbar (75 mmHg) absolute should, with the ends closed, maintain this pressure with an increase of not more than 33 mbar (25 mmHg) during one hour when the set is in air under normal atmospheric conditions.

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

23. PERFORMANCE

The complete set of equipment should be capable of delivering not less than 1000 ml of blood (which has been collected in acid citrate dextrose, and stored for not less than two weeks and is free of large clots) in 30 minutes under a static head of 1 metre and with the giving needle (see section 21) in position but not inserted in a vein.

In emergencies it may be necessary for the flow of blood to be assisted. The set should therefore be capable of delivering 500 ml in 2 minutes under a pressure of 1330 mbar (1000 mmHg) absolute and with the giving needle (see section 21) in position but not inserted in a vein.

24. MARKING

24.1 The container of each set of equipment should show the following information :

24.1.1 Description and diagram of contents.

24.1.2 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 which should be used for the injection of drugs or other solutions.

24.1.3 The year and month of sterilization.

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

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

24.1.6 The manufacturer's name and address.

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

III B. GIVING SETS FOR USE WITH MEDICAL FLUIDS OTHER THAN BLOOD AND BLOOD DERIVATIVES

25. GENERAL REQUIREMENTS

The set of equipment should satisfy the requirements of sections 13, 14, 15, 16, 17, 18, 19, 20, 21, 22 and 24 except that a filter as mentioned in section 13 and described in section 17 need not be provided if a safety filter (see section 26) is incorporated in the set.

26. SAFETY FILTER

If the set does not include a filter as specified in section 17, it should be provided with a coarse filter having a mesh aperture 1.0 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.

PART IV

GIVING SETS FOR REPEATED USE*

IV A. GIVING SETS FOR USE WITH BLOOD AND BLOOD DERIVATIVES

27. GENERAL DESCRIPTION

27.1 Components

The set should 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 should be so designed that the set can be completely dismantled for cleaning. A diagram of a typical giving set is shown in Figure 4.

27.2 Sterilization

It should be possible to sterilize the assembled complete set, by auto-claving 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 should 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 should be included in each load and, if required, samples of the sets should be tested for sterility, as outlined in Annex E.

27.3 Maintenance of sterility

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

28. MATERIALS

28.1 The materials from which the equipment is made should 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 should not cause any local reaction (see Annex D).

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

* This part of this ISO Recommendation may be disregarded by countries wishing to include only single-use sets in their standards.

29. CLOSURE-PIERCING DEVICE AND AIR-INLET ASSEMBLY

29.1 General

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

29.2 Closure-piercing device

The closure-piercing device should satisfy the following requirements :

(*a*) the length should be not less than 35 mm;

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

(*c*) the tubing mount should comply with the requirements of section 31;

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

29.3 Air-inlet assembly

The length of the air-inlet assembly should be such that it extends at least 25 mm beyond the end of the closure-piercing device fitted in position. The bore should 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 should 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.

30. MOUNTS OF NEEDLES OR PIERCING DEVICES

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

NOTES

1. In this ISO Recommendation 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.
2. The basic dimensions of conical fittings with 6/100 taper (see ISO Recommendation 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*) are as follows :

Minimum diameter of end of cone (reference diameter)	3.925 mm
Maximum diameter of end of cone	3.970 mm
Minimum diameter at opening of socket	4.270 mm
Maximum diameter at opening of socket	4.315 mm
Minimum length of cone	7.500 mm
Depth of socket	$7.500\ ^{0}_{+1.000}$ mm

31. TUBING MOUNTS

Tubing mounts of needles or adaptors should 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.

32. AIR FILTER

The air filter should 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 should be non-absorbent. Means of fixing the filter of the air-inlet assembly above the level of the fluid should be provided.

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

33. FILTER FOR TRANSFUSION FLUID

33.1 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 should be transparent. They should be capable of being easily cleaned and should be provided with tubing mounts complying with the requirements of section 31.

33.2 Filter

The filter should be made from smooth, non-wettable material and should 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.

34. DRIP CHAMBER AND COUNTER

The fluid should enter the drip chamber through a tube which should project for a short distance into the chamber. There should 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 should not be closer than 5 mm to the end of the drip tube. The drip tube should be so designed that 15 to 20 drops are equivalent to 1 ml when distilled water is used.

35. TUBING

The tubing should be made from natural rubber or other acceptable material. It should 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 1700 mm and the free length of tubing is not less than 1500 mm. At least a portion of this tubing, at the distal end, should be capable of reclosing, under the 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 should terminate in a cone.

36. FLOW REGULATOR

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

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

37. GIVING NEEDLE ASSEMBLY

The giving needle for insertion in the recipient's vein should be 35 to 40 mm long, should have an internal diameter of not less than 1.016 mm and should be suitably sharpened. The internal diameter should be not less than 70 % of the external diameter of the needle. The bore should be of uniform circular cross-section and the internal surface should be smooth. The butt of the delivery needle may be extended by means of flexible tubing of 4 cm length which should terminate with an adaptor having a conical socket.

Each set should be provided with an intravenous needle suitably protected against contamination and damage.

38. LEAKAGE TESTS

38.1 The sterilized set of equipment completely assembled, with one end closed, should not leak under an interior air pressure or 1580 mbar (1185 mmHg) absolute, when immersed in water at 20 to 30 °C for 2 minutes.

38.2 The sterilized set of equipment evacuated to an interior pressure of 100 mbar (75 mmHg) absolute should, with the ends closed, maintain this pressure with an increase of not more than 33 mbar (25 mmHg) during 1 hour when the set is in air under normal atmospheric conditions.

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

39. PERFORMANCE

The complete set of equipment should be capable of delivering not less than 1000 ml of blood (which has been collected in acid citrate dextrose, stored for not less than 2 weeks and is free of large clots) in 30 minutes under a static head of 1 metre and with a giving needle, complying with section 37, in position but not inserted in a vein.

In emergencies the flow of blood may require to be assisted. The set should therefore be capable of delivering 500 ml in 2 minutes under a pressure of 1330 mbar (1000 mmHg) absolute and with a needle in position but not inserted in a vein.

40. MARKING

40.1 The container of each set of equipment should show the following information :

40.1.1 Description and diagram of contents.

40.1.2 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 which should be used for the injection of drugs or other solutions.

40.1.3 The year and month of sterilization.

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

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

40.1.6 The manufacturer's name and address.

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

IV B. GIVING SETS FOR USE WITH MEDICAL FLUIDS OTHER THAN BLOOD AND BLOOD DERIVATIVES

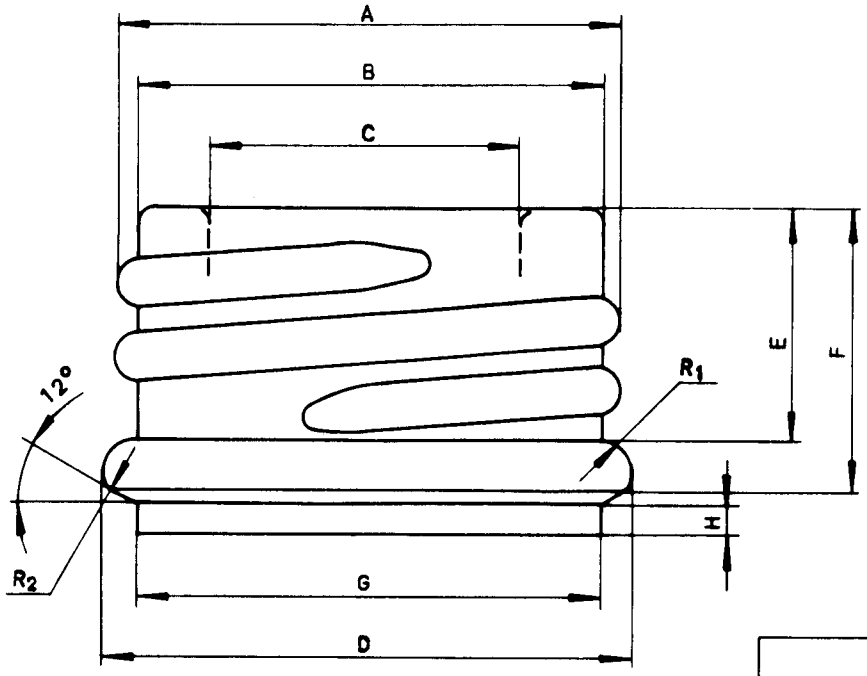
41. GENERAL REQUIREMENTS

The set of equipment should satisfy the requirements of sections 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38 and 40 except that a filter as mentioned in section 27 and described in clauses 33.1 and 33.2 need not be provided if a safety filter (see section 42) is incorporated in the set.

42. SAFETY FILTER

If the set does not include a filter as specified in clauses 33.1 and 33.2, it should be provided with a coarse filter having a mesh aperture 1.0 to 1.25 mm square and an area not less than that of the cross-section of the drip-chamber inlet or outlet.

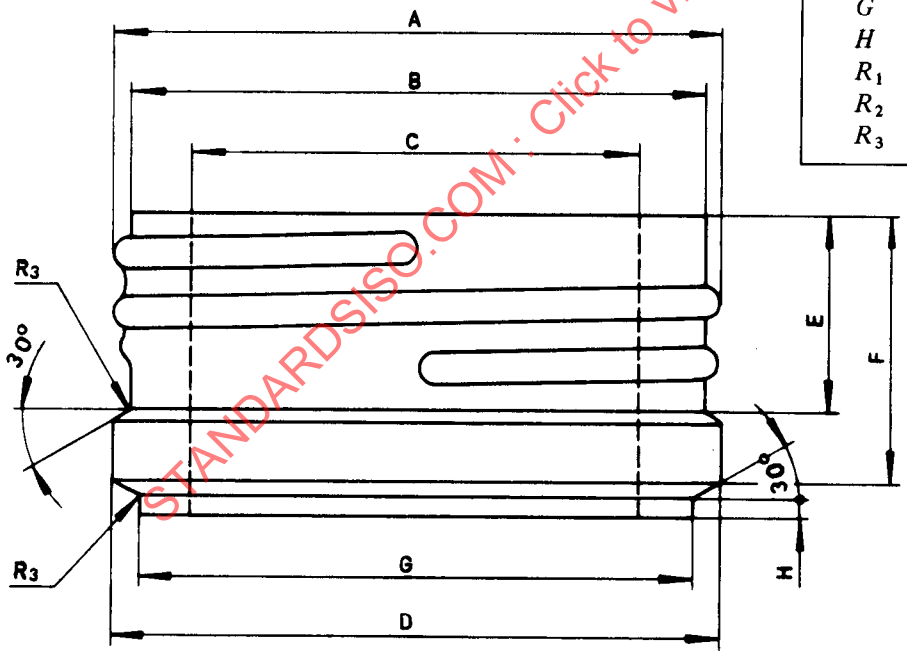
NOTE. – The purpose of the safety filter is to prevent the passage of clots or large particles, in the event of the set being used *in error* to administer blood or blood derivatives.



(*a*) Bottle with 22.5 mm neck

Dimensions in millimetres

Dimension	22.5 mm neck		30 mm neck	
	max.	min.	max.	min.
A	37.64	37.13	42.2	41.6
B	35.26	34.76	39.9	39.3
C	23.2	21.8	30.4	29.6
D	38.81	38.30	42.2	41.6
E	17.0	16.74	13.2	12.8
F	20.95	20.70	18.4	17.6
G	34.3	33.1	38.3	
H	2.0		1	
R_1	1.98		–	
R_2	0.40		–	
R_3			0.5	



(*b*) Bottle with 30 mm neck

FIG. 1 – External form of bottle neck