UDC 615.473 : 615.38

Ref. No. : ISO/R 1135-1969 (E)

+ 1 autoformule

ISO

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

ISO RECOMMENDATION

R 1135

TRANSFUSION EQUIPMENT FOR MEDICAL USE

1st EDITION

November 1969

Printed in Switzerland

Also issued in French and Russian. Copies to be obtained through the national standards organizations.

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.

CONTENTS

PART IV

GIVING SETS FOR REPEATED USE

ISO Recommendation | R 1135 | November 1969

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.

---

* 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.