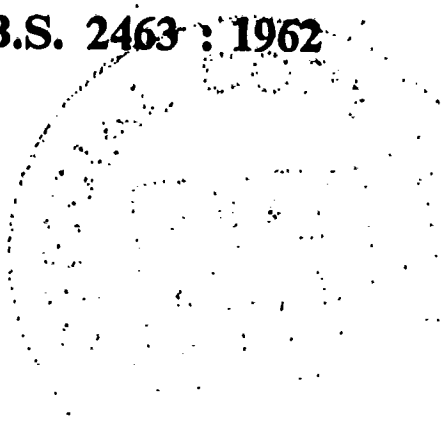


**SPECIFICATION FOR
TRANSFUSION
EQUIPMENT
FOR MEDICAL USE**

B.S. 2463 : 1962



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THIS BRITISH STANDARD, having been approved by the Surgical Instruments and Medical Appliances Industry Standards Committee and endorsed by the Chairman of the Chemical Divisional Council, was published under the authority of the General Council on 17th December, 1962.

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The Institution desires to call attention to the fact that this British Standard does not purport to include all the necessary provisions of a contract.

In order to keep abreast of progress in the industries concerned, British Standards are subject to periodical review. Suggestions for improvements will be recorded and in due course brought to the notice of the committees charged with the revision of the standards to which they refer.

A complete list of British Standards, numbering over 4000, indexed and cross-indexed for reference, together with an abstract of each standard, will be found in the Institution's Yearbook,

This standard makes reference to the following British Standards:

- B.S. 611. Petri dishes.
- B.S. 691. Clinical maximum thermometers.
- B.S. 903. Methods of testing vulcanized rubber. Part A7. Determination of hardness.
- B.S. 970. Wrought steel in the form of bars, billets and forgings up to 6 in ruling section, for automobile and general engineering purposes. En series.
- B.S. 1263. Hypodermic syringes for use in medical and surgical practice.
- B.S. 1470. Wrought aluminium and aluminium alloys. Sheet and strip.
- B.S. 3522. Hypodermic surgical mounted needles (Luer fitting).

British Standards are revised, when necessary, by the issue either of amendment slips or of revised editions. It is important that users of British Standards should ascertain that they are in possession of the latest amendments or editions.

The following B.S.I. references relate to the work on this standard:
Committee reference SGC/11 Draft for comment AB(SGC)7832

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CO-OPERATING ORGANIZATIONS

The Surgical Instruments and Medical Appliances Industry Standards Committee, under whose supervision this British Standard was prepared, consists of representatives from the following Government departments and professional and industrial organizations:

- *Admiralty
- *Air Ministry
- *Association of Hospital Matrons
- British Dental Association
- *British Medical Association
- British Paediatric Association
- *British Surgical Trades Association, Inc.
- *Federation of British Rubber and Allied Manufacturers
- Institute of British Surgical Technicians
- Medical Defence Union
- Medical and Dental Defence Union of Scotland
- Medical Protection Society
- Ministry of Agriculture, Fisheries and Food
- *Ministry of Health
- Queen's Institute of District Nursing
- Royal College of Midwives
- *Royal College of Nursing
- Royal College of Obstetricians and Gynaecologists
- Royal College of Physicians of London
- Royal College of Surgeons of Edinburgh
- *Royal College of Surgeons of England
- Royal College of Veterinary Surgeons
- Royal Faculty of Physicians and Surgeons of Glasgow
- *War Office

The Government departments and professional industrial organizations marked with an asterisk in the above list, together with the following, were directly represented on the committee entrusted with the preparation of this British Standard:

- Association of British Chemical Manufacturers
- Association of British Pharmaceutical Industry
- Association of Clinical Pathologists
- Biochemical Society
- British Chemical Ware Manufacturers' Association Ltd.
- British Closure Manufacturers' Association
- British Glass Industry Research Association
- British Lampblown Scientific Glassware Manufacturers' Association
- British Mechanical Rubber Manufacturers' Association
- Evans' Biological Institute
- Glass Manufacturers' Federation
- Guild of Public Pharmacists
- Medical Research Council
- National Blood Transfusion Service
- National Federation of Hospital Officers
- Rubber Surgical Equipment Manufacturers' Association
- Scottish National Blood Transfusion Association
- Society of Glass Technology

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BRITISH STANDARD SPECIFICATION FOR TRANSFUSION EQUIPMENT FOR MEDICAL USE

FOREWORD

This British Standard, first published in 1954, has been prepared under the authority of the Surgical Instruments and Medical Appliances Industry Standards Committee to deal with the requirements of transfusion equipment used by the National Health Services, the Admiralty, the War Office and the Air Ministry.

In view of the desirability of achieving interchangeability of the components of transfusion equipment with those used in other countries, requirements in this new edition have been specified as far as possible to be in accordance with the proposals being considered by Technical Committee ISO/TC 76—Transfusion Equipment for Medical Use, of the International Organization for Standardization.

The revised standard now includes requirements for disposable giving sets, intended for single use, and for equipment for the taking of blood. Experience gained since the publication of the first edition of this British Standard has necessitated the revision of parts of the specification. Some of these are concerned with form and dimensions and need no special comment. Certain special problems, however, have arisen in connection with the glass bottle. Crystalloid solutions stored for long periods may be rendered unfit for use by the formation of deposits. When B.S. 2463 was originally prepared it was considered that the quality of the glass was the major, if not the only, factor related to the formation of deposits and that bottles made from glass which met the specification for hydrolytic resistance tests described in the first edition would overcome this problem. It has been shown that the material of which the bottle closure is made, the method of preparation of the solutions, the quality of the chemicals used and possibly other factors can affect the formation of deposits. Because of these facts it has been decided to omit hydrolytic resistance tests for glass until more information has been collected upon which a specification of such tests can be based.

For certain items of equipment, including the closure, the drip counter and the filter chamber, performance characteristics have been specified but the design has not been specified in detail in order not to restrict development. Although the specification gives requirements for a suspension recess in the

bottle, other means of suspension can be employed if required by the purchasing authority.

NOTE 1. Where metric equivalents have been given, the figures in British units are to be regarded as the standard. The metric conversions are approximate. More accurate conversions should be based on the tables in B.S. 350, 'Conversion factors and tables'.

NOTE 2. In place of the customary, but incorrect, use of the pound as a unit of force, the unit called a pound-force (abbreviation lbf) has been used in this standard. It is the force that, when acting on a body of mass one pound, gives it an acceleration equal to that of standard gravity (32.1740 ft/s^2). The unit kilogramme-force (kgf) has a similar significance.

SPECIFICATION

SCOPE

1. This British Standard specifies transfusion equipment for the taking and giving of blood, the storage and giving of blood products and the short-term storage and giving of crystalloid solutions.

Section One specifies the glass bottle, screw cap, closure and disk.

Section Two specifies taking sets for blood.

Section Three specifies giving sets for repeated use with blood and blood derivatives.

Section Four specifies giving sets for single use with blood and blood derivatives.

Section Five specifies giving sets for use with medical fluids other than blood and blood derivatives.

TEST REQUIREMENTS

2. *a. Dimensions.* Representative samples of each batch of bottles, bottle caps, bottle closures or disks, taking or giving set components and complete taking or giving sets shall be tested for compliance with the requirements of the relevant clauses concerning dimensions. If not specified in this British Standard, the number of samples, the sampling procedure and the acceptance quality level shall be subject to agreement between purchaser and vendor.

b. Materials. A representative sample or samples of each batch of components used shall be tested for compliance with the requirements of the relevant clauses concerning composition and freedom from harmful impurities. The number and size of the samples, and the sampling procedure, shall be subject to agreement between purchaser and vendor.

A batch shall be deemed to comply with the requirements of this British Standard if none of the samples fails to pass the relevant tests.

c. Performance. Representative samples of each batch of glass bottles, closures, tubing, filters, drip chambers and complete sets shall be tested for compliance with the requirements of the relevant clauses concerning performance. If not specified in this British Standard, the number of samples and the

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sampling procedure shall be subject to agreement between purchaser and vendor.

A batch shall be deemed to comply with the requirements of this British Standard if:

(i) there are no failures in any performance test which is required to be satisfied by all the samples obtained by a specified sampling procedure, or if:

(ii) the percentage of failures in any performance test for which a complete pass cannot be ensured does not exceed the value specified in the relevant clause, or a value agreed between purchaser and vendor if no limit is specified.

SECTION ONE: GLASS BOTTLE, SCREW CAP, CLOSURE AND DISK

GLASS BOTTLE

3. *a. Form and dimensions.* The form and dimensions of the bottle shall comply with the requirements of Fig. 1. Embossing shall not extend more than 1 mm from the surface of the cylindrical portion of the bottle.

NOTE. The brimful capacity of the bottle is about 630 ml.

b. Material. The material of the bottle shall not yield, under normal conditions of use, substances having undesirable effects upon the contents or harmful effects on the patient receiving the contents.

c. Thermal resistance. The bottle shall withstand the temperatures encountered during normal conditions of use, including:

(i) Sterilization of the empty bottle by autoclaving in saturated steam at temperatures up to 140°C.

(ii) Heating of the empty bottle in air to 250°C, the rate of rise of temperature being not more than 5 degC/min.

(iii) Cooling of the bottle when normally charged and closed, by immersion in a liquid at - 79°C.

d. Thermal shock resistance. Transfusion bottles shall not break, crack or chip when given a thermal shock resistance test in water at a temperature difference of at least 40 degC, or a greater temperature difference as agreed between the purchaser and the vendor, the test being carried out in accordance with the procedure described in Appendix A.

e. Resistance to internal pressure. The bottles when completely filled with water shall withstand an internal gauge pressure of 150 lbf/in² (10.5 kgf/cm²). This pressure shall be reached in not more than 5 seconds and maintained for 1 min.

f. Mechanical strength. The bottle, charged with water to the total graduated capacity and itself immersed in water to the 500 ml mark in a suitable centrifuge cup, shall 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.

g. Graduation marks. The graduated capacity shall be 540 ml, within a tolerance of ± 12 ml. There shall be two scales on the same side of the bottle, one reading upwards from the base when the bottle is upright, and the other scale reading upwards when the bottle is inverted (see Fig. 1 and Clause 3a).

The graduation lines and numbers shall be moulded on the outside of the bottle.

Each scale shall show numbered graduation lines, 10 mm long on each side of the number, at 100 ml intervals and un-numbered graduation lines, 20 mm long, at the intermediate 50 ml intervals as illustrated in Fig. 1.

The numbers at each 100 ml mark shall be 6 mm high and shall lie between the two graduation lines to which they relate.

h. Means of suspension. Means of suspension of the bottle shall be provided as agreed between the purchaser and the vendor. If the bottle has a moulded recess near the base for suspension purposes, the moulding shall be suitable for use with a metal suspension band 12.7 mm in width; the form and dimensions of the recess shall be as shown in Fig. 3.

j. Neck finish. The neck finish shall comply with the requirements of Fig. 2. The external single screw thread shall have two complete turns and shall not be continuous with the bead round the base of the neck.

The interior of the neck shall be cylindrical, within the tolerances specified in Fig. 2, for a distance of at least 11 mm from the top of the bottle.

k. Inscription panel. An inscription panel, about 50 mm wide by 45 mm high, shall be situated as illustrated in Fig. 1, and shall have a surface suitable for marking with crayon or pencil.

m. Testing of bottles. The samples tested for compliance with Clauses 3a-3k shall be representative of the whole consignment. The number of samples taken from a batch of articles, and the acceptance quality level, shall be agreed between the supplier and the purchaser.

BOTTLE CAP

4. *a. Material.* The screw cap shall be made of aluminium alloy sheet complying with the requirements of B.S. 1470*, S1C- $\frac{1}{2}$ H or $\frac{3}{4}$ H, NS3- $\frac{1}{2}$ H or $\frac{3}{4}$ H, or NS4- $\frac{1}{2}$ H.

b. Thickness. The thickness of the aluminium alloy sheet used shall be 0.014 ± 0.001 in (0.33 to 0.38 mm).

* B.S. 1470, 'Wrought aluminium and aluminium alloys (sheet and strip)'.

c. Shape and dimensions. The screw cap shall comply with the requirements of Fig. 4, and shall fit the neck of the bottle specified in Clause 3j.

When the screw cap is used with the rubber closure specified in Clause 6, the cap shall have a central hole of diameter $0.551 + 0.010 - 0.000$ in ($14.00 + 0.26 - 0.00$ mm).

GENERAL REQUIREMENTS FOR MATERIALS FOR BOTTLE CLOSURE AND DISK

5. The material of the bottle closure and disk shall be suitable for use with parenteral fluids and shall not liberate substances having undesirable effects upon the contents of the transfusion bottle or harmful effects upon the patient receiving the contents.

When tested by the method described in Appendix B, the material shall be free from substances inhibitory to bacterial growth.

Any colouring matter used in compounding shall be fast to autoclaving in saturated steam at $121 \pm 1^\circ\text{C}$ for 1 hour.

CLOSURE

6. a. General. 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 neck of the bottle as specified in Clause 3j. The closure shall have an overall height between the limits 15–20 mm. The thickness of the piercing areas shall be not less than 5 mm, except for one or both of the areas marked '2' (see below), which shall have a small circular portion of nominal thickness 3 mm. An illustration of one type of suitable closure is given in Fig. 5.

b. Material. The closure shall be made of self-sealing elastomeric material such that, when aged for 168 hours at 70°C and 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 $121 \pm 1^\circ\text{C}$ for 1 hour, without impairing its function under conditions of normal use. If natural rubber is used, it shall also comply with the requirements of Clause 8.

c. Dimensions of flanged top. The dimensions of the flanged top of the closure shall be $4.0 - 0.0 + 0.4$ mm thick and $33.5 + 0.0 - 0.5$ mm diameter.

d. Embossed marks. The upper surface of the closure shall be marked as follows (see Fig. 5):

(i) An embossed ring of diameter 14.0 mm and divided into 4 quadrants by embossed lines.

(ii) The numbers '1' and '2' embossed as illustrated in Fig. 5.

NOTE. The quadrants marked '1' are the areas to be pierced by the taking set and those marked '2' are the areas to be pierced by the giving set.

e. Sealing tests. (i) The design and material of the closure shall be such that, after ageing for 168 hours at 70°C and sterilizing as in Clause 6b, the closure is capable of maintaining airtightness of the container at room temperature at a negative pressure of 200 mmHg, for 72 hours, after each quadrant '1' has been pierced by a non-coring needle of 2.4 mm external diameter and the needles have been withdrawn. This test is deemed to be satisfied if any change in absolute pressure is within the limits $-0 + 10$ mmHg.

A suitable method for carrying out this test is described in Appendix C.

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.

(ii) The closure shall not show any signs of leakage when the bottle is immediately inverted 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. These tests do not give any guarantee against bacterial contamination; this risk should be covered by other precautions. They are required only for closures that are to be used in the collection of blood.

DISK

7. *a. General design.* When a closure (as specified in Clause 6) is not used, the bottle cap shall be fitted internally with a disk, $4.0 - 0.0 + 0.4$ mm thick and $36.5 + 0.5$ mm diameter. The surfaces shall be smooth and not ridged.

b. Material. The disk shall be made of material complying with the requirements of Clauses 5 and 6b. If natural rubber is used it shall also comply with the requirements of Clause 8. If it is to be used for the collection of blood, the disk whether made of rubber or other material shall comply with the requirements of Clause 6e.

REQUIREMENTS FOR NATURAL RUBBER FOR CLOSURE AND DISK

8. *a. Raw materials.* The rubber mix used in the manufacture of the closure and disk shall be prepared from first quality natural Hevea rubber, and shall contain not less than 75 per cent by weight, or not less than 85 per cent by volume, of pure rubber hydrocarbon. It shall not contain any reclaimed rubber or vulcanized waste.

b. Vulcanization. The compounded rubber shall be heat-vulcanized and shall have a hardness of approximately 50 B.S. rubber hardness degrees* for the disk and approximately 40 B.S. rubber hardness degrees for the closure.

c. Low-temperature test. The rubber, after being stored at a temperature of -79°C , shall regain its original properties when restored to room temperature.

* B.S. 903, 'Methods of testing vulcanized rubber. Part A7. Determination of hardness'.

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SECTION TWO: TAKING SETS FOR BLOOD

GENERAL REQUIREMENTS

9. *a.* Blood-taking sets may be for either repeated use or single use (disposable). Alternatively some components may be disposable (e.g. tubing) and some components reusable (e.g. needles). Any component of the equipment that is intended to be reused shall be so designed that it can be cleaned.

b. Each taking set shall consist of the blood-collection assembly and the air-outlet assembly, which may be separate or combined. The assembled blood-taking set shall comply with the requirements of Clause 12*b* or Clause 23*b* in respect of sterilization.

c. The set shall be so packed that the interior of the set remains sterile during storage.

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

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

d. The blood-collection assembly shall consist of a needle for venepuncture (the blood-taking needle), connected by a length of tubing to a needle (the bottle needle) to be inserted through one of the quadrants marked '1' on the bottle closure. The overall length of this assembly should be such as is convenient for the exact method of collection used, but shall not be less than 24 inches (61 cm).

e. The air-outlet assembly shall consist of tubing carrying a non-absorbent cotton wool filter and fitted to a needle (the air-outlet needle) for piercing the other quadrant marked '1' on the bottle closure.

TUBING

10. *a.* The tubing used shall comply with the requirements of Clauses 14*a*, *b*, *d* and *e*, or with Clauses 24*a* and *b* and such part of Clause 29*a* as is appropriate. The use of opaque rubber tubing necessitates the introduction of a window in the blood collection assembly, about 2–3 in (5–7.5 cm) from the blood-taking needle. No window is necessary with translucent tubing, which should be in one continuous length.

NEEDLES

11. *a.* The tubing mounts shall either comply with the requirements of Clause 19, for use with reusable tubing, or shall 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.

b. 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.

c. Material. The needles shall be made from stainless steel complying with the requirements of one of the En 56 or En 58 series of steels specified in B.S. 970*.

d. Dimensions. (i) With the exception of the dimensions given below, all needles shall comply with the requirements of Clause 20a.

(ii) *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 tubing length of not less than 35 mm. The external diameter of the needle tubing shall be 1.9 mm, and the internal diameter shall be not less than 70 per cent of the external diameter.

(iii) *Bottle needle.* The needle tubing shall be not less than 35 mm in length. The bore of the bottle needle shall be not less than, and preferably shall be slightly greater than, that of the blood-taking needle. A needle tubing of 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 Clause 6e (ii)). The internal diameter of the needle tubing shall be not less than 70 per cent of the external diameter.

(iv) *Air-outlet needle.* The air-outlet needle shall have an internal diameter not less than 0.75 mm, an external diameter not greater than 1.9 mm, and a needle tubing length not exceeding 25 mm.

* B.S. 970, 'Wrought steels in the form of bars, billets, and forgings, up to 6 in ruling section, for automobile and general engineering purposes. En series'.

† See B.S. 3522, 'Hypodermic surgical mounted needles (Luer fitting)' for definitions.