

Transfusion equipment for medical use —

Part 1: Specification for collapsible containers for blood and blood components

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/11, upon which the following bodies were represented:

- Association of Anaesthetists of Great Britain and Ireland
- Association of Clinical Pathologists
- Biochemical Society
- British Glass Manufacturers' Confederation
- British Medical Association
- British Plastics Federation
- British Rubber Manufacturers' Association
- British Surgical Trades Association Incorporated
- Department of Health
- Guild of Hospital Pharmacists
- Medical Sterile Products Association
- Ministry of Defence
- Pharmaceutical Society of Great Britain
- Plastics and Rubber Institute
- Royal College of Pathologists
- Royal College of Surgeons of England
- Scottish National Blood Transfusion Service
- Society of Glass Technology

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Board of BSI and comes into effect on 31 December 1990

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Contents

	Page
Committees responsible	Inside front cover
Foreword	ii
1 Scope	1
2 Definitions	1
3 General	1
4 Design	2
5 Anticoagulants	3
6 Packaging	3
7 Labelling and marking	3
Appendix A Method of test for water vapour transmission	5
Appendix B Method of test for haemolytic effects	5
Appendix C Methods of test for chemical extracts	5
Appendix D Preparation of test solutions for the pyrogenicity test	7
Appendix E Method of test for rate of collection	7
Appendix F Recommendations for packaging	7
Figure 1 — Example of apparatus for applying the pressure	8
Publications referred to	Inside back cover

Foreword

This Part of BS 2463 has been prepared under the direction of the Health Care Standards Policy Committee. Together with BS 2463-2 it is a revision of BS 2463:1962, which is withdrawn.

The main difference between this revision and BS 2463:1962 is that this revision does not specify requirements for glass transfusion equipment. When BS 2463:1962 was published, glass bottles were widely used as containers for blood and blood components. Since then plastics containers have almost totally replaced glass for these purposes, with the exception that glass containers are still used for protein solutions and other intravenous fluids. Containers that are now in use for blood and blood components are single-use sterile plastics packs with integral donor tubes and phlebotomy needles. Various transfer packs may be added to the primary collecting pack, which contains the anticoagulant solution. One of the transfer packs may contain red cell preservative solution.

In order not to restrict future development, this Part of BS 2463 does not specify requirements for plastics materials to be used for manufacture of the packs nor does it give detailed dimensional requirements.

The requirements specified in this Part of BS 2463 are intended to ensure, as far as possible, the following:

- a) that the qualities of the blood and blood components are maintained;
- b) that the containers for blood and blood components are suitable for use with administration sets complying with BS 2463-2;
- c) that the intended contents of the containers can be efficiently and safely collected, identified, stored, separated and infused.

Particular attention has been paid to reducing to a minimum the risk of the following:

- 1) contamination;
- 2) air embolism during collection and administration;
- 3) errors in identification of containers and representative samples of their contents;
- 4) interaction between containers and their intended contents.

The importance of subvisible particle testing has been recognized and the procedures and limits are currently under review.

Product certification. Users of this British Standard are advised to consider the desirability of third party certification of product conformity with this British Standard based on testing and continuing surveillance, which may be coupled with assessment of a supplier's quality systems against the appropriate Part of BS 5750.

Enquiries as to the availability of third party certification schemes will be forwarded by BSI to the Association of Certification Bodies. If a third party certification scheme does not already exist, users should consider approaching an appropriate body from the list of Association members.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 8, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

1 Scope

This Part of BS 2463 specifies requirements for collapsible non-vented sterile containers for single use for the collection, transport, storage, separation and administration of whole blood and blood components. It also covers transfer packs, plasma transfer packs and other packs intended for use in the processing or administration of blood or its components. It is intended for both containers that are supplied containing anticoagulant solution and those that are supplied empty.

This Part of BS 2463 does not include requirements for semi-rigid plasma packs, syringes, needles and cannulae for injection, or special mechanical devices.

NOTE The titles of the publications referred to in this standard are listed on the inside back cover.

2 Definitions

For the purposes of this Part of BS 2463, the following definitions apply.

2.1 shelf life

the period between the date of sterilization of the container and the date after which the container should not be used for the collection of blood

2.2 container

the primary collecting pack complete with ports, transfer tubes and associated transfer packs (where applicable) and tube and needle for collecting blood

3 General

3.1 Transparency

The container shall be sufficiently transparent for its contents to be inspected.

NOTE The colour of the primary collecting pack should not significantly affect the colour of its contents.

3.2 Thermal stability

After the container has been filled to its nominal volume with 9 g/L sodium chloride solution, stored for 24 h at -80 ± 2 °C, followed immediately by storage for 24 h at 50 ± 2 °C, and subsequently returned to room temperature, it shall comply with 4.8.

3.3 Water vapour transmission

When tested in accordance with Appendix A, the mass loss from a primary collecting pack shall not exceed 2 % of the total mass of the anticoagulant and sodium chloride solution.

3.4 Resistance to distortion

When centrifuged, the supported primary collecting pack holding water to the nominal capacity shall withstand an acceleration of $5\,000\text{ g}^{1)}$ for 30 min at 4 °C and 37 °C without becoming permanently distorted.

3.5 Freedom from hazards

3.5.1 Haemolysis

When tested in accordance with Appendix B, the 0.5 % sodium chloride solution shall not give a haemolysis value greater than 10 % and the 0.4 % sodium chloride solution shall not give a haemolysis value that differs by more than 10 % from that given by the control solution.

3.5.2 Chemical extract

When tested separately in accordance with Appendix C, the plastics sheet and plastics tubing used for the manufacture of the primary collecting pack and the transfer pack, the transfer tubes and the outlet ports of containers shall comply with the following.

- a) *Oxidizable matter*. The difference between the volumes of 0.01 mol/L sodium thiosulphate solution used for the test solution and for the blank shall be not greater than 2.0 mL.
- b) *Ammonia*. The colour developed by the extract shall be no more intense than that obtained by treating the ammonia reference solution.
- c) *Organic phosphorus*. The colour produced shall be no more intense than that obtained by treating 25 mL of the blank solution.
- d) *pH*. The pH of the extract shall be between 4.5 and 7.0.
- e) *Residue on evaporation*. The residual mass of the extract shall not exceed that from the blank by more than 3.0 mg.
- f) *Clarity and colour*. The extract shall be clear and colourless when compared with the blank.
- g) *Other elements*. The extract shall contain not more than 1 mg/kg of antimony, arsenic, barium, chromium, copper, lead, silver and tin and not more than 0.1 mg/kg of cadmium.

3.5.3 Biological hazard

When the device in its final form is tested according to the principles and methods recommended in BS 5736-1 and BS 5736-3 to BS 5736-6, it shall be assessed as being free from biological hazard.

¹⁾ $g = 9.80665\text{ m/s}^2$.