

INTERNATIONAL STANDARD

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Plastics collapsible containers for human blood and blood components

Poches en plastique souple pour le sang et les produits du sang



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established 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. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 3826 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use*.

Annexes A and B form an integral part of this International Standard. Annex C is for information only.

Introduction

In some countries national pharmacopoeia or other government regulations are legally binding and these requirements may take precedence over this International Standard.

The manufacturers of the plastics container or the suppliers are expected to disclose in confidence to the national control authority, if requested by them, full details of the plastics material(s) and the components of the materials and their methods of manufacture, details of manufacture of the plastics containers including the chemical names and quantities of any additives, whether incorporated by the manufacturer of the containers or present in the raw material, as well as full details of any additives that have been used.

Plastics collapsible containers for human blood and blood components

1 Scope

1.1 This International Standard specifies requirements, including performance requirements for di-(2-ethylhexyl)phthalate (DEHP) plasticized poly(vinyl chloride) (PVC) for plastics collapsible, non-vented, sterile containers complete with collecting tube outlet port(s), integral needle and with optional transfer tube(s), for the collection, storage, processing, transport, separation and administration of blood and blood components. The containers may contain anticoagulant and/or preservative solutions, depending on the application envisaged. These requirements are intended to

- a) ensure that the quality of blood and blood components is maintained as high as possible;
- b) make possible efficient and safe collection, identification, storage, separation and transfusion of the contents, with special attention to reducing to a minimum the risks resulting from
 - contamination, in particular microbiological contamination,
 - air embolism,
 - errors in identification of containers and any representative samples of contents,
 - interaction between the container and its contents;
- c) ensure functional compatibility when used in combination with transfusion sets as specified in ISO 1135-4;

- d) provide maximum resistance to breakage and deterioration in a package of minimal mass and volume.

1.2 The requirements specified in this International Standard also apply to multiple units of plastics containers, e.g. to double, triple or quadruple units.

1.3 The term “plastics containers” is used throughout this International Standard to mean the container complete with collecting tube and needle, port(s), anticoagulant and/or preservative solutions and transfer tube(s) and associated container(s), where applicable.

1.4 Unless otherwise specified, all tests specified in this International Standard apply to the plastics container as prepared ready for use.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this international Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 247:1990, *Rubber — Determination of ash*.

ISO 1135-3:1986, *Transfusion equipment for medical use — Part 3: Blood-taking set*.

ISO 1135-4:1987, *Transfusion equipment for medical use — Part 4: Transfusion sets for single use*.

3 Dimensions and designation

3.1 Dimensions

See figure 1 and table 1. Only the dimensional values shown in figure 1 are binding; the dimensions given in table 1 are for guidance purposes only.

NOTES

- 1 The figure illustrates the components of a plastics container and, apart from the dimensions shown, does not form part of the requirements of this International Standard.
- 2 For guidance, additional dimensions are given in table 1. These dimensions are optional and are not requirements of this International Standard.

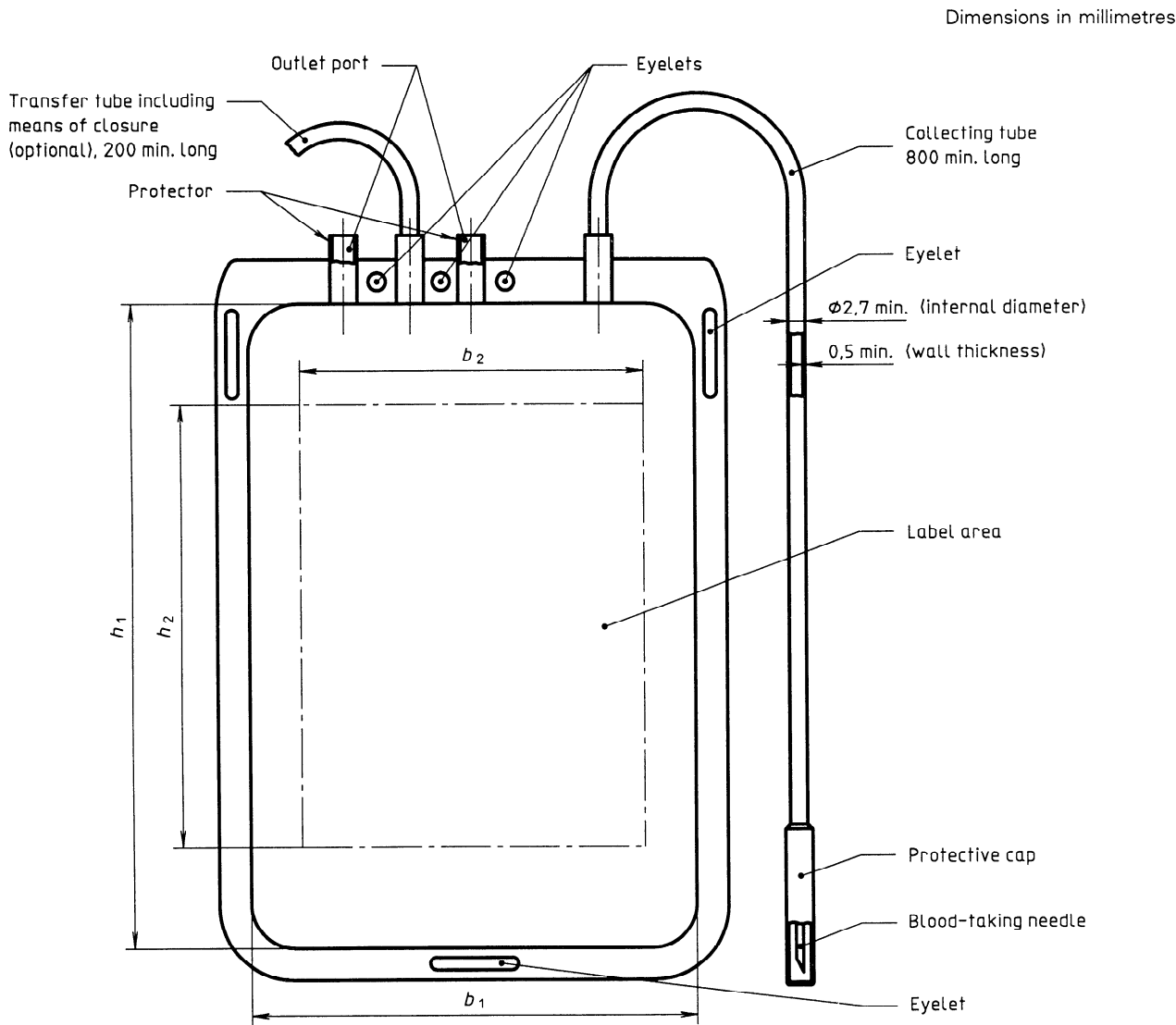


Figure 1 — Schematic representation of plastics container

Table 1 — Dimensions for plastics containers, label areas and nominal capacity (for guidance purposes only)

Dimensions in millimetres

Nominal capacity ml	Inside width b_1	Inside height h_1	Size of label area	
			$b_2 \pm 5$	$h_2 \pm 5$
100	75	120	60	85
250	120	130	90	85
400	120	170	100	100
500	120	185	100	100

3.2 Designation example

Designation example of a plastics collapsible container with a nominal capacity of 500 ml complying with the requirements specified in this International Standard:

Plastics container ISO 3826 - 500

4 Design

4.1 General

The design of the plastics container shall provide for the safe and convenient collection, storage, processing, transport, separation and administration of whole blood and blood components. The design and manufacture shall not adversely affect the preservation of blood and blood components. The container shall permit the preparation of plasma or centrifuged or resuspended cellular components with a minimal hazard of contamination by microorganisms. The container shall be functionally compatible with the transfusion set specified in ISO 1135-4. Its design shall also ensure that it can be used in a centrifuge cup.

4.2 Air content

4.2.1 The total volume of air contained in the blood collection pathway and the container used for the collection of blood and for each transfer container and its associated tubing shall not exceed 10 ml. The volume of air contained in each additional transfer container and associated tubing shall not exceed 10 ml.

4.2.2 When used in accordance with the manufacturer's instructions, the plastics container shall be capable of being filled with blood without air being introduced.

4.3 Emptying under pressure

The plastics container filled with a volume of water at a temperature of $23\text{ °C} \pm 2\text{ °C}$ equal to its nominal capacity and connected to a transfusion set as specified in ISO 1135-4 inserted in an outlet port (see 4.8) shall empty without leakage within 2 min when gradually squeezed between two plates to an internal pressure of 40 kPa above atmospheric pressure.

4.4 Pilot samples

The plastics container shall be designed so that pilot samples of unmistakable identity can be collected for the performance of appropriate laboratory tests without the closed system of the container being penetrated.

4.5 Rate of collection

4.5.1 The plastics container shall be flexible enough to offer minimum resistance to filling under normal conditions of use.

4.5.2 The plastics container shall be designed so that it is capable of being filled to its nominal capacity in less than 8 min when tested in accordance with B.2.

4.6 Collecting and transfer tube(s)

4.6.1 The plastics container may be provided with one or more collecting or transfer tube(s) to allow the collection and separation of blood and blood components.

The transfer tube shall be fitted with a device, which acts first as a seal and, when broken, permits the free flow of blood components in either direction.

4.6.2 The tubes shall be such that they can be sealed hermetically and do not collapse under normal use.

4.6.3 The plastics container, filled with water (see note 4 under 5.2.8) to its nominal capacity and sealed, and the tubes connected to the plastics container, shall form a hermetic seal and a tight leakproof joint which will withstand, without leakage occurring, a tensile force of 20 N, applied to the tubing for 15 s. The tensile force shall be applied at right angles to the edge of the joint and in the longitudinal axis of the plane of the container at a temperature of $23\text{ °C} \pm 2\text{ °C}$.

There shall be no leakage at the junctions and the container shall also conform to the requirements specified in 5.2.8.

4.6.4 Under visual inspection, the tubing shall not display any cracks, blisters, kinks or other defects.

4.7 Blood-taking needle

The needle shall be integral with the collecting tube and covered by a protective cap. The protective cap shall prevent leakage of anticoagulant and/or preservative solution from the plastics container during storage, shall maintain the sterility of the fluid path and shall be readily removable. The protective cap shall be tamper-evident and manufactured so that either it is impossible to replace or any attempt at manipulating it is blatantly obvious.

The blood-taking needle, as specified in ISO 1135-3, shall withstand, without working loose from the assembly, a tensile force of 20 N applied along the longitudinal axis of the tubing for 15 s.

4.8 Outlet port(s)

4.8.1 The plastics container shall be provided with one or more outlet ports for the administration of blood and blood components through a transfusion set. The port(s), which shall have a puncturable, non-resealable closure, shall allow connection of a transfusion set without leakage on insertion or during conditions of use, including emptying under pressure (see 4.3). To ensure functional interchangeability, the port(s) shall be of such size and design to allow insertion of a transfusion set having a closure-piercing device in accordance with ISO 1135-4. Before the closure is pierced by the point of the closure-piercing device, the outlet port(s) shall be tightly occluded by the closure-piercing device.

4.8.2 Each outlet port shall be fitted with a hermetically sealed, tamper-evident protector to maintain the sterility of the internal surface.

4.9 Suspension

The plastics container shall have adequate means of suspension or positioning, which do not interfere with use of the container during collection, storage, processing, transport and administration. The means of suspension or positioning shall be capable of with-

standing a tensile force of 20 N applied along the longitudinal axis of the outlet port(s) for 60 min at a temperature of $23\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ without breaking.

5 Requirements

5.1 General

The plastics container shall be transparent, virtually colourless (see 5.3.2), flexible, sterile, non-pyrogenic, free from toxicity (see 5.4) and non-frangible under conditions of use (see 5.2.5). It shall be compatible with the contents under normal conditions of storage. The container shall be sterilized in the final stage of manufacture, and the container shall not be tacky or become tacky during sterilization or, subsequently, during storage for its shelf-life at temperatures not exceeding $40\text{ }^{\circ}\text{C}$.

The plastics container shall be stable biologically, chemically and physically with respect to its contents during its shelf-life and shall not permit penetration of microorganisms. Any substances leached from the container by the anticoagulant and/or preservative solution, blood and blood components by either chemical interaction or physical dissolution, shall be within the limits specified.

In many countries there are national pharmacopoeias, government regulations or standards detailing suitable tests for assessing such chemical or physical interactions. However, if no such regulations are provided, the test methods indicated in table 2 shall be used.

5.2 Physical requirements

5.2.1 Conditions of manufacture

All processes involved in the manufacture, assembly and storage of the plastics container shall be carried out under clean and hygienic conditions in compliance with the appropriate national authorities in accordance with the relevant legislation and international agreements. Every practicable precaution shall be taken at all stages to reduce the risk of adventitious contamination by microorganisms or foreign matter.

5.2.2 Sterilization

5.2.2.1 The plastics container shall have been sterilized by autoclaving or any other method approved by the national control authority.