INTERNATIONAL STANDARD

ISO 3826-1

First edition
2003-11-15

Plastics collapsible containers for human blood and blood components —

Part 1: Conventional containers

Poches en plastique souple pour le sang et les composants du sang — Partie 1: Poches conventionnelles

Reference number
ISO 3826-1:2003(E)

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Published in Switzerland

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 3826-1 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This first edition of ISO 3826-1, together with other parts of ISO 3826 under preparation, cancels and replaces ISO 3826:1993.

ISO 3826 consists of the following parts, under the general title *Plastics collapsible containers for human blood and blood components*:

— *Part 1: Conventional containers*

The following part is under preparation:

— *Part 2: Graphical symbols*

Introduction

In some countries national pharmacopoeias or other government regulations are legally binding and these requirements take precedence over this part of ISO 3826.

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 plastics containers or present in the raw material, as well as full details of any additives that have been used.

Universal leucocyte depletion is mandatory in various countries. This part of ISO 3826 is considered a basic document for future standards which include technical innovations, e.g. integrated leucocyte filters.

The requirements in this part of ISO 3826 are intended to

a) ensure that the quality of blood and blood components is maintained as high as necessary;

b) make possible efficient and safe collection, identification, storage, separation and transfusion of the contents, with special attention to reducing or minimizing the risks resulting from

— contamination, in particular microbiological contamination,

— air embolism,

— errors in identification of plastics containers and any representative samples of contents,

— interaction between the plastics container and its contents;

c) ensure functional compatibility when used in combination with transfusion sets as specified in ISO 1135-4;

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

Plastics collapsible containers for human blood and blood components —

Part 1: Conventional containers

1 Scope

This part of ISO 3826 specifies requirements, including performance requirements, 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 plastics containers may contain anticoagulant and/or preservative solutions, depending on the application envisaged.

This part of ISO 3826 is also applicable to multiple units of plastics containers, e.g. to double, triple, quadruple or multiple units.

Unless otherwise specified, all tests specified in this part of ISO 3826 apply to the plastics container as prepared ready for use.

This part of ISO 3826 is not applicable to plastics containers with an integrated filter.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 1135-4:1998, *Transfusion equipment for medical use — Part 4: Transfusion sets for single use*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
plastics container
container, of plastics material, complete with collecting tube and needle, port(s), anticoagulant and/or preservative solutions and transfer tube(s) and associated container(s), where applicable

3.2
shelf-life
period between the date of sterilization and the expiry date after which the plastics container(s) should not be used for the collection of blood

4 Dimensions and designation

4.1 Dimensions

Figure 1 illustrates the components of a plastics container. The values of the dimensions shown in Figure 1 are binding and form part of the requirements of this part of ISO 3826; the dimensions given in Table 1 are for guidance only.

4.2 Designation example

Plastics containers are designated using the descriptor words “Plastics container” followed by the number of this part of ISO 3826, followed by the nominal capacity of the container, in millilitres. For example, the designation of a plastics container with a nominal capacity of 500 ml in accordance with this part of ISO 3826 is

Plastics container ISO 3826-1 - 500

5 Design

5.1 General

The design and manufacture 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 plastics container shall permit the collection of blood and the preparation of plasma or centrifuged or resuspended cellular components with a minimal hazard of contamination by microorganisms. The plastics 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.

5.2 Air content

5.2.1 The total volume of air contained in the plastics container system divided by the number of containers shall not exceed 15 ml.

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

5.3 Emptying under pressure

The plastics container, when filled with a volume of water at a temperature of (23 ± 5) °C equal to its nominal capacity and connected to a transfusion set as specified in ISO 1135-4 inserted in an outlet port (see 5.8), shall empty without leakage within 2 min when gradually squeezed between two plates to an internal pressure of 50 kPa above atmospheric pressure.

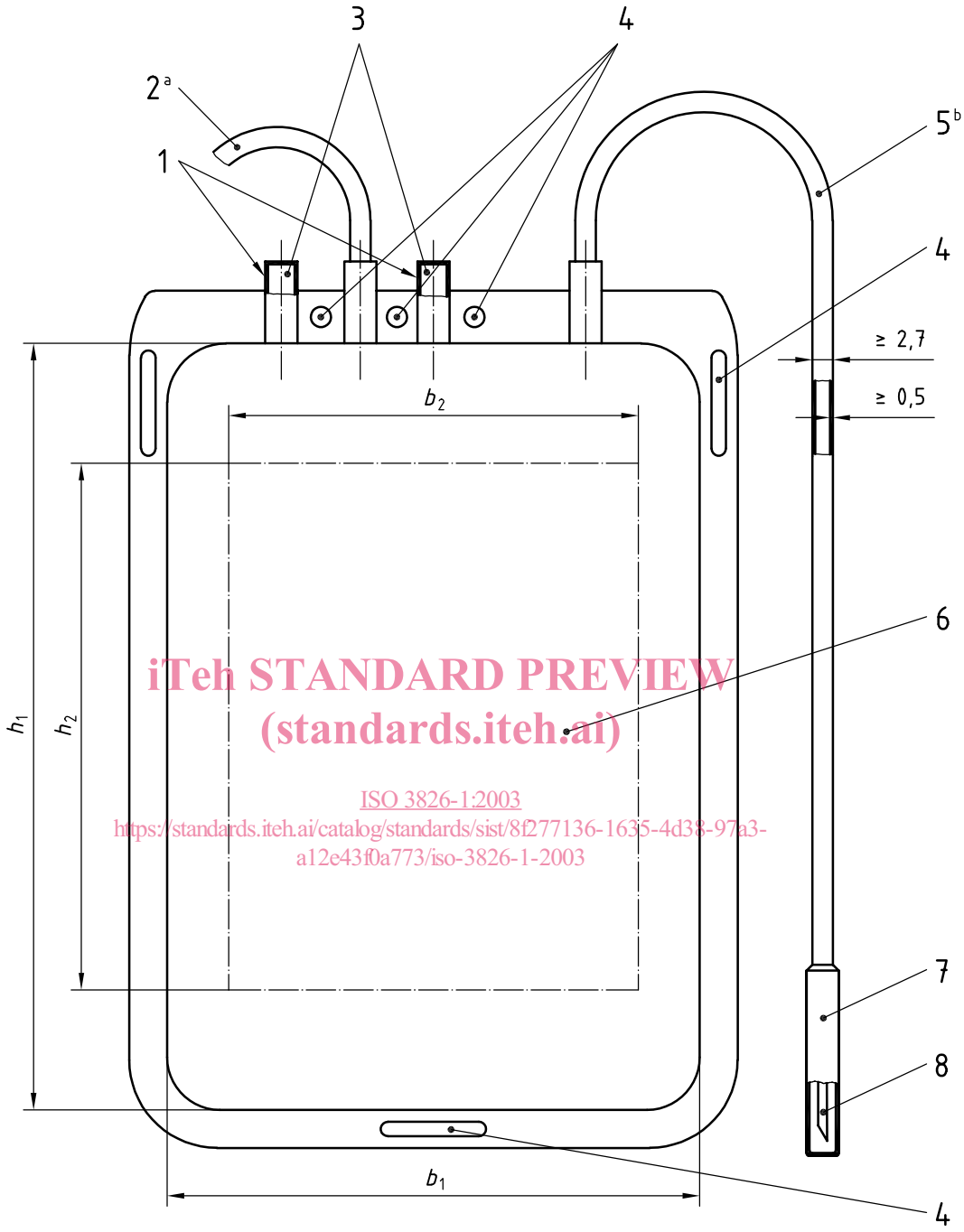
5.4 Pilot samples

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 plastics container being penetrated. This may be accomplished e.g. by using an unmistakable numbering system on the tubing.

5.5 Rate of collection

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.

Dimensions in millimetres



Key

1	protector	5	tube
2	transfer tube, including means of closure (optional)	6	label area
3	outlet port	7	protective cap
4	eyelets	8	blood-taking needle

[a] Length ⩾ 200 mm, internal diameter ⩾ 2,7 mm, wall thickness ⩾ 0,5 mm.

[b] Length ⩾ 800 mm if used for gravitational collection.

See Table 1 for explanation of symbols.

Figure 1 — Schematic representation of plastics container

Table 1 — Recommended dimensions for plastics containers, label areas and nominal capacity

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	105	105
500	120	185	105	105

5.6 Collection and transfer tube(s)

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

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

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

5.6.3 The plastics container, filled with water to its nominal capacity and sealed, and the tubes connected to the plastics container, shall form a hermetic seal and a tight leakproof joint (see Note in 6.2.7) 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 along the longitudinal axis of the plane of the plastics container at a temperature of (23 ± 5) °C.

There shall be no leakage at the junctions and the plastics container shall also conform to the requirements specified in 6.2.7.

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

5.7 Blood-taking needle

The blood-taking needle shall be integral with the collection 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.

The blood-taking needle may contain an anti-needle-stick device.

5.8 Outlet port(s)

5.8.1 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 having a closure-piercing device in accordance with ISO 1135-4 without leakage on insertion or during conditions of use, including emptying under pressure (see 5.3). 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. When used in accordance with manufacturer's instructions, the piercing device shall not damage the plastic film of the plastics container on insertion.

NOTE For the dimensions of the closure-piercing device, see ISO 1135-4.

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

5.9 Suspension

The plastics container shall have adequate means of suspension or positioning (see for example eyelets in Figure 1) which do not interfere with use of the plastics container during collection, storage, processing, transport and administration. The means of suspending or positioning the container shall be capable of withstanding a tensile force of 20 N applied along the longitudinal axis of the outlet port(s) for 60 min at a temperature of (23 ± 5) °C without breaking.

6 Requirements

6.1 General

The plastics container shall be transparent, virtually colourless (see 6.2.4), flexible, sterile, non-pyrogenic, free from toxicity (see 6.4) and non-frangible under conditions of use (see 6.2.5). It shall be compatible with the contents under normal conditions of storage. The plastics container shall meet the requirements for terminal sterilization, and shall not become tacky during sterilization and storage for its shelf-life at temperatures not exceeding 40 °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 plastics container by the contained 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, national pharmacopoeias specify formulations of different plastics materials such as flexible PVC with different plasticizers and other plastics materials, while government regulations or standards may detail suitable tests for assessing chemical or physical interactions.

6.2 Physical requirements

6.2.1 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 regulations, in accordance with 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.

6.2.2 Sterilization

6.2.2.1 The plastics container shall have been sterilized by autoclaving or any other validated method.

6.2.2.2 The method of sterilization used shall not adversely affect the materials or contents, nor cause any loosening of joints and deterioration of welds in the plastics material nor any major alteration in the shape of the plastics container.

6.2.2.3 The manufacturer shall be able to produce evidence acceptable to the national control authority of the effectiveness of the sterilization process actually used. If required by the national control authority, positive controls to check the effectiveness of sterilization shall be included in each sterilization lot.

6.2.3 Transparency

When tested as specified in B.1, the opalescence of the suspension shall be perceptible when viewed through the plastics container as compared with a similar plastics container filled with water.