
**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
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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, and blood processing equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 3826-1:2003), of which it constitutes a minor revision with the following changes:

- [Figure 1](#) on the schematic representation of plastics containers has been updated;
- [Table 1](#) has been amended to include a plastics container with a nominal capacity of 600 ml;
- [subclause 5.6.5](#) on requirements for sterile connection transfer tubing has been added;
- [subclause 5.8.1](#) on the outlet port(s) has been amended by a specification for placement of the septum and by a Note 2;
- [subclauses 5.8.3](#) and [5.8.4](#) on further requirements for the outlet port(s) have been added;
- Clause B.5 on a test for sterile connection of tubing has been added;
- [Annex C](#) on biological tests has been completely revised and shortened in order to incorporate the linkage to the ISO 10993 series;
- the Bibliography has been updated;
- minor editorial changes have been made throughout the whole document.

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

- *Part 1: Conventional containers*
- *Part 2: Graphical symbols for use on labels and instruction leaflets*
- *Part 3: Blood bag systems with integrated features*

The following parts are under preparation:

- *Part 4: Aphaeresis blood bag systems with integrated features*

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 other standards which include technical innovations.

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, <https://standards.iteh.ai/catalog/standards/sist/01cf4521-e13c-401d-9e04-22cd61cf195d/iso-3826-1-2013>
- d) provide a package with appropriate resistance to breakage and deterioration.

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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

ISO 3826-1:2013

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

ISO 1135-4:2012, *Transfusion equipment for medical use — Part 4: Transfusion sets for single use*

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

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization*

ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

ISO 10993-12, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*

3 Terms and definitions

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

3.1

plastics container

bag, 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 3826-1:2013, 500

5 Design

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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.

NOTE Typical plastics container systems are described in ISO 3826-3.

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 $(23 \pm 5) ^\circ\text{C}$ equal to its nominal capacity and connected to a transfusion set as specified in ISO 1135-4 inserted in an outlet port (see [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 compatibility 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

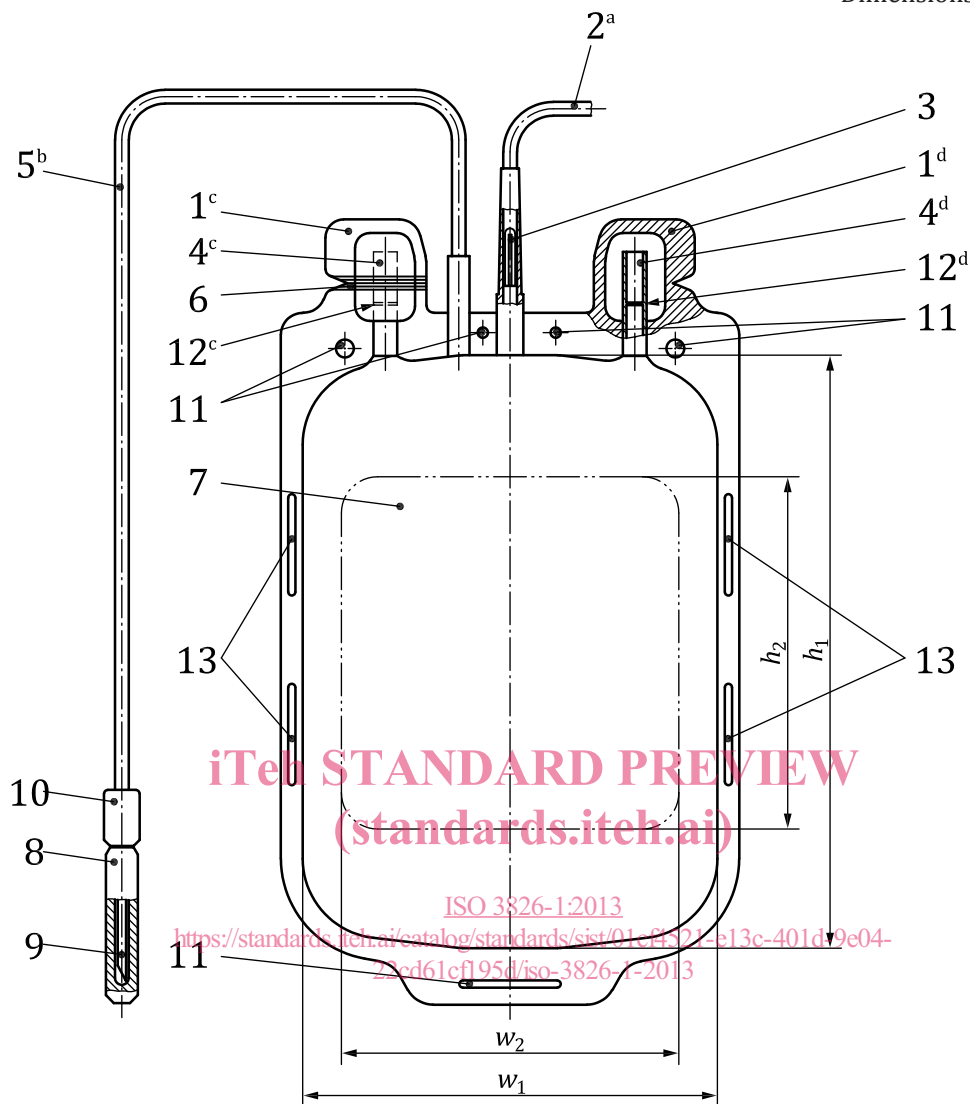
The plastics container shall be designed so that it is capable of being filled to its nominal capacity in less than 8 min when tested in accordance with B.2.

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Dimensions in millimetres



Key

- | | | | |
|---|-----------------------------|----|---------------------------------------|
| 1 | tamper evident protector(s) | 8 | tamper evident protective cap |
| 2 | transfer tube | 9 | blood-taking needle |
| 3 | means of closure (optional) | 10 | needle hub |
| 4 | outlet port(s) | 11 | eyelets |
| 5 | collection tube | 12 | puncturable non-resealable closure(s) |
| 6 | tear line of protector | 13 | side slits |
| 7 | label area | | |
- a Length ≥ 200 mm, internal diameter $\geq 2,7$ mm, wall thickness $\geq 0,5$ mm.
 b Length ≥ 800 mm if used for gravitational collection, internal diameter $\geq 2,7$ mm, wall thickness $\geq 0,5$ mm.
 c External view..
 d Cross-sectional view.

NOTE See [Table 1](#) for explanation of dimensions.

Figure 1 — Schematic representation of plastics container

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

Dimensions in millimetres

Nominal capacity ml	Inside width w_1	Inside height h_1	Size of label area	
			$w_2 \pm 5$	$h_2 \pm 5$
100	75	120	60	85
250	120	130	90	85
400	120	170	105	105
500/600	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, and if necessary to avoid unexpected flow between containers, 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 $(23 \pm 5) ^\circ\text{C}$.

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.

5.6.5 Requirements for sterile connection of transfer tubing: Tubing design shall allow the efficient transfer of blood and blood components between packs. Design should also allow the joining of tubes supplied by a single manufacturer or from different manufacturers using a sterile tube welding device. Typically, this is to enable the connection of separate satellite packs when preparing blood components by a 'secondary process'. Sterile tube welding devices join the two opposing ends of the tube while maintaining a sterile fluid pathway.

Manufacturers of sterile tube welding devices typically specify acceptable tube dimensions (external and/or internal diameter and wall thickness) for use on their equipment. Blood bag manufacturers must specify in their product documentation the material, internal and external diameters, and wall thickness of all their tubing to allow blood transfusion services to assess the suitability for tube welding.

When a blood transfusion service wishes to weld tubing of different specifications, they should carry out a validation before proceeding. A protocol is provided (see Clause B.5) as a minimum standard for such validations (see also Reference[5]).

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 internal and external surfaces of the blood-taking needle shall be clean and smooth. The bevel of the needle shall be sharp and free from ridges, burrs, and barbs.

The joint between the blood-taking needle and the needle hub shall withstand a static tensile (pull) force and compressive (push) force of 20 N for 15 s along the longitudinal axis.

The blood-taking needle may contain a needle-stick protection device in accordance with ISO 3826-3.

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 port septum placed (14 ± 2) mm from the top of the port, 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 1 For the dimensions of the closure-piercing device, see ISO 1135-4.

NOTE 2 When designing the outlet port to ensure good compatibility with closure-piercing devices, manufacturers should avoid the use of tubing that is highly inflexible. Thin-walled tubing (<1 mm) should also be avoided as this tends to twist and collapse on insertion.

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

5.8.3 When a closure-piercing device conforming to ISO 1135-4 is inserted into the blood bag port, this shall resist a pull force of 15 N for 15 s.

5.8.4 When tested in accordance with 5.3, the connection between the closure-piercing device and the blood bag port shall show no evidence of leakage.

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 the 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, biologically safe (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.