
**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,
- d) provide a package with appropriate resistance to breakage and deterioration.

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 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

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.

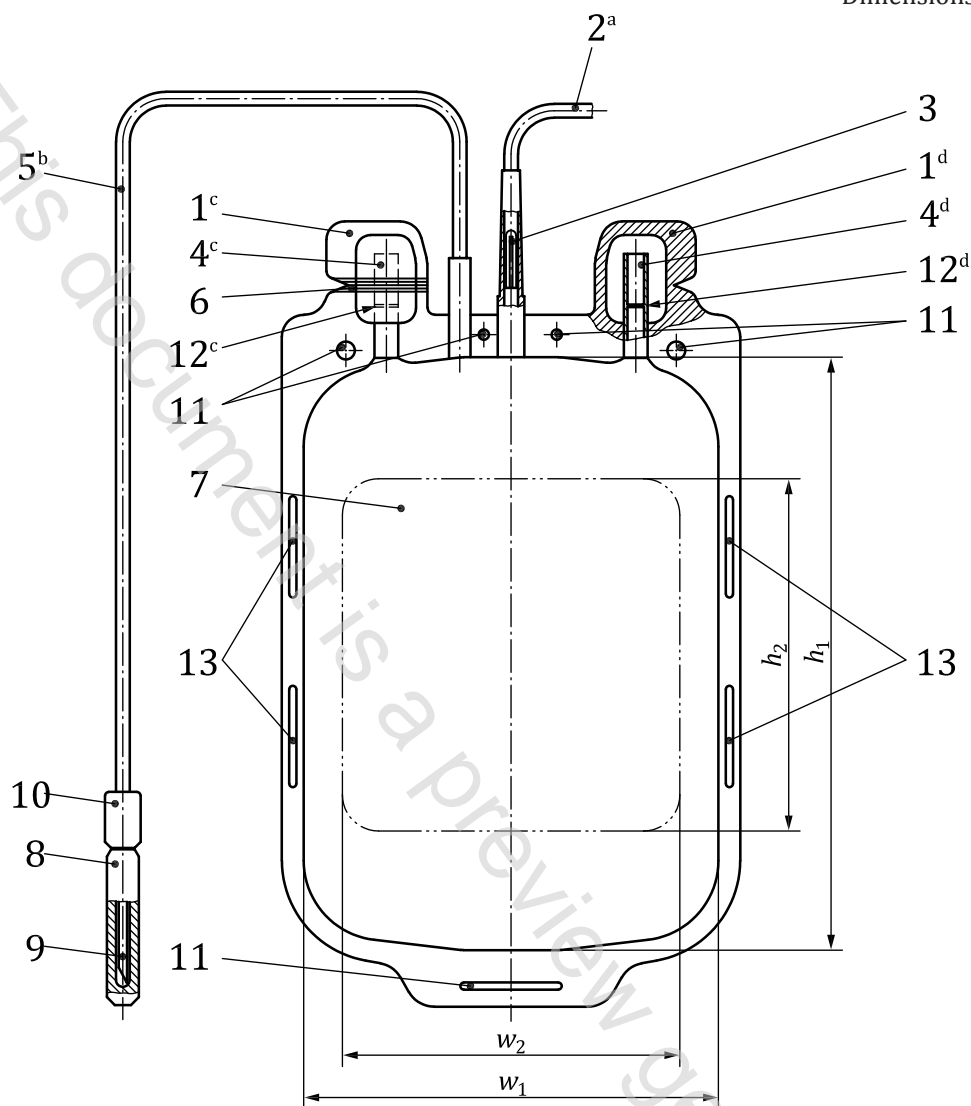
5.4 Pilot samples

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.

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