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Third edition
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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
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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This third edition cancels and replaces the second edition (ISO 3826-1:2013), which has been technically revised.

The main changes compared to the previous edition are as follows:

— in Clause 3 'Terms and definitions' four new entries have been added;

— in Clause 4, the designation example has been removed;

— Clause 5 'Design' has been revised, especially regarding the pilot samples, collection and transfer tube(s), blood-taking needle and outlet port(s);

— the physical requirements in 6.2 have been slightly amended;

— Clause 8 'Labelling' has been reviewed and amended with barcoding information;

— the normative references in Clause 2 and the Bibliography have been updated.

A list of all parts in the ISO 3826 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The manufacturers, or the suppliers, of plastics containers are expected to disclose in confidence to control authorities, 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 document is considered as a basic for other standards which include technical innovations.

The requirements in this document 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 or ISO 1135-5,

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 document specifies requirements, including performance requirements, for plastics collapsible, non-vented, sterile containers (known as plastics 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 can contain anticoagulant and/or preservative solutions, depending on the application envisaged.

This document 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 document apply to the plastics container as prepared ready for use.

This document is not applicable to plastics containers with an integrated filter.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1135-4, *Transfusion equipment for medical use — Part 4: Transfusion sets for single use, gravity feed*

ISO 1135-5, *Transfusion equipment for medical use — Part 5: Transfusion sets for single use with pressure infusion apparatus*

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

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*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

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

3.2
shelf life
<medical device> period between the date of sterilization and the use-by date (expiry date) of the plastics collapsible container for human blood and blood components after which the plastics container shall not be used for the collection of blood

3.3
sheeting
plastics material intended for the production of empty containers

[SOURCE: ISO 15747:2018, 3.12]

3.4
raw container
empty container that has not yet been sterilized and has no identification

[SOURCE: ISO 15747:2018, 3.11]

3.5
empty container
raw container with identification, which is suitable for the acceptance and storage of fluids where applicable and to be used for testing purposes

[SOURCE: ISO 15747:2018, 3.3, modified — "and administration of the injection solution" has been replaced by "of fluids where applicable and to be used for testing purposes".]

3.6
gauge pressure
pressure zero-referenced against local atmospheric pressure

Note 1 to entry: Container internal gauge pressure is:

— positive when the container is pressurized above the surrounding atmospheric pressure, and is

— negative when the container is subjected to suction.

[SOURCE: ISO 15747:2018, 3.4]

4 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 document; the dimensions given in Table 1 are for guidance only.

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 or ISO 1135-5. 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 ± 5) °C equal to its nominal capacity and connected to a transfusion set as specified in ISO 1135-4 or ISO 1135-5 inserted in an outlet port (see 5.8), shall empty without visual leakage (see 6.2.7) within 2 min when gradually squeezed between two plates to a gauge pressure of 50 kPa.

5.4 Pilot samples

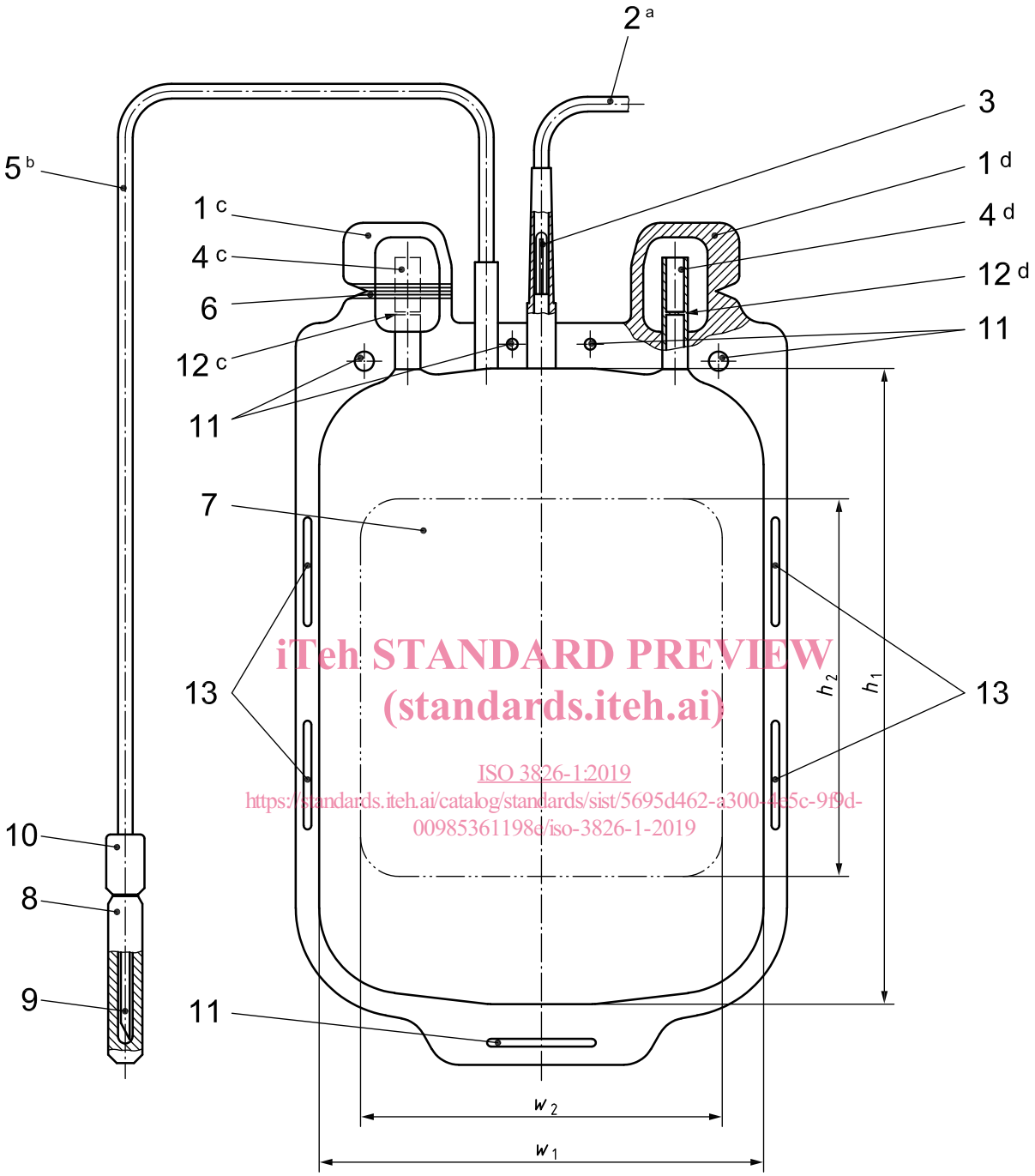
The plastics container shall be designed so that pilot samples of unmistakable identity can be collected for the performance of blood tests in the blood centre without the closed system of the plastics container being penetrated. This may be accomplished, e.g. by using an unmistakable numbering system on the tubing.

The tubing shall be designed so that stripping of the tubing up to 5 times with a tube stripper is possible and if applicable will not remove the existing numbering system when following the plastics containers instruction for use concerning tube stripping.

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)
2 transfer tube
3 means of closure (optional)
4 outlet port(s)
5 collection tube
6 tear line of protector
7 label area
8 tamper evident protective cap
9 blood-taking needle
10 needle hub
11 eyelets
12 puncturable non-resealable closure(s)
13 side slits

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

[b] Length ≥ 800 mm if used for gravitational collection, internal diameter ≥ 2,7 mm, wall thickness ≥ 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 opened, permits the free flow of blood components.

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 tight leakproof connection (see 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 ± 2) °C.

There shall be no leakage at the connection 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 shall 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, a validation should be carried out before proceeding. A protocol is provided (see B.5) as a minimum requirement 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 joint between the needle hub and the connected tubing shall withstand a static tensile (pull) 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 +1/−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 and 1135-5 without leakage (see 6.2.7) 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 Dimensions of the closure-piercing device can be found in ISO 1135-4 and ISO 1135-5.

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 or ISO 1135-5 is inserted into the blood bag port, this shall resist a static pull force of 15 N for 15 s and shall remain in place.

It shall be possible to pierce the insertion point with a closure-piercing device conforming to ISO 1135-4 or ISO 1135-5.

A reference spike is described in ISO 15747:2018, Annex D (metal version).

NOTE ISO/TS 23128[16] provides a general procedure for spike insertion force test method.

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 visible evidence of leakage (see 6.2.7).

