INTERNATIONAL STANDARD

ISO 3826-3

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Plastics collapsible containers for human blood and blood components —

Part 3: Blood bag systems with integrated features

Poches en plastique souple pour le sang et les composants du sang —

Partie 3: Systèmes de poches pour le sang avec accessoires intégrés

Reference number
ISO 3826-3:2006(E)

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Foreword

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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 3826-3 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

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 3: Blood bag systems with integrated features*

Part 2, which will cover the use of graphical symbols, is currently in preparation.

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 or suppliers of the plastic containers are expected to disclose in confidence to the national control authority, if requested by them, full details of the plastic material(s) and the components of the materials and their methods of manufacture, details of the manufacture of the plastic containers including the chemical names and quantities of any additives, whether incorporated by the manufacturer of the plastic 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 —

Part 3:
Blood bag systems with integrated features

1 Scope

This part of ISO 3826 specifies requirements, including performance requirements, for integrated features on plastic, collapsible, non-vented, sterile containers (blood bag systems). Blood bag systems need not contain all of the integrated features identified in this document.

The integrated features refer to:

— leucocyte filter;

— pre-donation sampling device;

— top-and-bottom bag;

— platelet storage bag;

— needle stick protection device.

In addition to ISO 3826-1, which specifies the requirements of conventional containers, this part of ISO 3826 specifies additional requirements for blood bag systems using multiple units. This part of ISO 3826 does not cover automated blood collection systems.

Unless otherwise specified, all tests specified in this part of ISO 3826 apply to the plastic container as prepared ready for use. Use chemical, physical and biological tests in accordance with ISO 3826-1, where applicable.

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 3826-1:2003, *Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3826-1 and the following apply.

3.1
leucocyte filter
LCF
filter used to reduce the content of leucocytes in blood or blood components

3.2
pre-donation sampling device
PDS
device integrated in the donor line of blood bag systems and designed to separate the first volume of donated blood

NOTE The pre-donation sampling device is integrated in the donor line through a Y-piece, such that blood may only flow into the pre-donation sampling device or into the blood bag.

3.3
top-and-bottom bag
TBB
bag containing top-and-bottom inlets and outlets

NOTE The top-and-bottom bag is part of a multiple bag system and is designed to allow centrifugation of anticoagulated whole blood. After centrifugation the plasma is separated through the top and red cell concentrate through the bottom outlet of the bag.

3.4
platelet storage bag
PSB
bag suitable for appropriate storage of a therapeutic dose of platelet concentrates, obtained from a single donation or a pool of donations

NOTE The platelet storage bag can stand alone or be part of a blood bag system.

3.5
needle stick protection device
NPD
device integrated in the donor line of blood bag systems, containing the donor needle, and designed to prevent undesirable needle sticks after use of the donor needle

4 Dimensions and designation

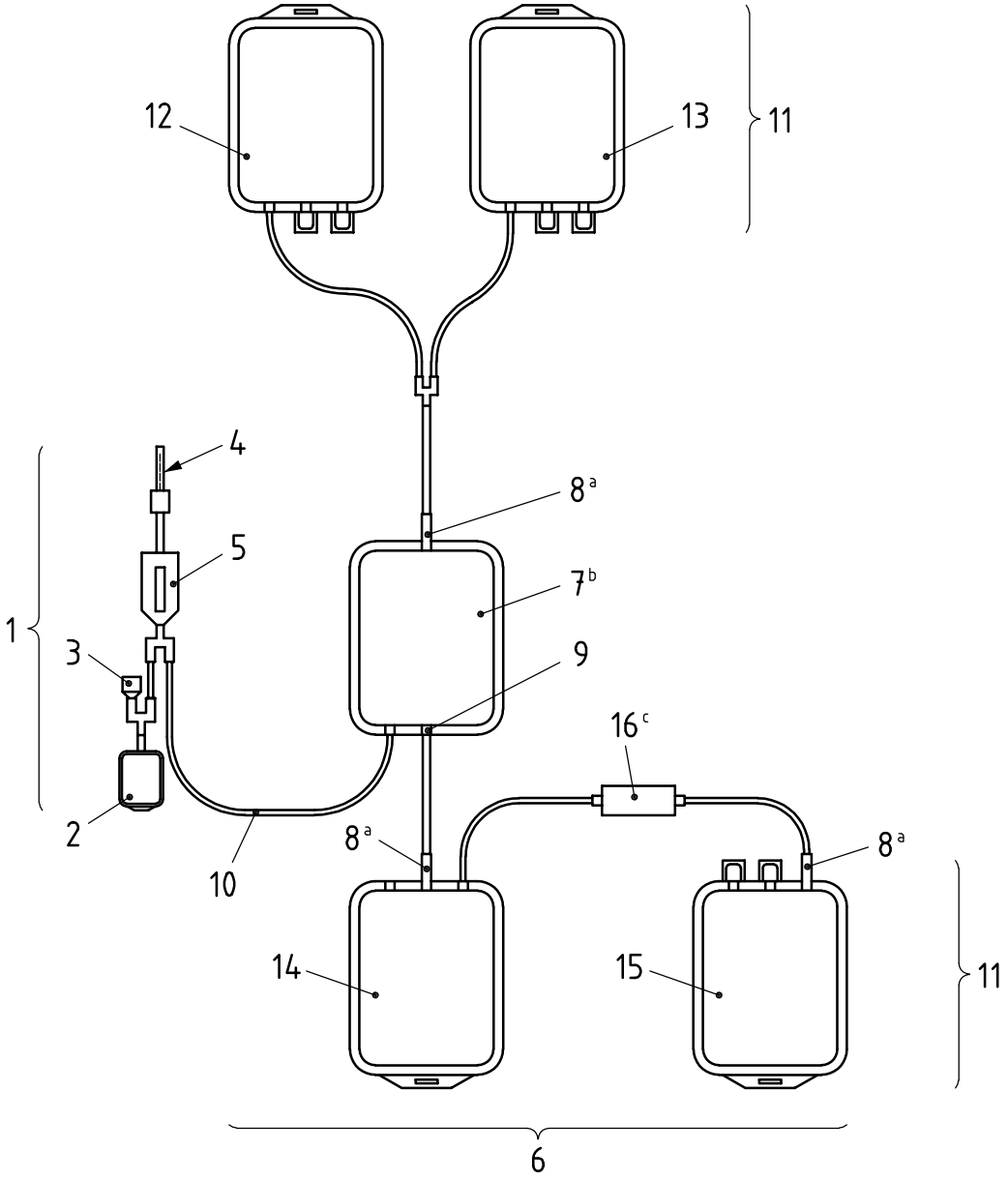
4.1 Dimensions

Figures 1 and 2 illustrate the components of a blood bag system with integrated features. The general drawings and the drawing of each feature are for guidance only. The dimensions shall be in accordance with those listed in ISO 3826-1:2003, 4.1, Figure 1.

4.2 Designation example

Plastics containers are designated using the descriptor words “Plastics container” followed by the number of this part of ISO 3826, in turn followed by the abbreviation of the relevant integrated feature given in Clause 3. For example, the designation of a plastics container with a leucocyte filter in accordance with this part of ISO 3826 is:

Plastics container ISO 3826-3 – LCF



Key

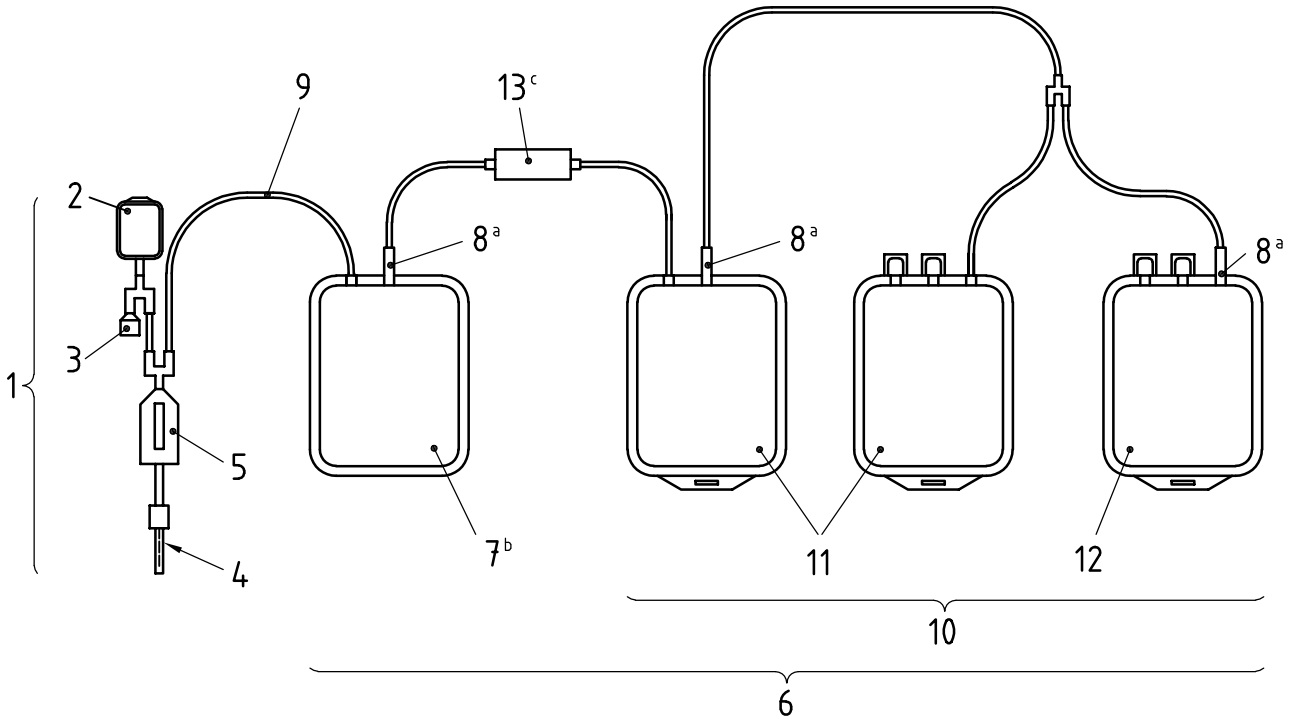
1	pre-donation sampling device (PDS)	9	bottom outlet
2	pre-donation sampling bag	10	collection tube
3	multiple sampling device	11	transfer bags
4	blood-taking needle	12	empty transfer bag
5	needle stick protection device (NPD)	13	platelet storage bag (PSB)
6	blood bag system	14	bottom empty transfer bag
7	top-and-bottom bag (TBB)	15	transfer bag with additive solution
8	(top) outlet	16	leucocyte filter (LCF)

a Means of closure. The means may be positioned at other sites.

b In the present configuration the TBB is the collection container and contains the anticoagulant.

c In the present configuration the LCF is a red cell concentrate filter.

Figure 1 — Schematic representation of components of a blood bag system with integrated features — Top-and-bottom bag system with integrated red cell filter, platelet storage bag and pre-donation sampling device



Key

1	pre-donation sampling device (PDS)	8	outlet
2	pre-donation sampling bag	9	collection tube
3	multiple sampling device	10	transfer bags
4	blood-taking needle	11	empty transfer bag
5	needle stick protection device (NPD)	12	transfer bag with additive solution
6	blood bag system	13	leucocyte filter (LCF)
7	collection bag		

a Means of closure. The means may be positioned at other sites.

b In the present configuration the collection bag contains the anticoagulant.

c In the present configuration the LCF is a whole blood filter.

Figure 2 — Schematic representation of components of a blood bag system with integrated features — Quadruple blood bag system with integrated whole blood filter and pre-donation sampling device

5 Design

5.1 Leucocyte filter

5.1.1 The leucocyte filter is integrated in plastic container(s) as a whole blood filter or a blood component filter. It is designed to reduce the leucocyte content of one whole blood unit or blood component unit. The filters may be designed to work by gravity or pressure filtration at 4 °C or ambient temperature, depending on required specifications.

Leucocyte filters may also be integrated in other transfusion equipment.

Leucocyte filters might be subject to national requirements and standards.

5.1.2 Manufacturers shall give recommendations for the intended use of the leucocyte filters considering parameters including:

— delay between blood collection and leucoreduction;

— capacity of the filter;

— blood filtration temperature;

— filtration height;

— use of pressure;

— suitability for centrifugation.

5.2 Pre-donation sampling device

5.2.1 The pre-donation sampling device shall permit the collection, under aseptic conditions, of a range of donor samples taken into evacuated sample tubes.

5.2.2 If the pre-donation sampling device includes a collection pouch, then its capacity shall be at least 35 ml.

5.2.3 The pre-donation sampling device shall be designed to be filled with a mean flow rate of at least 50 ml/min when tested in accordance with ISO 3826-1:2003, Clause B.2.

5.2.4 Means shall be provided which prevent the return of blood and/or air from the sampling site towards the donor and donation after the filling of the pre-donation sampling device. The means may or may not be integrated.

For collection of specific samples, it may be necessary to avoid the presence of anticoagulant and haemolysis in the pre-donation sample.

5.2.5 Manufacturers shall give recommendations for the optimal use of the pre-donation sampling device.

5.3 Top-and-bottom bag

5.3.1 The top-and-bottom bag usually works with an automatic press system that allows the use of, for example, optical sensors and a residual volume between the top and bottom layer containing a large content of platelets and leucocytes (the buffy coat).

5.3.2 If tubes of top and bottom outlets have different dimensions, on request they shall be provided by the manufacturers.

5.4 Platelet storage bag

5.4.1 Platelet storage bags shall have good gas permeability for both oxygen and carbon dioxide and shall allow storage of platelet concentrates under temperature controlled conditions for several days (under continuous agitation).

5.4.2 Platelet storability is also influenced by number of platelets, volume of platelet concentrate, size of the container and agitation and is usually assessed by observation of swirling and by measurement of pH, hypotonic shock response and aggregation.

5.5 Needle stick protection device

Manufacturers shall give recommendations for the optimal use of the needle stick protection device.

Needle stick protection devices might be subject to national requirements and standards.

5.6 Air content

The air contained in a filter sub-assembly or pre-donation pouch need not be included in the air volume calculation, in accordance with ISO 3826-1:2003, 5.2, if by design or operation of the system such inherent air does not end up in the final collected blood component product.

The air volume limit requirement does apply to other containers, such as the top-and-bottom bag and the platelet bag, when they are utilized as final storage containers within the system.

6 Requirements

Table 1 provides an overview of the requirements given in ISO 3826-1:2003, Clause 6, related to each of the integrated features specified in this part of ISO 3826.

Table 1 — Applicability to ISO 3826-1:2003, Clause 6, requirements, for blood bag systems with integrated features

Requirements (clause and short name in accordance with ISO 3826-1:2003)		Leucocyte filter	Pre-donation sampling device	Top-and-bottom bag	Platelet storage bag	Needle stick protection device
6.1	**General**	Yes [a]	Yes	Yes	Yes	Yes
6.2	**Physical requirements of individual plastic containers and integral features**					
6.2.1	Conditions of manufacture	Yes	Yes	Yes	Yes	Yes
6.2.2	Sterilization					
6.2.2.1	Sterilization method	Yes	Yes	Yes	Yes	Yes
6.2.2.2	Sterilization adverse affect	Yes	Yes	Yes	Yes	Yes
6.2.2.3	Sterilization effectiveness	Yes	Yes	Yes	Yes	No
6.2.3	Transparency	No	Yes	Yes	Yes	No
6.2.4	Coloration	No	Yes	Yes	Yes	No
6.2.5	Thermal stability	No	No	Yes	Yes	No
6.2.6	Water vapour transmission	No	No	Yes	No [b]	No
6.2.7	Resistance to leakage	Yes [c]	Yes [d]	Yes	Yes	No
6.2.8	Particulate contamination	Yes	Yes	Yes	Yes	No
6.3	**Chemical requirements**					
6.3.1	Requirements for the raw container or sheeting	No	Yes [e]	Yes	Yes	No
6.3.2	Requirements for the test fluid	No [f]	Yes [e]	Yes	Yes	No

Table 1 (*continued*)

Requirements (clause and short name in accordance with ISO 3826-1:2003)		Leucocyte filter	Pre-donation sampling device	Top-and-bottom bag	Platelet storage bag	Needle stick protection device
6.4	**Biological requirements**					
6.4.1	General	Yes	Yes	Yes	Yes	No
6.4.2	Impermeability for micro-organisms	Yes [g]	Yes [h]	Yes	Yes	No
6.4.3	Compatibility	Yes	Yes	Yes	Yes	No

[a] Leucocyte filters need not be flexible.

[b] The permeability of the material shall be suitable for supporting viable platelets for the given storage time. See specific requirements for platelet storage bags.

[c] Leucocyte filters shall be able to resist leakage under the maximum pressure exerted by normal working conditions depending on the filter type (i.e. gravity feed at maximum head height or plasma press).

[d] Pre-donation sampling pouch shall be able to withstand pressure test except for centrifugation and 4 °C test.

[e] Applies to container only.

[f] The filter shall fulfil the requirements given in the relevant pharmacopoeias for physiochemical tests for plastics.

[g] The leucocyte filter housing must be impermeable to micro-organisms. The filter is not intended to remove micro-organisms from blood or blood components.

[h] Applies to the contents of the sample pouch only. The transfer tube above the pouch should be permanently sealed before attempting to remove blood through the sample site coupler.

7 Packaging

Table 2 provides an overview of the requirements given in ISO 3826-1:2003, Clause 7, related to each of the integrated features specified in this part of ISO 3826.

Table 2 — Applicability to ISO 3826-1:2003, Clause 7, packaging, for blood bag systems with integrated features

Requirements (clause and short name in accordance with ISO 3826-1:2003)		Leucocyte filter	Pre-donation sampling device	Top-and-bottom bag	Platelet storage bag	Needle stick protection device
7.1	Scope	Yes	Yes	Yes	Yes	Yes
7.2	Shelf life	Yes	Yes	Yes	Yes	Yes
7.3	Over-package materials	Yes [a]	Yes [a]	Yes	Yes	Yes [a]
7.4	Over-package sealing	Yes	Yes	Yes	Yes	Yes
7.5	Over-package strength	Yes	Yes	Yes	Yes	Yes
7.6	Arrangement in over-package	Yes	Yes	Yes	Yes	Yes

[a] Dedicated over-packaging for these integral features is not required.

8 Labelling

Table 3 provides an overview of the requirements given in ISO 3826-1:2003, Clause 8, related to each of the integrated features specified in this part of ISO 3826.

Table 3 — Applicability to ISO 3826-1:2003, Clause 8, labelling, for blood bag systems with integrated features

Requirements (clause and short name in accordance with ISO 3826-1:2003)		Leucocyte filter	Pre-donation sampling device	Top-and-bottom bag	Platelet storage bag	Needle stick protection device
8.1	**General**	Yes	Yes	Yes	Yes	Yes
8.2	**Label on individual containers and integrated features**					
8.2 a)	Contents and use	Optional	Optional	Yes	Yes	No
8.2 b)	Anticoagulant/preservative formulation, collection volume	No	No	Yes	Yes	No
8.2 c)	Statement on sterility and pyrogenicity	No	No	Yes	Yes	No
8.2 d)	Instructions on deterioration	No	No	Yes	Yes	No
8.2 e)	Do not vent instruction	No	No	Yes	Yes	No
8.2 f)	Single use instruction	No	No	Yes	Yes	No
8.2 g)	Reference to instructions for use	No	No	Yes	Yes	No
8.2 h)	Manufacturer/supplier details	No	No	Yes	Yes	No
8.2 i)	Lot designation	Optional	No	Yes	Yes	No
8.3	**Label on blood bag system over-package**					
8.3 a)	Manufacturer/supplier details	Yes				
8.3 b)	Description of contents	Yes [a]	Yes [a]	Yes	Yes	Yes [a]
8.3 c)	Expiry date	Yes				
8.3 d)	Instructions on expiry after removal from over-package	Yes				
8.3 e)	Lot designation	Yes				
8.4	**Label on blood bag system shipping box**					
8.4 a)	Manufacturer/supplier details	Yes				
8.4 b)	Description of contents	Yes				
8.4 c)	Storage conditions	Yes				
8.4 d)	Lot designation	Yes				
8.4 e)	Expiry date	Yes				
8.4 f)	Instructions on expiry after removal from over-package	Yes				

Table 3 (*continued*)

Requirements (clause and short name in accordance with ISO 3826-1:2003)		Leucocyte filter	Pre-donation sampling device	Top-and-bottom bag	Platelet storage bag	Needle stick protection device
8.5	**Specific requirements for individual containers and integrated features**					
8.5 a)	Area for information on manufacturer and use	Optional	Optional	Yes	Yes	No
8.5 b)	Permit visual inspection of contents	Yes	Yes	Yes	Yes	No
8.5 c)	Ensure print does not diffuse	Yes	Yes	Yes	Yes	N/A [b]
8.5 d)	Label print legible at time of use	Yes	Yes	Yes	Yes	N/A [b]
8.5 e)	Suitability of label adhesive	Yes	Yes	Yes	Yes	N/A [b]
8.5 f)	Tamper evidence	Yes	Yes	Yes	Yes	N/A [b]
8.5 g)	Shall pass test according to ISO 3826-1:2003, Clause B.3	N/A [b]	N/A [b]	Yes	Yes [c]	N/A [b]

[a] Shall indicate which integral features are included.

[b] Non-applicable.

[c] Test for permanence of labelling need not include freezing at – 30 °C.

9 Anticoagulant and/or preservative solution

The quality of the anticoagulant and/or preservative solution, if any, shall satisfy the requirements of the national pharmacopoeia and national regulations.

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