
**Plastics collapsible containers for human
blood and blood components —**

Part 3:
**Blood bag systems with integrated
features**

iTeh STANDARD PREVIEW
Poches en plastique souple pour le sang et les composants du sang —
(standards.iteh.ai) **(standard.iteh.ai)**
Partie 3: Systèmes de poches pour le sang avec accessoires intégrés

ISO 3826-3:2006

<https://standards.iteh.ai/catalog/standards/sist/e4e8d5b0-6149-407a-b4e3-5943d6539b69/iso-3826-3-2006>



Reference number
ISO 3826-3:2006(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 3826-3:2006

<https://standards.iteh.ai/catalog/standards/sist/e4e8d5b0-6149-407a-b4e3-5943d6539b69/iso-3826-3-2006>

© ISO 2006

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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 3826-3 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*

[ISO 3826-3:2006](https://standards.iteh.ai/catalog/standards/sist/e4e8d5b0-6149-407a-b4e3-5943d6539b69/iso-3826-3-2006)

— *Part 3: Blood bag systems with integrated features*

<https://standards.iteh.ai/catalog/standards/sist/e4e8d5b0-6149-407a-b4e3-5943d6539b69/iso-3826-3-2006>

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.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[ISO 3826-3:2006](https://standards.iteh.ai/catalog/standards/sist/e4e8d5b0-6149-407a-b4e3-5943d6539b69/iso-3826-3-2006)

<https://standards.iteh.ai/catalog/standards/sist/e4e8d5b0-6149-407a-b4e3-5943d6539b69/iso-3826-3-2006>

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[ISO 3826-3:2006](#)

<https://standards.iteh.ai/catalog/standards/sist/e4e8d5b0-6149-407a-b4e3-5943d6539b69/iso-3826-3-2006>

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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

ISO 3826-3:2006
<https://standards.iteh.ai/catalog/standards/sist/e4e8d5b0-6149-407a-b4e3-5943d6539b69/iso-3826-3-2006>

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

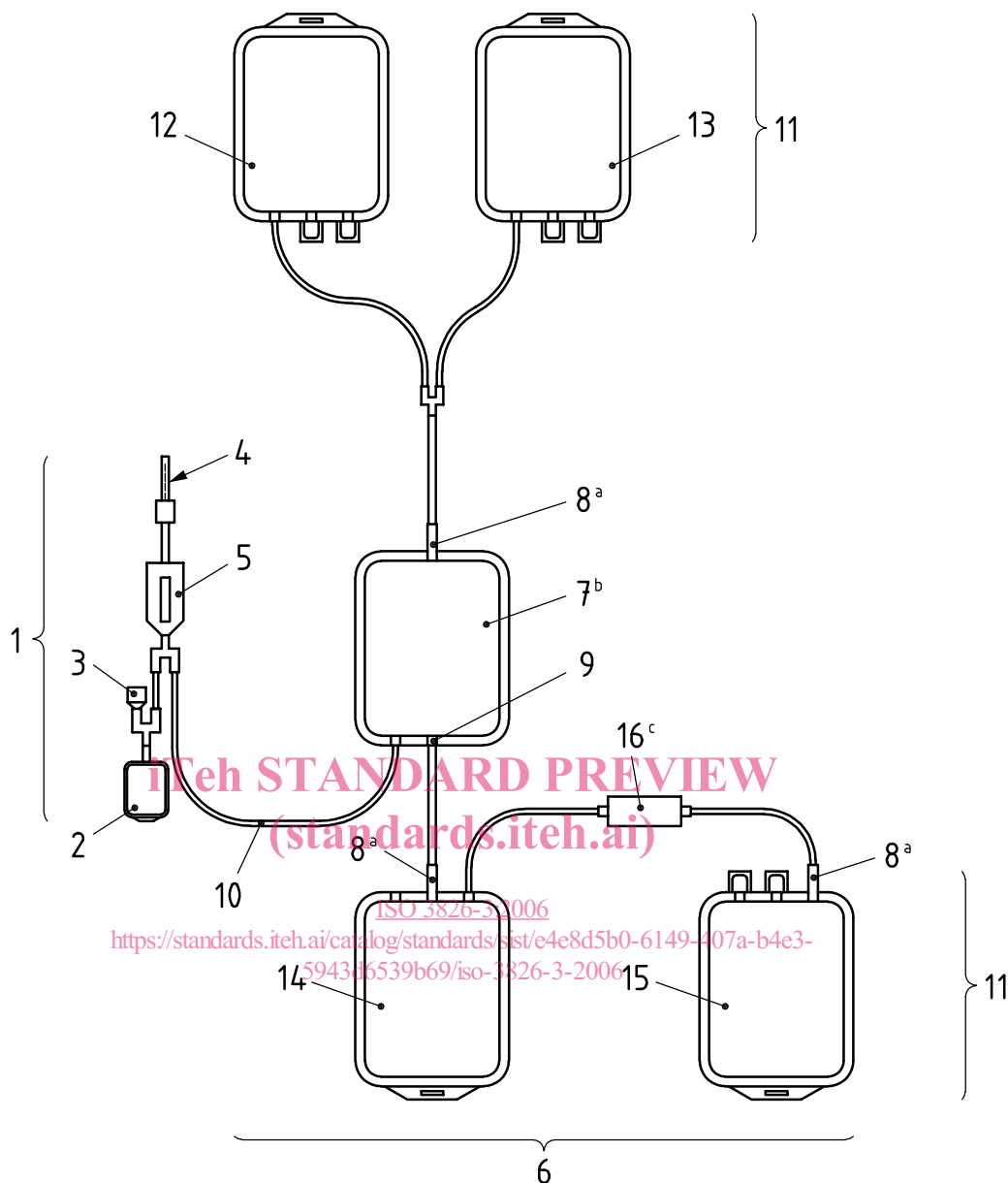
4.1 Dimensions

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

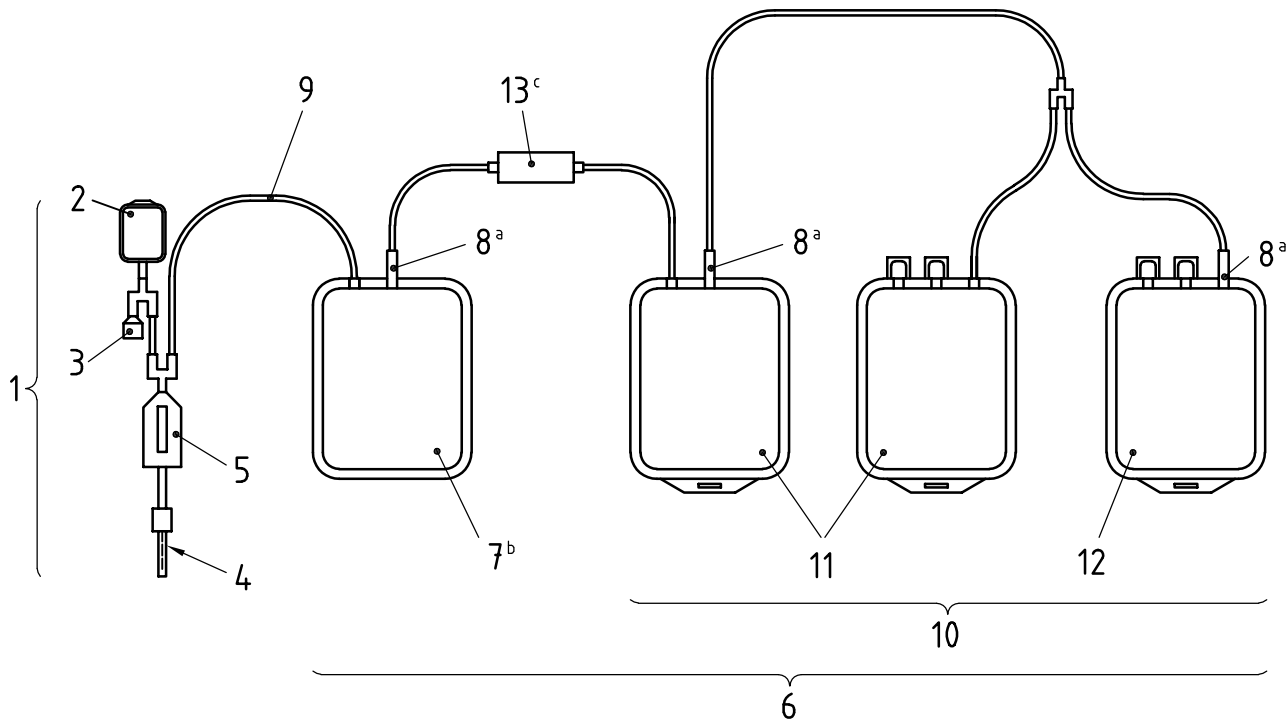
- | | |
|----------------------------------------|----------------------------------------|
| 1 pre-donation sampling device (PDS) | 9 bottom outlet |
| 2 pre-donation sampling bag | 10 collection tube |
| 3 multiple sampling device | 11 transfer bags |
| 4 blood-taking needle | 12 empty transfer bag |
| 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 to 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.