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

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

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

*Partie 4: Systèmes de poches d'aphérèse pour le sang avec
accessoires intégrés*

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Contents

	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Dimensions	4
5 Design	10
5.1 Leucocyte filter	10
5.2 Pilot samples	10
5.3 Access line needle and return line needle	11
5.4 Needle stick protection device	11
5.5 Pre-collection sampling device	11
5.6 Red blood cell storage bag	11
5.7 Plasma storage bag	12
5.8 Platelet storage bag	12
5.9 Post-collection sampling device	12
5.10 Collection and transfer tube(s)	12
5.11 Outlet port(s)	13
5.12 Suspension	13
6 Requirements	13
6.1 General	13
6.2 Physical requirements	14
6.2.1 Conditions of manufacture	14
6.2.2 Sterilization	14
6.2.3 Transparency	14
6.2.4 Coloration	14
6.2.5 Thermal stability	14
6.2.6 Water vapour transmission for plastics containers prefilled with storage solution or anticoagulant	14
6.2.7 Resistance to leakage	15
6.2.8 Insertion force	15
6.2.9 Pull force	15
6.2.10 Leakage after closure piercing	15
6.2.11 Particulate contamination	15
6.3 Chemical requirements	16
6.3.1 Requirements for the raw container or sheeting	16
6.3.2 Requirements for the test fluid	16
6.4 Biological requirements	17
6.4.1 General	17
6.4.2 Impermeability for microorganisms	17
6.4.3 Compatibility	17
7 Packaging	17
7.1 General	17
7.2 Shelf-life	17
7.3 Over-package materials	17
7.4 Over-package sealing	17
7.5 Over-package strength	18
7.6 Arrangement of components in the over-package	18
8 Labelling	18
8.1 General	18
8.2 Label on plastics containers	18

8.3	Label on over-package.....	18
8.4	Package insert or instructions for use.....	19
8.5	Label on shipping box.....	19
8.6	Label requirements.....	20
9	Anticoagulant and/or preservative solution.....	20
Annex A	(normative) Chemical tests.....	21
Annex B	(normative) Physical tests.....	26
Annex C	(normative) Biological tests.....	28
Bibliography	31

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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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](http://www.iso.org/foreword)

The committee responsible for this document is ISO/TC 76, *Transfusion, infusion and injection, and blood processing 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 2: Graphical symbols for use on labels and instruction leaflets*
- *Part 3: Blood bag systems with integrated features*
- *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, and
 - 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 and ISO 1135-5, and
- 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 4: Aphaeresis blood bag systems with integrated features

1 Scope

This part of ISO 3826 specifies requirements including performance requirements for aphaeresis blood bag systems with integrated features. Aphaeresis blood bag systems need not contain all of the integrated features identified in this part of ISO 3826.

The integrated features refer to:

- needle stick protection device;
- leucocyte filter;
- sterile barrier filter;
- pre-collection sampling device;
- red blood cell storage bag;
- plasma storage bag;
- platelet storage bag;
- polymorphonucleic (e.g. stem) cell storage bag;
- post-collection sampling devices; and
- connections for storage solutions, anticoagulant, and replacement fluid.

This part of ISO 3826 specifies additional requirements for blood bag systems used to collect varying quantities of blood components or cells by apheresis. This part of ISO 3826 can be used on automated or semi-automated blood collection systems.

In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this part of ISO 3826.

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 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*¹⁾

ISO 1135-4, *Transfusion equipment for medical use — Part 4: Transfusion sets for single use*²⁾

1) Will be replaced by ISO 80369-7.

2) Will be split up in two parts of which the revised ISO 1135-4 covers transfusion sets for single use, gravity feed and the new ISO 1135-5 covers transfusion sets for single use with pressure infusion apparatus.

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

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

ISO 3826-2, *Plastics collapsible containers for human blood and blood components — Part 2: Graphical symbols for use on labels and instruction leaflets*

ISO 3826-3, *Plastics collapsible containers for human blood and blood components — Part 3: Blood bag systems with integrated features*

ISO 8536-4, *Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed*

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*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 15747, *Plastic containers for intravenous injections*

ISO 23908, *Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling*

3 Terms and definitions

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

3.1
apheresis (apheresis)
process by which blood being removed from a subject is immediately separated into component parts, usually to allow a desired component or components to be retained while the remainder is returned to the subject

3.2
apheresis set
whole apheresis blood bag system with integrated features

Note 1 to entry: Can also be called an apheresis kit or harness.

3.3
centrifugation
process in which circular motion is applied to a chamber about a central axis such that the fluid contents of the chamber are separated according to density where the most dense is towards the outer circumference of motion and the least dense is towards the inner circumference of motion

3.4
connector
component that allows one part of the set to be connected to another

3.5**citrate anticoagulant**

citrate, in the form of sodium citrate or acid-citrate-dextrose, is added to the blood as it is drawn from the subject's circulation and binds or chelates ionised calcium within the blood, thereby, impeding those steps of the coagulation pathway that are dependent on the presence of ionised calcium

3.6**clamp**

device that prevents the flow of fluid through the lumen

Note 1 to entry: These can be locking (permanent) or non-locking (temporary).

3.7**extracorporeal circuit**

path followed by whole blood or blood components when they are outside the subject's circulation

3.8**fluid pathway**

route along which fluids (whole blood, blood components, ancillary intravenous solutions) pass composed of tubing, chambers, *connectors* (3.4) and pressure sensors, and needles

Note 1 to entry: The fluid pathway is constructed to ensure that the fluid within it remains sterile and to ensure that there are no restrictions or obstructions within it that might result in cellular damage or activation of the coagulation cascade.

3.9**leucocyte filter**

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

3.10**pilot sample**

sample of unmistakable identity to be used for testing

3.11**plasma**

blood plasma is a liquid component of blood

Note 1 to entry: It makes up of about 55 % of total blood volume.

3.12**plastics container**

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

3.13**platelets**

platelets or thrombocytes are small, irregularly shaped, clear cells with no nucleus involved in haemostasis leading to the formation of blood clots

3.14**platelet additive solution**

PAS

solution in which *platelets* (3.13) are suspended

3.15**red blood cell additive solution**

RAS

solution added to packed red cells to increase the storage life of red blood cells and prevent haemolysis

3.16

platelet storage bag

PSB

bag suitable for appropriate storage of a therapeutic dose of platelet concentrates obtained from a single donation

3.17

red blood cell storage bag

bag suitable for storage of a therapeutic dose of red cells obtained from a single donation

3.18

pre-collection sampling device

device integrated in the collect line of blood collection systems or aphaeresis disposable sets designed to allow blood samples to be obtained at the beginning of a collection procedure without breaching the sterility of the collected components

Note 1 to entry: Usually incorporates a small reservoir from which the required blood samples are withdrawn. If a skin plug is obtained at the point of venepuncture, it is likely to be trapped in the reservoir rather than being drawn into the collected component(s), thereby, reducing the risk of bacterial contamination of the collected component(s).

Note 2 to entry: Also called PDS (pre-donation sampling device).

3.19

post-collection sampling device

device that can be integrated to allow a blood component sample to be taken, for example, for sterility testing or bacterial screening

3.20

needlestick 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

Note 1 to entry: See ISO 23908.

3.21

replacement fluid

fluid used during an aphaeresis procedure to replace some or all of the blood volume associated with the collected components

3.22

anticoagulant safety connector

connector (3.4) specifically intended for use with *citrate anticoagulant* (3.5) to prevent accidental misconnection of anticoagulant with *replacement fluid* (3.21)

Note 1 to entry: An appropriate ISO standard is under preparation (ISO 18250-8).

3.23

shelf-life

period between the date of sterilization and the expiry date after which the sets should not be used

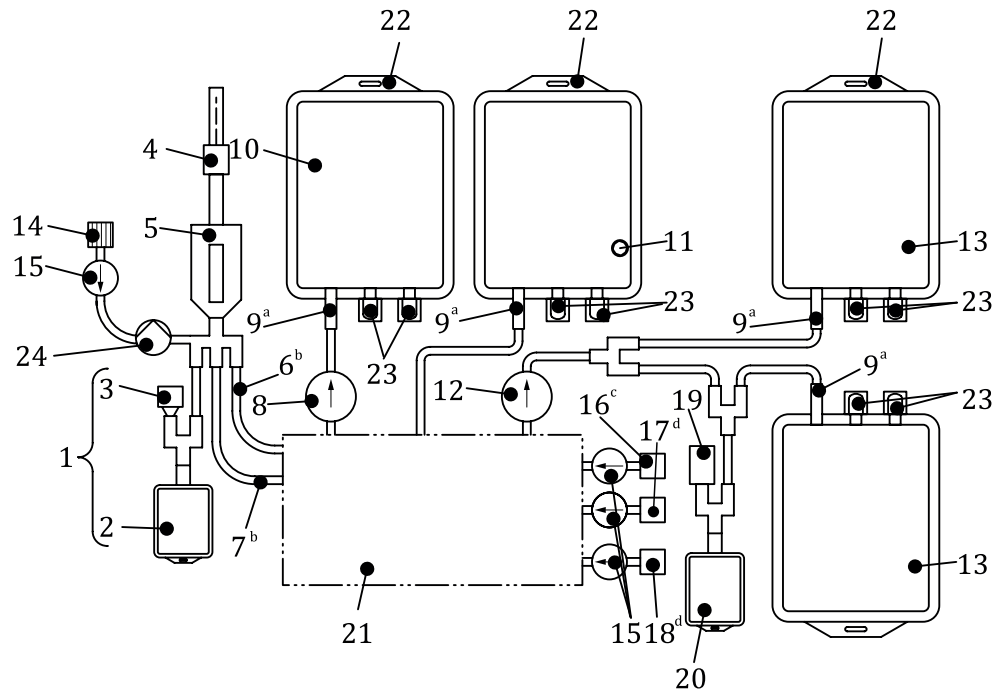
3.24

sterile barrier filter

filter intended to prevent micro-organisms or bacteria from entering a sterile *fluid pathway* (3.8)

4 Dimensions

Figure 1, Figure 2, Figure 3, and Figure 4 illustrate the components of an aphaeresis blood bag system with integrated features. The general drawings and the drawing of each feature are for guidance only.



Key

- | | |
|--|--|
| 1 pre-collection sampling device | 15 sterile barrier filter |
| 2 pre-collection sampling container | 16 replacement fluid line if applicable to the set shall be provided with spike in accordance with ISO 8536-4 or a needle for fluid containers with narrow septums |
| 3 multiple sampling device | 17 red cell additive solution (RAS) connection to the extracorporeal circuit - male luer in accordance with ISO 594-2 |
| 4 access and return line needle (or connection device) | 18 platelet additive solution (PAS) connection to the extracorporeal circuit - female luer in accordance with ISO 594-2 |
| 5 needle stick protection device (NPD) | 19 bacterial sampling port |
| 6 access line to aphaeresis extracorporeal circuit from donor or patient | 20 post-collection sample container |
| 7 return line from aphaeresis extracorporeal circuit to donor or patient | 21 aphaeresis extracorporeal circuit (not covered by this part of ISO 3826) |
| 8 leucocyte filter for red blood cells (LCF) | 22 hanger eyelet |
| 9 inlet port | 23 outlet port |
| 10 red blood cell storage bag | 24 anticoagulant metering pump |
| 11 plasma storage bag | a Means of closure. The means can be positioned at other sites. |
| 12 leucocyte filter for platelets (LCF) | b The position of the lines can be different than depicted. |
| 13 platelet storage bag (PSB) | c Spike design is defined in ISO 8536-4. |
| 14 anticoagulant safety connector for citrate anticoagulant | d Additive (preservative) solution lines are optional and can be different than depicted. |

Figure 1 — Schematic representation of components of a single needle donor aphaeresis blood bag system with integrated features — red cell blood bag with in-line leucocyte filter, platelet storage bag with in-line leucocyte filter, and pre-/post-donation sampling