AS 3787.1—1990

1ST ED.

Australian Standard®

General requirements for single-use, sterile, plasticized polyvinyl chloride (PVC) blood packs for whole blood and blood components

Part 1: Single blood packs

STANDARDS AUSTRALIA

This Australian Standard was prepared by Committee HT/6, Transfusion Equipment for Medical Use. It was approved on behalf of the Council of Standards Australia on 8 March 1990 and published on 17 September 1990.

The following interests are represented on Committee HT/6:

Australian Chamber of Commerce
Australian Medical Devices and Diagnostics Association
Australian Red Cross Society
Australian Society of Anaesthetists
Department of Administrative Services N.S.W.
Department of Community Services and Health
Department of Health, N.S.W.
Department of Health, Qld
Department of Health, Vic.
Department of Veterans Affairs
Health Department, W.A.
Royal Australasian College of Surgeons
Royal College of Pathologists of Australasia
South Australian Health Commission

Additional interests participating in preparation of Standard:

Australian Chemical Industry Council
Commonwealth Serum Laboratories

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PREFACE

This Standard was prepared by the Standards Australia Committee on Transfusion Equipment for Medical Use, under the direction of the Health Technology Standards Board.

This Part of AS 3787 deals with single blood packs whereas Part 2 of the Standard deals with multiple blood pack systems.

The Standard was originally developed by the Commonwealth Therapeutic Goods Standards Committee's Subcommittee on Blood Bags and submitted to Standards Australia as the basis for the development of an Australia Standard suitable for adoption as an Order under the Therapeutic Goods Act 1966.

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STANDARDS AUSTRALIA

Australian Standard

General requirements for single-use, sterile, plasticized polyvinyl chloride (PVC) blood packs for whole blood and blood components

Part 1—Single blood packs

1 SCOPE. This Standard specifies requirements for sterilized, non-vented, collapsible, plasticized polyvinyl chloride (PVC) single blood packs for the collection, storage, transportation and administration of whole blood.

The Standard does not apply to blood bag systems used for the freezing of red cells.

2 REFERENCED DOCUMENTS. The following documents are referred to in this Standard:

AS
1386 Cleanrooms and clean workstations

2103 Dial gauges and dial test indicators (metric series)

2134 Recommended practice for chemical analysis of materials by atomic absorption spectrometry
2134.1 Part 1: Flame atomic absorption spectrometry
2134.2 Part 2: Graphite furnace spectrometry

2145 Hypodermic equipment—Hypodermic needle tubing.

2385 Single-use (sterile) infusion sets for general medical use

CK19 Code of recommended practice for the chemical analysis of materials by ultraviolet visible spectrophotometry

BS
5736 Evaluation of medical devices for biological hazards
Part 4: Method of test for intracutaneous reactivity of extracts from medical devices

British Pharmacopoeia (BP), 1988, Vol. 2, Appendix XIVK, p.A183
British Pharmacopoeia (BP), 1988, Appendix XIII

Therapeutic Goods Order No. 11, Standards for sterile therapeutic goods
Therapeutic Goods Order No. 32, General requirements for labels of therapeutic goods

United States Pharmacopoeia (USP) XXII Monograph 85

3 DEFINITIONS. For the purposes of this Standard the definitions below apply.

3.1 Blood collection pack—a single pack, not connected to any other pack, and having an integral collection tube, needle, needle protector, outlet port and a soft-walled container (bag) containing a solution with anti-coagulant (see Figure 1).

3.2 Outer container—a container to hold one or more blood collection packs.

3.3 Collection tube/cross-matching tube—the tube through which blood is collected from the donor and a means by which blood from the blood collection pack can be sampled.

3.4 Outlet port—blood collection pack outlet with integral tamper-evident closure.

3.5 Suspension device—means by which the blood collection pack can be suspended.

3.6 Water for injections—water of purity satisfying the requirements of the British Pharmacopoeia.

4 DESIGN.

4.1 General. The design of the blood collection pack shall provide for the safe and convenient collection, storage, processing, transportation and administration of whole blood and red cell concentrates.

4.2 Cross-matching. The design of the blood collection pack shall permit the collection of clearly identified samples for laboratory testing without compromising the sterility of the blood collection pack.

5 BLOOD PACK COMPONENTS.

5.1 Tubing. The collection tube shall—

(a) comply with the requirements of Clauses 6.2.1, 6.2.2, 6.2.3, 6.2.4, 6.2.5, and 6.3;

(b) be not less than 2.7 mm in internal diameter;