AS 3864.2—2012

Australian Standard®

Medical refrigeration equipment—For the storage of blood and blood products

Part 2: User-related requirements for care, maintenance, performance verification and calibration

This Australian Standard® was prepared by Committee HE-020, Medical Refrigeration. It was approved on behalf of the Council of Standards Australia on 18 October 2012.
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The following are represented on Committee HE-020:

- Australia and New Zealand Society of Blood Transfusion
- Australian College of Nursing
- Australian Council on Healthcare Standards
- Australian Institute of Refrigeration, Air-conditioning and Heating
- Australian Red Cross Blood Service
- CHOICE
- Institute of Hospital Engineering Australia
- National Association of Testing Authorities Australia
- National Blood Authority
- Queensland Health
- Refrigeration and Air-conditioning Contractors Association of Australia
- Royal College of Pathologists Australasia (RCPA)
- Therapeutic Goods Administration

This Standard was issued in draft form for comment as DR AS 3864.

Standards Australia wishes to acknowledge the participation of the expert individuals that contributed to the development of this Standard through their representation on the Committee and through the public comment period.

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Part 2: User-related requirements for care, maintenance, performance verification and calibration

Originally as part of AS 3864—1991.
Previous edition part of AS 3864—1997.
Revised in part and redesignated as AS 3864.2—2012.

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PREFACE

This Standard was prepared by the Standards Australian Committee HE-020, Medical Refrigeration, to supersede part of AS 3864—1997, *Medical refrigeration equipment—For the storage of blood and blood products.*

The objective of this Standard is to safeguard recipients of blood transfusions by ensuring that blood and blood products are properly and safely stored at the required temperature in refrigeration equipment or walk-in rooms specifically manufactured for the purpose.

The Standard consists of two parts:

Part 1: Manufacturing requirements

Part 2: User-related requirements for care, maintenance, performance verification and calibration (this Standard

The principle differences between this edition and the 1997 edition are as follows:

(a) Separation of the Standard into two parts. Part 1 describes the requirements for manufacturers of medical refrigeration equipment used for storing blood and blood products. Part 2 is intended for the users of this type of equipment and describes the requirements for its care, maintenance, performance verification and calibration.

(b) Recognition of the variety of data management technologies available for acquisition and storage of data from temperature recording devices.

(c) Recognition of advancements in refrigeration system technology.

The term ‘normative’ has been used in this Standard to define the application of the appendix which it applies. A ‘normative’ appendix is an integral part of a Standard.

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Part 2: User-related requirements for care, maintenance, performance verification and calibration

SECTION 1 SCOPE AND GENERAL

1.1 SCOPE

This Standard specifies user-related requirements for the care, maintenance, performance verification and calibration of medical refrigeration equipment used for the storage of the following:

(a) Blood and blood products in the temperature range 2°C to 6°C.

(b) Frozen plasma and plasma products at a temperature of –25°C or lower.

This Standard covers both reach-in cabinets and walk-in rooms. This Standard is intended to be read in conjunction with AS 3864.1. Where the term 'the Standard' is used it refers to both Parts 1 and 2 of AS 3864.

NOTE: In some situations equipment that complies with the Standard may also be required to meet additional regulatory and/or clinical practice requirements. These requirements are outside the scope of the Standard.

1.2 REFERENCED DOCUMENTS

The following documents are referred to in this Standard:

AS	
3864	Medical refrigeration equipment—For the storage of blood and blood products
3864.1	Part 1: For the storage of blood and blood products, and containers for the transport of blood and blood products
AS ISO	
15189	Medical laboratories—Particular requirements for quality and competence
AS/NZS ISO	
9000	Quality management systems—Fundamentals and vocabulary
9001	Quality management systems—Requirements
ISO/IEC	
17025	General requirements for the competence of testing and calibration laboratories

1.3 DEFINITIONS

For the purpose of this Standard, the definitions below apply.

1.3.1 Accuracy

The degree of agreement between a measured value and the accepted reference value.

