

Australian Standard[®]

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

Part 1: Manufacturing requirements



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. This Standard was published on 23 November 2012.

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

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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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Australian Standard[®]

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

Part 1: Manufacturing requirements

Originated as part of AS 3864—1991.
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PREFACE

This Standard was prepared by the Standards Australia 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 (this Standard)

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

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 to which it applies. A ‘normative’ appendix is an integral part of a Standard.

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STANDARDS AUSTRALIA

Australian Standard

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

Part 1: Manufacturing requirements

SECTION 1 SCOPE AND GENERAL

1.1 SCOPE

This Standard specifies requirements for the manufacture of medical refrigeration equipment used within an ambient temperature range of 10°C to 43°C (see Note 1) for the storage of the following:

- (a) Blood and blood products in the temperature range 2°C to 6°C (see Sections 2 and 4);
- (b) Frozen plasma and plasma products at a temperature of –25°C or lower (see Sections 3 and 5)

This Standard covers both reach-in cabinets and walk-in rooms. This Standard is intended to be read in conjunction with AS 3864.2. Where the term ‘the Standard’ is used it refers to both Parts 1 and 2 of AS 3864.

NOTES:

- 1 Where medical refrigeration equipment is intended to be used in an air-conditioned atmosphere, only the ambient temperature range of 10°C to 32°C will be applicable for satisfying the requirements of this Standard, provided there is an adequate back-up electrical supply in case of power failure.
- 2 In some situations equipment meeting the scope of the Standard may also be required to meet additional regulatory requirements. These requirements are outside the scope of the Standard.

1.2 REFERENCED DOCUMENTS

The following documents are referred to in this Standard:

AS

- | | |
|--------|---|
| 1397 | Continuous hot-dip metallic coated steel sheet and strip—Coatings of zinc and zinc alloyed with aluminium and magnesium |
| 1627 | Metal finishing—Preparation and pretreatment of surfaces |
| 1627.0 | Part 0: Method selection guide |
| 2070 | Plastics materials for food contact use |
| 3864 | Medical refrigeration equipment—For the storage of blood and blood products |
| 3864.2 | Part 2: User-related requirements for care maintenance, performance verification and calibration. |
| 60529 | Degrees of protection provided by enclosures (IP Code) |

AS/NZS

- | | |
|--------|---|
| 1677 | Refrigeration systems |
| 1677.1 | Part 1: Refrigerant classification |
| 1677.2 | Part 2: Safety requirements for fixed applications |
| 3100 | Approval and test specification—General requirements for electrical equipment |

AS/NZS

4417 Marking of electrical products to indicate compliance with regulations

4417.1 Part 1: General rules for use of the mark

4417.2 Part 2: Specific requirements for electrical safety regulatory applications

ISO

R 916 Testing of refrigerating systems

1.3 DEFINITIONS

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

1.3.1 Blood pack

A container used to store whole blood or red cell products. The type of blood pack and its volume will depend on the specific blood product it contains.

1.3.2 May

Indicates the existence of an option.

1.3.3 Plasma pack

A soft-walled plastic container ('bag') used to store plasma products either in the liquid or frozen state. The type of plasma pack and volume will depend on the specific plasma product it contains.

1.3.4 Power consumption

The total power input to the refrigeration equipment.

1.3.5 Rated storage capacity

The capacity of the refrigeration equipment as stated by the manufacturer in terms of the number of standard blood packs (volume specification 450 mL $\pm$ 10%) or plasma packs (volume specification 300 mL $\pm$ 10%) able to be stored.

NOTE: The rated storage capacity may vary, depending on the type and volume of blood or plasma packs stored.

1.3.6 Service load capacity

The theoretical number of standard blood packs (volume specification 450 mL $\pm$ 10%) per hour that can be reduced from an entry temperature of 32°C to a storage temperature of 4°C in an ambient temperature of 32°C.

1.3.7 Shall

Indicates a mandatory requirement.

1.3.8 Should

Indicates a recommendation.

1.3.9 Standard blood pack

Blood pack with a volume specification of 450 mL $\pm$ 10%.

1.3.10 Standard plasma pack

Plasma pack with a volume specification of 300 mL $\pm$ 10%.

1.3.11 Ultra-low temperature freezer

A freezer providing a storage temperature of -40°C or below.

1.4 ELECTRICAL SAFETY

The refrigeration equipment shall comply with the relevant requirements of AS/NZS 3100.

1.5 CARE AND MAINTENANCE

Procedures for user-related care, maintenance, performance verification and calibration of medical refrigeration equipment used to store blood and blood products are given in AS 3864.2.

1.6 MARKING

1.6.1 General

In every state or territory of Australia, legislation has been enacted which requires that electrical equipment of a prescribed class or type cannot be marketed unless approved by the relevant approving authority. It may be essential in terms of the legislation that certain classes or types of article be marked with the approvals marking allotted by the relevant authority.

NOTE: Refer also to AS/NZS 4417, Parts 1 and 2.

1.6.2 Cabinet

The cabinet shall be marked in a legible and indelible manner with the following information in a readily accessible position:

- (a) Name or registered trade mark of the manufacturer or distributor.
- (b) Mains power supply voltage(s).
- (c) Rated full load current, in amperes.
- (d) If the use of the refrigeration equipment is limited to either alternating or direct current, it shall be marked 'AC' or 'DC' as appropriate.
- (e) Frequency (if AC).
- (f) Type, model, catalogue and serial number of the equipment or sufficient information to provide adequate identification for replacement parts and necessary servicing.
- (g) International number of the refrigerant used and its mass in kilograms.
- (h) Rated storage capacity.
- (i) Ambient temperature rating.

Additionally it is desirable for the cabinet to be marked with the approvals marking allotted by an approvals authority or regulatory authority, if applicable.

1.6.3 Refrigerated room

The refrigeration unit shall be marked in a legible and indelible manner in accordance with Clause 1.6.2, Items (a) and (g).

The entry door shall be marked with the rated storage capacity and any restrictions in its use, e.g. floor loading.

SECTION 2 SELF-CONTAINED REFRIGERATION EQUIPMENT FOR THE STORAGE OF BLOOD AND BLOOD PRODUCTS IN THE TEMPERATURE RANGE 2 °C TO 6 °C

2.1 SCOPE OF SECTION

This Section specifies requirements of self-contained reach-in refrigerators for the storage of blood and blood products across a range of ambient temperatures and complying with the appropriate requirements of Section 1.

2.2 CONSTRUCTION

2.2.1 External finish

The exterior finish of the cabinet shall be of any of the following materials:

- (a) Stainless steel.
- (b) Aluminium sheet.
- (c) Coated steel conforming to AS 1397.
- (d) Primed metal with corrosion-resistant coating.
- (e) Glass reinforced plastics.

2.2.2 Thermal insulation

Thermal insulation shall be provided. The insulation shall be vapour sealed. The insulation should be of the foamed-in-place type. If slab-type insulation is used, the slab shall be securely bonded to adjacent slabs and to the external and internal linings. Loose insulation shall not be used. A thermal break between the inner and outer surfaces shall be provided.

2.2.3 Internal finish

The interior lining of the cabinet shall be as specified for the external finish (see Clause 2.2.1). In addition, it should be smooth, scratch, stain and corrosion-resistant and of robust construction. It should be capable of being easily cleaned. Any seams shall be sealed by welding or other appropriate processes. Materials used for sealing or construction shall not be degraded by any commonly used sterilizing agents including alcohol.

There shall be no sharp corners, recesses or protrusions where dust or moisture could accumulate.

2.2.4 Shelves, drawers and partitions

Shelves and drawers shall be made of aluminium, stainless steel, or mild steel pre-treated in accordance with the relevant part of AS 1627 (guidance on the series is given in AS 1627.0) coated with a durable food grade, plastic material, the components and processing of which shall comply with AS 2070. Any materials used in the fittings shall be resistant to sterilizing agents, including alcohol.

Shelving shall be an open rack style and be capable of supporting baskets, shelves, drawers and partitions should be adjustable.

All shelves and horizontal partitions shall be capable of sustaining a loading of 100 kg/m² without permanent deformation. Shelves, drawers and partitions shall be smooth with no sharp edges, corners or burrs. Sliding or rotary components shall be capable of their full movement when loaded. Shelf supports should be durable, corrosion-resistant and supported to withstand continuous use.

Shelves, drawers, baskets, hooks and partitions shall be designed to allow adequate circulation of air and to prevent the intrusion of blood packs into areas required for air circulation. They shall also prevent blood packs from contacting the inner surfaces of the cabinet and maintain a minimum air space of 30 mm on all faces to promote correct air circulation.

Shelves, drawers, baskets and partitions shall be readily removable for cleaning and/or sterilization.

2.2.5 Pressure relief devices

A pressure relief device that is capable of relieving any pressure difference between the inside and outside air, shall be provided.

2.2.6 Doors and lids

The cabinet shall be provided with one or more front-opening insulated doors or lids, which shall be of the self-closing type and shall be suitably hinged and fitted with a resilient odourless gasket to form an airtight seal when a door is closed. Hinges shall be securely fixed to the external surface of the cabinet.

Where the fitting of a security lock to a door is either permitted or required by law, a key-operated lock may be fitted to the door of the cabinet. The door shall be easily opened from within when locked or unlocked by a force not greater than 70 N applied to the edge opposite the hinge side in line with the inside surface of the storage space side or, if a permanent obstruction prevents this position from being reached when the door is closed, in line with the edge of the obstruction nearest the hinged side of the door.

NOTE: Refrigeration equipment with lockable doors may be subject to local safety regulations. Approval for such features is outside the scope of the Standard, but should be sought where required.

2.2.7 Access

There shall be either—

- (a) a minimum clearance of 150 mm of the cabinet body or coolroom from the floor for ease of cleaning; or
- (b) the cabinet shall be mounted on adjustable castors.

NOTE: Built-in cabinets need not meet this requirement, provided that the cabinet is sealed to the floor in a watertight manner.

2.2.8 Levelling screws or castors

Where appropriate, means shall be provided for adjusting the level of the cabinet.

2.2.9 Load limits

Load limits restricting the storage height of blood and blood products on the uppermost shelf or drawer of the cabinet shall be clearly, permanently and conspicuously marked so that the marking cannot be readily removed.

Marking shall be either—

- (a) in the form shown in Figure 3.1; or
- (b) a marking with the words ‘Do not load beyond upper shelf/drawer extremities’ or words to that effect, on a readily visible black notice with white lettering 9 mm high.

2.3 LIGHTING

2.3.1 General

Lighting, where fitted, shall be such that the contents of the storage compartment can be seen without reliance on external lighting.

The lighting circuit shall be controlled by either a door-operated switch fitted to each door opening, or a separate on-off switch (in which case an auto-off function is desirable).

NOTE: The lighting should be of a type with low thermal output to minimize heat generation in the refrigerated area.

2.3.2 Lamps and lamp holders

Any lamp and lamp holder incorporated in a cabinet shall be designed, guarded or located so as to be protected against mechanical damage which may arise in the normal use of the cabinet. It is recommended that the use of glass is limited, unless shatter resistant or suitably protected from damage. Fittings shall be capable of being easily cleaned and maintained.

Light fittings shall be of the moisture-proof type and IP56 rated (as described in AS 60529).

2.4 REFRIGERATION SYSTEMS

2.4.1 General

Refrigeration systems shall be designed and constructed in accordance with AS/NZS 1677.1 and AS/NZS 1677.2.

2.4.2 Noise

The refrigeration systems should not produce any undue noise or vibration; the sound pressure level during normal use should not exceed 65 dB(A) when measured at 1.5 m from the source.

2.4.3 Ice-free operation

Where the evaporator is subject to frost accumulation, means shall be incorporated for the automatic removal of frost and the automatic disposal of defrost water.

Under normal operating conditions, condensate trays and fans should allow access for easy cleaning and maintenance purposes.

Under normal operating conditions, the cabinet evaporator shall not progressively accumulate frost or ice over successive defrost cycles.

2.4.4 Forced draught systems

For forced draught systems, automatic defrosting shall be provided and means shall be provided to automatically dispose of water condensate by external vaporization, by electromechanical means or by connection to a drain.

2.4.5 Security of refrigeration controller

The refrigeration controller shall not be readily accessible to unauthorized persons.

2.5 GENERAL CONDITIONS OF TESTING

General conditions of testing shall be in accordance with Appendix A.

2.6 PERFORMANCE REQUIREMENTS

2.6.1 Air circulation and temperature distribution

The air distribution shall ensure there is uniform temperature distribution within the refrigeration space. This should be fully checked during installation.

2.6.2 External surface temperature

When tested in accordance with Appendix B, at an ambient temperature of 32°C, the measured minimum external surface temperature of the cabinet shall be not more than 4°C below the air temperature measured at a distance 50 mm from, and normal to, the surface at that point.

2.6.3 Operation

When tested in accordance with Appendix C, each measured blood pack shall be maintained in the range 2°C to 6°C without any alteration of the thermostat setting having been made throughout the full test sequence.

2.6.4 Service load capacity

When determined in accordance with Appendix D, the service load capacity at 10°C, 32°C and 43°C, as applicable (see Clause 1.1) ambient temperature shall be within 10% of that stated by the manufacturer.

2.6.5 Power consumption

When determined in accordance with Appendix C, the power consumption of the refrigerator shall be within 15% of that stated by the manufacturer.

2.6.6 Compressor operating time

When determined in accordance with Appendix C at an ambient temperature of 32°C or 43°C, as applicable (see Clause 1.1), the compressor operating time shall not exceed 80%.

NOTE: This allowance is to accommodate for defrosting operation and to provide capacity for door openings.

2.6.7 Maximum cycling frequency

When tested in accordance with Appendix C at any condition, cycling frequency shall not exceed six starts per hour.

2.6.8 Heat insulating capacity

When determining in accordance with Appendix E, the time taken for any measured blood pack to reach the temperature of 10°C shall be at least 2 hours from the time the electrical supply is disconnected.

2.7 INFORMATION TO BE SUPPLIED BY THE MANUFACTURER

The following information shall be supplied with each cabinet by the manufacturer:

- (a) Complete operating instructions and installation procedure, including positioning.
- (b) Instructions dealing with general usage, cleaning and maintenance.
- (c) Rated storage capacity of the cabinet, stated as the total number of standard blood packs (volume specification 450 mL $\pm$ 10%) which can be accommodated.
- (d) Power consumption of the refrigerator under maximum load when tested in accordance with Appendix C, at an ambient temperature of 32°C.
- (e) Service load capacity.
- (f) The ambient temperature range in which the refrigerator is designed to be operated.
- (g) Reports and certificates for all testing conducted as per Clause 2.6.

SECTION 3 SELF-CONTAINED REFRIGERATION EQUIPMENT FOR THE STORAGE OF BLOOD PLASMA AND PLASMA PRODUCTS AT OR BELOW -25°C

3.1 SCOPE OF SECTION

This Section specifies requirements for reach-in, chest or upright type freezer for the storage of blood plasma and plasma products at a maximum temperature of -25°C across a range of ambient temperatures and complying with the appropriate requirements of Section 1.

3.2 CONSTRUCTION

3.2.1 External finish

The exterior finish of the cabinet shall be of any of the following materials:

- (a) Stainless steel.
- (b) Aluminium sheet.
- (c) Coated steel conforming to AS 1397.
- (d) Primed metal with corrosion-resistant coating.
- (e) Glass reinforced plastics.

3.2.2 Thermal insulation

Thermal insulation shall be provided. The insulation shall be vapour sealed. The insulation should be of the foamed-in-place type. If slab-type insulation is used, the slab shall be securely bonded to adjacent slabs and to the external and internal linings. Loose insulation shall not be used. A thermal break between the inner and outer surfaces shall be provided.

3.2.3 Internal finish

The interior lining of the cabinet shall be as specified for the external finish (see Clause 3.2.1). In addition, it should be smooth, scratch, stain and corrosion-resistant and of robust construction. It should be capable of being easily cleaned. Any seams shall be sealed, by welding or other appropriate processes. Materials used for sealing or construction shall not be degraded by any commonly used sterilizing agents, including alcohol.

There shall be no sharp corners, recesses or protrusions where dust or moisture could accumulate.

3.2.4 Shelves, drawers and partitions

Shelves and drawers shall be made of aluminium, stainless steel, or mild steel pre-treated in accordance with the relevant part of AS 1627 (guidance on the series is given in AS 1627.0) coated with a food grade, plastic material, the components and processing of which shall comply with AS 2070. Any materials used in the fittings shall be resistant to sterilizing agents, including alcohol.

Shelving shall be an open rack style and be capable of supporting baskets, shelves, drawers and partitions should be adjustable.

All shelves and horizontal partitions shall be capable of sustaining a loading of 100 kg/m^2 without permanent deformation. Shelves, drawers and partitions shall be smooth with no sharp edges, corners or burrs. Sliding or rotary components shall be capable of their full movement when loaded. Shelf supports should be durable, corrosion-resistant and supported to withstand continuous use.

Shelves, drawers, baskets and partitions shall be readily removable for cleaning and/or sterilization.

3.2.5 Pressure relief devices

A pressure relief device that is capable of relieving any pressure difference between the inside and outside air shall be provided.

3.2.6 Lids and doors

3.2.6.1 *For chest type*

The lid shall be spring balanced, insulated and have a gasket seal. The hinges should be robust and set to hold the lid opened in the upright position. When the lid is closed, the gasket shall ensure an airtight seal. The lid shall not be of the self-latching type. The equipment shall comply with any requirements of the relevant regulatory authority.

3.2.6.2 *For upright type*

The requirements for doors are as specified in Clause 2.2.5.

Upright-type devices shall have internal doors to minimize loss of cold air.

3.2.6.3 *Prevention of icing of door gasket*

A heater, for example mullion heater or other suitable method, shall be included on the device to eliminate icing up of the door gasket.

3.2.7 Access

There shall be either—

- (a) a minimum clearance of 150 mm of the cabinet body from the floor for ease of cleaning; or
- (b) the cabinet shall be mounted on adjustable castors.

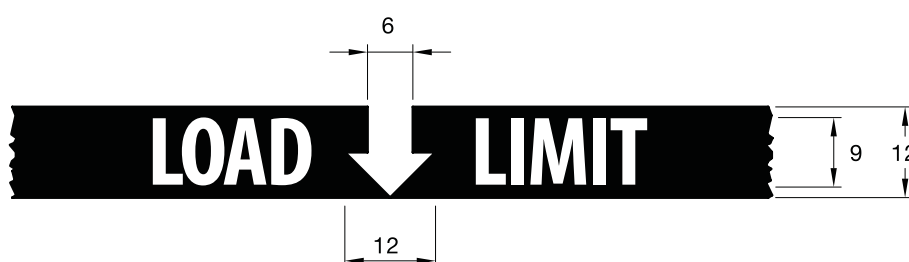
NOTE: Built-in cabinets need not meet this requirement, provided that cabinets are sealed to the floor in a watertight manner.

3.2.8 Levelling screws/castors

Where applicable, means shall be provided for adjusting the level of the cabinet.

3.2.9 Load limits

Load limits for the stacking of frozen plasma shall be clearly, permanently and conspicuously marked so that the marking cannot be readily removed. Marking shall be in the form shown in Figure 3.1, i.e. with black background, white lettering and an arrow marking repeated every 1.5 m.



DIMENSIONS IN MILLIMETRES

FIGURE 3.1 MARKING OF LOAD LIMIT FOR FREEZERS

Where the cabinet is of a type in which the load limit marking specified above may be obscured by frost, one of the following additional markings, on a readily visible black notice with white lettering 9 mm high, shall be provided as appropriate:

- (a) For the chest type, the words ‘Do not load above the top of basket/dividers’, or words to that effect.
- (b) For the upright type, the words ‘Do not load beyond shelf extremities’ or words to that effect.

3.3 LIGHTING

3.3.1 General

Lighting, where fitted, shall be such that the contents of the storage compartment can be seen without reliance on external lighting.

The lighting circuit shall be controlled by either a door/lid-operated switch fitted to each door/lid opening, or a separate switch (in which case an auto-off function is desirable).

NOTE: The lighting should be of a type with low thermal output to minimize heat generation in the refrigerated area.

3.3.2 Lamps and lamp holders

Any lamp and lamp holder incorporated in a cabinet shall be so designed, guarded or located so as to be protected against mechanical damage which may arise in the normal use of the cabinet. It is recommended that the use of glass is limited unless shatter resistant or suitably protected from damage. Fittings shall be capable of being easily cleaned and maintained.

Light fittings shall be of the moisture-proof type and IP56 rated (as described in AS 60529).

3.4 REFRIGERATION SYSTEM

3.4.1 General

The refrigeration system shall be designed and constructed in accordance with AS/NZS 1677.1 and AS/NZS 1677.2. Either static or forced draught systems may be used.

3.4.2 Static system

All surfaces of the internal lining of the chest-type freezer, except the lid, shall be refrigerated.

3.4.3 Forced draught system

For forced draught systems, automatic defrosting shall be provided and means shall be provided to automatically dispose of water condensate by external vaporization, by electromechanical means or by connection to a drain.

3.4.4 Ice-free operation

Where the evaporator is subject to frost accumulation, means shall be incorporated for the automatic removal of frost and the automatic disposal of defrost water.

Under normal operating conditions, condensate trays and fans should allow access for easy cleaning and maintenance purposes.

Under normal operating conditions, the cabinet evaporator shall not progressively accumulate frost or ice over successive defrost cycles.

3.4.5 Noise

The refrigeration system should not produce any undue noise or vibration; the sound pressure level during normal use should not exceed 65 dB(A) when measured at 1.5 m from the source.

3.4.6 Refrigeration control device

The refrigeration control device shall not be readily accessible to unauthorized persons.

3.5 GENERAL CONDITIONS OF TESTING

General conditions of testing shall be in accordance with Appendix A.

3.6 PERFORMANCE REQUIREMENTS

3.6.1 Air circulation and temperature distribution

The satisfactory distribution of air and uniform temperature distribution within the refrigerated space is a prime requisite and should be fully checked during installation.

3.6.2 Product temperature

When tested in accordance with Appendix F, the temperature reached by any test plasma pack shall not be higher than -25°C , inclusive of the defrost cycle.

3.6.3 Power consumption

When determined in accordance with Appendix F, the power consumption of the refrigeration equipment shall be within 15% of that stated by the manufacturer.

3.6.4 Operation

When tested in accordance with Appendix F, each measured plasma pack shall be maintained at or below -25°C without any alteration of the thermostat setting having been made throughout the full test sequence.

3.6.5 External surface temperature

When tested in accordance with Appendix G at an ambient temperature of 32°C , the measured external surface temperature of the cabinet shall be not more than 6°C below the air temperature measured at a distance 50 mm from and normal to the surface at that point.

3.6.6 Compressor operating time

When tested in accordance with Appendix F at an ambient temperature of 32°C or 43°C as applicable (see Clause 1.1), the compressor operating time shall not exceed 80%.

NOTE: This requirement only applies to equipment with automatic defrosting systems.

3.6.7 Maximum cycling frequency

When tested in accordance with Appendix F, the number of starts shall not exceed six per hour at any condition.

3.6.8 Heat insulating capacity

The temperature rise from -25°C of any measured plasma pack in the freezer, loaded to half its rated storage capacity, shall not exceed 5°C in one hour from the time the electrical supply is disconnected, measured in an ambient temperature of 32°C .

3.6.9 Service load capacity

When determined in accordance with Appendix D, the service load capacity at 10°C , 32°C and 43°C , as applicable (see Clause 1.1) ambient temperature shall be within 10% of that stated by the manufacturer.

3.7 INFORMATION TO BE SUPPLIED BY THE MANUFACTURER

The following information shall be supplied with each cabinet by the manufacturer:

- (a) Complete operating instructions, installation procedure including positioning.
- (b) Instructions dealing with general usage, loading, cleaning and maintenance.
- (c) Rated storage capacity of the cabinet, stated as the total number of standard plasma packs (volume specification 300 mL $\pm$ 10%) which can be accommodated.
- (d) Power consumption of the freezer under maximum load when tested in accordance with Appendix F, at an ambient temperature of 32°C.
- (e) The ambient temperature range in which the freezer is designed to be operated.
- (f) Reports and certificates for all testing conducted as per Clause 3.6.

SECTION 4 WALK-IN TYPE COOLROOMS FOR THE STORAGE OF BLOOD AND BLOOD PRODUCTS IN THE TEMPERATURE RANGE 2 °C TO 6 °C

4.1 SCOPE OF SECTION

This Section specifies requirements for walk-in type coolrooms for the storage of blood and blood products in the temperature range 2°C to 6°C across a range of ambient temperatures and complying with the appropriate requirements of Section 1.

4.2 CONSTRUCTION

4.2.1 General

The construction of the coolroom should be such that it is structurally adequate for sustaining all normal loadings due to system operation.

NOTE: During commissioning, any undue structural stress can be avoided if the room is cooled to the final operating temperature at a rate of not more than 8°C per day.

4.2.2 Crash barriers

Crash barriers shall be fitted to the walls and any door entrances where they may be exposed to damage to the interior and exterior finishes.

4.2.3 Joints

To prevent the movement of air or water vapour, joints shall be vapour sealed. The seal shall be completely non-porous to withstand cleaning. Materials used for sealing shall not be degraded by any commonly used sterilizing agents. All joints and seams within the coolroom shall be sealed to prevent entry and accumulation of potentially contaminating substances.

4.2.4 External finish

The exterior finish of the coolroom should be smooth, corrosion-resistant and easy to clean.

4.2.5 Thermal insulation

Thermal insulation shall be provided. The insulation shall be vapour sealed. The insulation should be of the foamed-in-place type. Slab-type insulation shall be securely bonded to both external and internal linings and to each other. Loose insulation shall not be used. A thermal break between the inner and outer surfaces shall be provided. Any heaters installed to prevent condensation shall be readily accessible for service.

4.2.6 Internal finish

4.2.6.1 Walls and ceiling

The interior lining of the wall and ceiling of the coolroom should be smooth, scratch-, stain- and corrosion-resistant, be of robust construction and should be capable of being easily cleaned. There shall be no sharp corners, recesses or protrusions where dust or moisture could accumulate. Any seams shall be sealed. Materials used for sealing or construction shall not be degraded by any commonly used sterilizing agents including alcohol.

4.2.6.2 Flooring

Flooring shall be insulated, vapour sealed and resistant to thermal shock. Flooring shall be designed for its intended load. If the intended loads are unknown, flooring shall withstand—

- (a) a minimum pressure of 15 kPa for storage heights of up to 3 m high;