



TITLE: Vaccine ultra-low temperature freezer compression cycle

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1. Scope

This specification defines the requirements for compression-cycle [ultra-low temperature \(ULT\) freezers](#) for vaccine storage at very cold temperatures. Three temperature zone designations are described: [hot zone](#), [moderate zone](#) and [temperate zone](#). It is anticipated that some ULT freezers may have to operate in a temperature controlled or an air-conditioned environment.

To assess whether an appliance meets this specification, it should be tested to verification protocol **WHO PQS E003/ULT01-VP.1**. The appliance should be tested in the warmest climate zone (air-conditioned or otherwise) for which it is designed.

Appliance design must account for performance degradation over the 10-year target life of the appliance in order to sustain designed freezer temperature and other appliance features (if included).

In addition, WHO PQS has identified an essential need for a robust power system to support the ULT freezer and any air conditioning system in the room where the ULT

freezer will be situated. Please refer to **WHO PQS E003/POW 01.0** for the requirements for a power system specification intended to provide [continuous electricity](#) to sustain operation of [ULT](#) systems that may include any or all of the following electricity consuming [load](#) devices: including [ULT](#) vaccine freezers, standard water-pack freezers, vaccine refrigerators, equipment monitoring systems (EMS), lighting, communications, office devices, ventilation and space cooling.

2. Terms and definitions

[Cool-down time](#): the time to reach stability from first switch-on.

[Continuous electricity](#): a power system which meets the requirements of WHO PQS E003/POW 01.0 intended to sustain operation of an [ULT](#) appliance and associated systems. This includes [ULT](#) vaccine freezers, standard water-pack freezers, vaccine refrigerators, equipment monitoring systems (EMS), lighting, communications, office devices, ventilation and space cooling.

[Gross volume](#): the measured volume of the airspace inside the internal compartment of the appliance with the door or lid shut.

[Freezer temperature](#): the warmest internal temperature that the freezer actually achieves in use¹. The freezer should not be warmer than this temperature +1°C. If more than one freezer temperature is possible by means of varying the control setting(s), the setting tested according to this verification protocol is the freezer temperature that will be prequalified.

[Holdover time](#): the time in hours during which all points in the vaccine or water-pack freezing compartment of the freezer remain within 30 degrees² warmer than the freezer internal temperature after the power supply has been disconnected.

[Hot zone](#): hot zone appliances must operate at a steady +43°C ambient temperature and over a +43°C/+25°C day/night cycling temperature range.

[In writing](#): communication by letter, fax or email.

[Legal manufacturer](#): the natural or legal person with responsibility for the design, manufacture or integration of components, packaging and labeling of a product or device before it is placed on the market under their own name, regardless of whether these operations are carried out by that person themselves or on their behalf by a third party.

[Moderate zone](#): moderate zone appliances must operate at a steady +27°C ambient temperature and over a +27°C/+10°C day/night cycling temperature range.

Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.

[Reseller](#): a commercial entity, licensed to act on behalf of a legal manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the legal manufacturer.

[Stable conditions](#): the temperature is stable when there is no marked trend or drift away from the mean temperature of a 24-hour measurement. If the temperature is cycling, it should repeat within 0.5°C during the periodicity. After stability, the appliance should exhibit manufacturer's stated holdover time. Note that temperature stability and compressor stability may not occur at the same time.

[Temperate zone](#): temperate zone appliances must operate at a steady +32°C ambient temperature and over a +32°C/+15°C day/night cycling temperature range.

¹At the time of drafting this protocol, precise storage requirements are not known and may vary for different vaccines. For example, if the freezer is set to achieve -80°C, everywhere in the vaccine storage space should be no warmer than -79°C.

²NOTE: This does imply that a vaccine can tolerate a 30-degree temperature increase. The [holdover time](#) is an indication of the insulation quality so that for example, different models can be compared.

[Ultra-low temperature \(ULT\) freezer](#): a vaccine freezer that complies with equipment performance specification E003/ULT01.1.

[User-intervention](#): any activity that is required to be executed by appliance users. Activities include, but are not limited to, thermostat adjustment and defrosting.

[Vaccine storage capacity](#): the volume where it is suitable (both thermally and ergonomically) to store vaccines. Everywhere within this volume must be at the freezer temperature or colder. Where a manufacturer declares more than one vaccine storage capacity for the same gross volume and external dimensions, the manufacturer must prequalify, with different branding, one model for each different storage capacity.

3. Normative references

Use most recent version.

EMAS: European Union Eco-Management and Audit Scheme.

EN ISO 6270-1 / ASTM D2247 / EN 13523-26: Determination of resistance to humidity – Part 1: Continuous condensation.

EN ISO 6270-2 / EN 13523-25: Determination of resistance to humidity – Part 2: Procedure for exposing test specimens in condensation-water atmospheres. GHS Rev 5. United Nations: Globally Harmonized System of Classification and Labelling of Chemicals.

IEC 60335-1: Amendment 1: Household and similar electrical appliances - Safety - Part 1: General requirements.

IEC 60335-2-24: 2007: Household and similar electrical appliances - Safety - Part 2-24: Particular requirements for refrigerating appliances, ice-cream appliances and ice-makers.

IEC 60364-1: 2005: Low-voltage electrical installations - Part 1: Fundamental principles, assessment of general characteristics, definitions.

IEC 61000-6-1 edition 2.0: 2005: Electromagnetic compatibility (EMC) Generic standards - Immunity for residential, commercial and light-industrial environments.

IEC 61000-6-3 edition 2.1: 2011: Electromagnetic compatibility (EMC) Generic standards - Emission standard for residential, commercial and light- industrial environments.

IEC 62552: 2007: Household refrigerating appliances – Characteristics/tests.

ISO 2409: 2013: Paints and varnishes – cross cut test (external cabinet).

ISO 6272 / EN 13523-5: Impact resistance - external cabinet.

ISO 9001: Quality Management Systems – Requirements.

ISO 14001: 2004: Environmental management systems - Requirements with guidance for use.

ISO 20282-1: 2006: Ease of operation of everyday products - Part 1: Context of use and user characteristics.

ISO/IEC 17025: 2017: General requirements for the competence of testing and calibration laboratories.

4. Requirements

4.1 General

An [ultra-low temperature freezer](#) is set to achieve a specified internal temperature. The precise internal temperature depends on vaccine storage requirements. Manufacturers may offer products which can be set to achieve one or more internal temperatures and which are suitable for one or more climate zones.

4.2 Performance

4.2.1 *Operating temperature range*

As indicated on the temperature zone rating sticker attached to the product (see **Annex 1**).

4.2.2 *Refrigeration system*

Cooling-cycle system operating on alternating current or direct current electricity cooling using a direct or indirect system.

4.2.3 *Voltage and frequency*

220-240-volt 50/60 Hz, 100-127-volt 50/60 Hz or low voltage d.c. options must be offered. Performance must be identical for all options, regardless of the nominal voltage and frequency rating of the appliance.

4.2.4 *Power supply*

To ensure a continuous power supply to the appliance and to any air-conditioning essential for good performance of the appliance, a dedicated system in accordance with **WHO PQS E003/POW 01.0** must be provided.

4.2.5 *Space not suitable for vaccine storage*

Internal space outside the correct internal temperatures e.g. space which is too warm, must be excluded from use by design.

4.2.6 *Temperature control*

The temperature control shall achieve the correct internal temperature for the intended vaccine storage. The vaccine load must remain at, or colder than the [freezer temperature](#) +1°C during any continuous ambient temperature test(s) or day/night cycling temperature test(s). Eutectic packs, if supplied, must remain in situ and not be accessible to the user. If more than one setting is possible, the setting tested according to the verification protocol is the [freezer temperature](#) that will be prequalified.

4.2.7 *Thermometer*

Externally readable cabinet-mounted electronic thermometer conforming to PQS specification **E006/TH06.2** but calibrated at least down to -80°C or the specified [freezer temperature](#).

4.2.8 *Cool-down time*

No standard set; however, performance data will be published.

4.2.9 Holdover time

No standard set; however, performance data will be published.

4.2.10 Starting voltage

10 out of 10 cold appliance starts at a voltage at least as low as 10% below manufacturers stated voltage³ must all be successful.

4.2.11 Power consumption

No standard set; however, results will be reported and listed in the product information sheet in kWh/day.

4.2.12 Evaporator configuration

If the evaporator is mounted in shelves there must be adequate protection to ensure the evaporator cannot be damaged in general use, e.g. from the insertion and removal of storage bins or trays, or from manual defrosting.

4.2.13 Corrosion resistance

The [legal manufacturer](#) must declare compliance that all internal and external components are protected against corrosion as appropriate to **EN ISO 6270-1 / ASTM D2247 / EN 13523-26, EN ISO 6270-2 / EN 13523-25, ISO 6272 / EN 13523-5 and ISO 2409:2013**. It should be expected that the skin and other parts of the appliance will be subject to condensate when operating in a warm humid environment. Critical components such as thermostatic controls and displays must not be vulnerable to any moisture. Evidence for compliance to this clause shall be demonstrated.

4.2.14 Electrical safety rating

Electrical safety: The [legal manufacturer](#) must declare compliance with **IEC 60335-1, IEC 60335-2-24** or equivalent standard as appropriate. Evidence for compliance to this clause shall be demonstrated.

4.2.15 EMC compliance

The [legal manufacturer](#) must declare EMC compliance with the latest edition of **IEC 61000-6-1 and IEC 61000-6-3**. Evidence for compliance to this clause shall be demonstrated.

4.2.16 Markings

Compressors must be marked with the blue identifying symbol shown in **Annex 2**. In addition, the freezer cabinet must be permanently marked, near the compressor position, with the chemical name of the refrigerant, or with the refrigerant number, amount of refrigerant formula or proportion (for blended refrigerants).

³For a continuous power system, the appliance will be operating on the manufacturer's rated voltage but on those rare occasions where this cannot be maintained, some tolerance in the appliance is desired.

4.2.17 Rating plate

There should be an external rating plate showing the following information:

- model number or ID
- serial number
- required voltage and frequency
- minimum VA rating required
- compatible types of voltage stabilizer
- climate zone(s)
- chemical name of the refrigerant, or the refrigerant number
- amount of refrigerant formula or proportion (for blended refrigerants)
- type of insulation
- vaccine storage volume.

4.2.18 Vaccine storage advice

All units must carry a factory-fitted non-removable label, designed to last the lifetime of the appliance, carrying the following information:

- vaccine freezers: vaccine storage instructions and the appropriate temperature zone symbol as **Annex 1**
- health and safety procedures
- a notice that PCMs or water packs should not be stored in the appliance at the same time.

The instructions should be fixed to the lid of chest freezers and near the top of the door on upright freezers. Instructions should be in one of the languages specified in Clause 4.12, as indicated by the purchaser at the time of ordering.

4.3 Environmental requirements

Ambient temperature range during transport, storage and use:

- -30°C to +70°C when the product is inactivated.
- -30°C to +50°C when the product is activated in use.

Ambient humidity range during transport, storage and use:

- 5% to 95% RH, non-condensing when the product is inactivated.
- 5% to 85% RH, non-condensing when the product is activated.

4.4 Physical characteristics

4.4.1 Overall dimensions

To allow for maneuvering around corners and through corridors and doorways, the minimum dimension of the product (either length, width or height) should not exceed 710 mm; exceptionally a minimum dimension up to 830 mm can be accepted, but this

may restrict the number of sites where the appliance can be installed. The maximum dimension should not exceed 1700 mm and the maximum diagonal (corner to corner) dimension must not exceed 1850 mm. All dimensions must be clearly stated on the PQS information sheet.

4.4.2 *Weight*

Mechanical lifting equipment will often not be available at the installation sites. It is recommended that the refrigerator and any associated components should be designed for lifting in such a way that no single worker is required to carry more than 25 kg while working on their own, or in a group. Mechanical lifting equipment at the [installation](#) sites is necessary when component weight exceed practical weight limits of the workforce.

4.5 Interface requirements

4.5.1 *Voltage stabilizer compatibility*

The appliance must be supplied with an appropriate device of equivalent performance to those voltage stabilizers that are currently prequalified according to PQS Specification **E007/VS01.5**. In some cases, this requirement may, be met by sub-components installed as part of the continuous power system compliant with PQS Specification **E003/POW 01.0**. A warning must be affixed to the unit stating the type(s) of voltage stabilizer with the minimum VA rating that may be used and the user's manual and spare parts list must clearly record this warning (see Clause 4.2.17). The connection between the freezer, the voltage stabilizer and the power supply system must be compatible.

4.5.2 *EMS facility*

The appliance must be supplied with a facility to log internal temperatures in accordance with PQS Specification **E006/TR03.2** or similar PQS specification so that temperature performance at least for the preceding month can be speedily downloadable via a direct connection or wireless connection. Downloading information via a cloud-based system alone is not acceptable in case an internet connection is not available.

4.5.3 *Temperature display and monitoring*

It is recommended that the external digital display of the warmest [freezer temperature](#) has a resolution of 0.1°C so that any drift away from the correct vaccine storage temperature can be obvious. There shall be acoustic and visual indications for temperature deviations (high and low), door open, condenser high temperature, power failure other failures, and low internal battery.

Alarm system shall be adjustable for warm and cold alarms and powered by a rechargeable battery with a minimum of 48 hours battery back-up for audio and visual alarm system and temperature recording device. There should be a provision to send alarms via SMS.

Other optional alarms: power failure, abnormal voltage, sensor error, filter screen check, thermostat failure, condenser clean, high ambient temperature.

4.5.4 Power lead

The appliance must be supplied with a power lead with a sealed-on plug compatible with the electrical socket standard in the country where the equipment must be installed. The power lead must be at least 1.5 metre and not more than 2.5 metre in length. There should be provision to secure extraneous lengths of the power lead so that it does not cause a trip hazard.

4.5.5 Defrosting

Freezer may be defrosted manually or have automatic defrosting.

4.6 Human factors

4.6.1 Generally

The product must be usable by the widest practicable range of active health workers, regardless of age, gender, size or minor disability, including colour blind users and long-sighted people without glasses, in accordance with the general principles laid out in **ISO 20282-1:2006**.

4.6.2 Control panel and thermometer

Controls, thermometer and other visual displays may be positioned on the front of the unit; preferably as close to eye level as possible. Alternatively, they may be mounted on top of the unit at a height not exceeding 1.3 metres. If a low-level position is essential, the display must be aligned so that it can easily be read without the user having to squat or kneel down. The on-off and/or defrost switch, if present, should be recessed or otherwise protected so that it is not possible inadvertently to activate it.

4.6.3 Thermostat settings

Thermostat settings may be factory set or in the case of multi-temperature appliances, they may be adjustable. A setting may only be adjusted via an appliance code or similar security to ensure that no casual adjustment can be made.

4.6.4 Door opening

The freezer should have a facility to allow the door to be quickly & effortlessly opened at any time. This could include a heated air vent with ice-cleaning plunger to prevent vacuum formation. Note this applies both to external and internal doors if fitted. It is recommended that an alarm should sound if the door is left open for a longer than usual time.

4.6.5 *Personal protection equipment*

Protective gloves and similar equipment to prevent freezer burn must be provided. There must be a warning sign on the door or lid of the freezer to remind users to handle very cold items, internal trays, bins etc. with care.

4.7 Materials and construction

4.7.1 *Refrigerant*

Hydrocarbon (HC) refrigerants such as R600a or other refrigerants with a global warming potential (GWP) ≤ 11 and zero ozone-depletion potential (ODP) are required. The suitability of alternative refrigerant gases will continue to be assessed and preference will be given to appliances that use gases with low GWP.

4.7.2 *Thermal insulation foaming agents*

Any gas complying with the limitations and deadlines set by the [Montreal/Kigali Protocols](#) on the elimination of ozone-depleting chemicals.

4.7.3 *Other restricted materials*

The product and its constituent components, including batteries, must not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated biphenyl ethers (PBDE).

4.7.4 *Freezer body*

The body should be made from plastic-coated steel or stainless-steel (minimum grade: Steel 18/10 AISI 304) or pre-painted galvanized steel or pre-painted galvanized aluminum.

4.7.5 *Door and locking*

The door or lid must have heavy duty hinges and must be fitted with a lock. At least two keys must be supplied with every unit. An inner door is optional.

4.7.6 *Door seal*

The door seal should be a silicone-based high-performance gasket with optional frozen relief door frame heating.

4.7.7 *Shelves*

Stainless steel or plastic-coated steel shelves (adjustable) to be designed with a minimum load of 15kg (35 lbs) per shelf.

4.8 Warranty

The appliance to be covered by a three-year replacement warranty from receipt of appliance in the event of any component failure arising from defective design, materials or workmanship.

4.9 Servicing provision

The product must be designed to achieve a maintenance-free life of not less than 10 years, apart from routine defrosting and cleaning and replacement of batteries (if applicable).

4.10 Spare parts and accessories

Legal manufacturer must ensure supply of spare parts for a minimum of 10 years from the time of cessation of the last production of appliance.

The following to be offered as optional accessories:

- cryo gloves in small, medium and large sizes
- ice scraper
- ice clearing brush
- seismic restraint kit

4.11 Disposal and recycling

The manufacturer must provide information to the buyer on the hazardous materials contained within the system and suggestions for resource recovery/recycling and/or environmentally safe disposal. For the European Union WEEE compliance in accordance with European Union Directive **2002/96/EC** is mandatory.

4.12 Instructions

Each appliance must include a separate user manual and technician installation manual in Arabic, English, French, Mandarin Chinese, Russian and Spanish. An English version of all instructions and manuals are required to be supplied at time of laboratory testing. Instructions must include easy to understand visuals whenever possible to avoid reliance on text. The instructions must be written for users and repair technicians covering the following topics:

- appliance installation procedures
- health and safety procedures, both for the appliance and for the power supply system
- compatible types of voltage stabilizer or equivalent protection systems
- basic operation and temperature adjustment (if applicable)
- vaccine storage instructions
- simple daily, weekly and monthly maintenance tasks
- method for defrosting
- periodic preventative maintenance checks
- diagnostic (trouble shooting) and repair procedures both for the appliance and for

- the power supply system
- itemized list of spare parts including part numbers
- end-of-life resource recovery and recycling procedures.

4.13 Training

Manufacturer and client to agree training for users including:

- operator health and safety and PSE both for the appliance and for the power supply system
- correct installation of the freezer and of the power supply system
- vaccine storage instructions
- thermostat setting (if applicable)
- maintenance of the frozen compartment including daily temperature checks
- cleaning of the appliance
- cleaning of any special components e.g. condenser, solar array
- method for defrosting.

4.14 Verification

In accordance with PQS Verification Protocol **E003/ULT01-VP.1**.

5. **Packaging**

Materials used for packaging the finished product must be free of ozone depleting compounds as defined in the [Montreal Protocol](#). The general specification of shipping containers will be subject to agreement with the individual procurement agencies.

6. **On-site installation**

To be discussed on procurement. The appliance must be installed with a dedicated system to provide continuous power to the appliance and to any air-conditioning essential for good performance of the appliance. The power supply must meet the requirements of PQS Specification **E003/POW 01.0** for which an initial site survey may be required.

7. **Product dossier**

The [legal manufacturer](#) or [reseller](#) must provide WHO with a prequalification dossier containing the following:

- Dossier examination fee in US dollars.
- General information about the [legal manufacturer](#), including name and address.
- Unique identification reference for the product type.
- Brand name of the product.
- Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability.
- A comprehensive set of photographs showing all external surfaces of the unit, the interior layout, the compressor and a close-up of the thermometer and the control panel.
- Certified photocopies of all type-approvals obtained for the product, including CE marking and the like.
- An example of a system which could supply continuous power to the appliance

(details of this power system may be dependent on location and a site survey). This power supply must be in accordance with PQS specification **E003/POW 01.0**.

- Certified photocopies of the [legal manufacturer's ISO 9001](#) quality system certification.
- Where relevant, certified photocopies of the [legal manufacturer's ISO14001](#) certification, EMAS registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is not mandatory; however, preference will be given to manufacturers who are able to demonstrate compliance with good environmental practice.
- Laboratory test report(s) proving conformity with PQS specifications.
- Indicative cost of the product per unit, per 10 units and per 100 units, EXW (Incoterms 2010).

8. On-site maintenance

Maintenance will be carried out by the end-user and/or his agents.

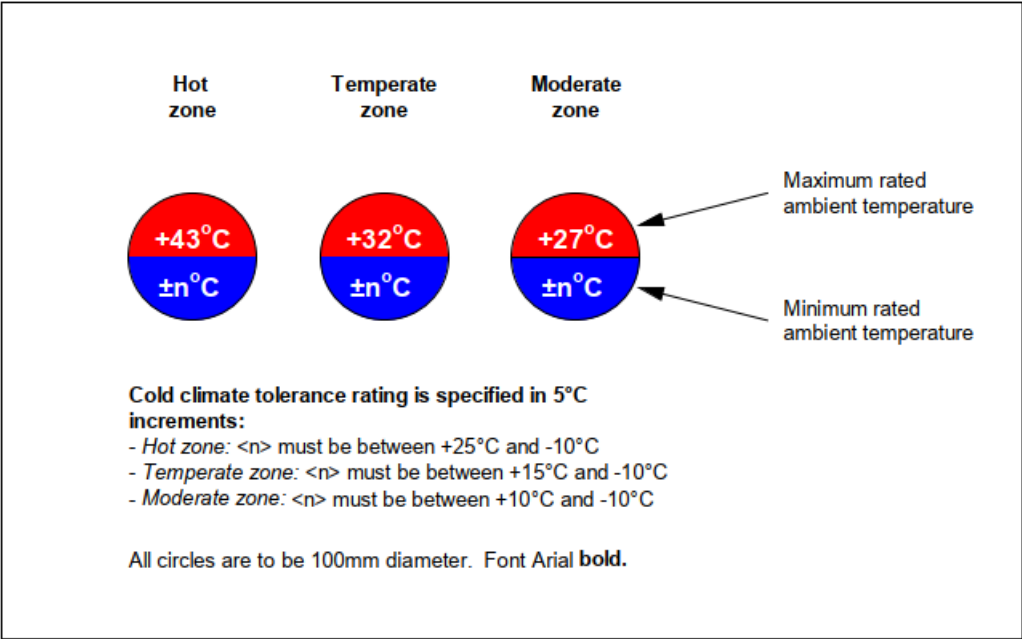
9. Change notification

The [legal manufacturer](#) or [reseller](#) must advise WHO immediately [in writing](#) of any changes which adversely affect the performance of the product after PQS prequalification has taken place. Any change that WHO considers would alter the test results obtained against the PQS verification protocol **E003/ULT01-VP.1** will result in a request for the product to be retested.

10. Defect reporting

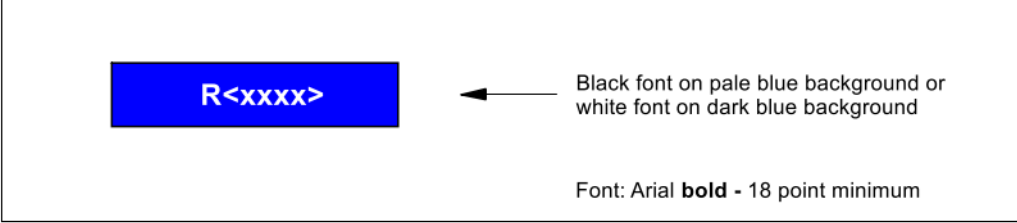
The [legal manufacturer](#) or [reseller](#) must advise WHO and the UN purchasing agencies [in writing](#) in the event of safety-related product recalls, component defects and other similar events. If requested to do so by WHO/UNICEF, the manufacturer must submit a report to WHO/UNICEF stating the number of affected systems and the number of component repairs/replacements provided, together with copies of any associated field reports.

Annex 1 - Temperature zone symbol for freezers

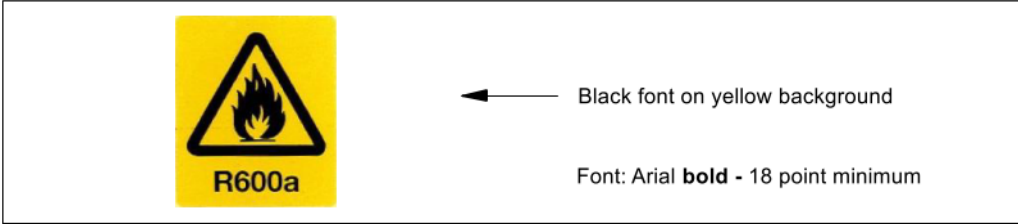


Annex 2 - Refrigerant symbols

Refrigerant label



R600a warning symbol



Revision history

Date	Change summary	Reason for change	Approved