



TITLE: Refrigerator or combined refrigerator-icepack freezer: compression cycle

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1. Scope:

This specification defines the requirements for compression-cycle refrigerators or combined refrigerator/icepack freezers for storing vaccine. Three temperature zone designations are described: [moderate zone](#), [temperate zone](#) and [hot zone](#). In addition appliances are tested to establish a [minimum rated ambient temperature](#) designation.

2. Normative references:

DIN 8985: 1983-05: *Testing the surfaces of installed refrigerators and freezers.*
EMAS: *European Union Eco-Management and Audit Scheme.*
IEC 60335-1: 2006: *Household and similar electrical appliances - Safety - Part 1: General requirements.*
IEC60335-2-24: 2007 - *Household and similar electrical appliances - Safety - Part 2-24: Particular requirements for refrigerating appliances, ice-cream appliances and ice-makers.*
ISO 9001: 2000: *Quality Management Systems – Requirements.*
ISO 14001: 2004: *Environmental management systems - Requirements with guidance for use.*
ISO/IEC 17025: 2000: *General requirements for the competence of testing and calibration laboratories.*
ISO 20282-1: 2006: *Ease of operation of everyday products - Part 1: Context of use and user characteristics.*

3. Terms and definitions:

Acceptable temperature range: The acceptable temperature range for storing vaccine is +2°C to +8°C. However, brief excursions outside these limits will be tolerated. Measured over a five day period of testing these excursions must not exceed any of the following parameters:

- The cumulative total of all excursions over +8°C must not exceed 12 hours.
- No excursion must exceed +20°C.
- The cumulative total of all excursions below +2°C must not exceed 12 hours.
- No excursion must reach 0°C.

To establish compliance with these requirements, the total hours of runtime for the *stable running*, *icepack freezing*, *day/night cycle* and *minimum rated ambient temperature* tests will be recorded. Temperature logger data will be analyzed to establish the cumulative number of hours with temperatures lying outside the **acceptable temperature range**. The results will then be normalized to establish the extent of excursions over an average five day period.

Holdover time: The time in hours during which all points in the vaccine compartment remain between +2°C and +10°C, at the maximum ambient temperature of the temperature zone for which the appliance is rated, after the power supply has been disconnected. The same holdover time, or better, must also be achieved at the **minimum rated ambient temperature**.

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: means communication by letter, fax or email.

Minimum rated ambient temperature: In addition to the day/night test, all appliances will be challenged by reducing the ambient temperature in 5°C increments below the lower limit for the model's rated temperature zone, down to a minimum of -10°C. This test is designed to determine the lowest constant ambient temperature at which the **acceptable temperature range** can be maintained with a full vaccine load. Once established, this figure will be displayed in the blue sector of the Annex 1 temperature zone symbol. This will enable purchasers in countries with low winter temperatures to select the most appropriate models.

Legal Manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his 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.

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.

4. Requirements:

4.1 General:

Compression-cycle refrigerators, with or without icepack freezing compartment, powered by mains electricity, are used primarily in areas with a reliable electricity supply (i.e. 20 or more hours of reliable electricity per typical day).

Manufacturers may offer products suitable for one or more temperature 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 cycle:*

Compression-cycle unit operating on alternating current electricity.

4.2.3 *Voltage and frequency:*

220-240 volt 50/60 Hz and 100-127 volt 50/60 Hz options are to be offered.

Performance is to be identical for all options, regardless of the nominal voltage and frequency rating of the appliance.

4.2.4 *Icepack freezing capacity:*

In combined units with freezer compartment, a minimum of 1.6 kg of icepack must be frozen per 24 hours whilst maintaining the temperature control specified in 4.2.5. For freezers with at least 50 litres of gross freezer volume a minimum of 2.4 kg of icepack must be frozen per 24 hours whilst maintaining the temperature control specified in 4.2.5.

4.2.5 *Areas not suitable for vaccine storage:*

Areas of an otherwise acceptable appliance which are too warm or too cold must be excluded from use by design – for example: baskets may be used to define safe storage zones and door storage shelves and vegetable storage compartments may be eliminated.

4.2.6 *Temperature control:*

- **Refrigerator compartment:** The entire vaccine load must remain within the [acceptable temperature range](#) during any continuous ambient temperature test(s) or day/night cycling temperature test(s). Combined units must achieve this performance with or without icepacks in the icepack compartment.
- **Icepack freezing compartment:** The icepack freezing compartment (if present) must remain below -5°C under the same ambient conditions.

4.2.7 *Thermostat:*

The thermostat must be set to prevent freezing in any part of the vaccine storage compartment. The thermostat must be effective throughout the ambient operating temperature range (including the [minimum rated ambient temperature](#) range where applicable – see clause 4.2.8). It must be designed so that it cannot be adjusted by the user. A means for adjustment by a technician is acceptable provided the device is protected from user interference (e.g. by location within the appliance cabinet). Alternatively, programmable thermostats may be password-protected.

4.2.8 *Thermometer:*

- **Option A:** Externally readable cabinet-mounted gas or vapour pressure dial thermometer.
- **Option B:** Externally readable cabinet-mounted electronic maximum-minimum thermometer conforming to PQS specification E06/TH06.

4.2.9 *Holdover time:*

Minimum 4 hours.

4.2.10 *Minimum rated ambient temperature:*

All models will be tested to establish their [minimum rated ambient temperature](#). The minimum acceptable performance rating is achieved if the product passes the day/night test for its nominal temperature zone. The maximum performance rating is achieved if the vaccine load remains within the [acceptable temperature range](#) at -10°C. A freeze-prevention circuit may be required to protect against freezing at low ambient temperatures.

4.2.11 *Compressor starting voltage:*

At 22% below manufacturers stated voltage, 10 out of 10 cold starts and 10 out of 10 hot starts must all be successful.

4.2.12 *Power consumption:*

No standard set, however consumption will be reported.

4.2.13 *Lock:*

The door or lid must be fitted with a lock. Two keys are to be supplied with every unit.

4.2.14 *Corrosion resistance:*

Internal and external cabinet, lid and frame protected against corrosion to DIN 8985.

4.2.15 *Electrical safety rating:*

Manufacturer to certify compliance with IEC 60335-1 and IEC60335-2-24.

4.2.16 *Markings:*

Compressors operating on R 134a refrigerant 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, formula or proportion (for blended refrigerants).

4.2.17 *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.
- **Combined freezers:** Vaccine storage instructions, icepack freezing instructions and the appropriate temperature zone symbol as Annex 1.

The instructions should be fixed to the lid of chest refrigerators and near the top of the door on upright refrigerators. Instructions should be in one of the languages specified in clause 4.11, as indicated by the purchaser at the time of ordering. If removable baskets are supplied fix a multi-lingual warning within the refrigerator instructing users to *Store vaccine in baskets only* or other appropriate instruction.

4.3 Environmental requirements:

4.3.1 *Ambient temperature range during transport and storage:*

-30°C to +55°C when the product is inactivated.

4.3.2 *Ambient humidity range during transport, storage and use:*

5% to 95% RH.

4.4 Physical characteristics:

4.4.1 *Overall dimensions:*

To allow for manoeuvring through corners, corridors and doorways, the minimum dimension of the product (either length, width or height) should not exceed 830mm, and preferably it should not exceed 710mm. The maximum dimension must not exceed 1700mm and the maximum diagonal (corner to corner) dimension must not exceed 1850mm.

4.4.2 *Weight:*

Not critical.

4.5 Interface requirements:

4.5.1 *Voltage stabilizer compatibility:*

All electrical components must be compatible with voltage stabilizers that use tap-changing technology. If the product contains components that are incompatible with this type of voltage stabilizer it must be supplied with an appropriate device of equivalent performance to those voltage stabilizers that are currently pre-qualified in PQS section E07. A warning must be affixed to the unit stating the type(s) of voltage stabilizer that may be used and the user's manual and spare parts list must clearly record this warning.

4.5.2 *Power lead:*

The product is to be supplied with a power lead with a sealed-on plug compatible with the electricity socket standard in the country where the equipment is to be installed. The power lead must be at least 1.5 meters and not more than 2.0 meters in length.

4.6 Human factors:

4.6.1 *Generally:*

The product must be useable by the widest practicable range of active health workers, regardless of age, gender, size or minor disability, including 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:*

The control panel must be positioned on the front of the unit. The on/off switch should be recessed or otherwise protected so that it is not possible inadvertently to switch the unit off. The thermometer dial must be positioned at the front of the unit and as close to eye level as possible within the constraints of the cabinet design.

4.7 Materials:

4.7.1 Refrigerant:

HFC (hydro fluorocarbon) or HC (hydrocarbon) refrigerant. CFC (chlorofluorocarbon) and HCFC (hydrochlorofluorocarbon) gases are not acceptable. The suitability of alternative refrigerant gases will continue to be assessed.

4.7.2 Thermal insulation foaming agents:

Any gas complying with the limitations and deadlines set by the [Montreal Protocol](#) 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).

4.8 Warranty:

The product is to be covered by a two year replacement warranty in the event of any component failure arising from defective design, materials or workmanship.

4.9 Servicing provision:

The product is to be designed to achieve a maintenance-free life of not less than 10 years apart from routine de-frosting and cleaning and replacement of batteries (if any).

4.10 Disposal and recycling:

The manufacturer is to 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.

4.11 Instructions:

User and maintenance instructions in Arabic, English, French, Mandarin Chinese, Russian and Spanish. The instructions are to be written for users and repair technicians and are to cover the following topics:

- installation procedures;
- compatible types of voltage stabilizer;
- temperature adjustments (if applicable);
- prevention of vaccine freezing;
- simple daily, weekly and monthly maintenance tasks;
- periodic preventative maintenance checks;
- diagnostic and repair procedures;
- itemized list of spare parts including part numbers;
- end-of-life resource recovery and recycling procedures.

4.12 Training:

Not required.

4.13 Verification:

In accordance with PQS Verification Protocol **E03/RF01-VP**.

5. **Packaging:**

Materials used for packaging the finished product are to 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:**

Not required.

7. **Product dossier:**

The [legal manufacturer](#) or [reseller](#) is to provide WHO with a pre-qualification 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.
- Certified photocopies of the legal manufacturer's ISO 9001: 2000 or more recent quality system certification. Note: Companies that are not ISO 9001-certified will be granted a period of 18 months following the date of publication of this document in which to achieve certification.
- Where relevant, certified photocopies of the [legal manufacturer's](#) ISO 14001:2004 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.
- Where available, laboratory test report(s) proving conformity with the product specifications.
- Indicative cost of the product per unit, per 10 units and per 100 units, EXW (Incoterms 2000).

8. **On-site maintenance:**

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

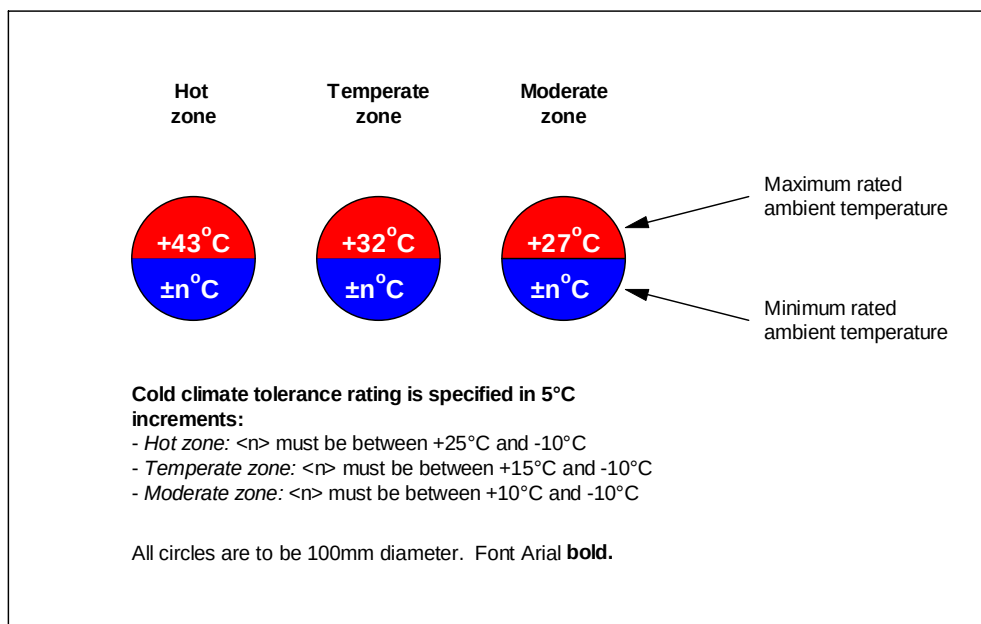
9. Change notification:

The [legal manufacturer](#) or [reseller](#) is to advise WHO [in writing](#) of any changes which adversely affect the performance of the product after PQS pre-qualification has taken place. Any change that WHO considers would alter the test results obtained against the PQS verification protocol **E03/RF01-VP** will result in a request for the product to be retested.

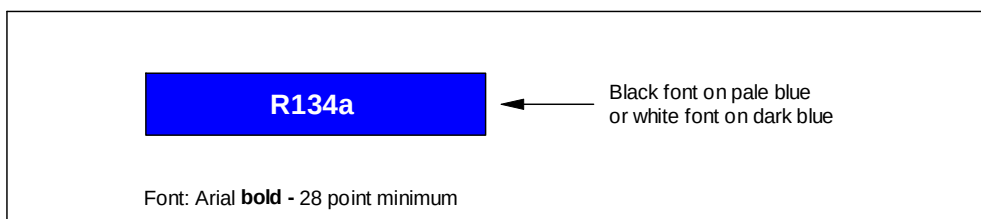
10. Defect reporting:

The [legal manufacturer](#) or [reseller](#) is to 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 is to 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 refrigerators



Annex 2 - R134a symbol



Revision history:			
Date	Change summary	Reason for change	Approved
23.05.2007	General edit with additional clauses plus Annexes 1 and 2.	Final revisions to PQS format.	UK
30.05.2007	SMc comments incorporated.		UK
02.08.2007	4.2.13: Lock spec changed. 4.4.1: Dims clarified.	Response to manufacturer's comment.	UK