



PQS On-site freeze protection test protocol

TITLE: Ice-lined refrigerator or combined ice-lined refrigerator and water-pack freezer: compression cycle

Product verification protocol: Based on E003/RF03-VP.3
Applies to specification ref(s): E003/RF03.2
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1. Scope:

This document describes the procedure for evaluating the freeze protection grade of compression cycle ice-lined refrigerators or combined refrigerator and water-pack freezers. This testing is only applicable to products that have already been pre-qualified by WHO PQS. The grade assigned from this testing will be included on the product’s PQS catalogue page.

2. Normative references:

- DIN 8985: 1983-05: *Testing the surfaces of installed refrigerators and freezers.*
- IEC 60335-1: 2006: *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 62552: 2007: *Household refrigerating appliances – Characteristics and test methods.*

ISO/IEC 17025: 2005: *General requirements for the competence of testing and calibration laboratories.*

WHO/PQS/E003/RF03.2: *Performance Specification: Ice-lined refrigerator or combined ice-lined refrigerator and water-pack freezer: compression cycle.*

WHO/PQS/E003/TPP-1.2: *Target Product Profile: Solar Direct Drive Refrigerator*

3. **Terms and definitions:**

Acceptable temperature range: The acceptable temperature range for storing vaccine is +2°C to +8°C inside the vaccine compartment not in contact with the compartment's walls. However, transient excursions outside this range will be tolerated, within the following limits:

- No excursion must exceed +20°C.
- No excursion must reach 0°C.

The cumulative effect of any excursions within the above range will be assessed over the five day period of the *day/night* test. For this test, the calculated mean kinetic temperature (MKT)¹ must remain within the range +2°C to +8°C when the default activation energy is set at 83,144 kJ per mol. Using the recorded temperature data, an MKT figure will be calculated for each sensor. The worst-case result will determine the outcome of the test. Excursions in other tests will be noted and must not exceed the defined upper and lower limits.

Freezing temperature: As sensors are placed in contact with the compartment's walls, freezing temperature is defined as any of the following conditions:

- Excursion equal to or below 0°C for longer than 1 hour.
- Excursion equal to or below -1°C for any amount of time.
- Inability to return to safe operating temperature (i.e. consistently between +2°C and +8°C) within 2 hours following an excursion equal to or below 0°C.

Freeze-protection classification: As described in **E003/TPP-1.2**

- **Grade A, user-independent freeze protection (UIFP):** when the appliance is used within its nominated temperature range (temperature zone +43°C, +32°C or +27°C and minimum rated ambient temperature) there is no intervention required by the user to ensure that the vaccines will not be exposed to freezing temperatures as defined earlier, whatever the position of the vaccine in the vaccine compartment.
- **Grade B, user-dependent freeze protection (UDFP):** Even if the appliance is used within its nominated temperature range, the user must comply with a procedure provided by the manufacturer and requiring one level of intervention (e.g., the requirement to use baskets or other items to avoid vaccine freezing constitute one level of intervention by the user).
- **Grade C, user-dependent freeze protection (UDFP):** Even if the appliance is used within its nominated temperature range, the user must comply with

¹ Refer to Seevers, R. et al. The Use of Mean Kinetic Temperature (MKT) in the Handling, Storage and Distribution of Temperature Sensitive Pharmaceuticals. Pharmaceutical Outsourcing, May/June 2009.

a procedure provided by the manufacturer requiring several levels of intervention (e.g., an absorption refrigerator not only requires the use of baskets, but also the adjustment of the wick).

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.

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.

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.

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.

User-Dependent Freeze Protection (UDFP): Refrigeration technology that requires equipment users (e.g. healthcare workers) to perform specific actions (user-interventions) necessary to ensure vaccine protection against freezing temperatures (e.g. store vaccines in baskets, away from compartment wall surfaces).

User-Independent Freeze Protection (UIFP): Refrigeration technology that ensures vaccine protection against freezing WITHOUT any actions (user-interventions) required on behalf of equipment users (e.g. healthcare workers).

User-Intervention: Any activity that is required to be executed by equipment users in order to ensure vaccine protection against freezing. Activities could include, but are not limited to, basket storage, storage compartment covers, thermostat/fuel adjustment, combustion component replacement, etc.

4. Applicability:

Type-testing will be carried out by the equipment manufacturer and audited by a WHO PQS approved agent.

5. Type-testing procedure:

5.1 *Test procedure:*

5.1.1 *Test temperatures:*

The specific tests listed below apply equally to **moderate zone**, **temperate zone** and **hot zone** appliances. Relevant test chamber temperatures are given in the following format M:<XX°C> for moderate zone; T:<XX°C> for temperate zone and H:<XX°C> for hot zone.

5.1.2 *Test 1: Cool-down and stabilization:*

Power: Continuous.

- **Step 1:** Set the test chamber temperature to M:+27°C, T:+32°C, H:+43°C and leave for 24 hours with the appliance empty, the lid or door open and the power supply switched off.
- **Step 2:** Begin and continue recording temperatures every minute for the entire duration of testing, close the lid or door of the appliance, switch it on and leave it to stabilize.
- **Step 3:** Once stabilization is achieved, switch off the power supply.

5.1.3 *Test 2: Freeze protection test:*

Power: Continuous

- **Step 1:** Continuing from Test 1, monitor the temperature of the vaccine compartment at one-minute intervals. At the moment when the warmest part of the appliance systematically exceeds +10°C², immediately restore power to the appliance.
- **Step 2:** Monitor the temperature of the vaccine compartment at one minute intervals while the appliance cools down and subsequently stabilizes.
- **Acceptance criterion:** Cool-down temperatures:
 - Do not drop below 0°C for longer than 1 hour.
 - Do not reach -1°C for any amount of time.
 - Return to safe operating temperature (i.e. consistently between +2°C and +8°C) within 2 hours.
- **Rejection criterion:** Failure to maintain safe storage temperature during cool-down and stabilization.

5.1.4 *Test 3: Door opening test:*

Power: Continuous

- **Step 1:** Continuing from Test 2, open the door/lid of the refrigerator and allow the compartment to stay fully open for 10 minutes.
- **Step 2:** Once 10 minutes has passed, close the door/lid and monitor temperatures for at least 2 hours as the appliance cools down.
- **Acceptance criteria:** Cool-down temperatures:
 - Do not drop below 0°C for longer than 1 hour.
 - Do not reach -1°C for any amount of time.
 - Return to safe operating temperature (i.e. consistently between +2°C and +8°C) within 2 hours.
- **Rejection criterion:** Cool-down temperatures do not meet the acceptance criteria.

5.2 *Test criteria for qualification:*

A final report must be issued after all testing is complete. The report of the tests must contain the following data and analyses:

- **Summary:** Conclusions, recommendations and assignment of freeze protection grade.
- **Test 1:** Results of cool-down test, including temperature graphs.
- **Test 2:** Results of freeze protection test, including temperature graphs.
- **Test 3:** Results of door opening test, including temperature graphs.

² The phrase 'systematically exceeds' means that the sensor temperature follows a continuous upward trend. Transient temperature spikes within the [acceptable temperature range](#) which are followed by a recovery to within the +2°C to +8°C range can be ignored.

- **Freeze protection analysis and grading:** All data collected and interventions implemented, with the exception of data from Test 2 cool-down, must be evaluated to assign a freeze protection grade according to the definition of [freezing temperatures](#) and the below intervention chart:

User-Intervention	Evaluation Criteria	Result
Basket storage	Any need to utilize baskets to protect vaccines from freezing.	add 1 user-intervention
Compartment covers	Any need to utilize vaccine compartment covers to protect vaccines from freezing.	add 1 user-intervention
Knob adjustment	Any adjustment of temperature knob or fuel regulator required to protect vaccines from freezing.	add 1 user-intervention
Wick adjustment	Any required adjustment of flame wick to operate unit and/or protect vaccines from freezing.	add 1 user-intervention

NOTE: This list of interventions is representative and does not include all possible user-interventions.

- Freeze protection grading criterion: The refrigerator's grade must be evaluated based on the number of user-intervention required to maintain safe storage within the 2-8°C compartment temperature range.
 - Grade A, user-independent freeze protection (UIFP): zero (0) interventions required.
 - Grade B, user-dependent freeze protection (UDFP): one (1) user-intervention required.
 - Grade C, user-dependent freeze protection (UDFP): greater than one (>1) user-interventions required.
- If at any point during testing, the unit fails to meet the criteria for "A" grade freeze protection, the testing must be stopped, a manufacturer prescribed intervention implemented and the testing restarted from Test 2. These interventions must be implemented one at a time so as to differentiate between single-intervention "B" grades and multi-intervention "C" grades.
- **Excursion analysis:** MKT excursion analysis based on test data in accordance with the [acceptable temperature range](#) definition.
- **Annexes:** Description of the test apparatus. Test chamber temperature records. Copy of reference thermometer calibration certificate(s). Diagrams showing the location and identification codes for temperature sensors, clearly distinguishing between sensors measuring vaccine, water-pack, freezer and evaporator temperatures. Additional supporting documentation requested and received from the [Legal Manufacturer](#) or [Reseller](#) during the course of the type-testing.

6. Quality control:

6.1 Quality control standards:

All testing and reporting must be carried out in accordance with the requirements of [ISO 17025:2005](#) or later edition.

6.2 Quality control implementation:

The testing will be carried out at the manufacturing plant or a laboratory agreed upon by WHO PQS. If at the manufacturing site, it will be carried out in the presence of an independent party agreed upon with WHO PQS. Data will be collected and analysed and a report will be submitted to PQS by the third party.

7. Freeze protection grade evaluation:

A product's grade will be included on the register of PQS pre-qualified equipment in accordance with WHO procedures provided the final report indicates full conformity with testing and assignment of appropriate grade.

8. Modified products:

The [legal manufacturer](#) or [reseller](#) must notify WHO [in writing](#) of any changes which affect the performance of the product. WHO will carry out a desk evaluation of the reported change(s). If any change is deemed adversely to affect the performance of the product, WHO may request full or partial re-verification based on the test procedures described in this document.

Annex 1 – General test conditions

The following conditions are applicable to all refrigerator and freezer tests.

Test conditions:

- Carry out tests in a test chamber in which temperatures can be controlled to $\pm 1^\circ\text{C}$ and humidity within the range of 45% to 75% unless otherwise stated below. Measure test chamber temperatures in accordance with IEC 62552, clause 8.2.
- Maximum test chamber temperatures of M:+27°C, T:+32°C and H:+43°C are required for the tests.
- Minimum test chamber temperatures down to -15°C may be required for the [minimum ambient temperature rating](#) test. The actual minimum required for a specific appliance should be discussed with the product manufacturer before the test commences.
- Temperatures within the appliance must be continuously monitored to an accuracy of $\pm 0.5^\circ\text{C}$ without the presence of the sensors influencing the test in any way. Thermocouples that are sealed within the appliance are most commonly used. Up to 16 simultaneous temperature measurements may be required for a single appliance. The suggested temperature sensor locations are shown in Annex 2. See Annex 3 for temperature sensor specifications.
- Position the test appliance in the test chamber with its back face 50 mm clear of one of the chamber walls. Ensure that it is accurately levelled.

Stabilization times:

Before measuring the performance of a refrigerator or freezer under normal running conditions, temperature conditions inside the appliance must be stable. This is normally assumed to have occurred when either:

- The thermostat has been cycling for 24 hours, or
- The temperature at each of corresponding points during successive operating cycles varies by less than $\pm 1^\circ\text{C}$ and there is no marked trend away from the mean temperature at that point over 24 hours.

Recording temperatures:

- Test appliances, either loaded or empty, as described above in the verification protocol.
- Take temperature readings once per minute.

Sensor placement:

- Place sensors in contact with the surface of the compartment's walls and at the centre of the vaccine load compartment as well as at other positions which are likely to experience extremes of temperature. Such positions might be near door seals, or where air circulation is restricted by the appliance design – see the Annex 2 sensor position diagrams and note.
- Fix the sensors in position so that they cannot be displaced during the course of the tests. Sensors may be fixed in position using thin rigid wire, tape or similar materials which do not affect the thermal performance of the appliance.
- After initial setup, do not alter the position of sensors during subsequent tests.
- Monitor all sensors so that an overall picture of the temperature distribution can be obtained.

Where applicable, the following points should also be monitored:

- Surface temperature of evaporator plates;
- Flue temperature;
- Condenser fins or outer skin temperatures.

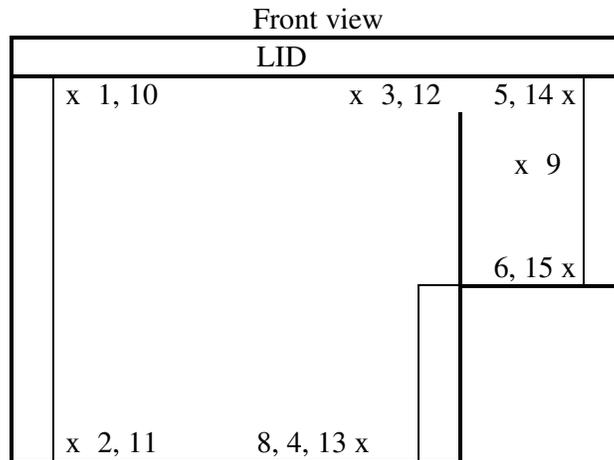
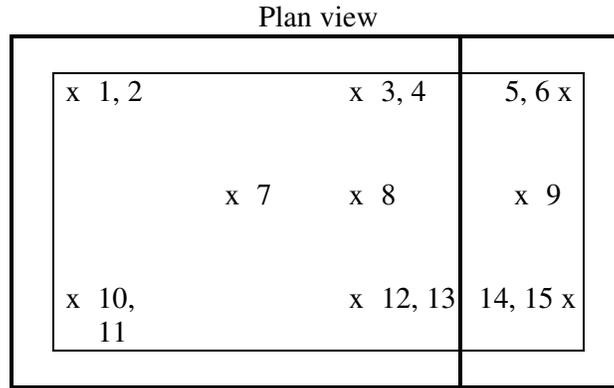
Dual compressor units:

Both compressors should be switched on during all tests.

Annex 2 – Temperature sensor positions

Approximate sensor positions are indicated by the figures. Except for sensors placed centrally in a compartment, the centre of sensors should be placed in direct contact with the vaccine compartment wall.

Ice-lined refrigerators and/or freezer



Annex 3 – Temperature sensor specification

Complying with IEC 62552, clause 8.7.1. Probe, accurate to $\pm 0.5^{\circ}\text{C}$, inserted into brass or tin-covered copper mass of $25\text{ g} \pm 5\%$ and of minimum external area (diameter = height = about 15.2 mm).

Revision history:			
Date	Change summary	Reason for change	Approved
28.08/.2015	freeze protection grading	.	DM
16/09/2015	Changes for consistency		DM