PQS Independent type-testing protocol

TITLE: Mains-powered refrigerator or combined mains-powered refrigerator and water-pack freezer: compression cycle

Product verification protocol:	E003/RF03-VP.3
Applies to specification ref(s):	E003/RF03.3
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Contents:

1. Scope

This document describes the procedure for verifying the performance of compression cycle ice-lined refrigerators or combined refrigerator and water-pack freezers. Previously, an appliance that passed the relevant tests would be pre-qualified with a specific temperature zone designation. Three temperature zones are described: moderate zone, temperate zone and hot zone; the scope of each category is defined in Section 3. However, from the point of issuance of this verification protocol, all appliances must pass the relevant tests in the hot

zone. In addition appliances must demonstrate a minimum rated ambient temperature of 10°C. This is in accordance with the revised performance specification as described in PQS E003/RF03.3.
Additionally, from the point of issuance of this protocol, the manufacturer is required to specify the minimum average daily duration of power (e.g., 8 hours per day, 4 hours per day) required for the appliance to operate. Relevant tests in this protocol will then provide the appliance with this indicated amount of power.

2. Normative references

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 and test methods.*
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: 2005: *General requirements for the competence of testing and calibration laboratories.*
WHO/PQS/E005/IP01: *Water-packs for use as ice-packs, cool-packs and warm-packs.*
WHO/PQS/E006/TH02.2: *Fixed gas or vapour pressure dial thermometer.*
WHO/PQS/E006/TH06.2: *Integrated electronic maximum-minimum thermometer, with factory programmed alarms, for vaccine refrigerators and freezers.*

3. Terms and definitions

Acceptable temperature range: The acceptable temperature range for storing vaccine is +2°C to +8°C. However, transient excursions outside this range will be tolerated, within the following limits:

- No excursion must exceed +20°C (± 0.5°C) for any amount of time.
- No excursion must drop below -0.5°C for any amount of time.
- No excursion must drop below 0°C for longer than 1 hour.
- Following an excursion below 0°C, the appliance must return to safe operating temperature (i.e., consistently between +2°C and +8°C) within 2 hours. This duration will be measured from the moment the temperature drops below 0°C and up until it returns to +2°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 on walls / lining of vaccine compartment:

For sensors placed in direct contact with the walls /lining of the vaccine compartment, freezing temperature is defined as any of the following conditions:

- Excursion between -0.5°C and 0°C for longer than 1 hour.
- Excursion equal to or below -0.5°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/TPP04.1**

- **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 temperatures below 0°C 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) in order to avoid vaccine freezing.

- **Grade C,** 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 requiring more than one level of intervention in order to avoid vaccine freezing. (e.g., the requirement to use baskets and insulation barriers or covers).

[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.

Gross internal volume: The measured volume of the airspace inside the internal compartment of the appliance with the door or lid shut. For combined appliances the gross freezer volume and the gross refrigerator volume are reported separately.

Holdover time: The time in hours during which all points in the vaccine compartment remain between +2°C and [+8°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.

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.

Minimum rated ambient temperature: In addition to the day/night test, all refrigeration 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.

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.

Primary container: Vial, ampoule, prefilled device, plastic dispenser or tube containing vaccine or diluent. Some products are supplied in a light card carton containing a single vial, ampoule, vial pair, vial-ampoule pair, or prefilled device.

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.

User-Dependent Freeze Protection (UDFP): Refrigeration technology that requires appliance users (e.g., healthcare workers) to perform specific actions (user-interventions) in order 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 requires appliance users (e.g., healthcare workers) to perform NO specific actions (user-interventions) in order to ensure vaccine protection against freezing temperatures.

User-Intervention: Any activity that is required to be executed by appliance 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, and combustion component replacement.
Vaccine net storage capacity: The net storage capacity is the space where it is suitable (both thermally and ergonomically) to store vaccines. Where manufacturers are declaring more than one vaccine storage capacity for the same gross volume and external dimensions, manufacturers must prequalify with different branding, one model for each different storage volume.
Water-pack: A flat, leak proof, plastic container, filled with tap water, complying generally with specification **PQS/E005/IP01**.
Water-pack freezing capacity: The maximum weight of water-packs which can be fully frozen, in one batch, during a 24 hour freezing cycle. During this period the temperature of the vaccine storage compartment must remain within the acceptable temperature range. The temperature of the water-pack freezing compartment must remain below -3ºC, except during the actual freezing process after unfrozen water-packs have been loaded.
Water-pack storage capacity: The maximum weight of fully frozen water-packs that can remain fully frozen at the end of testing over a five day period.

4. Applicability

Type-testing will be carried out by an independent ISO/IEC 17025 testing laboratory, accredited by WHO.

5. Type-testing procedure

5.1 Evidence of conformity assessment

Appliances must carry the CE mark, UL mark and/or equivalent internationally accepted evidence of conformity assessment.

5.2 Number of samples

The Legal Manufacturer or Reseller must supply the testing laboratory with a full duplicate set of the Product Dossier already supplied to WHO in accordance with the requirements of specification clause 7. One sample of the appliance is required. Ensure that the voltage and frequency rating of the sample(s) is suitable for the country where the test laboratory is located[2].

5.3 Test procedure

5.3.1 Test 1: Type examination

- **Step 1:** Unpack the appliance. Using the manufacturer's installation instructions only, set up the system components. Record the process and any problems encountered.
- **Step 2:** Check all samples for similarities between different models[3], dissimilarities between samples of one model, any defects or damage or any problem that make it difficult or impossible to test the appliance.

[2] If there is any doubt that the performance of the appliance will vary under the other nominal voltage/frequency combinations supplied by the manufacturer, he must be asked to comment in writing.

[3] The purpose of this inspection is to establish whether appliances offered by competing companies are re-badged versions of an otherwise identical appliance.

- **Step 3:** Record any differences between the samples ordered and those received.
- **Step 4:** Tabulate the following information for each model submitted for examination. Obtain any additional supporting information required in writing from the Legal Manufacturer or Reseller and attach this information to the report:
  Identification
  - Code (a unique identifier to be assigned by the testing laboratory);
  - Model;
  - Legal Manufacturer or Reseller;
  - Appliance type (i.e. vaccine refrigerators or combined unit);
  - Country of origin;
  - Conformity assessment markings (e.g. CE mark);
  - Temperature zone rating against which the appliance is to be tested.

  Performance characteristics
  (Note: the laboratory is to report by clause and in this same order as below)
  - Vaccine storage capacity conforms / does not conform to specification clause 4.2.1.
  - Ambient temperature of operation conforms / does not conform to specification clause 4.2.2.
  - Design of vaccine storage compartment conforms / does not conform to specification clause 4.2.3.
  - Vaccine freeze protection classification conforms / does not conform to specification clause 4.2.4.
  - Water-pack freezing compartment (optional) conforms / does not conform to specification clause 4.2.5.
  - Temperature control conforms / does not conform to specification clause 4.2.6.
  - Thermostat conforms / does not conform to specification clause 4.2.7.
  - Temperature monitoring and thermometer conform / do not conform to specification clause 4.2.8.
  - Holdover time conforms / does not conform to specification clause 4.2.9.
  - Power source, voltage, and frequency conform / does not conform to specification clause 4.2.10.
  - Refrigeration cycle conforms / does not conform to specification clause 4.2.11.
  - Compressor starting voltage conforms / does not conform to specification clause 4.2.12.
  - Power consumption conforms / does not conform to specification clause 4.2.13.
  - Condensation management and defrosting conforms / does not conform to specification clause 4.2.14.
  - Lock conforms / does not conform to specification clause 4.2.15.
  - Build quality conforms / does not conform to specification clause 4.2.16.
  - Electrical safety rating conforms / does not conform to specification clause 4.2.17.
  - Markings conform / do not conform to specification clause 4.2.18.

- Vaccine storage advice conforms / does not conform to specification clause 4.2.19
- Accessories conform / do not conform to specification clause 4.2.20.

Environmental requirements

- Ambient temperature range during transport and storage conforms / does not conform to specification clause 4.3.1.
- Ambient humidity range during transport, storage, and use conforms / does not conform to specification clause 4.3.2.

Physical characteristics

- Overall dimensions conform / do not conform to specification clause 4.4.1.
- Weight conforms / does not conform to specification clause 4.4.2.

Interface requirements

- Voltage stabilizer compatibility conforms / does not conform to specification clause 4.5.1.
- Power lead conforms / does not conform to specification clause 4.5.2.

Human factors

- General design of the appliance conforms / does not conform to specification clause 4.6.1.
- Control panel and thermometer conforms / does not conform to specification clause 4.6.2.
- PQS stickers conform / do not conform to specification clause 4.6.3.

Materials

- Record materials of all major visible components;
- Refrigerant conforms / does not conform to clause 4.7.1.
- Thermal insulation foaming agent conforms / does not conform to specification clause 4.7.2.
- Other restricted materials listed in clause 4.7.3 are / are not present.

Physical data

- Record major rectangular dimensions in centimetres (± 1.0 cm).
- Record weight in kilograms (± 0.25 kg).
- Record internal volumes of refrigerator and / or freezer compartment(s) in litres.
- Record estimated vaccine net storage capacity in litres.
- Record maximum water-pack capacity in kilograms, if freezer included.

Warranty

- Warranty conforms / does not conform to specification clause 4.8.

Essential spare parts

- Spare fuses (if used) conform / do not conform to specification clause 4.9.1.
- List of spare parts conforms / does not conform to specification clause 4.9.1.

Disposal and recycling

- Hazardous materials information conforms / does not conform to specification clause 4.10.

Instructions

- Instructions conform / do not conform to specification clause 4.11.

- **Step 5:** Take a three quarter view digital photograph of the appliance with the door open. A high-resolution digital image in jpeg format should be provided for attachment to the PQS report. Take at least three other photographs needed to illustrate components/features of the appliance in the report.
- **Acceptance criteria:** Inspection indicates full conformity with all major specification requirements.

5.3.2 Test temperatures and intermittent power profiles

As defined in Section 1, the tests listed below all involve hot zone conditions. Additionally, certain tests involve intermittent power. This should match the maximum power requirement specified by the manufacturer. If the manufacturer specified 8 hours per day of power required for the device to operate, during tests with intermittent power, the appliance must be provided with 8 hours of continuous power followed by 16 hours no power. Similarly, if the manufacturer specifies 4 hours per day of power required, during tests with intermittent power, the appliance must be provided with 4 hours of continuous power followed by 20 hours of no power.

5.3.3 Test 2: Cool-down, initial stabilization, and power consumption:

Power: Intermittent (see clause 5.3.2)

- **Step 1:** Set the test chamber temperature to +43°C and leave for 48 hours with the appliance empty, the lid or door open, and the power supply switched off.
- **Step 2:** Close the lid or door of the appliance, commence intermittent power supply to the appliance, and leave it to initially stabilize. Initial stabilization is accomplished when the appliance demonstrates all of the following:
  - The thermal storage has been cooled for a time period no less than the cool down time period stated in the instructions provided by the manufacturer. (e.g., if instructions state cool down time is 7 days then at least a 7 day cool down test is required); and
  - The internal temperatures in the vaccine storage compartment are within the acceptable temperature range; and
  - The cooling system has exhibited consistent on/off operation for the final two days of this test (e.g. the same number of on/off cycles per day for the final two days).
- **Step 3:** After stabilization, record temperatures every minute for 24 hours. During this period measure the energy consumption and determine the compressor duty cycle. Measure the duty cycle by timing from the end of one cycle to the end of a corresponding cycle approximately 24 hours later. Calculate the percentage 'on' time over this period. Measure electricity consumption over the same time scale and report as kWh/day.
- **Acceptance criterion:** Stabilized internal temperatures between +2°C and +8°C in the vaccine storage compartment and below -3°C in the water-pack freezing compartment (if present) achieved within the test period (after stabilization).
- **Rejection criterion:** Failure to stabilize within the acceptable temperature range(s). Halt the test if the appliance does not initially stabilize within the period specified by the Legal Manufacturer, plus one day.

5.3.4 Test 3: Stable running and continuous power consumption test:

Power: Continuous

- **Step 1:** When the internal temperature is stabilized at the end of Test 2, load the appliance with simulated, pre-conditioned vaccine as described in Annex 1. Ensure that the water-pack freezing compartment (if present) is empty.
- **Step 2:** Close the lid or door of the appliance and leave it to stabilize.
- **Step 3:** After temperature stabilization has been achieved, record temperatures every minute for 24 hours. During this period measure the energy consumption and determine the compressor duty cycle. Measure the duty cycle by timing from the end of one cycle to the end of a corresponding cycle approximately 24 hours later. Calculate the percentage 'on' time over this period. Measure electricity consumption over the same time scale and report as kWh/day.
- **Acceptance criteria:** Stabilized internal temperatures maintained between +2°C and +8°C in the vaccine storage compartment and below -3°C in the water-pack freezing compartment (if present). Power consumption to be reported.
- **Rejection criterion:** Failure to meet one or more of the acceptance criteria.

5.3.5 Test 4: Stable running and intermittent power consumption test:

Power: Intermittent (see clause 5.3.2)

- **Step 1:** Continue the Test 3 conditions (but with intermittent power) and the same temperature monitoring regime, but cycle the power supply intermittently until the temperature has re-stabilized and a minimum of three repeating 24 hour temperature profile cycles have been completed[4].
- **Step 2:** From the start of the next intermittent power-on cycle, measure the energy consumption and determine the compressor duty cycle. Measure the duty cycle by timing from the start of the power-on cycle to the end of the same cycle (i.e., 8 hour or 4 hours later, depending on the duration of the intermittent power cycle). Calculate the percentage 'on' time over this period. Measure and report electricity consumption over the same time scale and report as kWh/day.
- **Acceptance criterion:** Stabilized internal temperatures maintained between +2°C and +8°C in the vaccine storage compartment. Power consumption to be reported.
- **Rejection criterion:** Failure to meet the acceptance criterion.

5.3.6 Test 5: Water-pack freezing capacity and power consumption test:

Application: Combined units only.

Power: Intermittent (see clause 5.3.2)

- **Step 1:** Continue the Test 4 conditions.
- **Step 2:** Stabilize water-packs at +43°C.
- **Step 3:** Load a minimum of 1.6 kg of water-packs and not less than 2.4 kg per 50 litres of gross freezer volume of water-packs into the freezer compartment 8 hours after the beginning of the power off phase. Load the packs in accordance with user instructions including any rack or structure provided. Install the freezer thermocouples, centred as uniformly as

[4] With intermittent power, the load temperature may fluctuate over each 24 hour cycle.

possible between the loaded water-packs. The minimum distance between a thermocouple and the lid/door, wall or evaporator should be 30mm.

- **Step 4:** Record water-pack and vaccine load temperatures every minute for the following 24 hours.
- **Step 5:** At the end of the test period check that the water-packs are fully frozen (refer to Annex 4 for methodology measurement of ice production). Check that the vaccine load has remained within the +2°C and +8°C range throughout the 24 hour test period. Remove the frozen water-packs.
- **Step 6:** Repeat steps 3 to 5 introducing larger loads of stabilized water-packs up to the point when one or more of the following conditions occurs:
  - One or more of the water-packs does not fully freeze within the 24 hour period;
  - The temperature of the vaccine load breaches the +2°C and +8°C range on one or more sensors.

  Establish and record the maximum weight of water-packs that can be fully frozen whilst still meeting the requirements of specification clause 4.2.5 (refer to Annex 4 for the methodology for measurement of ice production). This is the appliance's 'water-pack freezing capacity'. Measure electricity consumption over the same time scale and report energy consumption in kWh/day.
- **Acceptance criteria:** Stabilized internal temperatures maintained between +2°C and +8°C in the vaccine storage compartment. For freezers of less than 50 litres, a minimum of 1.6 kg of water-pack must be frozen per 24 hours whilst maintaining the temperature control specified in 4.2.6. For freezers with at least 50 litres of gross freezer volume a minimum of 2.4 kg of water-pack must be frozen per 24 hours whilst maintaining the temperature control specified in specification clause 4.2.6.
- **Rejection criteria:** Failure to meet one or more of the acceptance criteria.

5.3.7 Test 6: Day/night test:

Power: Intermittent (see clause 5.3.2)

- **Step 1:** Stabilize the test chamber at +43°C. Load the appliance with simulated, pre-conditioned vaccine as described in Annex 1. Ensure that the water-pack compartment (if present) is empty.
- **Step 2:** Switch the appliance on with intermittent power and stabilize the vaccine load temperature between +2°C and +8°C and the water-pack freezing compartment (if present) below -3°C. Allow to run for a further 24 hrs.
- **Step 3:** Begin the day/night cycle by reducing the temperature of the test chamber to +25ºC over a 3-hour period. Hold this temperature for 9 hours. Raise the temperature to +43°C over a 3-hour period. Hold at +43°C for a further 9 hours. Reduce again to +25ºC again over a further 3 hr period. Repeat this simulated day/night temperature and intermittent power cycle cycle five times. Record the vaccine load temperature every minute.
- **Step 4:** Review the data and calculate the MKT for each sensor over the five day period [5]. Record the highest and lowest temperatures reached during the test.

[5] MKT may be calculated using the Stability System program, currently supplied free by ScienTek Software, Inc. http://www.stabilitysystem.com/II/request_mkt.htm

- **Acceptance criteria:** Vaccine load temperatures must remain within the acceptable temperature range throughout the test. The MKT of the worst-case sensor must not be outside the range +2°C to +8°C.
- **Rejection criteria:** Failure to maintain the vaccine load within the acceptable temperature range throughout the test, and/or the MKT of the worst-case sensor is outside the range +2°C to +8°C.

5.3.8 Test 7: Compressor starting test:

Power: Continuous.

- **Step 1:** Empty the appliance.
- **Step 2:** Switch on the appliance using a starting voltage 20% lower than the nominal voltage of the compressor.
- **Step 3:** Repeat Step 2 ten times from cold with the compressor at +43°C.
- **Step 4:** Repeat Step 2 ten times with the compressor at its normal stable running temperature.
- **Step 5:** Reduce the voltage to -22% of the nominal voltage, repeating steps 2 to 4 for each voltage.
- **Step 6:** If there is a test failure at or before the -22% voltage test, establish the likely cause of the problem and include the diagnosis in the test report.
- **Acceptance criterion:** Ten out of ten starts must be successful in both cold start and hot start tests at a minimum of 22% below the manufacturer's nominal voltage.
- **Rejection criterion:** One or more start failures.

5.3.9 Test 8: Holdover time test:

Power: Intermittent (see clause 5.3.2)

- **Step 1:** For units without water-pack freezing, continue the Test 4 conditions. For combined units, continue the Test 5 conditions but with the water-pack freezing compartment empty.
- **Step 2:** Cycle the power supply intermittently until the temperature has re-stabilized and the repeating 24-hour temperature profile from Test 4 has been re-established.
- **Step 3:** At the end of the next intermittent power-on cycle, switch off the power supply. If the compressor has already cycled off at this point record the elapsed time since the end of the previous compressor-on cycle (t).
- **Step 4:** Monitor the temperature of the vaccine load at one-minute intervals. At the moment when the warmest point in the load exceeds [+8ºC] record the elapsed time since power supply switch off and add this to the value 't' recorded in Step 3. Record the position of the warmest point.
- **Acceptance criterion:** A minimum of 20 hours at a continuous ambient temperature of +43°C. The report must also place the appliance into the appropriate holdover category, as defined in specification clause 4.2.9.
- **Rejection criterion:** Failure to meet the minimum holdover period for which the appliance is rated.

5.3.10 Test 9: Freeze protection classification test

Power: Continuous

- **Step 1:** At the end of Test 6, immediately switch on continuous power to the appliance and monitor the temperature of the vaccine compartment at one-minute intervals.

- **Step 2:** Maintain continuous power until the appliance cools down and the temperatures stabilize.
- **Acceptance criteria:** To receive "Grade A" for freeze protection, the appliance's cool-down temperatures:
    - Must not drop below 0°C for longer than 1 hour.
    - Must not reach -0.5°C for any amount of time.
    - Following any excursion below 0°C, within 2 hours the appliance must return to the acceptable temperature range (i.e., consistently between +2°C and +8°C).
- **Rejection criterion:** Failure to maintain safe storage temperature during cool-down and stabilization.

5.3.11 Test 10: Door opening test:

Power: Continuous

- **Step 1:** Continuing from Test 7, after an additional 1 hour of continuous power, open all compartment lids/doors of the appliance. This must include primary as well as secondary lids/doors, since some appliances have secondary lids/doors. Allow the compartment to stay fully open for 10 minutes.
- **Step 2:** Once 10 minutes have passed, close the lid/door and monitor temperatures of the vaccine compartment for at least 2 hours as the appliance cools down and internal temperatures stabilize.
- **Acceptance criteria:**
    - To receive "Grade A" for freeze protection, the appliance's cool-down temperatures:
        - Must not drop below 0°C for longer than 1 hour.
        - Must not reach -0.5°C for any amount of time.
        - Following any excursion below 0°C, within 2 hours the appliance must return to the acceptable temperature range (i.e., consistently between +2°C and +8°C).
- **Rejection criteria:**
    - Failure to maintain safe storage temperature during cool-down and stabilization.

5.3.12 Test 11: Minimum rated ambient temperature test:

Power: Intermittent (see clause 5.3.2)

- **Step 1:** Stabilize the test chamber at +10ºC. If the manufacturer specifies a lower minimum rated ambient temperature of operation +10ºC, stabilize the test chamber at the specified temperature, rounded up or down to the nearest increment of 5ºC.
- **Step 2:** Load the appliance with simulated, pre-conditioned vaccine as described in Annex 1.
- **Step 3:** Switch the appliance on with intermittent power and stabilize the vaccine load temperature between +2°C and +8°C and the water-pack freezing compartment (if present) below -3°C. At the same time, for combined units, stabilize the minimum specified water-pack load at the current ambient temperature.
- **Step 4:** After stabilization, run an intermittent power cycle. Load the stabilized water-packs (combined units only) eight hours after the beginning of the power-off phase.

- **Step 5:** Record temperatures every minute. At the end of the 24-hour test period, remove the water-packs from the freezing compartment (if applicable) and check that they are fully frozen.
- **Acceptance criteria:** The vaccine load temperature remains within the +2°C to +8°C range throughout the 24 hour cycle and the minimum water-pack load (if applicable) is fully frozen by the end of the cycle.
- **Rejection criterion:** Failure to pass this test.

5.4 *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 and recommendations, including confirmation of the temperature zone(s) for which the appliance is suitable.
- **Test 1:** Comments on samples received, tabulated data on the type-examination test and relevant photographs.
- **Test 2:** Results of cool-down test, including temperature graphs.
- **Test 3:** Results of stable running and consumption test (continuous power), including temperature graphs.
- **Test 4:** Results of stable running and consumption test (intermittent power), including temperature graphs.
- **Test 5:** Results of water-pack freezing test, including temperature graphs.
- **Test 6:** Results of day/night test, including temperature graphs.
- **Test 7:** Results of compressor starting test.
- **Test 8:** Results of holdover time test, including temperature graphs.
- **Test 9:** Results of the freeze protection classification test, including temperature graphs. Refer to Annex 5 for methodology for freeze protection analysis and grading.
- **Test 10:** Results of the door opening test, including temperature graphs and photographs of the vaccine vial before and after visual inspection for condensation.
- **Test 11:** Results of minimum rated ambient temperature test, including
- **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 checklist:

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 checklist:

An on-site inspection of the manufacturing plant is not required.

6.3 Quality control evaluation:

Not required.

7. Pre-qualification evaluation:

An appliance will qualify for inclusion on the register of PQS pre-qualified ice-lined refrigerator appliance in accordance with WHO procedures provided the final report indicates full conformity with the requirements of specification **E003/RF03.2.**

8. Modified appliances:

The legal manufacturer or reseller must notify WHO in writing of any changes which affect the performance of the appliance. WHO will carry out a desk evaluation of the reported change(s). If any change is deemed adversely to affect the performance of the appliance, 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 ±1ºC 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 H:+43ºC is 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 appliance manufacturer before the test commences.
- Temperatures within the appliance must be continuously monitored to an accuracy of ± 0.5ºC 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:

Initial stabilization is accomplished when the appliance demonstrates all of the following:

- The thermal storage has been cooled for a time period no less than the cool down time period stated in the instructions provided by the manufacturer. (e.g. if instructions state cool down time is 7 days then at least a 7 day cool down test is required); and
- The internal temperatures in the vaccine storage compartment are within the acceptable temperature range; and
- The cooling system has exhibited consistent on/off operation for the final two days of this test (e.g. the same number of on/off cycles per day for the final two days).

Before measuring the performance of a refrigerator or freezer under normal running conditions, internal temperature conditions in the vaccine storage compartment 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 ±1ºC and there is no marked trend away from the mean temperature at that point over 24 hours.

Vaccine storage capacity measurement:

- Measure vaccine storage capacity using cardboard boxes, plastic foam or wooden blocks, 100 x 100 x 100 mm, 100 x 100 x 50 mm, and 50 x 50 x 50 mm.

- Fill the appliance up to the maximum loading line recommended by the manufacturer.
- Where baskets and shelves are supplied, these should be used to hold the dummy load. Do not place any boxes outside the zone designated by the manufacturer for vaccine storage.
- Do not place the dummy load in the fast freeze compartments of vaccine freezers.

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 surfaces of the vaccine storage compartment and at the centre of the vaccine load 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 notes.
- For non-Grade A appliances and where vaccine storage baskets are supplied with the appliance, fix sensors within the volume(s) defined by the internal faces of the basket(s).
- 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.

Dummy vaccine load:

Make up a dummy vaccine load[6] using partially filled water-packs.

- Measure the chosen water-packs to establish their nominal unit volume in litres (length x width x thickness in cm/1000).
- Select the number of empty water-packs required to build a dummy load whose nominal volume is equal to the measured vaccine net storage capacity in litres divided by five, ± 5%.
- Partially fill the water-packs with equal volumes of water so that the mass of the load is equal to the nominal load volume x 0.4 kg (0.4 kg per litre).

Pre-condition the dummy load at +8°C and place in the appliance as follows so that it does not interfere with the sensor positions already established:

Front-opening appliances:

- Stack the partially filled water-packs evenly on the shelves designated for vaccine storage.

Top-opening refrigerators:

[6] The dummy load described below is intended to approximate the minimum vaccine load in a well managed refrigerator holding a 25% safety stock.

- Stack the partially filled water-packs evenly on the bottom of baskets supplied for vaccine storage.
- If baskets are not required to keep vaccine away from the base and walls of the appliance, stack the partially filled water-packs evenly on the base of the appliance.

Top-opening freezers:

- Stack the partially filled water-packs evenly on the base of the appliance.

Water-packs:
Tests which require water-packs must use 0.3, 0.4 or 0.6 litre water-packs conforming to PQS specification **E005/IP01.**

Dual compressor units:
Both compressors should be switched on during all tests.

Multi-fuel and multi-function appliances:

- Multi-fuel appliance (typically absorption refrigerators or freezers) will be lengthy and costly to test, so a decision on which options should be tested will be made by WHO on a case by case basis.
- In the case of appliances which can be run either as a freezer or as a refrigerator, the first set of tests should test the refrigerator function and the second set should test the freezer function.

Annex 2 – Temperature sensor positions

Approximate sensor positions are indicated by the figures.

The probes are to be placed in direct contact with the surfaces of the vaccine storage compartment and should not be inserted into brass or tin-covered copper mass, as required in the previous version of this protocol. These probes must be directly in contact with the walls of the vaccine storage compartment. However, the probes that are placed in more central locations in the vaccine storage compartment are to remain in brass- or tin-covered copper mass. For non-Grade A appliances and if baskets are used for vaccine storage, the sensors should be located inside the basket(s) but not touching the basket material.

Figure 1: Refrigerators with integral water-pack freezing section

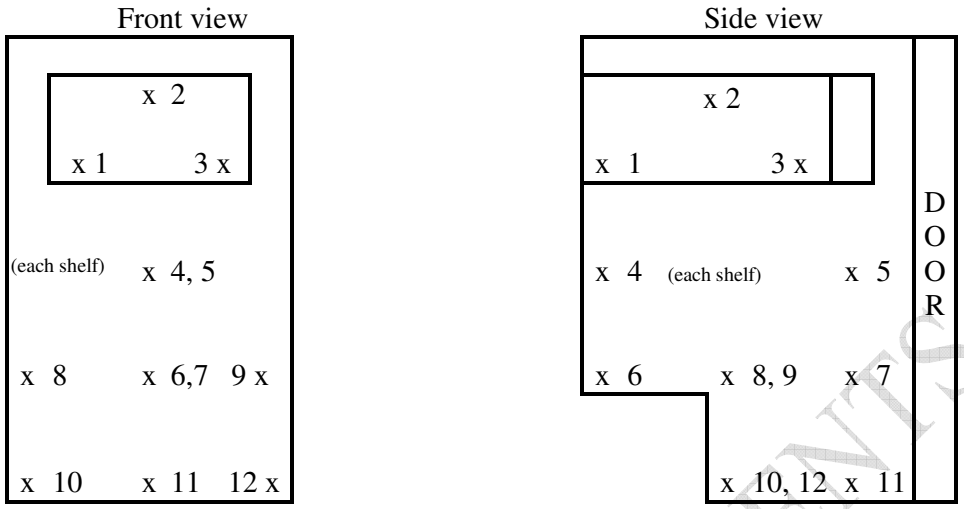


Figure 2: Refrigerator with separate freezer

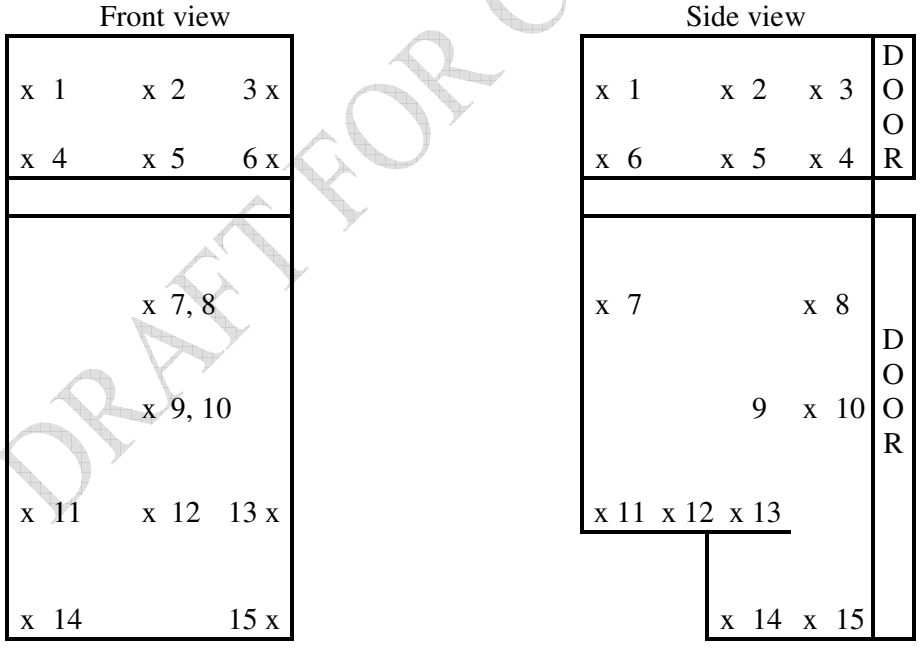
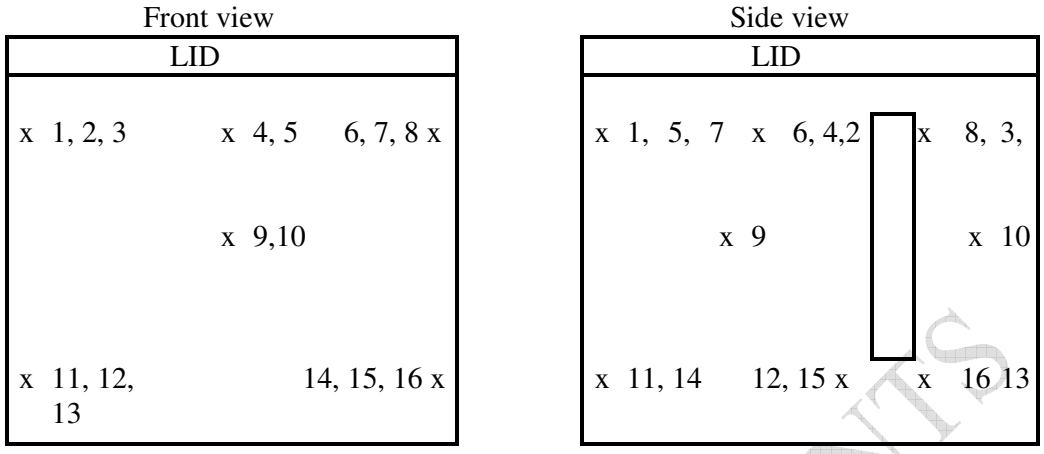


Figure 3: Chest type refrigerator/freezer



Annex 3 – Temperature sensor specification

Complying with IEC 62552, clause 8.7.1. Probe, accurate to ±0.5°C. Only probes for central locations and not directly in contact with a vaccine storage compartment surface are to be inserted into brass or tin-covered copper mass of 25 g ± 5 % and of minimum external area (diameter = height = about 15.2 mm).

Annex 4 – Methodology for measurement of ice production

The following tests are used to determine whether a water-pack is fully frozen, partially frozen, or unfrozen. While the assessment is not 100% accurate, misclassifications are usually conservative in nature: water-packs that are fully frozen are sometimes classified as partially frozen rather than partially frozen water-packs being classified as fully frozen. A fully frozen water-pack contains only ice. A partially frozen water-pack contains both ice and water. An unfrozen water-pack contains only water

Perform the all of the following tests on the water-pack:

- Shake test - Shake the water-pack while holding the water-pack near the assessor's ear. If the sound of water sloshing in the water-pack is heard, then the water-pack fails the shake test.
- Tilt test – Tilt the water-pack back and forth while looking for the movement of air or water in the water-pack. If the movement of air or water is observed, then the water-pack fails the tilt test.
- Bulge test – Water expands when it freezes. Examine the water-pack for localized bulging near the centreline of the water-pack when viewing the water-pack from the side. If localized bulging is not present, then the water-pack fails the bulge test.
- Classify the water-pack as follows:
    - If the water-pack passes all three tests, then the water-pack is fully frozen.

If the water-pack fails one or more tests, then the water-pack is partially frozen or unfrozen and fails the test.

Annex 5 – Methodology for 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.

Revision history:			
Date	Change summary	Reason for change	Approved
23.03.2007	General edit	Final revisions to PQS format.	UK
26.04.2007	Revised to SMc comments & teleconference UK, SMc, AG 26.04.07		UK
16.05.2007	Final review version. Minimum ambient temperature test substituted for cold climate freeze protection test. Other minor changes.	Response to SMc and SS comments.	UK
23.05.2007	Areas not suitable for vaccine storage definition omitted (moved to specification). Holdover time definition corrected. Water-pack freezing capacity definition corrected. 5.3.1: Minor additions. 5.4: Minor correction. 5.4: Excursion analysis added.	Consistency with other VPs.	UK
31.05.2007	5.3.8: Maximum freezer compartment temperature added	SMc. Consistency with other VPs.	UK
06.07.2010	General: 'combination' changed to 'combined'. 'Icepack' changed to 'water-pack'. Scope: Note added. 2: Normative references updated. 3: Acceptable temperature range and holdover time definition changed. Water-pack definition clarified. Water-pack freezing capacity definition amended. Vaccine storage capacity amended. 5.3.3: Minor clarifications. Step 3 clarification. 5.3.4: Step 1 changed. Other minor clarifications. 5.3.5: Step 1 and Step 2 merged and amended. Other minor clarifications. Footnote added. 5.3.6: Step 3 clarification. Clarification re water-pack load. Cross-reference corrections. 5.3.7: Steps 1-4 re-written. 5.3.8: 'Continuous' power changed to 'Intermittent' and cycle timing defined. Acceptance and rejection criteria amended. 5.3.10: Clause amended. Step 1 and Step 6 re-written. Step 4 clarified. Footnote added. Acceptance and rejection criteria reworded. 5.4: MKT added. Annex 1: General amendment. Annex 3 added.	Response to comments from manufacturers, testing laboratories and others.	