PQS Independent type-testing protocol

TITLE: Refrigerator or combined refrigerator and water-pack freezer: compression-cycle. Solar direct drive without battery storage

Product verification protocol:	E003/RF05-VP.2
Applies to specification ref(s):	E003/RF05.2
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Contents:

1. Scope:

This document describes the procedure for verifying the performance of compression-cycle vaccine refrigerators or combined refrigerator and water-pack freezers powered by a solar electric system with no battery. A product that passes the relevant tests will be pre-qualified with a specific temperature zone designation and a minimum ambient temperature rating.

Manufacturers can offer a product for testing at one or more of the three temperature zones. If testing is carried out for more than one zone, the full range of tests described in this document must be carried out for the hottest temperature zone selected. When testing for the selected lower temperature zones, the following tests may optionally be omitted: water-pack freezing and power consumption; holdover time; compressor starting; minimum rated ambient temperature and autonomy.

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/RF05.2: *Performance Specification: Refrigerator or combined refrigerator and water-pack freezer: compression-cycle. Solar direct drive without battery storage.*
WHO/PQS/E003/PV01.2: *Performance specification: Solar power system for compression-cycle vaccine refrigerator or combined refrigerator and water-pack freezer.*
WHO/PQS/E003/PV01-VP1.2: *Type-examination protocol: Solar power system for compression-cycle vaccine refrigerator or combined refrigerator and water-pack freezer.*
WHO/PQS/E003/PV01-VP2.2: *Quality assurance protocol: Solar power system for compression-cycle vaccine refrigerator or combined refrigerator and water-pack freezer.*

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.
- 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.

[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.

Autonomy: Time in days that a solar refrigerator, or combined refrigerator and water-pack freezer, can maintain the vaccine load within the acceptable temperature range under low solar radiation conditions (e.g. rain). Autonomy is determined as described in **E003/PV01** – Section 4.1.2 and measured as described in **E003/RF05-VP.2**.
Holdover time: The time in hours without solar energy input during which all points in the vaccine compartment remain between +2°C and +10°C without solar energy input and at the maximum ambient temperature of the temperature zone for which the appliance is rated.
Hot zone: Hot zone units 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.
Manufacturer's gross volume: The manufacturer's stated gross volume or, for purposes of comparison, the internal free volume, including the space occupied by the freezing compartment, and the volume occupied by shelves, but excluding the space taken by the ice-lining or other type of thermal storage, if present.
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.
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.
Solar radiation reference period: The minimum average daily solar radiation on the plane of the solar array that is required to properly power the solar refrigerator, or combined refrigerator and water-pack freezer, expressed in kWh/m²/day.
Temperate zone: Temperate zone units must operate at a steady +32°C ambient temperature and over a +32°C/+15°C day/night cycling temperature range.
Vaccine storage capacity: The net capacity in an appliance available for the storage of vaccines. It is measured in litres in the following manner:

- **Freezers:** Load the vaccine storage compartment up to the manufacturer's loading markings with boxes or blocks measuring 100x100x100 mm or

100x100x50 mm, packed so that there is minimal air space between each column of packets or between the packets and any adjoining wall. The total volume of the dummy load, in litres, represents the net volume available for the storage of vaccines.

- **Refrigerators:** Load the vaccine storage compartment up to the manufacturer's loading markings with boxes or blocks measuring 100x100x100 mm or 100x100x50 mm, packed so that there is a minimal air space between each column of packets or between the packets and any adjoining wall. If baskets are provided, load the boxes or blocks into the baskets in the same manner. The total volume of the dummy load, in litres, represents the net volume available for the storage of vaccines.

Water-pack: Flat plastic container, filled with water, conforming to specification **E005/IP01**.

Water-pack freezing capacity: The maximum net amount of solid ice which remains at the end of a night phase in the water-pack freezing test. During the test the temperature of the vaccine storage compartment must remain within the acceptable temperature range.

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:*

Products 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 product is required. A compatible solar power system is not required. If more than one version of the product is available (for example, for different temperature zones), provide one sample of each version.

5.3 *Test procedure:*

5.3.1 Solar power simulator:

Refer to specification **E003/PV01** for solar power system specifications.

a. All performance tests use a direct current source to simulate a solar power array. To simulate a solar power array, use an electronic power supply or multiple power supplies connected to timers. The combined power supply and timer accuracy must be of ±5% or better. The power supply must simulate a solar radiation reference period by staging the power output with at least four output stages equal to 0.0 kWh/m^2, 0.1 kWh/m^2, 0.5 kWh/$m^2$and 0.7 kWh/m^2.

b. The appliance manufacturer must specify the appropriate target solar radiation reference period corresponding to a value expressed in kWh/m^2/day; normally between 1.0 and 6.0 kWh/m^2/day, designed to represent the average daily solar radiation received over a 24 hour period.

The manufacturer must also specify the required solar power profile including:

- Volts.
- Amperes.
- The daily run time in hours.
- Suggested cool down time.

c. Amperage will be verified from solar module data sheets and will be based on solar module specifications as reported under standard test conditions (STC =1000 W/m2 at 25˚C). The current will vary directly with the power supply output variables (e.g. use 70% of reported STC value for output stage 0.7 kWh/m2). The voltage may remain constant or may vary only if compressor voltage varies with corresponding amperage.

d. Any solar radiation reference period can be simulated based on the table below[2]:

Day with 1.0 kWh/m²/day (IEC 62124)
5 hour at 200 W/m²
14 hours at 0 W/m²
Day with 3.5 kWh/m²/day (interpolated)
1 hour at 50 W/m2
2.5 hours at 250 W/m²
0.5 hours at 350 W/m²
4 hours at 450 W/m²
0.5 hours at 350 W/m²
2.5 hours at 250 W/m²
1 hour at 50 W/m²
Day with 6.0 kWh/m²/day (IEC 62124)
1 hour at 100 W/m²
3 hours at 500 W/m²
4 hours at 700 W/m²
3 hours at 500 W/m²
1 hour at 100 W/m²
12 hours at 0 W/m²

e. The simulated solar power supply must be set up, as described above, to model a typical solar radiation pattern experienced over an average day at the target solar radiation reference period. Note that in actual field conditions the power supply will be a solar array with similar power output to the manufacturer's specified power supply.

f. The power supply and runtime will be based on the solar radiation reference period the manufacturer specifies and this will be reported as the minimum solar resource for which the product is pre-qualified.

[2] For example, if the appliance manufacturer specifies a solar array with operating characteristics of 10 amps DC (STC) operating at 15 Vdc and a solar radiation reference period of 6.0 kWh/m2-day the simulated day would consist of 12 hours at 0 amps, then 1 hour at 1.0 amps, then 3 hours at 5.0 amps, then 4 hours at 7.0 amps, then 3 hours at 5.0 amps and then 1 hour at 1.0 amps. The voltage remained constant at 15.0 Vdc.

5.3.2 Test 1: Type examination:

- **Step 1:** Unpack the product. 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 which make it difficult or impossible to test the 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;
  - Product 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:
  - Temperature zone rating sticker conforms/does not conform to Annex 1 design (specification clause 4.2.1).
  - Cycle type conforms/does not conform to specification clause 4.2.2.
  - Voltage and frequency conforms/does not conform to specification clause 4.2.3
  - Combined units only: Water-pack freezing compartment capacity conforms/does not conform to recommendations in specification clause 4.2.5.
  - Exclusion of areas not suitable for vaccine storage conforms/does not conform to specification clause 4.2.6.
  - Thermostat type conforms/does not conform to specification clause 4.2.8.
  - Thermometer conforms/does not conform to specification clause 4.2.9.
  - Defrost switch conforms/does not conform to specification clause 4.2.14.
  - Lock conforms/does not conform to specification clause 4.2.15.
  - Corrosion resistance 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.

  Environmental requirements:

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

- 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:
- Electrical component compatibility conforms/does not conform to specification clause 4.5.1.

Human factors:
- General design of the product conforms/does not conform to specification clause 4.6.1.
- Control panel and thermometer conforms/does not conform to specification clause 4.6.2.

Materials and construction:
- 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 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.

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 any other photographs needed to illustrate features of the product in the report.
- **Acceptance criteria:** Inspection indicates full conformity with all major specification requirements. System setup must be straightforward and trouble-free.

5.3.3 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.

5.3.4 Test 2: Cool-down:

Power: Simulated solar power as clause 5.3.1.

- **Step 1:** Set the test chamber temperature to M:+27ºC, T:+32°C, H:+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, switch it on and leave it to stabilize.
- **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. Report the solar power profile (see 5.3.1) and total hours to cool down.
- **Acceptance criterion:** Stabilized internal temperatures maintained between +2°C and +8°C in the vaccine storage compartment and below 0°C in the water-pack freezing compartment (if present) achieved within the test period. Water-pack freezing compartment excursions above 0°C are permitted during the night phase of the simulated solar power cycle. No standard set for the cool-down time but the period will be reported. Halt the test if the temperature does not stabilize within the period specified by the manufacturer, plus six hours.
- **Rejection criterion:** Failure to stabilize within the required temperature range(s).

5.3.5 Test 3: Stable running and power consumption test:

Power: Simulated solar power as clause 5.3.1.

- **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 between +2°C and +8°C and reach a state where the compressor is cycling due to thermostat regulation.
- **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. Report the solar power profile (see 5.3.1).
- **Acceptance criteria:** Stabilized internal temperatures maintained between +2°C and +8°C in the vaccine storage compartment and below 0°C in the water-pack freezing compartment (if present). Water-pack freezing compartment excursions above 0°C are permitted during the night phase of the simulated solar power cycle. No standard set for power consumption but the figure will be reported.
- **Rejection criterion:** Failure to meet one or more of the acceptance criteria.

5.3.6 Test 4: Water-pack freezing capacity and power consumption test:

Application: Combined units only.

Power: Simulated solar power as clause 5.3.1.

- **Step 1:** Continue the Test 3 conditions. Set airflow restrictor (combined units only) or switch on fast-freeze switch (freezers only). DO NOT adjust the freezer thermostat.

- **Step 2:** Stabilize water-packs at M:+27ºC, T:+32°C, H:+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, if possible in a row and with the edges perpendicular to the evaporator surface. Install the freezer thermocouples, centred as uniformly as 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 start of the next day cycle (100W/m²) check that the vaccine load has remained within the +2°C and +8°C range throughout the test period. Remove the frozen water-packs, drain off any liquid water and check the net weight of frozen ice remaining.
- **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:
  - The total net weight of frozen ice remaining has not increased since the previous cycle.
  - 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 ice that can be frozen whilst still meeting the requirements of specification clause 4.2.4. 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:** In combined units with freezer compartment, a minimum of 1.6 kg net of ice must remain fully frozen at the end of the night-time phase of a 24 hour cycle whilst maintaining the temperature control specified in specification clause 4.2.7. For freezers with at least 50 litres of gross freezer volume a minimum of 2.4 kg net of ice must remain frozen at the end of the night-time phase of a 24 hour cycle whilst maintaining the temperature control specified in specification clause 4.2.7.
- **Rejection criterion:** Failure to meet one or more of the acceptance criteria.

5.3.7 Test 5: Storage of frozen water-packs test:

Application: Combined units only.

Power: Simulated solar power as clause 5.3.1.

- **Step 1:** If Test 4 was successful, allow the appliance to stabilize for a further 24 hours with the freezing compartment empty.
- **Step 2:** Stabilize water-packs at M:+27ºC, T:+32°C, H:+43°C.
- **Step 3:** Load 1.6 kg of water-packs in the freezer compartment, if possible in a row and with the edges perpendicular to the evaporator surface. Install the freezer thermocouples, centred as uniformly as 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 night-time phase of a 24 hour cycle remove the frozen water-packs, drain off any liquid water from each water-pack into a vacuum flask and check the net weight of frozen ice remaining.

Immediately return the chilled melt water to the water-packs and place them back in the compartment. Check that the vaccine load has remained within the +2°C and +8°C range throughout the 24 hour test period.

- **Step 6:** Repeat steps 2 to 5 until the total net weight of ice remaining has not increased since the previous cycle, the water-pack compartment is full, or there is a failure at step 5. Record the maximum weight of ice that can be stored at the end of a night-time phase. This is the appliance's 'water-pack storage capacity'.
- **Acceptance criterion:** No standard set, however performance data will be published on the PQS data sheet. The objective is that the appliance should be able to store at least 8 kg net of fully frozen ice at the end of the night-time phase of a 24 hour cycle.

5.3.8 Test 6: Autonomy test:

Power: Simulated solar power as clause 5.3.1.

- **Step 1:** For units without water-pack freezing, continue the Test 3 conditions. For combined units, continue the Test 5 conditions with the water-pack freezing compartment loaded to the measured 'water-pack storage capacity'. Leave the vaccine storage compartment to stabilize between +2°C and +8°C.
- **Step 2:** Connect appliance to a reduced output power supply at the time when the compressor is turned off at the end of the daily compressor cycle. The reduced output power supply must provide the same voltage and daily runtime as specified by the manufacturer, but no more than 5% of the maximum ampere input specified by the manufacturer based on the specified solar radiation reference period.
- **Step 3:** Monitor the temperature of the vaccine load at one minute intervals. At the moment when the warmest point in the load systematically exceeds +8°C[4] record the elapsed time since switch off. Record the position of the warmest point.
- **Acceptance criterion:** Minimum 72 hours at solar radiation reference period. Transient excursions within the acceptable temperature range will be accepted during the test period, provided that sensor temperatures subsequently revert to within the +2°C to +8°C range.
- **Rejection criterion:** Failure to meet the minimum period at the upper temperature of the temperature zone for which the appliance is rated.

5.3.9 Test 7: Holdover time test:

Power: Simulated solar power as clause 5.3.1.

- **Step 1:** Stabilize the test chamber at M:+27ºC, T:+32°C, H:+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 and stabilize the vaccine load temperature between +2°C and +8°C and the water-pack freezing compartment (if present) below 0°C, subject to the permitted night phase excursions. Once the temperature has stabilized, record temperatures every minute.
- **Step 3:** Switch off the power supply at the end of the last compressor ON phase in the simulated solar power cycle immediately before the 0 W/m^2

[4] 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.

period of the cycle. 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 +10ºC, record the elapsed time since switch off and add this to the value 't' recorded in Step 3. Record the position of the warmest point.
- **Acceptance criterion:** Minimum 20 hours at a continuous ambient temperature of M:+27ºC, T:+32°C, H:+43°C.
- **Rejection criterion:** Failure to meet the minimum period at the upper temperature of the temperature zone for which the appliance is rated.

5.3.10 Test 8: Day/night test:

Power: Simulated solar power as clause 5.3.1.

- **Step 1:** Stabilize the test chamber at M:+27ºC, T:+32°C, H:+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 and stabilize the vaccine load temperature between +2°C and +8°C and the water-pack freezing compartment (if present) below 0°C, subject to the permitted night phase excursions. Allow to run for a further 24 hrs.
- **Step 3:** Over a 3-hour period reduce the temperature of the test chamber to M:+10ºC, T:+15ºC, H:+25ºC. Hold this temperature for 9 hours. Raise the temperature to M:+27ºC, T:+32°C, H:+43°C over a 3-hour period. Hold at M:+27ºC, T:+32°C, H:+43°C for a further 9 hours. Reduce again to M:+10ºC, T:+15ºC, H:+25ºC again over a further 3 hr period. Repeat this simulated day/night 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. Record the highest and lowest temperatures reached during the test.
- **Acceptance criterion:** 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 criterion:** 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.

5.3.11 Test 9: Minimum rated ambient temperature test:

Power: Simulated solar power as clause 5.3.1.

- **Step 1:** If the manufacturer's stated minimum ambient operating temperature is lower than the simulated night time temperature in the day/night test, stabilize the test chamber at this temperature, rounded up or down to the nearest 5ºC [5]. Otherwise stabilize the test chamber at M:+10ºC, T:+15ºC, H:+25ºC.
- **Step 2:** Load the appliance with simulated, pre-conditioned vaccine as described in Annex 1.

[5] For example, if the manufacturer's rated minimum operating temperature for a temperate climate appliance is +8ºC, start the test at +10ºC. If no minimum temperature is given, start the test at +15ºC.

- **Step 3:** Switch the appliance on and stabilize the vaccine load temperature between +2°C and +8°C and the water-pack freezing compartment (if present) below -0°C, subject to the permitted night phase excursions. At the same time, for combined units, stabilize the minimum specified water-pack load at the current ambient temperature[6].
- **Step 4:** Load the stabilized water-packs (combined units only) and leave the appliance to run for 24 hours.
- **Step 5:** Record temperatures every minute. At the end of the night-time phase, remove the water-packs from the freezing compartment (if applicable) and check that they are frozen to the minimum extent established in Test 4.
- **Step 6:**
  - Condition 1: The vaccine load has remained within the +2°C to +8°C range and (in combined units only) water-packs are frozen as defined in Step 5. Lower the temperature of the test chamber by 5°C and repeat steps 3 to 5. Continue this cycle until **either**: the minimum water-pack load (if applicable) is no longer frozen to the minimum extent established in Test 4 **or**: the vaccine load temperature strays outside the +2°C to +8°C range **or** the temperature of the test chamber reaches -15°C.
  - Condition 2: The vaccine load has not remained within the +2°C to +8°C range and/or (in combined units only) water-packs are not frozen as defined in Step 5. Raise the temperature of the test chamber by 5°C and repeat steps 3 to 5. Continue this cycle until the minimum water-pack load (if applicable) is frozen to the minimum extent established in Test 4 **and** the vaccine load temperature remains within the +2°C to +8°C range Stop the test cycle if the appliance fails at the simulated night time temperature used in the day/night test.
- **Acceptance criteria:** Record the lowest temperature increment at which 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. This temperature is the minimum rated ambient temperature for the appliance [7] and this figure, rounded up to the nearest 5°C, will be printed in the blue sector of the temperature zone symbol (see specification Annex 1).
- **Rejection criterion:** Failure to pass the test at the simulated night time temperature used in the day/night 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 for which the product is suitable and confirmation of the minimum rated ambient temperature.

[6] 'Minimum load' in this context is the gross volume of water-packs needed to produce the acceptable minimum mass of ice (1.6kg or 2.4kg) at the end of a night-time phase as established in Test 4.

[7] Although the test chamber may reach -15°C during the test, the minimum rated ambient temperature will never be below -10°C.

- **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, including temperature graphs.
- **Test 4:** Results of water-pack freezing test (if applicable), including temperature graphs.
- **Test 5:** Results of storage of frozen water-packs test (if applicable), including temperature graphs.
- **Test 6:** Results of autonomy test, including temperature graphs.
- **Test 7:** Results of holdover time test, including temperature graphs.
- **Test 8:** Results of day/night test, including temperature graphs.
- **Test 9:** Results of minimum rated ambient temperature test, including temperature graphs.
- **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:

A product will qualify for inclusion on the register of PQS pre-qualified equipment in accordance with WHO procedures provided the final report indicates full conformity with the requirements of specification **E003/RF05.2**

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 ±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 M:+27ºC, T:+32ºC and H:+43ºC 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 ± 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 15 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 ±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 and 100 x 100 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 at the centre of the vaccine load compartment and 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.
- Where sensors are located in the vaccine storage compartment place them within the volume designated by the manufacturer for vaccine storage.
- Where vaccine storage baskets are supplied with the appliance, fix sensors within the volume(s) defined by the internal faces of the basket(s).
- 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.

Dummy vaccine load:

Make up a dummy vaccine load[8] 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 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:

- 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.

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

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 equipment (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. Except for sensors placed centrally in a compartment, the centre of sensors should be placed 50 ±10 mm away from the lining of the water-pack freezing compartment or vaccine storage compartment. 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

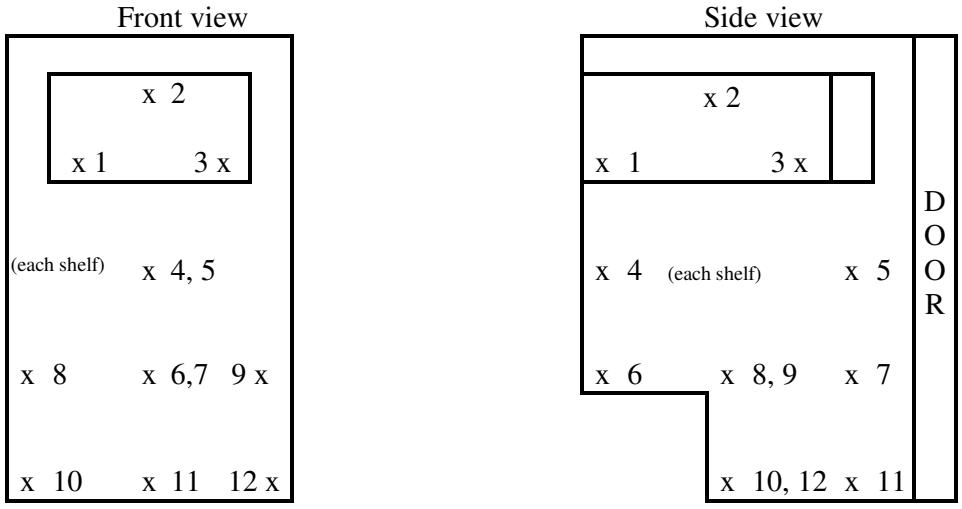


Figure 2: Refrigerator with separate freezer

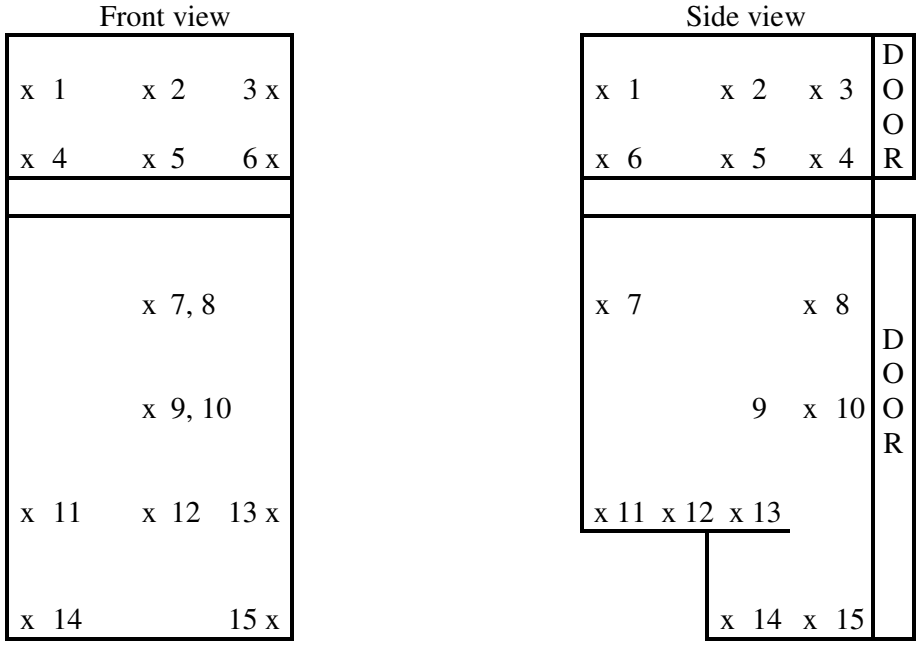
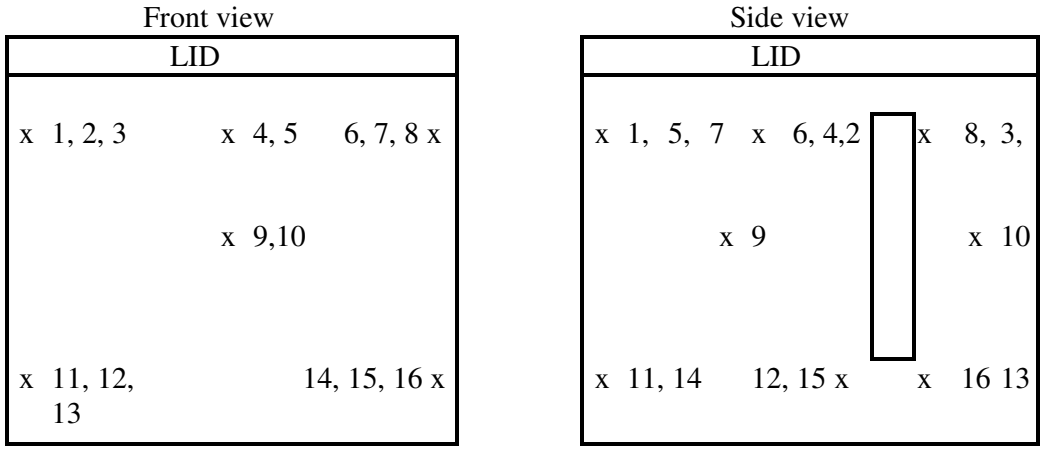


Figure 3: Chest type refrigerator/freezer



Annex 3 – Temperature sensor specification

Complying with IEC 62552, clause 8.7.1. Probe, accurate to ±0.5°C, inserted into brass or tin-covered copper mass of 25 g ± 5 % and of minimum external area (diameter = height = about 15.2 mm).

Revision history:			
Date	Change summary	Reason for change	Approved
09.05.2007	Revised to SMc comments & teleconference UK, SMc, AG 26.04.07		UK
16.05.2007	Final review version. Cool temperature freezing test omitted. Other minor changes.	Covered by Minimum rated ambient temperature test. Response to SMc comments.	UK
23.05.2007	Definition of 'areas not suitable for vaccine storage' deleted. 5.3.2: Minor additions 5.4: Excursion analysis added.	Consistency with other VPs.	UK
08.08.2007	Final review.		UK
06.07.2010	Scope: Note added. 'Icepack' changed to 'water-pack'. 2: Normative references updated. 3: Acceptable temperature range and holdover time definition changed. Autonomy definition clarified. Water-pack definition clarified. Water-pack freezing capacity definition amended. Vaccine storage capacity amended. 5.3.1: Cross reference corrected. Power cycle table amended. 5.3.2 - Step 4: Reference to spec clause 4.2.5 added. 5.3.4: Minor clarification. Step 1, 2 and 3 amended. 5.3.5: Minor clarifications. Step 1, 2 and 3 amended. 5.3.6: clarification re water-pack load. Step 5, Step 6 and acceptance criteria amended. Cross references corrected. 5.3.7: Step 5, Step 6 and acceptance criteria amended. 5.3.8: Step 1 re-written. Acceptance criterion wording changed. Footnote added. 5.3.9: Step 1: 'full' changed to 'empty'. Step 2: minor clarification. Step 3 amended. 5.3.10: Acceptance and rejection criteria changed to include MKT. 5.3.11: Clause amended. Step 1, Step 5 and Step 6 re-written. Footnotes added. 5.4: MKT excursion analysis. 7: 'ice-lined refrigerator' deleted. 7: 'RF03' replaced with 'RF05' Other cross references updated. Annex 1: General amendment. Annex 2: Figure 1: Sensor 9 position corrected. Annex 3 added.	Response to comments from manufacturers, testing laboratories and others.	