PQS Independent type-testing protocol

TITLE: Refrigerator or combined refrigerator and water-pack freezer: compression cycle

Product verification protocol:	E003/RF01-VP.2
Applies to specification ref(s):	E003/RF01.2
Issue date:	6 July 2010
Date of last revision:	2 August 2007

Contents:

1. Scope:

This document describes the procedure for verifying the performance of compression cycle refrigerators or combined refrigerator and water-pack freezers. A product that passes the relevant tests will 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. In addition appliances are tested to establish a minimum rated ambient temperature designation.

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 and minimum rated ambient temperature.

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/RF01.2: *Performance Specification: Refrigerator or combined refrigerator and water-pack freezer: compression cycle.*

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.
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.
Holdover time: The time in hours during which all points in the vaccine compartment remain between +2°C and +10°C, after the power supply has been disconnected, at the maximum ambient temperature of the temperature zone for which the appliance is rated.
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

[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.

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.

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.

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 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.

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. If more than one version of the product is available (for example, for different climate zones), provide one sample of each version. 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 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).

  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.

---

[2] If there is any doubt that the performance of the product 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 products offered by competing companies are re-badged versions of an otherwise identical product.

- 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 specification clause 4.2.4.
- Exclusion of areas not suitable for vaccine storage conforms/does not conform to specification clause 4.2.5.
- Thermostat type conforms/does not conform to specification clause 4.2.7.
- Thermometer conforms/does not conform to specification clause 4.2.8.
- Lock conforms/does not conform to specification clause 4.2.13.
- Corrosion resistance conforms/does not conform to specification clause 4.2.14.
- Electrical safety rating conforms/does not conform to specification clause 4.2.15.
- Markings conform/do not conform to specification clause 4.2.16.
- Vaccine storage advice conforms/does not conform to specification clause 4.2.17.

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 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.

5.3.2 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.

Note: Domestic refrigerators typically have separate vegetable compartments in the bottom. These areas usually operate at higher temperatures and are not normally used for storing vaccine. Analyse and report temperature distribution data from these areas separately so that the values obtained for the vegetable compartment do not distort those for the main compartment.

5.3.3 Test 2: Cool-down:

Power: Continuous.

- **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.
- **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.
- **Rejection criterion:** Failure to stabilize within the required temperature range(s).

5.3.4 Test 3: Stable running and power consumption test:

Power: Continuous

- **Step 1:** When the internal temperature(s) are 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:** 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: Water-pack freezing capacity and power consumption test:

Application: Combined units only.

Power: Continuous.

- **Step 1:** Continue the Test 3 conditions.
- **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 end of the test period check that freezing compartment is below -3°C and the water-packs are frozen. Check that the vaccine load has remained within the +2°C and +8°C range throughout the 24 hour test period. Remove the 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 4.2.4. 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 of water-pack must be frozen per 24 hours whilst maintaining the temperature control specified in specification clause 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.

5.3.6 Test 5: Holdover time test:

Power: Continuous.

- **Step 1:** For units without water-pack freezing, continue the Test 3 conditions. For combined units, continue the Test 4 conditions but with the water-pack freezing compartment empty.

- **Step 2:** Stabilize the vaccine load temperature between +2°C and +8°C and the water-pack freezing compartment (if present) below -3°C. Once the temperature has stabilized, record temperatures every minute.
- **Step 3:** Switch off the power supply at the start of a compressor ON phase. Record the length of the preceding compressor OFF period (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 power supply switch off and add this to the value 't' recorded in Step 3. Record the position of the warmest point.
- **Acceptance criterion:** Minimum 4 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.

5.3.7 Test 6: Day/night test:

Power: Continuous.

- **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 -3°C. 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 [4]. Record the highest and lowest temperatures reached during the test.
- **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. Freezer compartment temperature (if applicable) must remain below -3ºC.
- **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 and/or freezer compartment temperature (if applicable) exceeds -3ºC.

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 M:+27ºC, T:+32°C, H:+43°C.

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

- **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: Minimum rated ambient temperature test:

Power: Continuous.

- **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 and water-packs (if applicable) as described in Annex 1.
- **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 -3°C.
  At the same time, for combined units, stabilize the minimum specified water-pack load at the current ambient temperature.
- **Step 4:** Load the 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 24 hour test period, remove the water-packs from the freezing compartment (if applicable) and check that they are fully frozen.
- **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 fully frozen. 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 not fully frozen, **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 +2°C to +8°C range and/or (in combined units only) water-packs are not fully frozen. 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 fully frozen **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

[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.

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 [6] 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(s) for which the product 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 water-pack freezing capacity test, including temperature graphs and power consumption.
- **Test 5:** Results of holdover time 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 minimum rated ambient temperature test, including temperature graphs.
- **Excursion analysis:** MKT excursion analysis based on the day/night 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.

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

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/RF01.2**

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[7] 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.

[7] 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

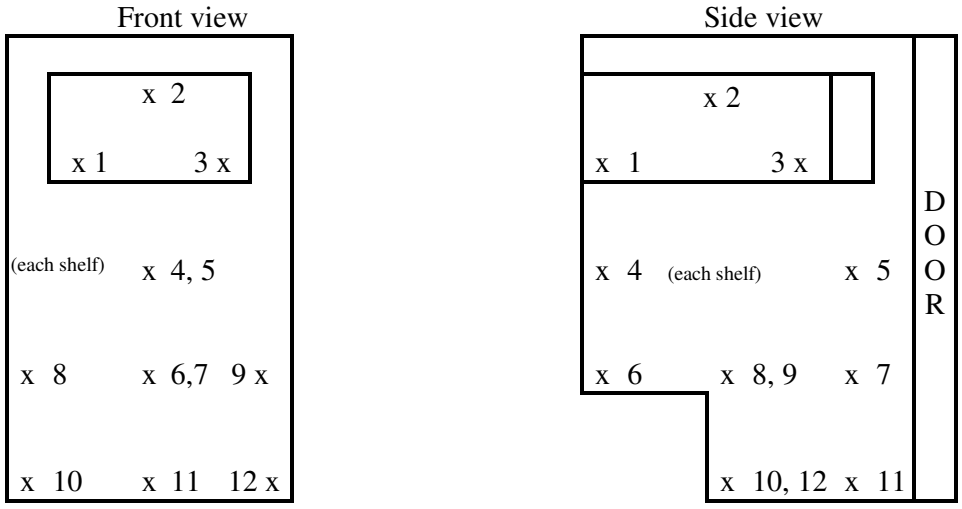


Figure 2: Refrigerator with separate freezer

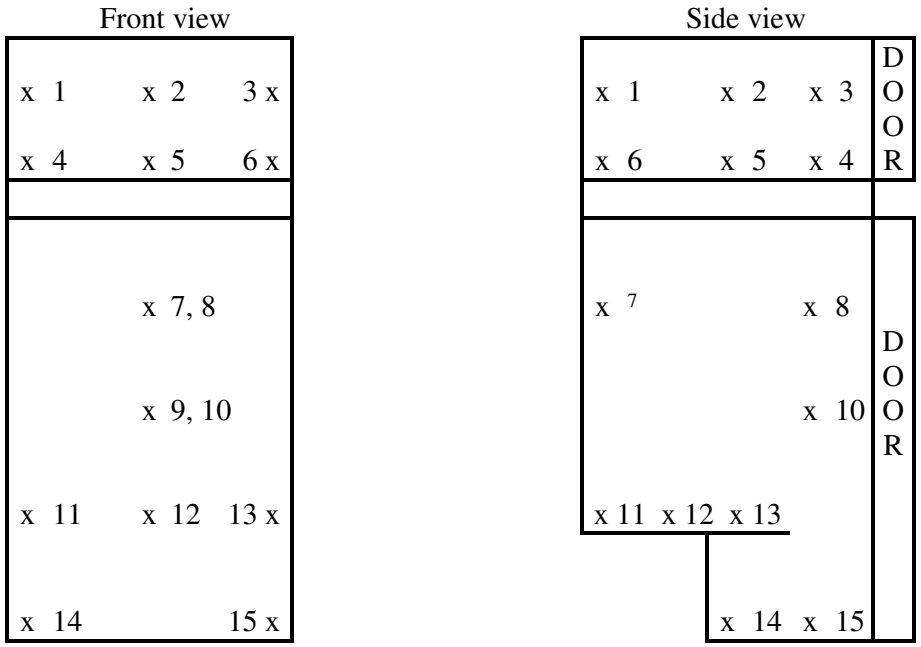
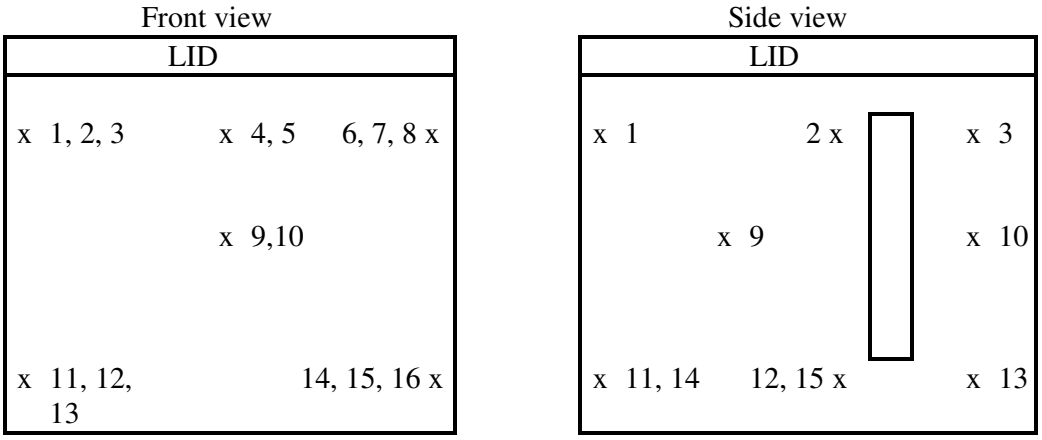


Figure 3: Chest type refrigerator/freezer



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
23.05.2007	General edit	Final revisions to PQS format.	UK
31.05.2007	SMc comments incorporated.		UK
02.10.2007	5.3.6: Acceptance criterion changed to 4 hours.		UK
06.07.2010	Scope: Note added. 'Icepack' changed to 'water-pack'. 2: Normative references updated. 3: Acceptable temperature range definition changed. Water-pack definition clarified. Water-pack freezing capacity definition. Vaccine storage capacity amended. 5.3.3: Minor clarification. Step 3 amended. 5.3.4: Steps 1 and 2 merged. Step 1 amended. Other minor clarifications. 5.3.5: Clarification re water-pack load. Step 5: (to -3ºC or below) deleted. Cross references corrected. 5.3.6 – Step 2: minor clarification. 5.3.6 – Step 1 re-written. Step 3 and Step 4 amended. Acceptance criterion: changed to 4 hours. 5.3.7: MKT excursion analysis added. Acceptance and rejection criteria amended. 5.3.9: Clause amended. Step 1 and Step 6 re-written. Footnote added. Rejection criterion reworded. 5.4: MKT excursion analysis. Annex 1: General amendment. Annex 2: Figure 1: Sensor 9 position clarified Annex 3 added.	Response to comments from manufacturers, testing laboratories and others.	