WHO/PQS/RF02-VP.3
Original: English
Distribution: General

PQS Independent type-testing protocol

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

Product verification protocol:	E003/RF02-VP.3
Applies to specification ref(s):	E003/RF02.3
Issue date:	6 July 2010
Date of last revision:	10 September 2020

Contents

1. Scope

This document describes the procedure for verifying the performance of absorption cycle refrigerators or combined refrigerator and water-pack freezers. Previously, an appliance that passed the relevant tests would be prequalified 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 +10ºC or lower. This is in accordance with the revised performance specification as described in PQS **E003/RF02.3**.

2. Normative references

(use most recent version)

BSI BS 2869: 2017 Fuel oils for agricultural, domestic and industrial engines and boilers.
EMAS: European Union Eco-Management and Audit Scheme.
EN ISO 6270-1 / ASTM D2247 / EN 13523-26: 2014 Determination of resistance to humidity – Part 1: Continuous condensation.
EN ISO 6270-2 / EN 13523-25: 2014 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: 2020 Amendment 1: Household and similar electrical appliances - Safety – Part 1: General requirements.
IEC 60335-2-24: 2020 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: 2019 Electromagnetic compatibility (EMC) Generic standards - Immunity for residential, commercial and light-industrial environments.
IEC 61000-6-3 edition 2.1: 2020 Electromagnetic compatibility (EMC) Generic standards - Emission standard for residential, commercial and light-industrial environments.
IEC 62552-1: 2015 Household refrigerating appliances – Characteristics and test methods.
ISO 2409: 2021 Paints and varnishes – cross cut test (external cabinet).
ISO 6272 / EN 13523-5: 2014 Impact resistance - external cabinet.
ISO 9001: 2015 Quality Management Systems – Requirements.
ISO 14001: 2015 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: 2017 General requirements for the competence of testing and calibration laboratories.
WHO/PQS/E005/IP01.3: Coolant-packs type water-packs (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.
WHO/PQS/E007/VS01.5: Voltage stabiliser for mains electric 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 may exceed +20°C (± 0.5°C) for any amount of time.
- No excursion may drop below -0.5°C for any amount of time.
- No excursion may drop below 0°C for longer than one hour.
- Following an excursion below 0°C, the appliance must return to a safe operating temperature (i.e. consistently between +2°C and +8°C) within two hours. This duration will be measured from the moment the temperature drops below 0°C and 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 one hour,
- Excursion equal to or below -0.5°C for any amount of time; or
- Inability to return to safe operating temperature (i.e. consistently between +2°C and +8°C) within two hours following an excursion equal to or below 0°C.

Freeze protection classification:

- **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 a 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 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.
Icepack storage capacity: The maximum number of fully-frozen water-packs that can remain fully frozen at the end of water-pack storage compartment testing.
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: The lowest constant ambient temperature at which the acceptable temperature range can be maintained with a full vaccine load. All models must be able to operate at a continuous minimum ambient temperature of +10.0°C or lower whilst maintaining the acceptable temperature range.
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.
Phase change material (PCM): A material, other than water, which changes state between solid and liquid or changes between two different solid crystallization states over a defined temperature range, absorbing or releasing heat during the phase change. This process is reversible and can be useful for thermal control in cold chain devices and products.
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.

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. For multi-fuelled appliances with electric option 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 makes 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);

[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.

- Model;
- Legal manufacturer or reseller;
- Appliance type (i.e. vaccine refrigerator or combined appliance);
- Country of origin;
- Conformity assessment markings (e.g. CE mark);
- Temperature zone rating against which the appliance is to be tested.

Performance characteristics (Note: laboratory must report on each clause and in this same order as below)

- Temperature zone rating sticker conforms/does not conform to Annex 1 design (specification clause 4.2.1).
- Refrigeration type and input voltage (if applicable) 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 sticker conforms/does not conform to Annex 3 specification clause 4.2.4 (Note: Grade A, B or C).
- Combined appliances only: Water-pack storage compartment capacity conforms/does not conform to specification clause 4.2.6.
- Thermostat type conforms/does not conform to specification clause 4.2.8.
- Temperature monitoring and thermometer conforms/does not conform to specification clause 4.2.9.
- Flame failure device conforms/does not conform to specification clause 4.2.10.
- Indicator light conforms/does not conform to specification clause 4.2.13 (multi-fuelled appliances with electric option only).
- Condensation management and defrost 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 (multi-fuelled appliances with electric option only).
- Markings conform/do not conform to specification clause 4.2.18.
- Vaccine storage advice conforms/does not conform to specification clause 4.2.19.
- Electromagnetic compatibility conforms/does 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 (multi-fuelled appliances with electric option)

- Electrical components conform/do 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. Manufacturer to certify in writing that the conformance to clause 4.6.1.
- Control panel, indicator light, and thermometer conform/do not conform to specification clause 4.6.2.
- PQS stickers conform/do not conform to specifications clause 4.6.3.

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.

PCM

- PCM, if used, conforms/does not conform to the specification in clause 4.7.4. Manufacturer to provide documentation confirming compliance with **WHO/PQS/E005/PCMC0.1**– PCM specification for Phase-change material containers.

Physical data

- Record major rectangular dimensions in centimetres (± 1.0 cm).
- Record weight in kilograms (± 0.25 kg).
- Record internal volume of refrigerator and freezer compartment in litres.
- Record gross volume of all vaccine and water-pack storage compartments
- 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.

Packaging

- Packaging conforms/does not conform to specification clause 5.

- **Step 5:** Take a three-quarter view digital photograph of the appliance with the door open. Take additional photographs showing all external surfaces of the appliance, the interior layout, the vaccine storage compartment, the cooling system and a close-up of the thermometer, indicator light(s), the control(s), control panel and any special features or identified weaknesses of the appliance. High resolution digital images should be provided for attachment to the PQS report.

Acceptance criteria: Inspection indicates full conformity with all major specification requirements. System setup must be straightforward and trouble-free.

5.3.2 Test temperatures, kerosene quality and testing multi-fuelled appliances

All appliances are to be tested to hot zone temperatures and per Annexes 1, 2, 3, 4 and 5. Record test room ambient and internal cabinet temperatures for at least 48 hours prior to all tests.

Kerosene-fueled appliances should be tested using kerosene as specified in specification **E003/RF02** – Annex 6.

WHO and the appliance manufacturer will agree whether tests should also be carried out under electrical power. If electrical power tests are to be carried out, these will normally be done after the gas or kerosene tests have been completed. Report the test results under both power sources as described in clause 5.4

5.3.3 Test 2: Cool-down, initial stabilisation, and energy consumption

- **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 energy supply switched off.
- **Step 2:** Close the lid or door of the appliance, commence with energy supply for a 24-hour day and leave it to initially stabilise. Initial stabilisation is accomplished when the appliance demonstrates all of the following:
  - The internal temperatures in the vaccine storage compartment are within the acceptable temperature range; and if the cooling system exhibits on/off cycling then
  - 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:** During stabilisation record temperatures every minute, and continue to do so for 24 hours after stabilisation. During this period measure the energy consumption and determine the duty cycle (100% if constantly on). If the cooling system exhibits on/off cycling 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 of 'on' time over this period and report daily energy consumption. If tested with electricity, measure electricity consumption over the same time scale and report as kWh/day.

Acceptance criterion: Stabilised 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 stabilisation). No standard set for the cool-down time but the period will be reported.

Rejection criterion: Failure to stabilise within the acceptable temperature range(s). Halt the test if the appliance does not initially stabilise within the period specified by the legal manufacturer plus one day.

5.3.4 Test 3: Stable running and energy consumption

- **Step 1:** When the internal temperature is stabilised 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 stabilise the internal temperatures between +2°C and +8°C. If the cooling system exhibits on/off cycling it reaches a state where the cooling circuit is cycling due to thermostat regulation.
- **Step 3:** After temperature stabilisation has been achieved, record temperatures every minute for 24 hours. During this period measure the energy consumption and report daily energy consumption. If tested with electricity, 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 of 'on' time over this period and report consumption in kWh/day.

Acceptance criteria: Stabilised 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). No standard set for energy consumption but the figure will be reported.

Rejection criterion: Failure to meet one or more of the acceptance criteria.

5.3.5 Test 4: Water-pack freezing capacity, storage compartment capacity and energy consumption

- **Application:** Combined appliances only.
- **Step 1:** Continue the Test 3 conditions.
- **Step 2:** Stabilise 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. Load the packs in accordance with user instructions including any rack or structure provided. 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 freezer and refrigerator compartment temperatures every minute for the following 24 hours. Measure energy consumption and the cooling system duty cycle over the same duration.
- **Step 5:** At the end of the 24-hour 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 stabilised water-packs up to the point when one or more of the following conditions occurs:
  - the total net weight of fully-frozen water-packs has not increased since the previous cycle;
  - until the freezing compartment is full; and/or
  - the temperature of the vaccine load breaches the +2°C to +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 daily water-pack freezing capacity. Measure energy consumption over the same time scale and report energy consumption.
- **Step 7:** At the start of the next continuous power phase of a 24-hour cycle load water-packs equal to the minimum daily water-pack freezing capacity determined in Step 6 into the freezer compartment in accordance with user instructions which includes any rack or structure provided for holding water-packs. The process to achieve the maximum freezing capacity must be stated in the user instructions.
- **Step 8:** Record freezer and refrigerator compartment temperatures every minute for the following 24 hours. Measure and report energy consumption. If tested with electricity, record cooling system duty cycle over the same duration. Report energy consumption, percentage on-time over the same time scale and graphically display on/off cycles.
- **Step 9:** At the end of the next 24-hour period remove all water-packs and quickly determine which are fully frozen and which are not fully frozen per instructions in Annex 1 – Fully-frozen water-pack determination. Record each water-pack volume, location and condition (i.e. fully frozen or not fully frozen). Replace all packs immediately and add more stabilised water-packs in accordance with user instructions. Note: It must be possible to remove frozen water-packs without any undue force or delay. Defrosting the freezer to enable removal is not acceptable.
- **Step 10:** Repeat Steps 7 to 9 up to the point when either:
  - the total net weight of fully-frozen water-packs has not increased since the previous cycle;
  - until the freezing compartment is full; or
  - the temperature of the vaccine load breaches the +2°C to +8°C range on one or more sensors.

  The number and volume of fully-frozen water-packs at the end of Step 10 are to be reported. This is the appliance's water-pack storage compartment capacity.

Acceptance criteria (water-pack freezing capacity): Stabilised internal temperatures maintained between +2°C and +8°C in the vaccine storage compartment. For freezers of less than 50 litres of gross freezer volume a minimum of 1.6 kg of fully-frozen water-packs must remain fully frozen at the end of a 24-hour test phase whilst maintaining the temperature control specified in 4.2.7. For freezers with at least 50 litres of gross freezer volume a minimum of 2.4 kg of fully-frozen water-packs per 50 litres of gross freezer volume must remain fully frozen at the end of a 24 hour test phase whilst maintaining the temperature control specified in 4.2.7. No standard set for

power consumption but report the daily energy consumption, the percentage on-time during the test time and graphically display on/off cycles.

Acceptance criteria (water-pack storage compartment capacity): Stabilised internal temperatures maintained between +2°C and +8°C in the vaccine storage compartment. For freezers of less than 50 litres of gross freezer volume a minimum of 3.4 kg of fully-frozen water-packs must remain fully frozen at the end of Step10 whilst maintaining the temperature control specified in 4.2.7. For freezers with at least 50 litres of gross freezer volume a minimum of 4.8 kg of fully-frozen water-packs per 50 litres of gross freezer volume must remain fully frozen at the end of Step 10 whilst maintaining the temperature control specified in 4.2.7. No standard set for power consumption but report the daily energy consumption, the percentage on-time during the test time and graphically display on/off cycles.

Rejection criterion: Failure to meet one or more of the acceptance criteria.

5.3.6 Test 5: Day/night, frozen water-pack storage, and energy consumption

- **Application:** Day/night and energy consumption apply to all appliances. Frozen water-pack storage instructions apply only to combined appliances.
- **Step 1:** Incorporating the result from Test 4, allow the appliance to stabilise for a further 24 hours only with the water-pack freezing compartment filled equivalent to the final water-pack storage compartment capacity result from Test 4.
- **Step 2:** For further loading (see Step 6), label and stabilise additional water-packs at +43°C.
- **Step 3:** Commencing with the start of the next 24-hour period hold the temperature of the test chamber to M:+27ºC, T:+32°C, H:+43°C, for a further 12 hours. Then lower the temperature to M:+10ºC, T:+15ºC, H:+25ºC over a three-hour period. Hold at M:+10ºC, T:+15ºC, H:+25ºC for a further nine hours. Next raise the ambient temperature to M:+27ºC, T:+32°C, H:+43°C over a further three-hour period. Hold at M:+27ºC, T:+32ºC, H:+43ºC for a further nine hours. Repeat this simulated day-night cycle for five complete 24-hour cycles in total.
- **Step 4:** At the end of the first 24-hour period remove a minimum of 1.6 kg of packs and not less than 2.4 kg per 50 litres of gross freezer volume of packs from the freezer compartment. These packs will not be returned to the freezer at this time.
- **Step 5:** Record compartment temperatures every minute for the whole test. Measure energy consumption and the cooling system duty cycle over the same test duration and report energy consumption over each 24-hour test phase. If tested with electricity report the percentage on-time and graphically display on/off cycles.
- **Step 6:** At the end of the next 24-hour period load water-packs which have been stabilised at +43°C. This loading replaces the packs removed in Step 4.
- **Step 7:** At the end of the 24-hour period record each pack volume, location and condition (i.e. fully frozen or not fully frozen) per instructions in Annex 1- Fully-frozen water-pack determination. Except for packs

which are to be removed in Step 4, return packs to exact positions without delay.

- **Step 8:** Repeat Steps 3 to 7 until five complete day-night cycles have been completed. If possible, packs removed in each repetition of Step 4 must include packs by rotation not previously removed. Record and report the maximum number and volume of fully-frozen water-packs that can remain fully frozen at the end of every night-time phase.
- **Step 9:** Review the data and calculate the MKT for each sensor in the vaccine storage compartment over the five-day period. Record the highest and lowest temperatures reached during the test.

Acceptance criterion: Vaccine storage compartment 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. No standard is set for the number of fully-frozen and non-fully frozen water-packs at the end of each 24-hour period, but results should be reported as the quantity and volume of stored frozen water-packs that can remain fully frozen at the end of testing over a five-day period. No standard set for energy consumption but report the daily energy consumption. If tested with electricity, report energy consumption in kWh/day, the percentage of 'on' time during the five-day test time, and graphically display on/off cycles.

Rejection criterion: Failure to meet one or more of the acceptance criteria.

5.3.7 Test 6: Holdover time

- **Step 1:** For appliances without water-pack freezing, continue the Test 3 conditions. For combined appliances, continue the Test 4 conditions but with the water-pack freezing compartment empty.
- **Step 2:** Provide energy until the refrigerator and freezer temperatures have re-stabilised.
- **Step 3:** At the end of the next on cycle or the end of the next 24-hour period, switch off the energy supply. If the cooling circuit has already cycled off at this point, record the elapsed time since the end of the previous 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 the energy supply switched off and add this to the value 't' recorded in Step 3. Record the position of the warmest point.

Acceptance criterion: A minimum of four hours at a continuous ambient temperature of +43°C.

Rejection criterion: Failure to meet the minimum holdover period for which the appliance is rated.

5.3.8 Test 7: Freeze protection classification

- **Step 1:** At the end of Test 6, immediately switch on the appliance and monitor the temperature of the vaccine compartment at one-minute intervals.
- **Step 2:** Maintain energy availability until the appliance cools down and the temperatures stabilise.

Acceptance criteria: To receive a Grade A for freeze protection classification, the appliance must meet the definition of Grade A freeze protection (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 a vaccine in the vaccine compartment) and the appliance's cool-down temperatures:

- Must not drop below 0°C for longer than one hour.
- Must not reach -0.5°C for any amount of time.
- Following any excursion below 0°C, the appliance must return to the acceptable temperature range within two hours (i.e. consistently between +2°C and +8°C).

Rejection criterion: Failure to maintain acceptable temperature range during cool-down and stabilisation.

5.3.9 Test 8: Door opening

- **Step 1:** Continuing from Test 7, after an additional one hour of energy availability, open all compartment lids/doors of the appliance. This must include both the primary lids/doors as well as any secondary lids/doors present on the appliance. 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 two hours as the appliance cools down and internal temperatures stabilise.

Acceptance criteria: To receive a Grade A for freeze protection classification, the appliance must meet the definition of Grade A freeze protection and the appliance's cool-down temperatures:

- Must not drop below 0°C for longer than one hour.
- Must not reach -0.5°C for any amount of time.
- Following any excursion below 0°C, the appliance must return to the acceptable temperature range within two hours (i.e. consistently between +2°C and +8°C).

Rejection criteria: Failure to maintain acceptable temperature range during cool-down and stabilisation.

5.3.10 Test 9: Minimum rated ambient temperature

- **Step 1:** Continuing from Test 8, stabilise the test chamber at the temperature specified by the manufacturer rounded up or down to the nearest 5ºC.[4] If no minimum temperature is given, start the test at +10ºC. For combined appliances, also stabilise the minimum specified water-pack freezing capacity load at the current ambient temperature[5].
- **Step 2:** Load the appliance with simulated, pre-conditioned vaccine as described in Annex 1.
- **Step 3:** Switch the appliance on with energy and stabilise the vaccine load temperature between +2°C and +8°C and the water-pack freezing compartment (if present) below -3°C. For combined appliances, also stabilise the minimum specified water-pack load at the current ambient temperature.

- **Step 4** For combined appliances only: Load the stabilised water-packs and leave the appliance to run for 24 hours.
- **Step 5:** Run the appliance for a minimum of 72 hours at test chamber ambient temperature of +10ºC, or at a lower temperature if specified by the manufacturer. Record temperatures every minute. At the end of every 24-hour period, remove the water-packs from the freezing compartment (if applicable) and check that they are fully frozen to the minimum water-pack freezing capacity established in Test 4. Return the packs to the freezer immediately.
- **Step 6:** After a minimum of 72 hours of operation, determine which of these two conditions apply:
  - Condition 1- The vaccine load has remained within the +2°C to +8°C range, and (in combined appliances only) water-packs are fully frozen as defined in Step 5. → *Conclude the testing.*
  - Condition 2 - The vaccine load has not remained within the +2°C to +8°C range, and/or (in combined appliances only) water-packs are not frozen as defined in Step 5. → Raise the temperature of the test chamber by 5°C or to a maximum of +10ºC and repeat Steps 1 to 5. Halt the test cycle if the appliance fails at +10°C.
- **Step 7:** Report the test chamber ambient temperatures, appliance temperatures and condition of water-packs in a graphical display, and for the entire test period starting with Step 1 through the completion of Step 6. If the appliance passes the testing report the minimum rated ambient temperature.

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 test period, and the minimum water-pack load (if applicable) is fully frozen by the end of the cycle. This temperature is the minimum rated

[4] For example, if the manufacturer's rated minimum operating temperature for a temperate climate appliance is +3ºC, start the test at +5ºC.

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

ambient temperature for the appliance[6] and this figure, if not 0ºC or any multiple of 5ºC, is then rounded up to the nearest 5°C and must be +10ºC or lower. The result will be printed in the blue sector of the temperature zone symbol (see **E003/RF02** Annex 1).

Rejection criterion: Failure to pass the test at a simulated temperature of +10ºC or lower.

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, certifications, and relevant photographs.
- **Test 2:** Results of cool-down test, including hours to initial stabilisation, temperature and energy graphs.
- **Test 3:** Results of stable running and energy consumption test, including temperature and energy graphs.
- **Test 4:** If applicable, results of water-pack freezing capacity, storage compartment capacity test, including temperature and energy graphs.
- **Test 5:** Results of day/night and freezer storage capacity tests, including MKT analysis, temperature and energy graphs.
- **Test 6:** Results of holdover time test, including temperature graphs.
- **Test 7:** Results of the freeze protection classification test, including temperature graphs. Refer to Annex 5 for methodology for freeze protection analysis and grading.
- **Test 8:** Results of the door opening 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] Although the test chamber may reach -15°C during the test, the minimum rated ambient temperature will never be below -10°C.

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** 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. Prequalification evaluation

An appliance will qualify for inclusion on the register of PQS prequalified ice-lined refrigerator appliance in accordance with WHO procedures, provided the final report indicates full conformity with the requirements of specification **E003/RF02.**

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.

Stabilisation times:

Initial stabilisation 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 three days then at least a three-day cool down test is required);
- 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 net storage capacity measurement:

- Measure vaccine net 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 required to avoid freezing temperatures, 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[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 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:

- Stack the partially filled water-packs evenly on the bottom of baskets supplied for vaccine storage.

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

- 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 or multiple cooling circuit appliances:
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.

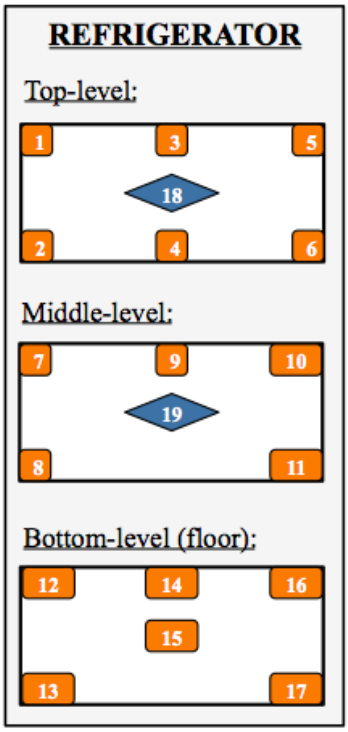
Annex 2 – Temperature sensor positions

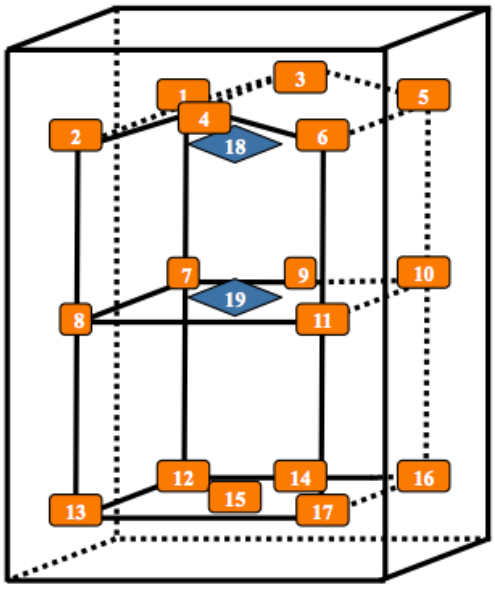
Approximate sensor positions are indicated by the Annex 2 figures. Except for ambient sensors placed centrally in a compartment the surface sensors are positioned in direct contact with the vaccine storage compartment. If baskets are used to define the vaccine storage compartment, all sensors are to be located inside the basket(s) and the surface sensors are to be in contact with the basket material and as shown in the Annex 2 figures.

The surface sensors that are to be placed in direct contact with the walls of the vaccine storage compartment are not to be inserted into brass or tin-covered copper mass, as required in the previous version of this protocol. These surface sensors must be directly in contact with the walls of the vaccine storage compartment. However, the ambient sensors that are placed in more central locations in the vaccine storage compartment are to remain in a brass- or tin-covered copper mass.

UPRIGHT COMPARTMENT

17 Surface sensors
2 Ambient sensors

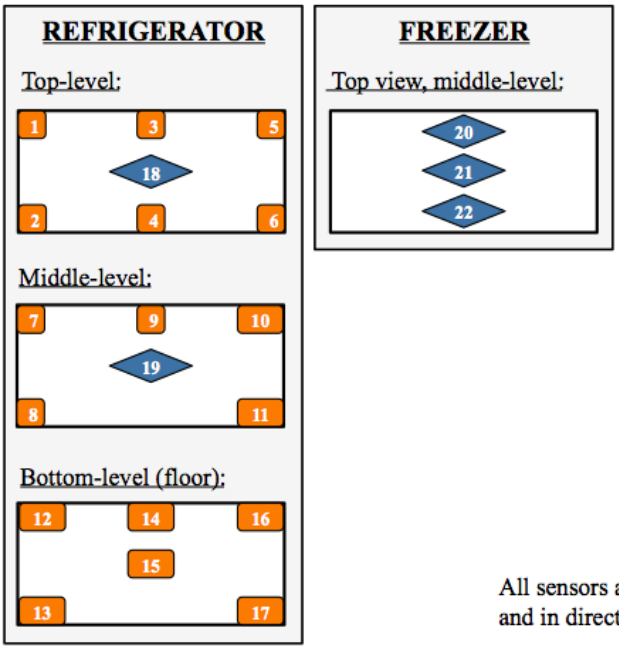


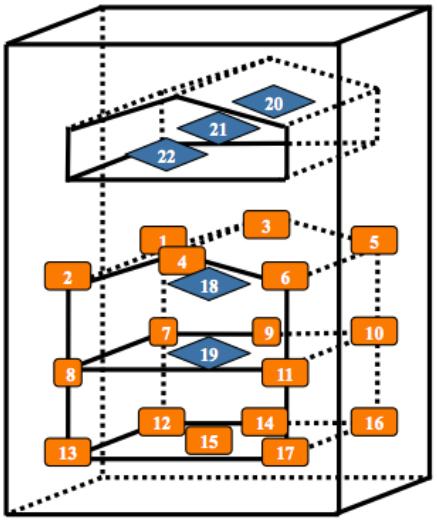


All sensors are to be positioned according to this layout and in direct contact with compartment surfaces.

UPRIGHT COMPARTMENT – WITH FREEZER

17 Surface sensors
5 Ambient sensors





All sensors are to be positioned according to this layout and in direct contact with compartment surfaces.

CHEST COMPARTMENT – NO STEP

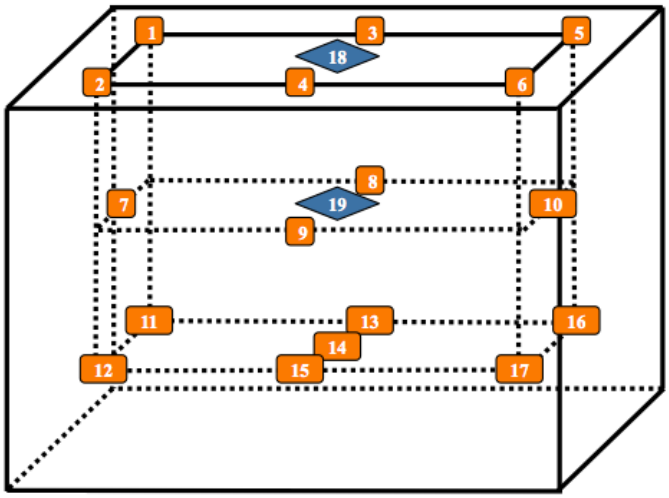
17 Surface sensors
2 Ambient sensors

REFRIGERATOR

Top-level (fill line):

Middle-level:

Bottom-level (floor):



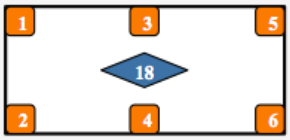
All sensors are to be positioned according to this layout and in direct contact with compartment surfaces.

CHEST COMPARTMENT – WITH STEP

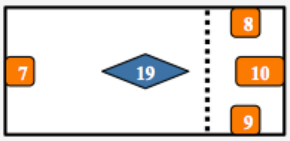
17 Surface sensors
2 Ambient sensors

REFRIGERATOR

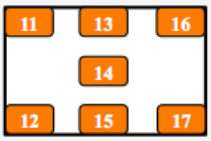
Top-level (fill line):

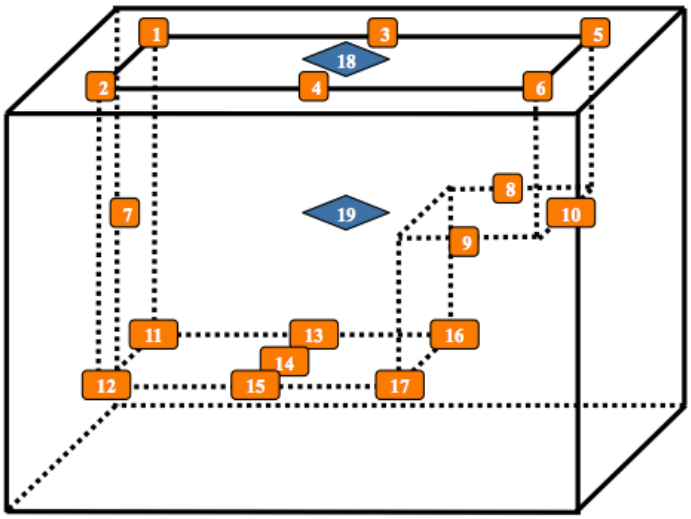


Middle / step-level:



Bottom-level (floor):

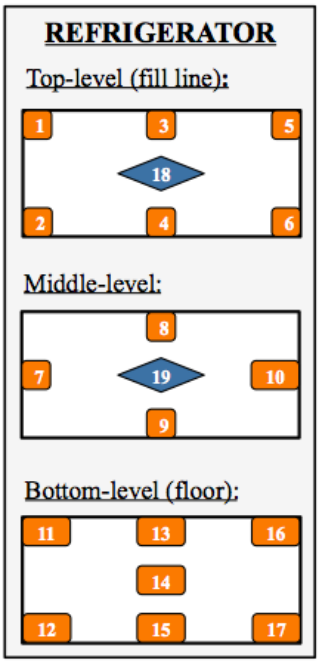


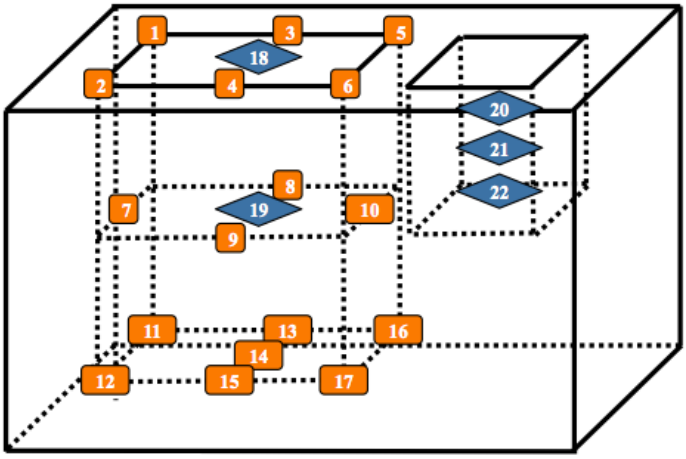


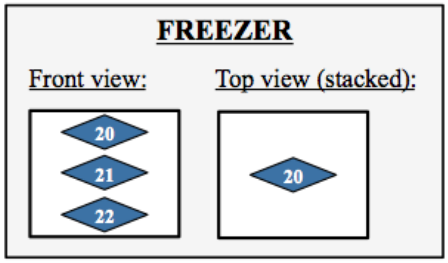
All sensors are to be positioned according to this layout and in direct contact with compartment surfaces.

CHEST COMPARTMENT – WITH FREEZER

17 Surface sensors
5 Ambient sensors

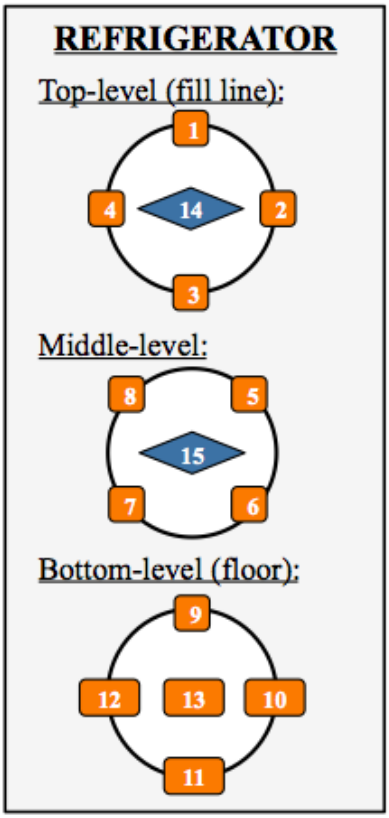


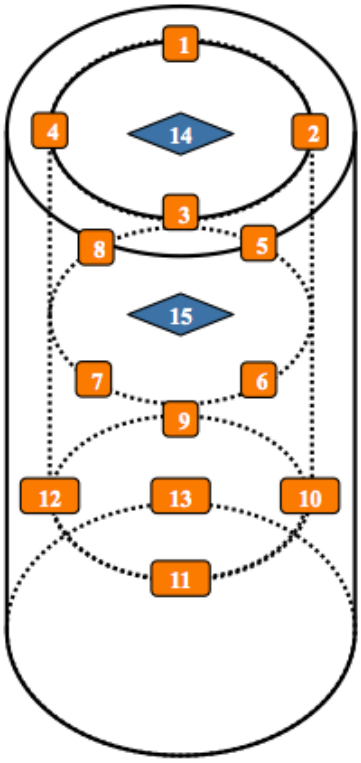




CYLINDRICAL CHEST COMPARTMENT

13 Wall sensors
2 Ambient sensors





Annex 3 – Temperature sensor specification

Surface sensors in contact with the vaccine compartment surfaces must comply with **IEC 62552**, clause 8.7.1 with probe accurate to ±0.5°C but are not to be inserted into brass or tin-covered copper mass of 25 g ± 5 %. Ambient sensors not in contact with the vaccine storage compartment are to comply with **IEC 62552**, clause 8.7.1 with sensor, 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).

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 localised bulging near the centreline of the water-pack when viewing the water-pack from the side. If localised 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 utilise baskets to protect vaccines from freezing.	add 1 user-intervention
Compartment covers	Any need to utilise 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 appliance 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-interventions 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 appliance 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.

Annex 6 - Kerosene quality for testing

Specification details to **BSI BS 2869:2017** for kerosene Class C2 are to be used for testing appliances.

Revision history			
Date	Change summary	Reason for change	Approved
4.10.2017	Major revision to harmonize all appliance verification protocols.	All vaccine refrigerator, vaccine freezer and water-pack freezer technologies to have common minimum performance. Managers and users will rely on a common performance criteria regardless of what refrigeration technology selected.	I.Gobina
4.10.2017	1. Scope changed to require all appliances tested to Hot zone temperatures (+43°C).	Hot zone performance is most demanding and is required of all appliance technologies.	I.Gobina
4.10.2017	2. Normative references updated and increased.	All appliances to comply with improved, updated or most recent versions.	I.Gobina
4.10.2017	3. Terms and definitions harmonized for all appliances technologies.	New requirements and definition clarifications including acceptable temperature range, freeze protection classification and more stringent holdover requirement that now matches acceptable vaccine temperature specification.	I.Gobina
4.10.2017	5.3.1 Test 1: Type examination to comply with PQS E003 RF02.3 revisions and enhanced laboratory test reporting requirements.	All appliances to comply with improved and updated specification requirements.	I.Gobina
4.10.2017	5.3.3 Test 2 Cool down acceptance criteria based on initial stabilization definition.	Previously there was no formal acceptance criteria. Consistent definitions now used for all refrigeration technologies.	I.Gobina
4.10.2017	5.3.5 Test 4: Water-pack freezing acceptance requires specified minimum capacities.	Previously there were exceptions to minimum freezing capacity. Consistent definitions now used for all refrigeration technologies.	I.Gobina
4.10.2017	5.3.6 Test 5: Day/night test expanded to include frozen water-pack storage.	Revised testing more accurately reflects field conditions and is consistent for all refrigeration technologies.	I.Gobina
4.10.2017	5.3.7 Test 6 Holdover time test protocol modified to reflect stricter performance requirement.	All appliances to comply with improved and updated specification requirements.	I.Gobina
4.10.2017	5.3.8 Test 7: Freeze protection classification added.	Potential for vaccine freezing is minimized when user interventions are minimized. Testing confirms freeze protection in vaccine storage areas.	I.Gobina

4.10.2017	5.3.9 Test 8: Door opening	Potential for vaccine freezing is minimized when user interventions are minimized. Testing confirms freeze protection in vaccine storage areas.	I.Gobina
4.10.2017	5.3.10 Test 9: Minimum rated ambient temperature acceptance criteria of +10°C or lower.	Revised testing more accurately reflects field conditions and is consistent for all refrigeration technologies.	I.Gobina
4.10.2017	Annex 1: General test conditions modified.	All appliance technologies to be consistently tested and results to be consistently reported.	I.Gobina
4.10.2017	Annex 2: Temperature sensor positions modified.	Additional sensor positions and instructions provide more accurate test results.	I.Gobina
25.09.2018	clause 3 (Terms and definitions) PCM definition added.	Reflect change to allowance of water-based and PCM-based buffers	I.Gobina
25.09.2018	Bullet on PCM conformity with relevant product specification and compliance with PCM materials specification added to clause 5.3.1 (Type examination)	Reflects change to allowance of PCM-based buffer materials as per product specification.	I.Gobina
10.09.2020	Formatting and minor edits for style.		I.Gobina