



TITLE: Refrigerator or combined refrigerator and water-pack freezer: Solar direct drive with ancillary rechargeable battery.

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1. Scope

Note: The RF06 category will expire and no longer be prequalified after two years from the date of this revision.

This document describes the procedure for verifying the performance of vaccine refrigerators or combined refrigerator and [water-pack](#) freezer (collectively known as appliances) powered by a solar electric system with ancillary rechargeable battery. An appliance that passes the relevant tests will be prequalified with a [hot zone](#) designation, a [minimum ambient temperature rating](#) and [freeze-protection classification](#). If testing is carried out for more than one temperature zone, all tests (except [minimum ambient temperature rating](#)) must be conducted for each optional temperature zone.

2. Normative references

EMAS: European Union Eco-Management and Audit Scheme.
EN ISO 6270-1 / ASTM D2247 / EN 13523-26: Determination of resistance to humidity – Part 1: Continuous condensation.
EN ISO 6270-2 / EN 13523-25: Determination of resistance to humidity - Part 2: Procedure for exposing test specimens in condensation-water atmospheres. GHS Rev 5. United Nations: Globally Harmonized System of Classification and Labelling of Chemicals.
IEC 60335-1: Amendment 1: Household and similar electrical appliances - Safety - Part 1: General requirements.
IEC 60335-2-24: 2007: Household and similar electrical appliances - Safety - Part 2-24: Particular requirements for refrigerating appliances, ice-cream appliances and ice-makers.
IEC 60364-1: 2005: Low-voltage electrical installations - Part 1: Fundamental principles, assessment of general characteristics, definitions. IEC 61000-6-1 edition 2.0: 2005: Electromagnetic compatibility (EMC) Generic standards - Immunity for residential, commercial and light-industrial environments.
IEC 61000-6-3 edition 2.1: 2011: Electromagnetic compatibility (EMC) Generic standards - Emission standard for residential, commercial and light- industrial environments.
IEC 62552: 2007: Household refrigerating appliances – Characteristics/tests.
ISO 2409: 2013: Paints and varnishes – cross cut test (external cabinet).
ISO 6272 / EN 13523-5: Impact resistance - external cabinet. ISO 9001: Quality Management Systems – Requirements.
ISO 14001: 2004: Environmental management systems - Requirements with guidance for use.
ISO 20282-1: 2006: Ease of operation of everyday products - Part 1: Context of use and user characteristics.
ISO/IEC 17025: 2005: General requirements for the competence of testing and calibration laboratories.
WHO/PQS/E003/PV01: Performance specification: Solar power system for compression-cycle vaccine refrigerator or combined refrigerator and water- pack freezer.
WHO/PQS/E003/PV01-VP1.2: Type-examination protocol: Solar power system for compression-cycle vaccine refrigerator or combined refrigerator and water-

pack freezer.

WHO/PQS/E003/PV01-VP2.2: Quality assurance protocol: Solar power system for compression-cycle vaccine refrigerator or combined refrigerator and water-pack freezer.

WHO/PQS/E003/RF06.4: Performance specification: Refrigerator or combined refrigerator and water-pack freezer: Solar direct drive with ancillary rechargeable battery.

WHO/PQS/E005/IP01: Water-packs for use as ice-packs, cool-packs and warm-packs.

WHO/PQS/E006/TH02: Fixed gas or vapour pressure dial thermometer.

WHO/PQS/E006/TH06: Integrated electronic maximum-minimum thermometer, with factory programmed alarms, for vaccine refrigerators and freezers

WHO/PQS/E006/TR06: 30-day electronic temperature logger.

3. Terms and definitions

Acceptable compartment humidity: The acceptable compartment humidity is 55% or lower at +2-8°C during relevant verification testing. However, transient excursions during testing above this value will be tolerated, with the following limits:

- No excursion may exceed 65% at +2-8°C when the appliance is supplied with power and after any initial starting period defined in verification protocols.
- The average compartment humidity during relevant verification testing remains 55% or lower at +2-8°C when the appliance is supplied with power and after any initial starting period defined in verification protocols.

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 ($\pm 0.5^\circ\text{C}$) for any amount of time.
- No excursion must drop below -0.5°C for any amount of time.
- No excursion must drop below 0°C for longer than 1 hour.
- Following an excursion below 0°C, the appliance must return to safe operating temperature (i.e., consistently between +2°C and +8°C) within 2 hours. This duration will be measured from the moment the temperature drops below 0°C and up until it returns to +2°C.

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

Ambient humidity: The relative humidity (%) of the chamber in which the appliance is being tested.

Autonomy (freezer): Time in days that a solar direct drive water-pack freezer can maintain the minimum capacity of fully frozen water-packs under low solar radiation conditions (e.g. rain). Autonomy is measured as described in **E003/RF06-VP.4.**

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

Autonomy (refrigerator): Time in days that a solar refrigerator, or combined refrigerator and water-pack freezer, can maintain the vaccine load within the acceptable temperature range under low solar radiation conditions (e.g. rain). Autonomy is measured as described in **E003/ RF06-VP.4**. Installation site autonomy is determined as described in **E003/PV01** – clause 4.1.2.

Compartment humidity: The relative humidity (%) of the vaccine compartment of the appliance.

Freezing temperature (on walls/lining of vaccine compartment):

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

- Excursion between -0.5°C and 0°C for longer than 1 hour.
- Excursion equal to or below -0.5°C for any amount of time.
- Inability to return to safe operating temperature (i.e., consistently between +2°C and +8°C) within 2 hours following an excursion equal to or below 0°C.

Freeze-protection classification:

- **Grade A, user-independent freeze protection (UIFP):** When the appliance is used within its nominated temperature range (temperature zone +43°C, +32°C or +27°C and **minimum rated ambient temperature**) there is no intervention required by the user to ensure that the vaccines will not be exposed to freezing temperatures below 0°C whatever the position of the vaccine in the vaccine compartment.
- **Grade B, user-dependent freeze protection (UDFP):** Even if the appliance is used within its nominated temperature range, the user must comply with a procedure provided by the manufacturer and requiring one level of intervention (e.g., the requirement to use baskets or other items) in order to avoid vaccine freezing.
- **Grade C, user-dependent freeze protection (UDFP):** Even if the appliance is used within its nominated temperature range, the user must comply with a procedure provided by the manufacturer requiring more than one level of intervention in order to avoid vaccine freezing. (e.g., the requirement to use baskets and insulation barriers or covers).

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.

Hot zone: **Hot zone** units must operate at a steady +43°C ambient temperature and over a +43°C/+25°C day/night cycling temperature range.

Humidity control: A functional capability of a vaccine storage compartment, by which relative humidity levels are controlled while power is available such that limited or no condensation accumulates on compartment, vial or secondary carton surfaces and mould growth is inhibited.

In writing: means communication by letter, fax or email.

Installation: The appliance specified in this document, connected to a Type 2 solar power system complying with specification **E003/PV01**.

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.

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.

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.

Reseller: A commercial entity, licensed to act on behalf of a legal manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the legal manufacturer.

Solar radiation reference period: The minimum average daily solar radiation on the plane of the solar array that is required to properly power the solar refrigerator, or combined refrigerator and water-pack freezer, expressed in kWh/m²/day.

Temperate zone: Temperate zone units must operate at a steady +32°C ambient temperature and over a +32°C/+15°C day/night cycling temperature range.

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): 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 net 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 **E005/IP01**.

Water-pack freezing capacity: The daily maximum weight of fully frozen water-packs which remain at the end of the night phase of the water-pack freezing test.

Water-pack storage compartment capacity: The maximum number of fully frozen water-packs that can remain fully frozen at the end of testing over a five-day period.

4. Applicability

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

5. Type-testing procedure

5.1 Evidence of conformity assessment

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 appliance is required. A compatible solar power system is not required. If more than one version of the appliance is available provide one sample of each version.

5.3 Test procedure

5.3.1 *Solar power simulator*

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

- a. All performance tests use a direct current source to simulate a solar power array. To simulate a solar power array, use an electronic power supply or multiple power supplies connected to timers. The combined power supply and timer accuracy must be of $\pm 0.1\%$ or better. The power supply must simulate a [solar radiation reference period](#) by staging the power output with at least five output stages equal to 0.0 kW/m², 0.05 kW/m², 0.25 kW/m², 0.35 kW/m² and 0.45 kW/m².
- b. The minimum [solar radiation reference period](#) for all appliances is 3.5 kWh/m²/day designed to represent the average daily solar radiation received over a 24-hour period. All appliances must be tested at the minimum [solar radiation reference period](#) of 3.5 kWh/m²/day or less. The manufacturer must also specify the required solar power profile including:
 - Volts and Amperes (Imp from solar module specification).
 - The daily run time in hours and suggested cool down time.
- c. Amperage will be verified from solar module data sheets and will be based on solar module Imp specifications as reported under standard test conditions (STC = 1000 W/m² at 25°C). The current will vary directly with the power supply output variables (e.g. use 45% of reported STC value for output stage 0.45 kW/m²). The voltage may remain constant or may vary only if cooling system voltage varies with corresponding amperage.
- d. Any additional [solar radiation reference period](#) can be simulated based on the table below²:

² For example, if the appliance manufacturer specifies a solar array with operating characteristics of 10 amps DC (STC) operating at 18 Vdc with the minimum [solar radiation reference period](#) of 3.5 kWh/m²-day the simulated day would consist of 12 hours at 0 amps, then 1 hour at 0.5 amps, then 2.5 hours at 2.5 amps, then 0.5 hours at 3.5 amps, then 4 hours at 4.5 amps, then 0.5 hours at 3.5 amps,

Day with 1.0 kWh/m²/day (IEC 62124)
5 hour at 200 W/m ²
14 hours at 0 W/m ²
Day with 3.5 kWh/m²/day (interpolated)
1 hour at 50 W/m ²
2.5 hours at 250 W/m ²
0.5 hours at 350 W/m ²
4 hours at 450 W/m ²
0.5 hours at 350 W/m ²
2.5 hours at 250 W/m ²
1 hour at 50 W/m ²
Day with 6.0 kWh/m²/day (IEC 62124)
1 hour at 100 W/m ²
3 hours at 500 W/m ²
4 hours at 700 W/m ²
3 hours at 500 W/m ²
1 hour at 100 W/m ²
12 hours at 0 W/m ²

- e. The simulated solar power supply must be set up, as described above, to model a typical solar radiation pattern experienced over an average day at the minimum [solar radiation reference period](#). Note that in actual field conditions the power supply will be a solar array with similar power output to the manufacturer's specified power supply.
- f. The power supply and runtime will be based on the [solar radiation reference period](#) the manufacturer specifies and this will be reported as the minimum solar resource for which the product is prequalified.

5.3.2 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 models³, 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](#).
 - Type (i.e. vaccine refrigerator or combined appliance).

then 2.5 hours at 2.5 amps and then 1 hour at 0.5 amps. The voltage remained constant at 18.0 Vdc.

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

- Country of origin.
- Conformity assessment markings (e.g. CE mark).
- Temperature zone rating(s) against which the appliance is to be tested.

Performance characteristics:

- Temperature zone rating sticker conforms/does not conform to Annex 1 design (specification clause 4.2.1).
- Refrigeration type and input voltage 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.
- Indicator light conforms/does not conform to specification clause 4.2.10.
- Power system requirements and voltage conforms/does not conform to specification clause 4.2.13. Manufacturer to certify **in writing** that the power system conforms to **E003/PV01**.
- 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.
- 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:

- Electrical component compatibility conforms/does not conform to specification clause 4.5.1.
- Power switch conforms/does not conform to specification clause 4.5.2.

- Ancillary battery pack conforms/does not conform to specification clause 4.5.3. Manufacturer to certify [in writing](#) that the conformance to clause 4.5.3.
- Battery alarm conforms/does not conform to specification clause 4.5.4.

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 conforms/does not conform to specification clause 4.6.2.

Materials and construction:

- Record materials of all major visible components.
- Refrigerant (if used) 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 volumes of refrigerator and/or freezer compartment(s) 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) conforms/does 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 compressor or 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.

5.3.3 Test temperatures

All appliances are to be tested to [hot zone](#) temperatures and per Annexes 1, 2 and 3. Record test room ambient and internal cabinet temperatures for at least 48 hours prior to all tests. The specific tests listed below apply equally to [moderate zone](#), [temperate zone](#) and [hot zone](#) appliances. Relevant test chamber temperatures are given in the following format M:<XX>°C for [moderate zone](#); T:<XX>°C for [temperate zone](#) and H:<XX>°C for [hot zone](#).

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

- **Power:** Simulated solar power as clause 5.3.1.
- **Step 1:** Set the test chamber temperature to M:+27°C, 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 initially stabilize. Initial stabilization is accomplished when the appliance demonstrates all of the following:
 - The thermal storage has been cooled for a time period no less than the cool down time period stated in the instructions provided by the manufacturer (e.g. if instructions state cool down time is 7 days then at least a 7-day cool down test period is required); and
 - The internal temperatures in the [vaccine storage compartment](#) are within the [acceptable temperature range](#); and
 - The cooling system has exhibited consistent on/off operation for two consecutive days of this test (e.g. the same number of on/off cycles per day).
- **Step 3:** During initial stabilization, record temperatures every minute for 24 hours. During this period measure the energy consumption and determine the compressor or cooling circuit duty cycle. Measure electricity consumption and the cooling system duty cycle over the same test duration and report energy consumption in kWh/day, the percentage on-time over the 12-hour solar phase and graphically display on/off cycles. Report the solar power system voltage and amperage, solar profile (see 5.3.1) and total hours to cool down.

Acceptance criterion: Stabilized internal temperatures maintained between +2°C and +8°C in the [vaccine storage compartment](#) and below 0°C in the [water-pack](#) freezing compartment (if present) achieved within the test period. [Water-pack](#) freezing compartment excursions above 0°C are permitted during the night phase and first three hours of the 12-hour solar phase of the simulated solar power cycle. No standard set for the cool-down time but the period will be reported.

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

5.3.5 Test 3: Humidity control

- **Power:** Simulated solar power as clause 5.3.1.
- **Step 1:** When the internal temperature is stabilized at the end of Test 2 (compartment stabilized between +2-8°C, chamber +43°C and relative humidity of 65%), start recording humidity and temperature monitors at a rate of one measurement per minute.
- **Step 2:** 5 minutes before the solar radiation reference period begins, open the lid or door of the appliance and start a 5-minute timer.
- **Step 3:** Load the appliance with the pre-conditioned Dummy Evaporative Load described in Annex 1. Ensure that the water-pack freezing compartment (if present) is empty.
- **Step 4:** At the conclusion of the 5-minute period, close the lid or door of the appliance. This should coincide with the beginning of the solar radiation reference period as described in 5.3.1. Allow the appliance to run for 4 hours.
- **Step 5:** After this initial 4-hour period, continue recording temperature and relative humidity every minute for 8 hours. This will be the test period.

Acceptance criteria:

If the following acceptance criteria are met, the vaccine refrigerator will be recognized as having Humidity Control.

1. Stabilized internal temperatures maintained between +2°C and +8°C in the vaccine storage compartment and below 0°C in the water-pack freezing compartment (if present) achieved within the test period. Water-pack freezing compartment excursions above 0°C are permitted during the night phase and first three hours of the 12-hour solar phase of the simulated solar power cycle.
2. Average compartment humidity at or below 55% for the duration of the 8-hour test period.
3. Compartment humidity does not exceed 65% for the duration of the 8-hour test period.

Rejection criteria: Failure to maintain the required average compartment humidity, with no excursion above 65% humidity, for the duration of the test period and within the required temperature range.

NOTE: As of the publishing of this verification protocol version, refrigerators will be required to be tested for humidity control as part of the laboratory verification protocol, but compliance with the humidity control acceptance criteria will not be required until publishing of an updated version of this document. The results of the testing must still be reported. The intended time frame will be to require compliance as of January 2023, pending review of equipment performance tests up to that time and publication of updated specifications and verification protocols.

5.3.6 Test 4: Stable running and power consumption

- **Power:** Simulated solar power as clause 5.3.1.
- **Step 1:** After completing Test 3 remove the dummy evaporative load and 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 the internal temperatures between +2°C and +8°C and reach a state where the compressor or cooling circuit is cycling due to thermostat regulation.
- **Step 3:** After internal temperature stabilization has been achieved, record temperatures every minute for 24 hours. During this period measure the energy consumption and determine the compressor or cooling circuit duty cycle. Measure electricity consumption and the cooling system duty cycle over the same test duration and report energy consumption in kWh/day, the percentage on-time over the 12-hour solar phase and graphically display on/off cycles. Report the solar power profile (see 5.3.1).

Acceptance criteria: Stabilized internal temperatures maintained between +2°C and +8°C in the [vaccine storage compartment](#) and below 0°C in the [water-pack](#) freezing compartment (if present). [Water-pack](#) freezing compartment excursions above 0°C are permitted during the night phase and first three hours of the 12-hour solar phase of the simulated solar power cycle. No standard set for power consumption but the figure will be reported.

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

5.3.7 Test 5: Water-pack freezing capacity, water-pack storage compartment capacity and power consumption

- **Application:** Combined appliances only.
- **Power:** Simulated solar power as clause 5.3.1.
- **Step 1:** Continue the Test 4 conditions. DO NOT adjust the freezer thermostat.
- **Step 2:** Label and stabilize [water-packs](#) at M:+27°C, T:+32°C, H:+43°C.
- **Step 3:** At the end of the 12-hour night-time phase of a 24-hour cycle load a minimum of 1.6 kg of [water-packs](#) and not less than 2.4 kg of [water-packs](#) per 50 litres of gross freezer volume into the freezer compartment in accordance with user instructions which includes any rack or structure provided for holding [water-packs](#). The process⁴ to achieve the maximum freezing capacity must be stated in the user instructions.
- **Step 4:** Record freezer and refrigerator compartment temperatures every minute for the following 24 hours. Measure electricity

⁴ Manufacturer should state the number of [water-packs](#) to be loaded to give the maximum daily [water-pack freezing capacity](#) and the number of [water-packs](#) to be loaded on Day 1, Day 2, Day 3 etc. to give the maximum [water-pack storage compartment capacity](#)

consumption and the cooling system duty cycle over the same duration. Report energy consumption in kWh/day, percentage on-time over the 12-hour solar phase and graphically display on/off cycles.

- **Step 5:** At the end of the next 12-hour night phase remove all [water-packs](#) and 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). Do not return frozen packs to the freezer at this time.

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 6:** Repeat steps 3 to 5 loading more stabilized [water-packs](#) in accordance with user instructions up to the point when either:
 - the total net weight of fully frozen [water-packs](#) has not increased since the previous cycle; or
 - 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 6 are to be reported. This is the appliance's daily [water-pack freezing capacity](#).

- **Step 7:** At the end of the 12-hour night-time 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 electricity consumption and the cooling system duty cycle over the same duration. Report energy consumption in kWh/day, percentage on-time over the 12-hour solar phase and graphically display on/off cycles.
- **Step 9:** At the end of the next 12-hour night phase 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 stabilized [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; or 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): Stabilized 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 the 12-hour night 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 the 12-hour night phase whilst maintaining the temperature control specified in 4.2.7. No standard set for power consumption, but report the energy consumption in kWh/day, the percentage on-time during the 12-hour solar phase and graphically display on/off cycles.

Acceptance criteria (water-pack storage compartment capacity): Stabilized 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 energy consumption in kWh/day, the percentage on-time during the 12-hour solar phase and graphically display on/off cycles.

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

5.3.8 Test 6: Day/night, frozen water-pack storage and power consumption

- **Application:** Day/night and power consumption apply to all appliances. Frozen [water-pack](#) storage instructions apply only to combined appliances.
- **Power:** Simulated solar power as clause 5.3.1.
- **Step 1:** Incorporating the result from Test 5, allow the appliance to stabilize 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 5.
- **Step 2:** For further loading (see Step 6), label and stabilize additional [water-packs](#) at M: +27°C, T: +32°C, H: +43°C.
- **Step 3:** Beginning with a 12-hour day phase of a 24 hour solar cycle hold the temperature of the test chamber to M:+27°C, T:+32°C, H:+43°C, for a further 12-hours. Then lower the temperature to M:+10°C, T:+15°C, H:+25°C over a 3 hour period. Hold at M:+10°C, T:+15°C, H:+25°C for a further 9 hours. Next raise the ambient temperature to M:+27°C, T:+32°C, H:+43°C over a further 3 hour period. Hold at M:+27°C, T:+32°C, H:+43°C for a further 9 hours. Repeat this simulated day-night cycle for five complete 24-hour solar cycles in total.
- **Step 4:** At the end of the first 12-hour night-time phase of a 24-hour solar cycle 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 electricity consumption and the cooling system duty cycle over the same test duration and report energy consumption in kWh/day, the percentage on-time over the 12-hour solar phase and graphically display on/off cycles.
- **Step 6:** At the end of the 12-hour solar day phase load [water-packs](#) which have been stabilized in accordance with Step 2. This loading replaces the packs removed in Step 4⁵.
- **Step 7:** At the end of the next night phase, 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 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 set for the number of fully frozen and non-fully frozen packs at the end of each night-time phase but results to 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 power consumption but report the energy consumption in kWh/day, the percentage on-time during the 12 hour solar phase and graphically display on/off cycles.

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

5.3.9 Test 7: Autonomy and power consumption

- **Power:** Simulated solar power as clause 5.3.1.
- **Step 1:** For appliances without [water-pack](#) freezing, continue the Test 4 conditions with the [vaccine storage compartment](#) stabilized between +2°C and +8°C. For combined appliances, continue the Test 6 conditions with the [water-pack](#) freezing compartment loaded to the measured [water-pack storage capacity](#) and the [vaccine storage compartment](#) stabilized between +2°C and +8°C.

⁵ 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 2:** Connect appliance to a reduced output power supply at the time when the compressor or cooling circuit is turned off at the end of the 12-hour solar cycle. The reduced output power supply must provide the same voltage and daily runtime as specified by the manufacturer, but no more than 5% of the solar array ampere (Imp) input specified by the manufacturer based on the [solar radiation reference period](#). Measure electricity consumption and the cooling system duty cycle over the same test duration and report energy consumption in kWh/day, the percentage on-time over the 12-hour solar phase and graphically display on/off cycles.
- **Step 3 (refrigerator autonomy):** Monitor the temperature of the vaccine load at one-minute intervals. Discontinue Step 3 (refrigerator [autonomy](#)) testing at the moment when the warmest point in the load systematically exceeds +8°C⁶ record the elapsed time since switched off and report as the refrigerator [autonomy](#). Record the position of the warmest point and report refrigerator [autonomy](#) in hours.
- **Step 4 (freezer autonomy):** At the end of each 12-hour night phase remove [water-packs](#) one at a time and determine which are fully frozen and which are not fully frozen per instructions in Annex 1: Frozen Water-pack Determination. Record each [water-pack](#) volume, location and condition (i.e. fully frozen or not fully frozen) and without delay place them back in the freezing compartment. At the end of each night phase visually inspect the level of fully frozen packs and record. Discontinue Step 3 (freezer [autonomy](#)) testing when the load of fully frozen [water-packs](#) fall below the minimum daily [water-pack](#) freezing requirement (i.e. either a minimum of 1.6 kg of [water-packs](#) and not less than 2.4 kg per 50 litres of gross freezer volume of frozen [water-packs](#) remaining). Round down to nearest half day increment to report the freezer [autonomy](#) period in increments of half days.

Acceptance criterion: Refrigerator [autonomy](#) minimum 72 hours at the minimum [solar radiation reference period](#) and when tested for the [hot zone](#). Transient excursions within the [acceptable temperature range](#) will be accepted during the test period, provided that sensor temperatures subsequently revert to within the +2°C to +8°C range. Freezer [autonomy](#) minimum overnight (0.5 day) at the [solar radiation reference period](#) and when tested for the [hot zone](#).

Rejection criterion: Failure to meet the minimum [autonomy](#) periods during [hot zone](#) testing.

5.3.10 Test 8: Freeze-protection classification test

- **Power:** Simulated solar power as clause 5.3.1.
- **Step 1:** At the end of Test 7, immediately provide sufficient power to switch on the appliance and run it continuously and monitor the temperature of the vaccine storage compartment at one-minute

⁶ The phrase 'systematically exceeds' means that the sensor temperature follows a continuous upward trend. Transient temperature spikes within the [acceptable temperature range](#) which are followed by a recovery to within the +2°C to +8°C range can be ignored.

intervals.

- **Step 2:** Maintain continuous power until the appliance cools down and the internal temperatures stabilize.

Acceptance criteria: To receive a **Grade A** for [freeze-protection classification](#), the appliance's cool-down temperatures:

- Must not drop below 0°C for longer than 1 hour.
- Must not reach -0.5°C for any amount of time.

Following any excursion below 0°C, within 2 hours the appliance must return to the [acceptable temperature range](#) (i.e., consistently between +2°C and +8°C).

Rejection criterion: Failure to maintain [acceptable temperature range](#) during cool-down and stabilization.

5.3.11 Test 9: Door opening test

- **Power:** Simulated solar power as clause 5.3.1.
- **Step 1:** Continuing from Test 8, after an additional 1 hour of continuous power open all compartment lids/doors of the appliance. This must include primary as well as secondary lids/doors, since some appliances have secondary lids/doors. Allow the compartment to stay fully open for 10 minutes.
- **Step 2:** Once 10 minutes have passed, close the lid/door and monitor temperatures of the vaccine storage compartment as the appliance cools down and internal temperatures stabilize.

Acceptance criteria: To receive a **Grade A** for [freeze-protection classification](#), the appliance's cool-down temperatures:

- Must not drop below 0°C for longer than 1 hour.
- Must not reach -0.5°C for any amount of time.
- Following any excursion below 0°C, within 2 hours the appliance must return to the [acceptable temperature range](#) (i.e. consistently between +2°C and +8°C).

Rejection criteria: Failure to maintain [acceptable temperature range](#) during cool-down and stabilization.

5.3.12 Test 10: Minimum rated ambient temperature

- **Power:** Simulated solar power as clause 5.3.1.
- **Step 1:** Continuing from Test 8, stabilize the test chamber at +10°C or at a lower temperature specified by the manufacturer rounded up or down to the nearest 5°C⁷. At the same time, for combined appliances, stabilize the minimum specified [water-pack freezing capacity](#) load at the current ambient temperature⁸.

⁷ For example, if the manufacturer's rated minimum operating temperature for a temperate climate appliance is +3°C, start the test at +5°C. If no minimum temperature is given, start the test at +10°C.

⁸ 'Minimum load' in this context is the gross volume of [water-packs](#) needed to produce the acceptable minimum mass of ice (1.6kg or 2.4kg) at the end of a night-time phase as established in Test 4.

- **Step 2:** Load the appliance with simulated, pre-conditioned vaccine 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 0°C, subject to the permitted night phase excursions.
- **Step 4:** Load the stabilized [water-packs](#) (combined appliances only) and leave the appliance to run for 24 hours.
- **Step 5:** Run the appliance for a minimum of 72 hours at test chamber ambient of +10°C or at a lower temperature if specified by the manufacturer. Record temperatures every minute. At the end of the night-time phases, 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 the 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 +10°C and repeat steps 1 to 5. Halt the test cycle if the appliance fails at +10°C.
- **Step 7:** Report and graphically display the test chamber ambient temperatures, appliance temperatures and condition of [water-packs](#) through the entire test 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 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 appliance⁹ and this figure, if not 0°C or any multiple of 5, is then rounded up to the nearest 5°C and must be +10°C or lower. The result will be printed in the blue sector of the temperature zone symbol (see **E003/RF06** Annex 1).

Rejection criterion: Failure to pass the test at a simulated night time temperature of +10°C or lower.

⁹ Although the test chamber may reach -15°C during the test, the [minimum rated ambient temperature](#) will never be below -10°C.

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, [freeze-protection classification](#) and confirmation of the [minimum rated ambient temperature](#).
- **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 stabilization, temperature and power graphs.
- **Test 3:** Results of humidity control test including indication of compliance or non-compliance with the bulleted acceptance criteria, calculated average humidity of the defined test period, absolute maximum instantaneous relative humidity during the defined test period, and graphs of the temperature and relative humidity from test start to end.
- **Test 4:** Results of stable running and consumption test, including temperature and power graphs.
- **Test 5:** If applicable, results of daily [water-pack freezing capacity](#) test and [water-pack storage compartment capacity](#), including temperature and power graphs.
- **Test 6:** If applicable, results of day/night and storage of frozen [water-packs](#) test (if applicable), including MKT analysis, temperature and power graphs.
- **Test 7:** Results of [autonomy](#) test, including temperature and power graphs.
- **Test 8:** Results of [freeze protection classification](#) test, including temperature graphs.
- **Test 9:** Results of door opening test, including temperature graphs.
- **Test 10:** 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 (if measured). Additional supporting documentation requested and received from the [legal manufacturer](#) or [reseller](#) during the course of the type-testing.

6. Quality control checklist

5.5 Quality control standards

All testing and reporting must be carried out in accordance with the requirements of **ISO 17025:2005** or later edition.

5.6 Quality control checklist

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

5.7 Quality control evaluation

Not required.

7. **Prequalification evaluation**

A product will qualify for inclusion on the register of PQS prequalified equipment in accordance with WHO procedures provided the final report indicates full conformity with the requirements of specification **E003/RF06**.

8. **Modified products**

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

Annex 1 – General test conditions

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

Test conditions:

- Carry out tests in a test chamber in which temperatures can be controlled to $\pm 1^{\circ}\text{C}$ and humidity to $\pm 10\%$ unless otherwise stated below. Measure test chamber temperatures in accordance with **IEC 62552**, clause 8.2.
- Maximum test chamber temperatures of M: $+27^{\circ}\text{C}$, T: $+32^{\circ}\text{C}$ and H: $+43^{\circ}\text{C}$ are required for the tests.
- Minimum test chamber temperatures down to -15°C may be required for the [minimum ambient temperature rating](#) test. The actual minimum required for a specific appliance should be discussed with the product manufacturer before the test commences.
- Temperatures within the appliance must be continuously monitored to an accuracy of $\pm 0.5^{\circ}\text{C}$ without the presence of the sensors influencing the test in any way. Thermocouples that are sealed within the appliance are most commonly used. Up to 22 simultaneous temperature measurements may be required for a single appliance. The suggested temperature sensor locations are shown in Annex 2. See Annex 3 for temperature sensor specifications.
- Position the test appliance in the test chamber with its back face 50 mm clear of one of the chamber walls. Ensure that it is accurately levelled.

Stabilization times:

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

- The thermal storage has been cooled for a time period no less than the cool down time period stated in the instructions provided by the manufacturer. (e.g. if instructions state cool down time is 7 days then at least a 7-day cool down test period 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 two consecutive days of this test (e.g. the same number of on/off cycles per day).

Before measuring the performance of an appliance under normal running conditions, internal temperature conditions in the vaccine storage compartment must be stable.

Internal stabilization is normally assumed to have occurred when either:

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

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.

Fully frozen water-pack determination:

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 a [water-pack](#):

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

Recording temperatures:

- Test appliances, either loaded or empty, as described above in the verification protocol.
- Take temperature and humidity 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.
- 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.

Humidity sensor:

- Follow the existing guidelines outlined for temperature sensor placement in Annex 2.
- Place the humidity sensor at the same location as temperature sensor #19 (refer to Annex 2). Humidity sensor location must be < 10 cm away from this temperature sensor.
- The humidity sensor must be accurate to $\pm 3\%$ in the range of 25% to 75%.

Dummy vaccine load:

Make up a dummy vaccine load¹⁰ 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, $\pm 5\%$.
- 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 vaccine freezers:

- Stack the partially filled [water-packs](#) evenly on the base of the appliance.

Dummy evaporative load:

A dummy evaporative load will be used in place of the dummy vaccine load for the humidity control test. General test conditions of the dummy vaccine load will apply to the dummy evaporative load.

Prepare a dummy evaporative load using open-top glass containers.

- The internal height of the container shall be at least 2.0 cm.

¹⁰ The dummy load described below is intended to approximate the minimum vaccine load in a well-managed refrigerator holding a 25% safety stock.

- Measure the surface area of the container opening in cm² (length x width for rectangular dishes, diameter x diameter x 0.785 for circular dishes). If the container has drafted walls, measure the length, width, and/or diameter at a height of 0.5 cm below the top rim.
- Select the number of containers required to build a dummy evaporative load whose surface area in cm² is equal to the measured vaccine net storage capacity in litres multiplied by six, $\pm 10\%$.
- Estimate the volume required to fill all the dummy evaporative load containers to within 0.5 cm of their tops. Fill a separate water storage container with at least that much water.

Pre-condition the dummy evaporative load and filled water storage containers at +8°C. Fill the dummy evaporative load containers with conditioned water to within 0.5 cm from the top of each container and place in the appliance as follows so that they do not interfere with the sensor positions already established:

Front-opening appliances:

- Place the filled containers spaced approximately evenly from each other and the walls and door on the shelves designated for vaccine storage.

Top-opening refrigerators:

- Place the filled containers spaced approximately evenly from each other and the walls and door 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, place the filled containers 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 **E05/IP01**.

Dual compressor or multiple cooling circuit appliances:

All compressors or all cooling circuits 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.

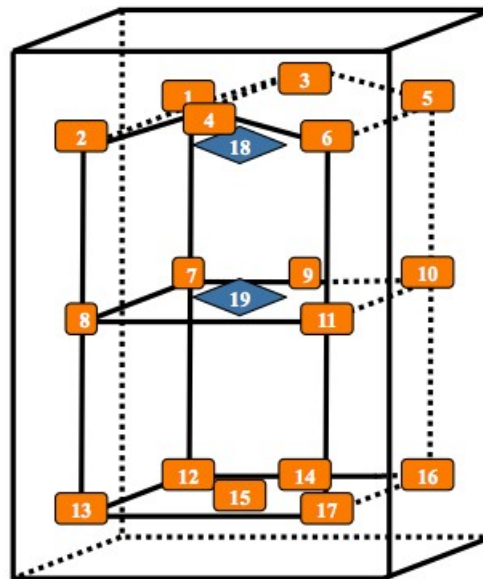
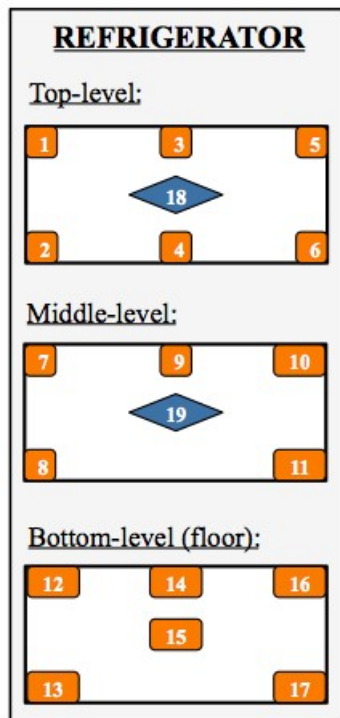
Annex 2 – Temperature sensor positions

Approximate sensor positions are indicated by the 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

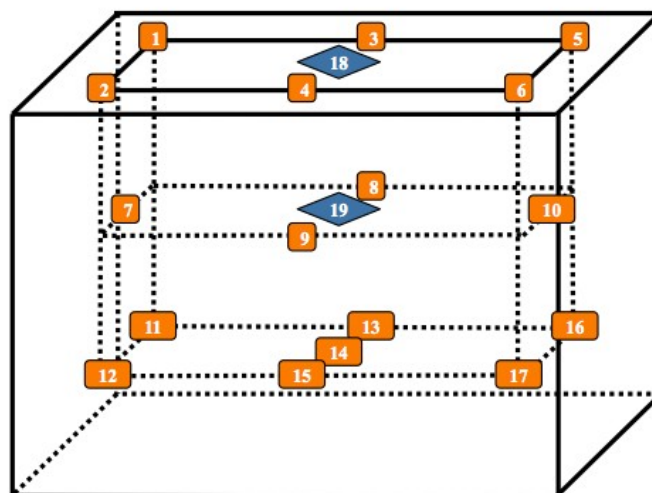
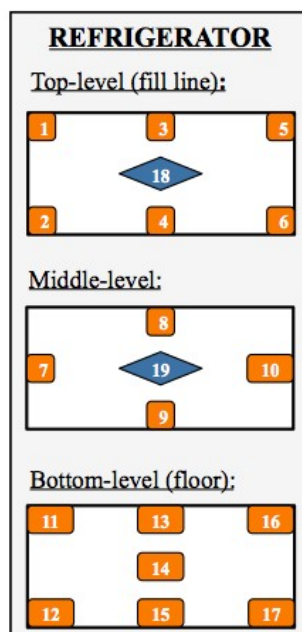
- 17 Surface sensors
2 Ambient sensors



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



CHEST COMPARTMENT – NO STEP

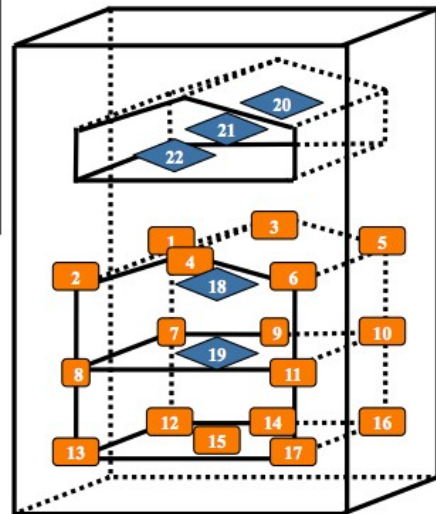
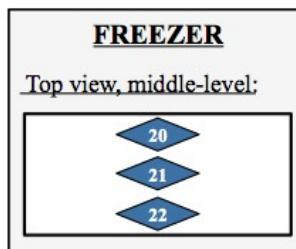
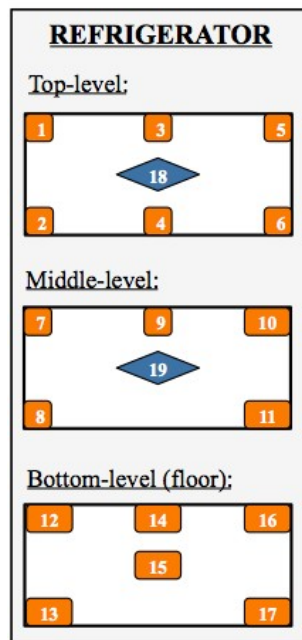
- 17 Surface sensors
2 Ambient sensors



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



UPRIGHT COMPARTMENT – WITH FREEZER

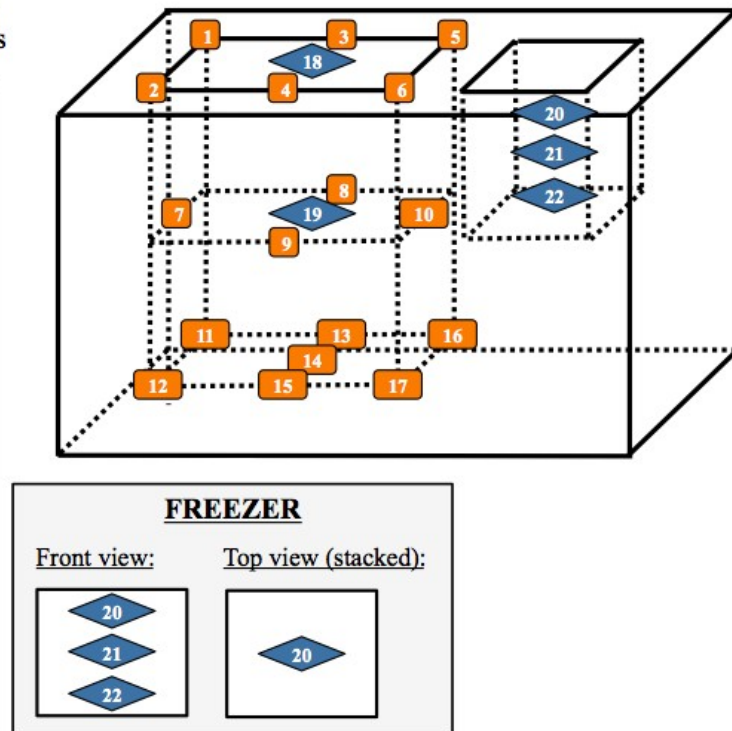
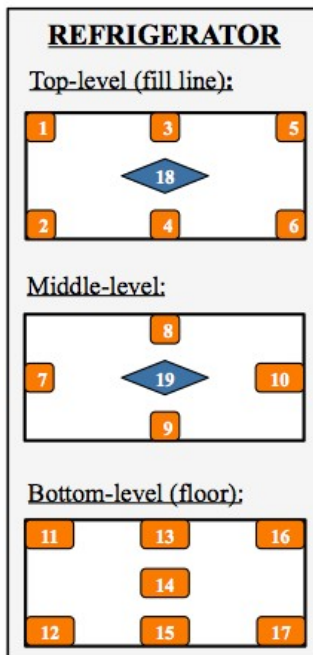
 Surface sensors
 Ambient sensors





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

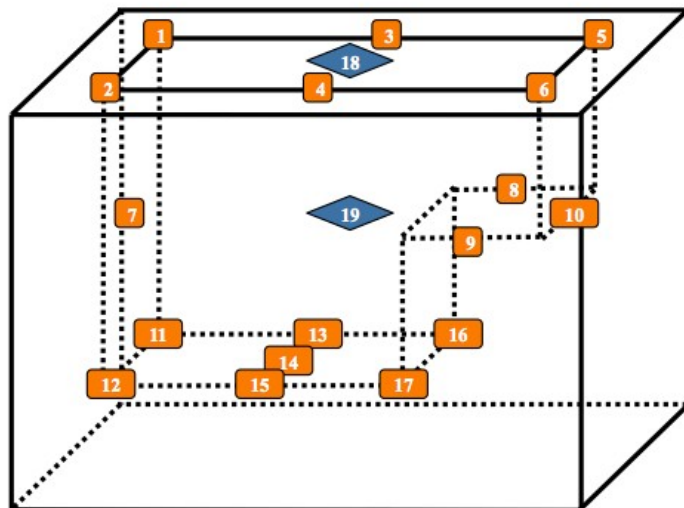
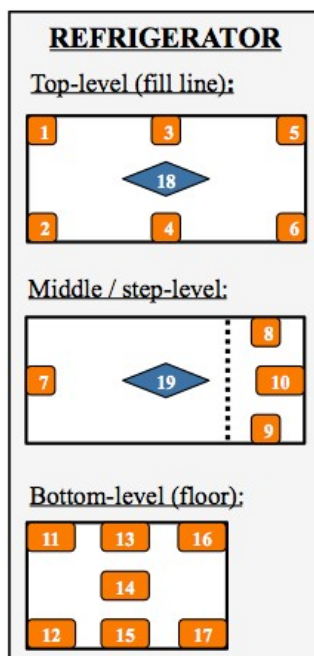
CHEST COMPARTMENT – WITH FREEZER

 Surface sensors
 Ambient sensors



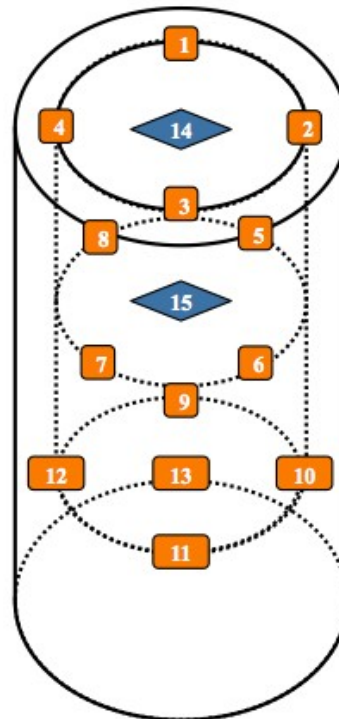
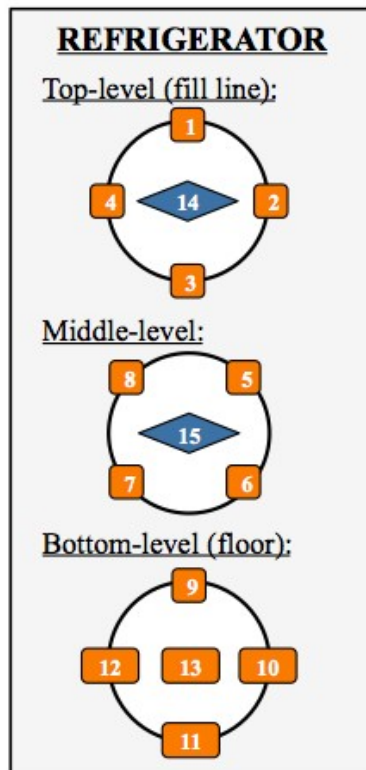
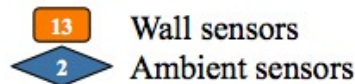
CHEST COMPARTMENT – WITH STEP

 Surface sensors
 Ambient sensors



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

CYLINDRICAL CHEST COMPARTMENT



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 $\pm 0.5^{\circ}\text{C}$ but are not to be inserted into brass or tin-covered copper mass of $25\text{ g} \pm 5\%$. Ambient sensors not in contact with the vaccine storage compartment are to comply with **IEC 62552**, clause 8.7.1 with sensor, accurate to $\pm 0.5^{\circ}\text{C}$, inserted into brass or tin-covered copper mass of $25\text{ g} \pm 5\%$ and of minimum external area (diameter = height = about 15.2 mm).

Revision history			
(revisions since 15 September 2016):			
Date	Change summary	Reason for change	Approved
21.09.2018	Clause 3 (Terms and definitions) PCM definition added	Reflect change to allowance of water-based and PCM-based buffers	I. Gobina
21.09.2018	Bullet on PCM conformity with relevant product specification and compliance with PCM materials specification added to Clause 5.3.2 (Type examination)	Reflects change to allowance of PCM-based buffer materials as per product specification.	I. Gobina
15.09.2020	Terms & definition updated to include humidity-control	Reflect requirements included in the 2020 Humidity Control TPP	I. Gobina
15.09.2020	Clause 5.3.4 Test 3 added, clause 5.3.5 Test 4 edited, clause 5.4 Test 3 added, Annex 1 & 2 added to all to include / reflect humidity control tests.	Reflect requirements included in the 2020 Humidity Control TPP	I. Gobina