PQS Type-testing protocol

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Contents

1. Scope

This document describes the procedure for verifying the performance of transportable, powered appliances generally intended for temporary storage and transport of vaccines. An appliance that passes the relevant tests will be prequalified with a hot zone designation, a minimum ambient temperature rating, a designation as a lightweight, medium-weight, or heavy-weight appliance and a freeze protection classification. Long term performance tests are not included because the use cases are assumed to be for short-term storage (i.e. less than seven days at a time).

2. Normative references

(Use the most recent version.)

ASTM D4169-09: *Standard Practice for Performance Testing of Shipping Containers and Systems*.
ASTM D5276-09: *Standard Test Method for Drop Test of Loaded Containers by Free Fall.*
ASTM D999-08: *Standard Test Methods for Vibration Testing of Shipping Containers.*
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: 2010+AMD1:2012+AMD2:2017 CSV: *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 60529: Consolidated Edition 2.1 (incl. am1): *Degrees of protection provided by enclosures* (IP Code).
IEC 61000-6-1 Edition 3.0: 2016: *Electromagnetic compatibility (EMC) Generic standards - Immunity for residential, commercial and light-industrial environments.*
IEC 61000-6-3:2006+AMD1: 2010 CSV: *Electromagnetic compatibility (EMC) Generic standards - Emission standard for residential, commercial and light-industrial environments.*
IEC 62552-1: *Household refrigerating appliances – Characteristics and test methods*.
IEC 62552-3: *Household refrigerating appliances – Characteristics and test methods - Part 3: Energy consumption and volume*

ISO 8362-1: *Injection containers and accessories -- Part 1: Injection vials made of glass tubing.*
ISO 9187-1: *Injection Equipment For Medical Use - Part 1: Ampoules For Injectables.*
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/IEC 17025: *General requirements for the competence of testing and calibration laboratories.*
ISO 20282-1: 2006: *Ease of operation of everyday products - Part 1: Context of use and user characteristics.*
UL 2054: *Standard for Household and Commercial Batteries.*
UL 2595: *General Requirements for Battery-Powered Appliances*
WHO/PQS/E003/PV01: *Performance specification: Solar power system for compression-cycle vaccine refrigerator or combined refrigerator and water-pack freezer.*
WHO/PQS/E006/TH06.2: *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 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 exceeding +20°C for any amount of time (after the appliance is turned on and initially cools).
- No excursion below -0.5°C for any amount of time.
- No excursion 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 calculated mean kinetic temperature (MKT)[1] must remain within +2°C to +8°C when the default activation energy is set at 83.144 kJ per mol when calculated over the duration of any testing that requires maintaining this range.

Active cooling: Any cooling or other heat transfer that is powered or driven by anything besides the spontaneous, passive transfer of heat due to temperature differential and related passive effects such as natural convection.
Cool-down time: The time in hours required for the appliance to cool, starting from the time the appliance is switched on and ending when sustained and safe acceptable temperatures are measured at all locations inside the vaccine storage compartment.

[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.

Freeze protection classification: The freeze protection classification is based on the number of user-interventions required to ensure freeze protection.

- Grade A, user-independent freeze protection (UIFP): when the appliance is used within its nominated temperature range (upper hot zone temperature +43°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 outside of the acceptable temperature range, whatever the position of the vaccines in the vaccine storage 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 legal manufacturer and requiring one level of intervention (e.g., the requirement to use baskets or any other single item constitutes one level of intervention by the user) in order to ensure that the vaccines will not be exposed to freezing temperatures outside of the acceptable temperature range.
- 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 legal manufacturer requiring more than one level of intervention (e.g., the requirement to use baskets and insulation barriers or covers) in order to ensure that the vaccines will not be exposed to freezing temperatures outside of the acceptable temperature range.

Heavy-weight appliance: A transportable, powered appliance movable by multiple people for short periods, intended primarily for temporary and/or long-term vaccine storage and transport by powered vehicle. All appliances shall be designated by the legal manufacturer as one of the three appliance types further defined within *Section 4* of this document.

Holdover time: The time in hours during which all points in the vaccine storage 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 appliance has initially cooled and stabilized, the power supply has been subsequently disconnected, and no other power sources are actively cooling the appliance.

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

In writing: Communication by letter, fax or email.

Independence: The time in hours during which all points in the vaccine storage compartment remain between +2°C and +8°C, at a constant ambient test temperature of +43°C after all external power inputs have been disconnected or switched off. (This may include both passive cooling as well as active cooling if powered by internal sources integrated into the appliance, e.g. an integrated battery or evaporative cooling system. Independence is distinct from holdover time in that it may include both active cooling and passive cooling while holdover time only includes passive cooling capacity.)

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 the person's own name, regardless of whether

these operations are carried out by that person or on that person's behalf by a third party.

Lightweight appliance: A transportable, powered appliance movable by a single person for extended periods, intended primarily for short-term transport with or without a vehicle for transportation. All appliances shall be designated by the legal manufacturer as one of the three appliance types further defined within *Section 4* of this document.

Maximum loaded mass: The mass of an appliance when fully loaded with vaccines at a density of 0.8 kg per litre of vaccine net storage capacity and with any components necessary to operate within the acceptable temperature range fully prepared and in place.

Medium-weight appliance: A transportable, powered appliance movable by a single person or multiple people for short periods, intended primarily for longer-range transportation by a vehicle (e.g. truck, motorbike, camel). All appliances shall be designated by the legal manufacturer as one of the three appliance types further defined within *Section 4* of this document.

Minimum rated ambient temperature: The lowest constant ambient temperature at which the acceptable temperature range can be maintained with a full vaccine load. In addition to the day/night test, all appliances must be able to operate at a continuous minimum ambient temperature of +10°C or below. All appliances will be tested at +10°C and may be additionally tested at a lower temperature not below -10°C if specified by the legal manufacturer. Once established, this figure will be displayed in the blue sector of the temperature zone symbol. This will enable purchasers in countries with low winter temperatures to select the most appropriate models.

Passive cooling: Cooling or heat transfer driven exclusively by temperature differential that occurs spontaneously through and between the components of the appliance, its contents and the ambient environment.

Phase Change Material or 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.

Stationary components: Components of an appliance system that are not intended to be transported with the appliance. This might include charging or docking stations that would not be carried with the appliance when used to transport vaccines.

User-intervention: Any activity that is required to be executed by appliance users (e.g., healthcare workers) in order to ensure vaccine protection against freezing temperatures. Activities could include, but are not limited to, basket storage, the requirement to use storage compartment covers, thermostat/fuel adjustment, placement of removable liners or barriers, charging a battery, or thermally conditioning the appliance or components thereof.

Vaccine net storage capacity: The net storage capacity is the space where it is suitable (both thermally and ergonomically) to store vaccines with any components necessary to operate within the acceptable temperature range fully prepared and in place. If a legal manufacturer would declare more than

one vaccine net storage capacity for the same internal and external dimensions, they must prequalify with different branding, one model for each different storage volume. The new vaccine storage capacity will be published as volume in litres.
Vaccine storage compartment: The zone within the appliance which is designated by the legal manufacturer as suitable for storing vaccines.

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 shall 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 shall supply the testing laboratory with a full duplicate set of the Product Dossier that will be supplied to WHO in accordance with the requirements of **WHO/PQS/E003/TS01** specification *Clause 7*. One sample of the appliance is required. If more than one version of the product is available (for example, for different climate zones), provide one sample of each version. Ensure that the voltage and frequency rating of the sample is suitable for the country where the test laboratory is located.[2]

5.3 Test procedures

All tests shall be carried out using the same, single sample appliance to ensure that the retest of performance after robustness testing is effective. All tests shall be carried out in the order in which they are written in this testing procedure with the following allowable exceptions. Limited deviations in the test order may be allowable to facilitate more efficient testing given the broad range of appliances to which this testing can apply. Specifically, Test 3 through Test 6 may be carried out in a modified order. In this case, the reasoning and deviation shall be explained and documented in the test report and it is still recommended that Test 3 occur first to establish comfortability with the appliance and baseline performance. Furthermore, the IP rating test, Test 7 may be carried out at any time in the testing sequence prior to Test 8 with the modified order documented in the test report.

[2] If there is any doubt that the performance of the appliance will vary under the other nominal voltage/frequency combinations supplied by the legal manufacturer, they shall be asked to explain in writing, and the difference be recorded in the test report.

5.3.1 Solar power simulator

If the appliance can be powered by solar power, a simulation of a solar day is necessary for testing. Otherwise, this section can be disregarded. Refer to specification **WHO/PQS/E003/PV01** for solar power system specifications.

a) 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 shall be of ±1.0% 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 solar radiation reference period for this protocol is 3.5 kWh/m²/day designed to represent the average daily solar radiation received over a 12-hour period. A simulated solar night is not necessary because the appliance shall be prepared for use within 12 hours. All solar powered appliances must be tested at this solar radiation reference period of 3.5 kWh/m²/day. The legal manufacturer must also specify the required solar power profile including volts and amperes (current at the maximum power point from the solar module specification - Imp).

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 appliance system voltage varies with corresponding amperage.

d) The solar radiation reference period will be simulated based on the table below[3]:

Day with 3.5 kWh/m²/day (interpolated)
1 hour at 50 W/m²
2.5 hours at 250 W/m²
0.5 hours at 350 W/m²
4 hours at 450 W/m²
0.5 hours at 350 W/m²
2.5 hours at 250 W/m²
1 hour at 50 W/m²

e) When using this solar radiation reference period in preparing the appliance for use, the solar day should begin at the same time as the preparation procedure.

[3]For example, assume the appliance legal manufacturer specifies a solar array with operating characteristics of 10 amps DC (STC) operating at DC 18 V. Using this solar radiation reference period of 3.5 kWh/m²-day the simulated day would consist of 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, then 2.5 hours at 2.5 amps and then 1 hour at 0.5 amps. The voltage would remain constant at DC 18.0 V.

5.3.2 Preparation for use procedure(s)

Preparation for use in the case of an AC-chargeable, battery powered appliance would essentially be plugging in the appliance and charging the battery fully but not turning on the appliance and cooling it down. Because this protocol is applicable to many appliance types, the term preparation for use refers to equivalent procedures for other appliance types. The legal manufacturer shall provide instructions to prepare the appliance for use. This shall include multiple, separate procedures if there are multiple, intended ways to power the appliance. The legal manufacturer shall clearly indicate to the testing laboratory how many separate ways there are to power and prepare the appliance (e.g. DC through a car, mains AC, solar PV, mechanical, application of heat etc.). The legal manufacturer shall also designate a primary procedure if multiple procedures are indicated.

For testing purposes, preparation for use cannot include active or passive cooling down of the vaccine storage compartment. In actual use outside of this verification protocol, an appliance may be turned on and cooling down while charging or preparing itself for use. In order to measure cool-down time, however, the on/off mechanism must be capable of keeping active cooling from initiating. In some special appliance cases it may be impossible, by design, to stop passive cooling. In these cases, the legal manufacturer shall contact WHO to discuss and confirm the acceptability of the specific appliance design. Regardless, all appliances must still meet the minimum, 24-hour delayed use scenario per **WHO/PQS/E003/TS01.** In these cases, due to the potential difficulty in measuring cool-down time, deviations shall be discussed and agreed between the legal manufacturer, WHO PQS, and the test laboratory prior to testing.

Note that some appliances will have the capability to be partially recharged or powered after initial preparation for use. However, for testing purposes, after initial preparation for use, no additional, external power or energy input is allowed. This is intended to test the simulated case that no additional power source of any type can be assumed after initial preparation for use.

5.3.3 Test 1: Type examination

- **Step 1:** Unpack the appliance. Using the legal manufacturer's instructions only, set up the system components. Record the process and any problems encountered.
- **Step 2:** Check all samples for similarities between different models[4], dissimilarities between samples of one model, any defects or damage or any problems that make it difficult or impossible to test the appliance.
- **Step 3:** Record any differences between the samples ordered and those received.

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

- **Step 4:** Record the preparation for use procedure(s) provided by the legal manufacturer.
- **Step 5:** 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:

i. Code (a unique identifier to be assigned by the testing laboratory).
ii. Model and serial number.
iii. Legal manufacturer or reseller.
iv. Appliance type (i.e. lightweight, medium-weight, or heavy-weight appliance).
v. Country of origin.
vi. Conformity assessment markings (e.g. CE mark, UL mark).

Performance characteristics:

vii. Refrigeration cycle conforms/does not conform to specification *Clause 4.2.2*.
viii. Indicator of proper preparation for use conforms/does not conform to specification *Clause 4.2.8*.
ix. Thermostat conforms/does not conform to specification *Clause 4.2.9*.
x. The temperature monitoring and alarm conforms/does not conform to specification *Clause 4.2.10*
xi. Power system conforms/does not conform to specification *Clause 4.2.14*.
xii. Batteries conform/do not conform to specification *Clause 4.2.15*. For appliances containing or using batteries, the legal manufacturer has supplied evidence of and declared compliance with **UL 2054**, and additionally **UL 2595** as applicable.
xiii. Closure and lock conform/do not conform to specification *Clause 4.2.16*.
xiv. Electrical safety conforms/does not conform to specification *Clause 4.2.17* and the legal manufacturer has supplied evidence of and declared compliance with the relevant standards.
xv. Electromagnetic compatibility conforms/does not conform to specification *Clause 4.2.18* and the legal manufacturer has supplied evidence of and declared compliance with the relevant standards.
xvi. Shape conforms/does not conform to specification *Clause 4.2.19*.
xvii. Hinges conform/do not conform to specification *Clause 4.2.20*.
xviii. Carrying components conform/do not conform to chemical resistance requirements in specification *Clause 4.2.21*.

Environmental requirements:

xix. Confirmation in writing from legal manufacturer that material properties at ambient temperatures during transport, storage and use conform/do not conform to specification *Clause 4.3.2*.
xx. Confirmation in writing from legal manufacturer that material properties and functionality at relative humidity during transport, storage and use conform/do not conform to specification *Clause 4.3.2.*

Interface requirements:

xxi. Voltage stabilization or protection (if required) conforms/does not conform to specification *Clause 4.5.1*. Independent laboratory test results demonstrating conformity with the relevant tests from **WHO/PQS/E007/VS01** must be submitted.
xxii. Solar PV system and interface (if applicable) conforms/does not conform to specification *Clause 4.5.2*. Independent laboratory test results demonstrating conformity with the relevant tests from **WHO/PQS/E003/PV01** must be submitted.
xxiii. Power switch conforms/does not conform to specification *Clause 4.5.3*.
xxiv. Power lead conforms/does not conform to specification *Clause 4.5.4.*
xxv. Alerts and alarms conform/do not conform to specification *Clause 4.5.5*. The testing laboratory will confirm with the legal manufacturer that alarms are present as specified, all requirements in this clause are met, but need not verify that the alarms are accurate through temperature-controlled testing.
xxvi. Compatibility with distribution method conforms/does not conform to specification *Clause 4.5.7.*
xxvii. The appliance and appliance labelling conform/do not conform to specification *Clause 4.5.9*.

Human factors:

xxviii. Human factors design conforms/does not conform to specification *Clause 4.6.1*.
xxix. Markings and labelling conform/do not conform to specification *Clause 4.6.2*.
xxx. Vaccine storage advice conforms/does not conform to specification *Clause 4.6.3*.

Materials:

xxxi. Record materials used for all major components, including exterior casing, insulation, interior casing, hinges, catches and stays.
xxxii. Casing materials conform/do not conform to specification *Clause 4.7.1*.

xxxiii. Thermal insulation foaming agents conform/do not conform to specification *Clause 4.7.2*.

xxxiv. Refrigerant conforms/does not conform to specification *Clause 4.7.3*.

xxxv. Other restricted material use conforms/does not conform to specification *Clause 4.7.4*.

xxxvi. Confirmation in writing from legal manufacturer that vacuum insulation panels (if used) conform/do not conform to specification *Clause 4.7.5*.

xxxvii. PCM (if applicable) conforms/does not conform to specification *Clause 4.7.6*. Confirmation in writing from legal manufacturer including any necessary laboratory test results demonstrating conformity with the relevant tests from **WHO/PQS/E005/PCMC0.1-VP0.1** must be submitted.

xxxviii. Confirmation in writing from legal manufacturer that corrosion resistance conforms/does not conform to specification *Clause 4.7.7*.

xxxix. Confirmation in writing from legal manufacturer that chemical resistance conforms/does not conform to specification *Clause 4.7.8*.

Warranty:

xl. Warranty conforms/does not conform to specification *Clause 4.8*.

Servicing provision:

xli. Servicing provision conforms/does not conform to specification *Clause 4.9*.

Disposal and recycling:

xlii. Disposal and recycling information conforms/does not conform to specification *Clause 4.10*.

Instructions:

xliii. User and maintenance instructions conform/do not conform to specification *Clause 4.11*.

- **Step 6:** Take a digital photograph of the appliance with the door or lid open and with any additional, removable components in place. Take close-up photographs of the hinges (if used), catches, carrying handles or straps and any ancillary components such as removable baskets or liners. Take additional photographs showing all external surfaces of the appliance, the interior layout, the vaccine storage compartment, the compressor or cooling system (if accessible) and a close-up of the thermometer, indicator light(s), the control(s), control panel and any special features or identified, potential weaknesses of the appliance.

High resolution digital images should be provided for attachment to the WHO PQS report.

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

5.3.4 Test 2: Dimensions, weights and vaccine storage capacity

Test conditions: Testing room at +21°C (±3°C). Record conditions at the time of the test.

- **Step 1:** Record the maximum external dimensions in centimetres (length, width and height, with handles folded, (± 0.5 cm)) of the transportable portion of the appliance. Round all dimensions **up** to the next cm. If the appliance includes a docking station or other stationary components not intended for use during transportation, do not include these in the measurement.
- **Step 2:** Measure the internal dimensions of the vaccine storage compartment in accordance with the gross volume measurements in **IEC 62552-3** Annex H, measuring the orthogonal dimensions of approximately cuboid spaces and calculating the total volume. Record this as the gross volume and include it in the test report. As needed, convert this volume to litres and report as the vaccine net storage capacity as a volume in litres. If baskets, shelves, or other supplemental components are necessary for correct temperature performance including freeze-protection, these should be in place during measurement. Do not include any space outside the zone designated by the legal manufacturer or limited by these components for vaccine storage.
- **Step 3:** Record the mass of the appliance in kilograms (± 0.1 kg). If the appliance has ancillary components, include these in the total mass if they are intended to be transported with the appliance (e.g. car charger). Do not include them in the total mass if they are not intended to be transported with the appliance (e.g., mains powered docking station, other stationary components for recharging, etc.).
- **Step 4:** Multiply the vaccine net storage capacity from Step 2 by 0.8, add this product to the measured mass from Step 3 and record this total figure as the maximum loaded mass (in kg).[5]

Acceptance criteria: The measured vaccine net storage capacity shall be greater than 1.5 litres for lightweight appliances, greater than 1.5 litres for medium-weight appliances and greater than 5.0 litres for heavy-weight appliances. The maximum loaded mass shall not exceed 8 kg for lightweight appliances, 25 kg for medium-weight appliances, and 50 kg for heavy-weight appliances.

[5] 0.8 kg/litre is the 95th percentile density of the mix of vaccines procured by UNICEF in 2011.

Rejection criteria: Either of the following:

- The maximum loaded mass is outside the designated range.
- Vaccine net storage capacity is below the minimum designated volume.

5.3.5 Test 3: Primary performance

- **Step 1:** Set the test chamber to +43°C.
- **Step 2:** Condition the appliance in the test chamber for at least 48 hours with temperature sensors located as shown in *Annex 2*. Keep the door or lid of the sample open, no load in the vaccine storage compartment, the appliance turned off, disconnected from any external power sources, and with any internal thermal, electrical, chemical or other energy storage completely depleted or discharged.
- **Step 3:** Assemble a dummy vaccine load comprising partially filled water-packs, or other sealable plastic containers[6] that can be used to fill the vaccine storage compartment to a combined density of 0.5 kg of water per litre of the measured vaccine net storage capacity. Pre-condition the dummy load at +8°C for at least 24 hours.
- **Step 4:** Begin monitoring and recording temperatures at one-minute intervals. In addition to temperature measurements, whether active cooling is occurring must also be monitored and logged at the same time intervals. The testing laboratory will most likely need to discuss with the legal manufacturer how to detect whether active cooling is occurring.
  - **For appliances that use electricity:** power, in watts, used by the appliance must also be monitored and recorded. Begin recording power to the appliance at the same time.
- **Step 5:** Follow the legal manufacturer's directions for proper preparation of the appliance for use as detailed in *Section 5.3.2*. Record the time at which the preparation process is initiated and the time at which it is completed and calculated the time it took to prepare for use.
  - **For appliances that use electricity:** Record (or calculate after testing and recording) the total amount of energy used during the preparation of the appliance for use.
- **Step 6:** After the appliance indicates that it is properly prepared for use, disconnect it from any external power sources. Record the time.
- **Step 7:** Leave the appliance in the chamber for 24 hours to simulate delayed use.
- **Step 8:** Remove the dummy vaccine load from its +8°C location and quickly place in the appliance so that it does not interfere with the sensor positions already established. If possible, do not have the load components in direct, physical contact with any sensors. This may not be possible depending on the configuration of the compartment and shelving etc. The load should be placed as quickly as is reasonably possible, in order to minimize any load-temperature rise above +8ºC. Although dependent on appliance configuration, load size and other

[6] Appliances with smaller or irregularly shaped vaccine storage compartments may not be able to accommodate water-packs meeting PQS specification IP01.

specifics of the setup, this should ideally take fewer than five minutes and must take no more than 10 minutes.

- **Step 9:** Close the lid or door of the appliance, and switch the appliance on. The time from switching the appliance on until the temperature measurements at all monitoring locations (as shown in *Annex 2*) reach +8ºC or colder will be recorded as the cool-down time.
- **Step 10:** Leaving the appliance on but still disconnected from any external power sources, continue the test until all temperature sensors have warmed back up to +20°C or above.
- **Step 11:** After the test is finished, from the measured temperature data, calculate independence as the time from the last time point used to calculate the cool-down time until the first temperature measurement at any location was measured as warmer than +8°C. Additionally, calculate holdover time as the time from the end of the last instance of active cooling until the first temperature measurement at any location above +8°C. The holdover time will thus be a portion of the independence. NOTE: Some appliance may be incapable of distinguishing when active cooling has stopped if turned on. In these cases, holdover time shall be reported as "0: incalculable".

  Acceptance criteria: After the delayed use of the appliance by 24 hours in Step 7, All monitoring locations remain within the acceptable temperature range from the last time point used to calculate cool-down time until the last time point used to calculate independence. The measured and calculated cool-down time is less than four hours and the measured and calculated independence is greater than 12 hours. There is no requirement for holdover time but it will be reported. The time to prepare the device is less than 12 hours.

  Rejection criterion: If any of the following are true:
  - Any monitoring location does not remain in the acceptable temperature range (after the vaccine storage compartment initially cools down).
  - The calculated cool-down time is greater than the maximum for acceptance.
  - The calculated independence is less than the minimum for acceptance.
  - The time it takes the device to be properly prepared for use is greater than the maximum for acceptance.
  - The appliance is not able to meet any of these rejection criteria after the minimum required delayed use of the appliance by 24 hours in Step 7.

5.3.6 Test 4: Low voltage preparation

(If the procedure for preparing the appliance for use does not require use of or connection to an external, AC, electrical power source, skip this test.)

- **Step 1:** Set the test chamber to +43°C.
- **Step 2:** Condition the appliance in the test chamber as in *Test 3, Step 2*.

- **Step 3:** Condition the dummy load as in *Test 3, Step 3*.
- **Step 4:** Begin monitoring and recording temperatures and active cooling as in *Test 3, Step 4*.
- **Step 5:** Follow the legal manufacturer's directions for proper preparation of the appliance for use as detailed in *Section 5.3.2*. However, set supply voltage to the appliance at 22% lower than the nominal AC voltage specified. The legal manufacturer may request testing at a voltage lower than 22% below the nominal AC voltage. If so, record that number and include it in the report. Record the time at which the preparation process is initiated.
- **Step 6:** After the appliance indicates that it is properly prepared for use, disconnect it from any external power sources. Record the time. If the appliance took more than 12 hours to reach the indication, stop the test.
- **Step 7:** Remove the dummy vaccine load from its +8°C location and place in the appliance as in *Test 3, Step 8.*
- **Step 8:** Close the lid or door of the appliance and switch the appliance on.
- **Step 9:** Continue monitoring and recording temperatures and active cooling from the time the appliance is switched on until the temperature of the warmest of the sensors located as shown in *Annex 2* first reaches +8ºC.
- **Step 10:** Compare this low-voltage cool-down time to the cool-down time calculated in *Test 3*.
- **Step 11:** Note any abnormalities or issues potentially due to the low voltage.

  Acceptance criterion: The low-voltage cool-down time remains less than four hours.

  Rejection criteria: If either of the following are true:
  - The time taken to prepare for use is greater than 12 hours.
  - The low-voltage cool-down time is greater than the maximum for acceptance.

5.3.7 Test 5: Door opening test

- **Step 1:** Set the test chamber to +43°C.
- **Step 2:** Condition the appliance in the test chamber for at least 48 hours with temperature sensors located as shown in *Annex 2*. Keep the door or lid of the sample open, no load in the vaccine storage compartment, and the appliance turned off and disconnected from any external power sources. Note that for this test, energy storage need not be completely discharged.
- **Step 3:** Condition the dummy load as in *Test 3, Step 3*.
- **Step 4:** Begin monitoring and recording temperatures and active cooling as in *Test 3, Step 4*.
- **Step 5:** Follow the legal manufacturer's directions for proper preparation of the appliance for use as detailed in *Section 5.3.2*.
- **Step 6:** After the appliance indicates that it is properly prepared for use, disconnect it from any external power sources.

- **Step 7:** Remove the dummy vaccine load from its +8°C location and place in the appliance as in *Test 3, Step 8.*
- **Step 8:** Close the lid or door of the appliance and switch the appliance on.
- **Step 9:** Continue monitoring and recording temperatures and active cooling from the time the appliance is switched on until the temperature measurements at all monitoring locations (as shown in *Annex 2*) reach +8ºC or colder. Note the time. It will later be compared to the cool-down time calculated in *Test 3.*
- **Step 10:** After an additional hour open the lid or door of the appliance. Allow the vaccine storage compartment to stay fully open for 10 minutes.
- **Step 11:** Once 10 minutes have passed, close the lid or door and continue monitoring temperatures and active cooling for two more hours and then end the test.

  Acceptance criteria: All monitoring locations remain within the acceptable temperature range from the last time point of the cool-down period until the end of the test with the exception that temperature excursions above +20°C are allowable for the duration of the door opening and 30 minutes thereafter. The time to cool-down is less than four hours.

  Rejection criteria: If any of the following are true:
  - Any monitoring location does not remain in the acceptable temperature range (after the vaccine storage compartment initially cools down) with the allowable excursions noted in the acceptance criteria.
  - The time to cool-down is greater than the maximum for acceptance.

5.3.8 Test 6: Minimum Rated Ambient Temperature

NOTE: Prior to this test, the test laboratory should confirm with the legal manufacturer, the minimum ambient temperature at which the legal manufacturer expects the appliance to function.

- **Step 1:** Set the test chamber to +10°C, or a lower test temperature if specified by the legal manufacturer.
- **Step 2:** Condition the appliance in the test chamber as in *Test 3, Step 2*.
- **Step 3:** Condition the dummy load as in *Test 3, Step 3*.
- **Step 4:** Follow the legal manufacturer's directions for proper preparation of the appliance for use as detailed in *Section 5.3.2*.
- **Step 5:** After the appliance indicates that it is properly prepared for use, disconnect it from external power sources and begin monitoring and recording temperatures at one-minute intervals.
- **Step 6:** Remove the dummy vaccine load from its +8°C location and place in the appliance as in *Test 3, Step 8.*
- **Step 7:** Close the lid or door of the appliance and switch the appliance on.

- **Step 8:** After 24 hours, if all monitoring locations have remained within the acceptable temperature range, end the test.
- **Step 9:** Record chamber temperature setting at which all monitoring locations remained within the acceptable temperature range. This is the minimum rated ambient temperature. This temperature rounded up to the next 5°C will be printed in the blue sector of the temperature zone symbol on the appliance (see *specification Annex 1*).
- **Step 10:** Evaluate and record the freeze protection classification grade based on the number of legal manufacturer-required user-interventions to prepare the appliance for freeze prevention.
  - **Grade A:** 0 user-interventions
  - **Grade B:** 1 user-intervention
  - **Grade C:** 2+ user-interventions

  Acceptance criterion: The minimum rated ambient temperature was recorded at +10°C or colder.

  Rejection criterion: Failure of the appliance to keep all monitoring locations within the acceptable temperature range at a chamber temperature setting of +10°C or colder.

5.3.9 Test 7: IP rating test to IEC 60529

- **Step 1:** Obtain an independent test report from the legal manufacturer showing full conformity with **IEC 60529: IP54** (or higher) for the transportable appliance. The legal manufacturer shall ensure that the appliance is turned on and operational (i.e. running) during the testing.

  NOTE: The stationary components of the appliance are not required to pass the **IP54** testing, and stationary components shall not be included in the testing.
- **Step 2:** If the legal manufacturer cannot supply documentation, carry out an **IP54** test on all components of the appliance that are not stationary components with the lid or door closed and latched and the appliance turned on and operational (i.e. running) during the testing. Record results.

  Acceptance criteria: IP54 test passed with no noted ingress of water into the internal, vaccine storage compartment of the appliance. As noted in the IP testing, ingress may be allowable into other areas of the appliance, but it must remain fully functional. This functionality will be further verified in subsequent *Test 10*.

  Rejection criteria: Any of the following: the **IP54** test is failed, there is water ingress into the internal, vaccine storage compartment, or the appliance did not remain fully functional, to be further verified in subsequent *Test 10*.

5.3.10 Test 8: Drop test

Test conditions: Testing room at +21°C (±3°C). Record conditions at the time of the test.[7]

- **Step 1:** Assemble a dummy vaccine load comprising partially filled water-packs, or other sealable plastic containers[8] that can be used to fill the vaccine storage compartment to a combined density of 0.5 kg of water per litre of the measured vaccine net storage capacity. In addition, assemble a sealed plastic bag containing eight vials and two ampoules as described in *Annex 3.*
- **Step 2:** Stabilize the load including vials and ampoules in a cold room or refrigerator at +8°C for a minimum of 24 hours.
- **Step 3:** Follow the legal manufacturer's directions for proper preparation of the appliance for use as detailed in *Section 5.3.2*.
- **Step 4:** Activate or turn on the appliance and allow it to cool-down in the testing room for half of the cool-down time calculated in *Test 3*.
- **Step 5:** Place the conditioned load in the vaccine storage compartment. If vial and ampoule holders or other containment is included in the appliance, place the vials and ampoules as indicated in the instructions or by the legal manufacturer, removing them from the plastic bag as needed. Otherwise, simply place the plastic bag with the vials and ampoules in the vaccine storage compartment with the dummy load.
- **Step 6:** Excluding any stationary components if applicable, mark the faces of the appliance and carry out a full free-fall drop sequence from a height of 0.85 metres (measured from the lowest part of the appliance at the start of each test) onto a smooth dense concrete surface, without rupture hazard.
- **Step 7:** Leaving the appliance operational (i.e. turned on), drop test (excluding any stationary components if applicable) in accordance with **ASTM D5276** and in the column sequences shown in the tables below, working down each column and from left to right. Alternative sequences may have to be agreed for products that have different shape characteristics from those described, but 11 drops shall be carried out in all cases:

For rectangular appliances

Face	Edges	Corners
1 (Bottom)	1-2 (Front bottom)	2-3-5 (Front bottom side)
2 (Front)	1-3 (Back bottom)	2-3-6 (Back bottom side)
3 (Back)	1-4 (Side bottom)	
4 (Either side)	2-4 (Front side)	
	3-4 (Back side)	

[7] Notwithstanding ASTM standard D5276, Clause 6.2, only one sample will be drop tested.

[8] Appliances with smaller or irregularly shaped vaccine storage compartments may not be able to accommodate water-packs meeting PQS specification IP01.

For cylindrical or octagonal appliances

Face	Edges (chimes)	Edges (chimes)
(Bottom)	(Front bottom)	(Midpoint of either side, bottom front)
(Front)	(Back bottom)	(Midpoint of either side, bottom back)
(Back)	(Left side bottom)	
(Left side)	(Right side bottom)	
(Right side)		

Stop the test after the final drop or when part of the load falls out, whichever is the sooner. If the load falls out prematurely due to failure of the hinges and/or catches, terminate the test. After each drop note any obvious damage that has occurred.

- **Step 8:** Record all damage to the appliance and the incidence of broken vials and/or ampoules (if any). Additionally, document visible damage to the appliance with photographs.

  Acceptance criteria: At the end of the test sequence there must be no damage that significantly affects the performance of the appliance (this will also be confirmed in *Test 10*). The lid or door must still close and latch correctly. Superficial and repairable damage to the appliance and damage to vials or ampoules is acceptable, but shall be reported.

  Rejection criteria: If any of the following are true:
  - There is damage to the lid or door that prevents closure.
  - The door or lid opens during testing.
  - There is damage that significantly affects the performance of the appliance.

5.3.11 Test 9: Vibration test

Test conditions: Testing room at +21°C (±3°C). Record conditions at the time of the test.

- **Step 1:** Assemble a dummy vaccine load as in *Test 8, Step 1*.
- **Step 2:** Stabilize the load as in *Test 8, Step 2*.
- **Step 3:** Follow the legal manufacturer's directions for proper preparation of the appliance for use as detailed in *Section 5.3.2*.
- **Step 4:** Activate or turn on the appliance and allow it to cool-down in the testing room for half of the cool-down time calculated in *Test 3*.
- **Step 5:** Place the conditioned load in the vaccine storage compartment as in *Test 8, Step 5*.
- **Step 6:** Excluding any stationary components if applicable and with the device still on, carry out **ASTM D4169-09**: Schedule F Loose Load Vibration to Assurance Level 1, Acceptance Criterion 3, Distribution Cycle DC3 utilizing test method **ASTM D999-08** Test Method B - Repetitive Shock Test (Rotary Motion).

Acceptance criteria: At the end of the test sequence there must be no damage to any vials or ampoules and no damage that affects the performance of the appliance. The lid or door must still close and latch correctly. Superficial and repairable damage to the appliance is acceptable.

Rejection criteria: If any of the following are true:
- There is damage to any vial or ampoule.
- There is damage to the lid or door that prevents closure.
- There is damage that affects the performance of the appliance.

5.3.12 Test 10: Post drop and vibration, primary performance re-test

- **Step 1:** Set the test chamber to +43°C.
- **Step 2:** Condition the appliance (the same sample that has already gone through IP, drop and vibration testing) in the test chamber as in *Test 3, Step 2*.
- **Step 3:** Condition the dummy load as in *Test 3, Step 3*.
- **Step 4:** Begin monitoring and recording temperatures and active cooling as in *Test 3, Step 4*.
- **Step 5:** Follow the legal manufacturer's directions for proper preparation of the appliance for use as detailed in *Section 5.3.2*. Record the time at which the preparation process is initiated.
- **Step 6:** After the appliance indicates that it is properly prepared for use, disconnect it from any external power sources. Record the time.
- **Step 7:** Remove the dummy vaccine load from its +8°C location and place in the appliance as in *Test 3, Step 8*.
- **Step 8:** Close the lid or door of the appliance and switch the appliance on. The time from switching the appliance on until the temperature measurements at all monitoring locations (as shown in *Annex 2*) reach +8ºC or colder will be recorded as a post-drop testing cool-down time.
- **Step 9:** Leaving the appliance on but disconnected from any external power sources, continue the test until all temperature sensors have warmed back up to +20°C or above.
- **Step 10:** Calculate the post-drop testing independence as the time from the last time point used to calculate the post-drop testing cool-down time until the first temperature measurement at any location above +8°C. Additionally, calculate post-drop testing holdover time as the time from the end of the last instance of active cooling until the first temperature measurement at any location above +8°C. NOTE: Some appliance may be incapable of distinguishing when active cooling has stopped if turned on. In these cases, holdover time shall be reported as "0: incalculable".
- **Step 11:** Note any abnormalities, marked changes in performance, or issues potentially due to the previous low-voltage testing, IP testing, drop testing, or vibration testing. If possible, diagnose any probable cause(s) and record them in the test report.

Acceptance criteria: All monitoring locations remain within the acceptable temperature range from the last time point used to calculate post-drop testing cool-down time until the last time point used to calculate post-drop testing independence. The calculated post-drop testing cool-down time is less than four hours and the calculated post-drop testing independence is greater than 12 hours and no less than 50% of the independence value measured in *Test 3*. There is no requirement for post-drop testing holdover time but it will be reported. No other significant issues or performance changes are noted.

Rejection criterion: If any of the following are true:

- Any monitoring location does not remain in the acceptable temperature range (after the vaccine storage compartment initially cools down).
- The calculated post-drop testing cool-down time is greater than the maximum for acceptance.
- The calculated post-drop testing independence is less than the minimum for acceptance.
- The calculated post-drop testing independence is less than 50% of the independence measured in *Test 3*.
- Any other significant changes in performance or issues as compared to *Test 3*. Significant changes shall generally be judged by the testing laboratory.

5.3.13 Test 11: Multiple power sources

- **Step 1:** Confirm the number of possible ways the legal manufacturer indicated the appliance could be powered or prepared for use.
- **Step 2:** If that number is greater than one, retest the appliance using each power source or procedure separately. For each, carry out *Test 3: Primary performance*, *Test 4: Low voltage preparation* (as applicable), *Test 5: Minimum Rated Ambient Temperature*, and *Test 6: Door opening test*. *Tests 7* through *Test 10* do not need to be repeated.

  Acceptance criterion: All acceptance criteria are met in the additional tests.

  Rejection criterion: Any of the rejection criteria are met in the additional tests.

5.4 Test criteria for qualification

A final report must be issued after all testing is complete. Each test shall have a full analysis of all logged temperatures (including ambient temperatures) which summarizes the maximum, minimum and mean temperatures for each sensor and for different sections of all tests.

Temperature results shall also be presented graphically so that all instantaneous peaks and troughs can be clearly seen with t = 0 hours at the

start of each test. Power consumption and/or active cooling indication should be displayed with each temperature graph.

Energy and Power consumption, if applicable to the test and appliance, should also be analyzed. This includes calculation of the total kWh used over the testing period, the average power in kW, and graphs allowing analysis of instantaneous power at any point in the test.

The report of the tests must contain the following data and analyses:

- **Summary:** Conclusions and recommendations.
- **Test 1:** Provide general comments on the samples received including comments on the overall standard of construction, tabulated results of the type inspection and photographs of samples.
- **Test 2:** Results of dimensions, weights and vaccine storage capacity test including the recorded external dimensions, calculated maximum loaded mass, calculated vaccine net storage capacity and confirmation of the appliance designation as a lightweight, medium-weight, or heavy-weight appliance.
- **Test 3:** Results of the primary performance test including the time measured for proper preparation of the appliance, cool-down time, independence, holdover time, and temperature graph(s). Additionally, if the appliance is or can be powered by electricity, report the total energy used by the appliance during preparation for use and the average power in kW used over the same time period.
- **Test 4:** Results of the low voltage preparation test including temperature graph(s).
- **Test 5:** Results of the door open test including the time measured for proper preparation of the appliance, cool-down time, independence, holdover time, and temperature graph(s).
- **Test 6:** Results of minimum rated ambient temperature test, including the minimum rated ambient temperature, the minimum temperature recorded by any sensor during the test at the minimum rated ambient temperature, the freeze protection classification, and temperature graph(s).
- **Test 7:** Results of IP rating test, or commentary on the independent test report submitted by the legal manufacturer.
- **Test 8:** Results of drop test.
- **Test 9:** Results of vibration test.
- **Test 10:** Results of the second primary performance test including the time measured for proper preparation of the appliance, cool-down time, independence, holdover time, and temperature graph(s).
- **Test 11:** Results as listed above for all additional, repeat testing required by the multiple power sources test.
- **Annexes:** A pre-approved test protocol verifying that the procedures set out in this document have been followed. The applicable WHO PQS specification. Diagrams showing the location and identification codes for temperature sensors, clearly distinguishing between sensors. Additional supporting documentation requested and received from the legal manufacturer or reseller during the course of the type-testing.

- Description of the test apparatus including test chamber temperature records. Temperature sensor calibration history and pre-test calibration records to be kept on file for inspection.

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**.

6.2 Quality control checklist

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

6.3 Quality control evaluation

Not required explicitly for this protocol but auditing may occur by WHO PQS as needed.

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 **WHO/PQS/E003/TS01**.

8. Modified products

The legal manufacturer or reseller must notify WHO in writing of any changes in form, fit or function which may affect the performance of the product. WHO will carry out a desk evaluation of the reported change(s). If any change is deemed 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 appliance to be set up in accordance with **IEC 62552-1** Figure A.2.

- Test sample to remain in the test ambient for a sufficient time to achieve a condition where the whole appliance is at the applicable temperature for at least 48 hours before testing commences.
- Carry out tests in a test chamber in which temperatures can be controlled to ±1ºC and relative humidity within the range of 65% to 75% unless otherwise stated below. Humidity for each test shall be stated in the report.
- The test ambient should be measured at each side of the appliance in accordance with **IEC 62552-1** *Figure A.2* & *Clause A.4.5* except where there is a vent (e.g. a fan outlet for cooling part of the appliance), where the ambient on that side should be measured at a similar distance in front of the appliance.
- All test chamber logged ambient temperatures shall be within ±1ºC with the mean of the logged ambient within ±0.5ºC.
- The speed of the air in the test chamber shall be 0.5 m/s or lower.
- All temperatures must be continuously monitored to a total uncertainty no worse than ±0.5ºC from the tip of the sensor to displayed readings or captured data. The influence of any instrumentation or temperature sensor set-up on appliance performance shall be minimized. e.g. gaps in the door seal cause by temperature sensor wires must be sealed.
- Up to 24 simultaneous temperature measurements may be required for a single appliance. The suggested temperature sensor specification and locations are shown in *Annex 2*.
- Position the test appliance in the test chamber with its back face no more than 50 mm clear of one of the chamber walls. This clearance may be less than 50 mm where appropriate spacers are provided. This clearance must not be larger than 50 mm even if larger spacers are provided.
- Ensure that the appliance is accurately levelled.

Minimum test chamber temperatures colder than 0°C may be required for the minimum rated ambient temperature test. The actual minimum required for a specific appliance should be discussed with the product legal manufacturer before the test commences.

Annex 2 – Temperature sensors and monitoring locations

Temperature sensors shall comply with **IEC 62552-1**, *Clause A.2.6* with a total sensor uncertainty of ±0.5°C[9], inserted into brass or tin-covered copper mass of 25 g ± 5% and of minimum external surface area (diameter = height = about 15.2 mm).

Approximate sensor positions are indicated by the figures below. Except for ambient sensors placed centrally in a compartment, the copper masses containing the surface sensors are positioned so that they are in direct contact with the vaccine storage compartment. If baskets or other components are used to define the vaccine storage compartment, all sensors are to be located inside those components and the metal mass containing the surface sensors are to be in contact with the basket material in similar locations to those shown in the figures.

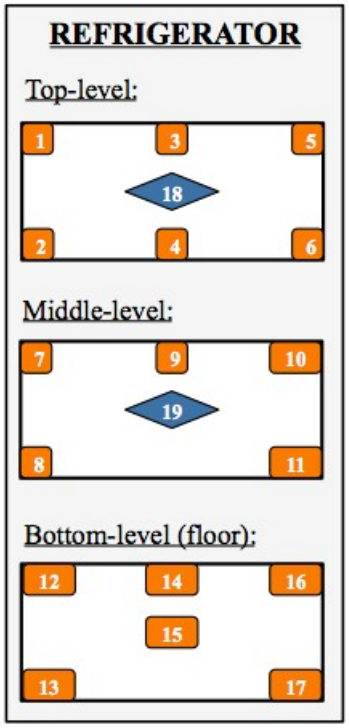
If the tested appliance is either a lightweight appliance or a medium-weight appliance with less than 5 litres of vaccine net storage capacity, due to the relatively small vaccine storage compartment, a minimum of five sensors shall be used. For these appliances with primarily rectangular vaccine storage compartments, as shown in the first diagram below, these absolute minimum sensor locations shall include surface sensor locations of an upper vertex, lower vertex, and bottom centre as well as non-surface sensor locations in the centre and top-centre of the vaccine storage compartment (e.g. locations 2, 13, 15, 18, and 19 in the first diagram below). If the geometry of the noted appliances is not rectangular, similar locations shall be used. For all other appliances, if the general geometry of the vaccine storage compartment is not the same as any of the four figures below, 15 to 19 sensors should be located in a similar arrangement within the vaccine storage compartment. Alternative configurations should include sensors at indicative locations for all surfaces, edges, and corners in the vaccine storage compartment as well as at other positions that are likely to experience extremes of temperature. Such positions might be near door seals or areas where air circulation is restricted by the appliance design.

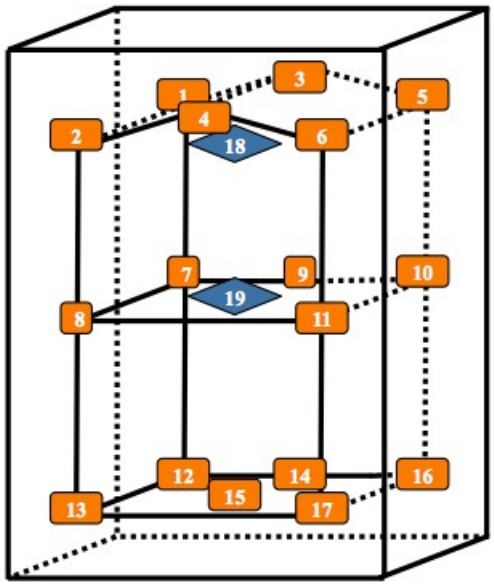
Sensors may be fixed in position using thin rigid wire, tape or similar materials that will minimally affect the thermal performance of the appliance. Sensor leads can be introduced into the container using one of two methods: through the lid or door or through the door seal, taking care to affect the quality of the seal as little as possible or through a hole in the geometric centre of the lid or door, taking care to seal the outer and inner entries adequately.

[9] Total uncertainty being from the tip of the sensor to the readout or data-recording.

UPRIGHT COMPARTMENT

17 Surface sensors
2 Ambient sensors

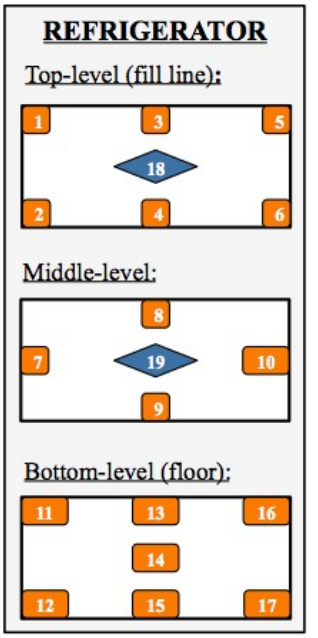


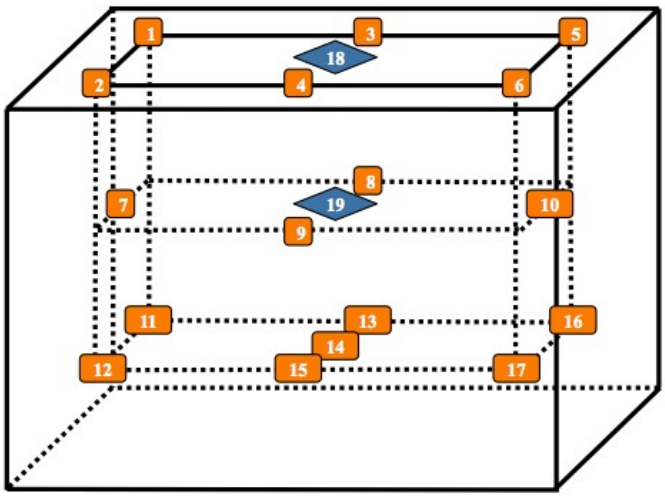


All sensors are to be positioned according to this layout and in direct contact with compartment surfaces.

CHEST COMPARTMENT – NO STEP

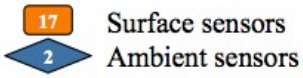
17 Surface sensors
2 Ambient sensors

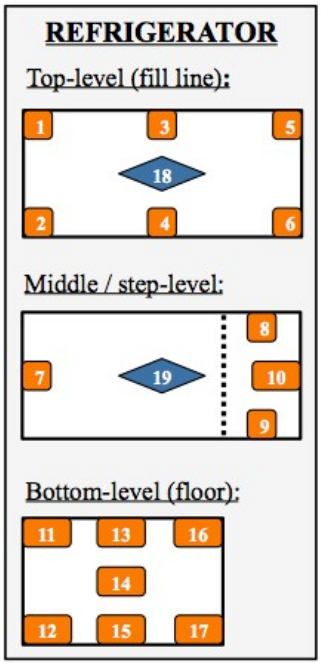


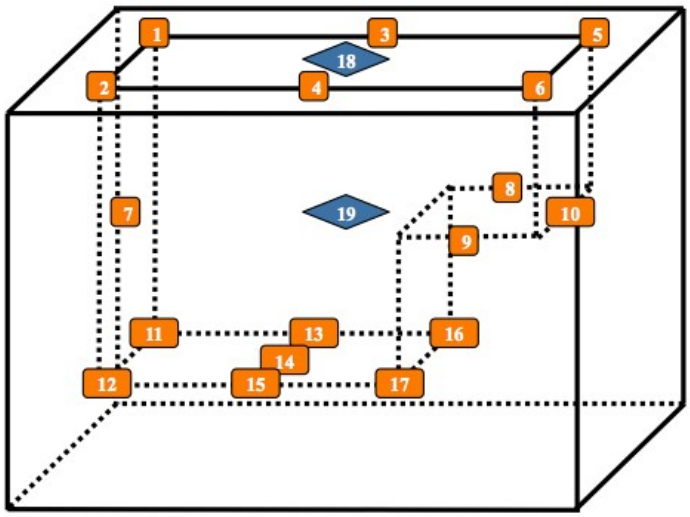


All sensors are to be positioned according to this layout and in direct contact with compartment surfaces.

CHEST COMPARTMENT – WITH STEP

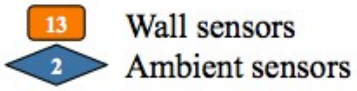


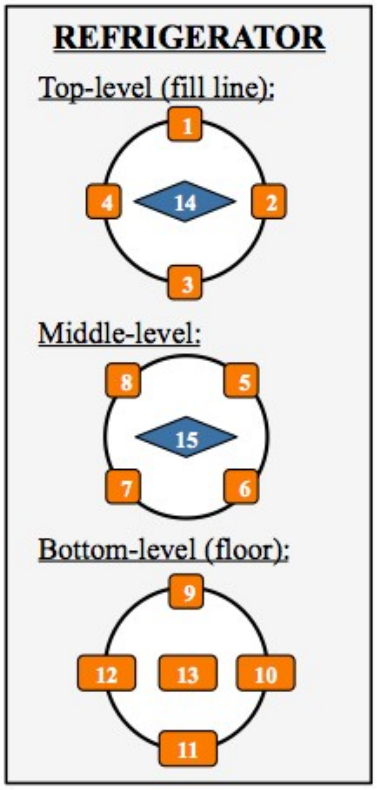


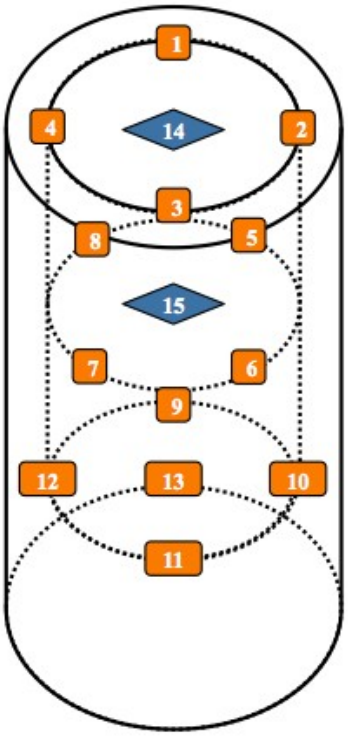


All sensors are to be positioned according to this layout and in direct contact with compartment surfaces.

CYLINDRICAL CHEST COMPARTMENT







Annex 3 – Vial and ampoule specification for dummy load

- Empty vials complying with **ISO 8362**, size 4R.
- Empty 5mL ampoules complying with **ISO 9187**, either open or closed stem.

ISO standard vials and ampoules can be obtained from:

Adelphi Healthcare Packaging
Olympus House,
Mill Green Road,
Haywards Heath,
West Sussex, RH16 1XQ,
UK
T: +44 (0)1444 472300
F: +44 (0)1444 472329
E: sales@adelphi-hp.com

There are numerous other suppliers.

Revision history			
Date	Change summary	Reason for change	Approved