PQS performance specification

WHO/PQS/E003/TS01.1
Original: English
Distribution: General

TITLE: Transportable, powered vaccine storage appliances

Specification reference:	E003/TS01.1
Product verification protocol:	E003/TS01-VP.1
Issue date:	30 April 2021
Date of previous revision:	New specification

Contents

1. Scope

This specification defines the requirements for transportable, powered appliances generally intended for temporary storage and transport of vaccines. The appliances may use combinations of passive cooling and active cooling powered by sources including mains electricity or other alternating current (AC) sources, dedicated solar photovoltaics (PV), or 12 V to 24 V or other direct current (DC) sources. In order for the appliances to be transportable, many designs will require power input from stationary sources and some energy storage mechanism. Appliances may include thermal storage materials or internal batteries for energy storage. Other power sources (including heat and mechanical sources) as well as other means for energy storage may be acceptable, but shall be discussed with PQS prior to prequalification testing and approval. Heat sources that require an open flame or other combustion for operation are not acceptable. If dedicated solar PV is used, it must comply with **WHO/PQS/E003/PV01**, which specifies acceptable solar power systems.

The appliance may use active cooling to manage temperatures in the vaccine storage compartment using compression cycles, absorption cycles, thermoelectric components, or other means. Three temperature zone designations have been used in other PQS specifications; however, only the hot zone temperatures will be used for this specification. In addition, appliances shall be tested to establish a minimum rated ambient temperature designation. If field testing is required, the PQS Secretariat shall pre-approve all field study plans in advance.

Appliance design shall account for performance degradation over the 10-year or greater target life of the appliance, in order to sustain the acceptable temperature range and other appliance features (if included) for that time period. The appliance and all ancillary components shall be designed to withstand the conditions under which these appliances are used, including, but not limited to, the following:

- Transport by air, sea and over rough, dusty road surfaces.
- High temperatures in transport, storage, and operation.
- Low temperatures in transport, storage, and operation.
- High humidity in transport, storage, and operation.
- Operating locations with high wind and high density of dust particles.
- Operating locations in corrosive marine environments.
- Users with inconsistent training.
- Users with no specialized maintenance tools.
- Inconsistent and intermittent mains power including both transient and long-term voltage and frequency variability.

2. Normative references

(Use the most recent version.)

ASTM D5276-09: *Standard Test Method for Drop Test of Loaded Containers by Free Fall.*
ASTM D4169-09: *Standard Practice for Performance Testing of Shipping Containers and Systems*.
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 60364-1: 2005: *Low-voltage electrical installations - Part 1: Fundamental principles, assessment of general characteristics, definitions.*
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 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.
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.*
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.

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 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.

[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.

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 Annex 1 temperature zone symbol. This will enable purchasers in countries with low winter temperatures to select the most appropriate models.
Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.
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.
Primary container: Vial, ampoule, pre-filled device, plastic dispenser or tube containing vaccine or diluent. Some products are supplied in a carton made of light card stock or paperboard containing a single vial, ampoule, vial pair, vial-ampoule pair, or pre-filled device.

Reseller: A commercial entity, licensed to act on behalf of a legal manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the legal manufacturer.
Secondary carton: A carton containing a number of individual primary containers. Most countries have traditionally stored and distributed vaccines in these cartons.
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 vaccine net 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. Requirements

4.1 General

Transportable, powered vaccine storage appliances may be used in multiple settings for transport from locations with reliable power or electricity supply (i.e., 20 or more hours of reliable electricity per typical day) to areas with less reliable, or no electricity. They may also be used for short-term storage in locations that do not or cannot support a more permanent refrigeration point in the cold chain. Appliances, including any stationary components, shall carry the CE mark, UL mark, and/or equivalent internationally accepted evidence of conformity assessment. The mass, volume, and intended use of the appliance should fall within one of the three following categories for the purposes of this specification and the corresponding verification protocol **WHO/PQS/E003/TS01-VP.1**:

- **Lightweight appliance**: intended primarily for short-term vaccine transport with or without a vehicle for transportation and sized for carrying by one person likely to a single destination - having a maximum loaded mass of less than 8 kg and a vaccine net storage capacity of greater than 1.5 litres.
- **Medium-weight appliance**: intended primarily for longer-range transportation, possibly to multiple destinations by a vehicle (e.g. truck, motorbike, donkey, camel), and movable for at least short distances by a single person - having a maximum loaded mass of

less than 25 kg and a vaccine net storage capacity of greater than 1.5 litres.

- **Heavy-weight appliance**: intended primarily for temporary, short-term vaccine storage and transport by powered vehicle and movable by two or more people to and from a vehicle - having a maximum loaded mass of less than 50 kg and a vaccine net storage capacity of greater than 5 litres.

4.2 Performance

If the appliance is intended to be powered, charged, or otherwise prepared for use by more than a single type of power source or process, performance will be tested and verified separately with each source or process.

4.2.1 Operating temperature range

All appliances shall be suitable for operation in the hot zone (+43°C maximum temperature) and at a minimum rated ambient temperature of +10°C or lower, whilst maintaining the acceptable temperature range in the vaccine storage compartment.

4.2.2 Refrigeration cycle

Refrigeration can be accomplished using a compression cycle with one or two compressors or with thermoelectric components. Other means of cooling (e.g. absorption-cycle, evaporative cooling), may also be acceptable but shall be discussed with PQS prior to prequalification testing and approval. However, absorption-cycles or other appliances that require an open flame or other combustion during use or preparation are not allowed due to safety concerns specific to transportable appliances.

4.2.3 Design of vaccine storage compartment

The vaccine storage compartment shall be designed so that no area or surface that reaches temperatures outside of the acceptable temperature range in normal use or during testing can be used to store vaccines either by inadvertent or deliberate misuse.

As per the classification of freeze protection features (*Section 3, Terms and Definitions*) appliances complying with this requirement without demanding any intervention from the user will be published as Grade A. Others will be published as Grade B or Grade C depending on the number of user-interventions required.

4.2.4 Vaccine freeze protection classification

The classification shall be designated by the legal manufacturer and indicated on the freeze protection classification sticker attached to the appliance (see *Annex 3*). The number of user-interventions required to ensure that the vaccines will not be exposed to freezing temperatures

when the appliance is used within the hot zone temperature range and minimum rated ambient temperature will be classified and reported as Grade A, Grade B, or Grade C. These grades are defined in *Section 3 Terms and Definitions*.

4.2.5 Temperature control

The entire vaccine load shall remain within the acceptable temperature range during any continuous ambient temperature test(s) or cycling temperature test(s) and down to the minimum rated ambient temperature in the minimum rated ambient temperature test (see *Section 4.2.13*). For appliances that are intended to be powered, charged, or otherwise prepared for use by more than a single power source or process, this requirement applies to operation when powered, charged, or prepared by each possible power source or process independently.

4.2.6 Cool-down time

The appliance shall be able to cool the vaccine storage compartment to +8°C or below within four hours or less without any external power input. Internal or integrated power sources such as batteries, rechargeable chemical mechanisms, or others can be used for this cooling task. This functionality will be tested at +43°C after following any instructions for charging or otherwise preparing the appliance and after the appliance indicates that it is prepared and safe for use. The cool-down time will be established in verification testing per the verification protocol **WHO/PQS/E003/TS01-VP**.

4.2.7 Use-Reuse cycle

The appliance shall be capable of being charged, conditioned, or otherwise prepared for use within 12 hours of a previous use, while receiving any manufacturer-specified minimum power requirements for the appliance. It shall also be possible to delay the use of the appliance by a minimum of 24 hours after being fully charged or prepared for use, and meet all performance requirements (e.g. cool-down time, independence, etc.).

4.2.8 Indicator of proper preparation for use

If the appliance needs to be charged, conditioned, or otherwise prepared before being used to transport vaccines, there shall be a clear indication for the user to assess whether the appliance is ready. Preferred designs will hinder the user from loading or using the appliance unless it is properly prepared. However, if this functionality is not present, an obvious indication to the user will be acceptable. This safe-for-use indication may be an obvious light or display, temperature reading, coloured indicator, or other form.

4.2.9 Thermostat

The thermostat or other control mechanism shall be set to prevent freezing in any part of the vaccine storage compartment. It shall be effective throughout the ambient operating temperature range (down to the minimum rated ambient temperature – see *Section 4.2.13*). It shall be designed so that it cannot be adjusted by the user. A means for adjustment by a technician is acceptable provided the device is protected from user interference (e.g. by location within the appliance cabinet). Alternatively, programmable thermostats may be password-protected. Bulb and capillary tube thermostats are not acceptable.

4.2.10 Temperature monitoring and thermometer

The appliance shall be equipped with a permanent, externally readable thermometer or display of one of the following types:

- A cabinet-mounted electronic thermometer conforming to PQS specification **WHO/PQS/E006/TH06** of Type A or B as referred to in that specification. Referring to version TH06.2 of that specification, the requirements on the power source of the appliance can be ignored.
- An electronic thermometer powered by a photovoltaic cell conforming to PQS specification **WHO/PQS/E006/TH06** which forms part of the device. This type draws no power from the appliance in which it is installed and is referred to as Type C in that specification. Referring to version TH06.2 of that specification, the requirements on the power source of the appliance can be ignored.

The location at which the temperature is monitored for display shall be in the zone of the compartment with the lowest temperature during appliance operation. If the appliance is or can be housed in a secondary carrier for transport (e.g. a backpack or satchel), it is allowable for the temperature display to be covered by the secondary carrier as long as the user is not required to open the primary appliance to view the temperature reading.

OPTIONAL: Additionally, some appliances may be equipped with a temperature monitoring functionality that supports the transfer of data to another system for analysis purposes. This functionality is optional and can be combined with, or separate from the external monitor or display. However, if it is included, it must comply with the following:

- If the temperature monitoring device is separate and not permanently physically integrated with the appliance, it shall be a 30-day temperature logger, prequalified by WHO PQS as complying with **WHO/PQS/E006/TR06**. The sensor shall be located in an integrated holder within the vaccine storage compartment with or without an external sensor lead. The holder shall be positioned so that the device can easily be read by the health worker, and shall be located so that temperature readings are

taken in the zone of the compartment with the lowest temperature during appliance operation.

- If the legal manufacturer ships temperature monitoring devices with appliances, the temperature monitoring device and its battery shall not be adversely impacted by the shipping and storage conditions as specified in *Section 4.3*.
- If the legal manufacturer ships temperature monitoring devices separately, they should arrive at the same destination as the appliance shipment, within the same week, and addressed to the same consignee. This is necessary to allow for coordinated in-country receipt and assembly of the appliances and temperature monitoring devices. Separate shipments of temperature monitoring devices shall be tracked and coordinated by the legal manufacturer.
- The legal manufacturer shall also provide the consignee with the expected number of replacement temperature monitoring devices throughout the 10-year expected lifetime of the appliance, so that the temperature monitoring device is always active on-site (i.e. if the monitoring devices have a design life of two years, a total of five devices will need to be supplied at two-year intervals). This cost is expected to be included in the upfront price of the appliance that is quoted to WHO PQS and purchasers. Scheduled replacement dates of the temperature monitoring devices must also be mentioned by the legal manufacturer in the instructions (see *Section 4.11*).

4.2.11 Independence

The appliance shall be able to maintain temperatures in the vaccine storage compartment between +2°C and +8°C for a minimum of 12 hours without any external power input or user interaction. This applies while in a location with a constant ambient temperature of +43°C. This independence time will be established in testing per verification protocol **WHO/PQS/E003/TS01-VP** after the appliance has initially cooled-down with all external power sources disconnected or switched off. Independence may include both powered, active cooling using energy stored by the device and passive cooling.

4.2.12 Holdover time

It is recommended that the appliance be able to maintain temperatures in the vaccine storage compartment between +2°C and +8°C for an extended period of time without any active cooling or power input. A holdover time of four hours or greater is recommended in case of failure or malfunction of any active cooling components in the appliance. This applies while in a location with a constant ambient temperature of +43°C. This holdover time will be established in testing per verification protocol **WHO/PQS/E003/TS01-VP** after the appliance has initially cooled down and all external power sources or means for active cooling have been disconnected, exhausted or switched off.

Holdover time is distinct from independence in that it only includes passive cooling capacity, while independence may include both active cooling and passive cooling.

4.2.13 Minimum rated ambient temperature

All models will be tested to verify their stated minimum rated ambient temperature. Appliances shall be able to operate at a continuous minimum ambient temperature of +10°C or lower. A freeze-prevention circuit may be required to protect against freezing at low ambient temperatures. For appliances that can be powered by more than a single power source, this requirement applies to operation while powered by each possible power source independently. This minimum rated ambient temperature will be established in testing per verification protocol **WHO/PQS/E003/TS01-VP.**

4.2.14 Power system requirements and consumption

If the appliance is designed to receive mains power, 220-240 volt 50/60 Hz and 100-127 volt 50/60 Hz options shall be offered. Thermal performance should be functionally comparable for all options, regardless of the nominal voltage and frequency rating of the appliance. The electrical components and system shall be selected and designed to be capable of withstanding inconsistencies in mains power including both transient and long-term voltage and frequency variability.

If the appliance is designed to operate using DC it should generally be a 12 - 24 volt DC system. Other voltages may be acceptable but shall be discussed with PQS prior to qualification testing and approval. The electrical components and system shall be selected and designed to be capable of withstanding inconsistencies in the voltage and current that may be delivered to the appliance through vehicles or other DC sources.

There is no standard set for power or total energy consumption, however consumption will be reported in all tests as appropriate. All mains powered appliances shall be capable of starting and operating at 22% below the legal manufacturer's stated voltage, as tested in the verification protocol **WHO/PQS/E003/TS01-VP**.

4.2.15 Batteries

For appliances containing or using batteries the legal manufacturer shall supply evidence of compliance with UL 2054 as well as a material safety data sheet. For appliances using solar PV, if batteries are included as part of the stationary components and power system, they shall comply with specification **WHO/PQS/E003/PV01**.

If the batteries are used to power all or part of the primary appliance cooling system, they shall be rechargeable and:

- Replaceable by a technician, but not easily accessible or removable by the user,
- Of maintenance-free design, and
- Robust enough to power the appliance and cool it within the acceptable temperature range for at least five years with expected cycling and recharging. The minimum intended lifetime of the appliance is 10 years so one battery replacement is allowed during that lifetime.

If single-use, non-rechargeable (i.e. primary cell) batteries are used to power secondary functions in the appliance (e.g. temperature monitoring, alarm system, etc.), they shall be:

- Replaceable by a user given detailed direction or instructions,
- A common type of battery that can be easily sourced in the locations where the equipment is procured
- Of maintenance-free design, and
- Robust enough to power the applicable functions for at least two years with a target lifetime of three years. The minimum intended lifetime of the appliance is 10 years so five or fewer replacements are allowed during the appliance lifetime.

NOTE: Battery performance can be significantly affected by temperature and state of charge. The usable lifetime must take into account that storage and use temperatures may frequently be elevated. Any manufacturer calculations, design, and testing should consider the hot zone temperature of +43°C and that temperatures in transportation vehicles or with exposure to sun could sometimes exceed this value.

Lithium batteries:
Lithium-based batteries can pose fire risks and are not allowed as part of PV systems per **WHO/PQS/E003/PV01**. Lithium-based batteries are also not allowed as part of the stationary components of the appliance system. Lithium-based batteries may be used in the primary, transportable portion of the appliance system; however, extreme caution, risk assessment and mitigation shall be used by the legal manufacturer in the appliance design, material selection, and production.

The appliance may be exposed to harsh environmental conditions, as noted throughout this specification, that must be considered in terms of appliance and battery safety. Temperatures during transport, especially when located inside vehicles or exposed to direct sunlight, may exceed +43°C or reach below 0°C in certain regions of use. The legal manufacturer shall design the appliance, including necessary battery management systems, to account for safe operation under these conditions. As relevant, standard UL 2595 shall be applied in addition to UL 2054 to ensure the safety of appliance operation. If lithium-based batteries are used, the total capacity shall not exceed 1000 Wh and it is

recommended that 300 Wh not be exceeded.[2] Furthermore, the legal manufacturer should consider that shipping and transport of lithium-based batteries are frequently difficult and restricted especially through international borders. It is recommended to consider this in both sizing and selecting the chemistry of appliance batteries.

4.2.16 Closure and lock

The lid, door, or other closure should be fitted with a mechanism to secure it in place so that the appliance does not open if it is dropped onto its side or onto its lid when full. Acceptable closure devices include, but are not confined to, magnetic or mechanical catches. It must not be possible for a catch to open accidentally once engaged due to vibrations or other similar, unintended causes. Mechanical catches shall be recessed so that they are fully protected against damage during transport and storage. Catches shall be maintenance-free, without need for lubrication and shall be secured to the container in a manner that prevents loosening due to vibration and frequent use. If the appliance is designated as medium-weight or heavy-weight, it shall be fitted with either an integrated lock or the door or lid must be fitted with a robust tab or other component to accommodate a padlock. If the lock is integrated or a padlock is shipped with the appliance, two keys shall be supplied with every unit to allow one set of spare key(s). Additionally, if the lock is integrated, the subcomponent shall be available as a spare part and be able to be changed by a technician.

4.2.17 Electrical and other safety considerations

For appliances with relevant electrical components, the legal manufacturer shall supply evidence of and declare compliance with **IEC 60335-1**, **IEC 60335-2-24** and **IEC 60364-1**.

If the appliance, including any stationary components, presents additional safety risks to the user or other people likely to be in the vicinity of use such as children and patients, the legal manufacturer shall provide a narrative description of the design features, precautions, mitigants and other steps taken to address these safety risks. Specifically, this shall be provided for PQS review in the dossier for appliances that require potentially hazardous chemicals and/or high pressure (other than those used in common compressor driven cooling systems) and/or the intentional application of heat at temperatures above +50°C. Failure to comply with this initial reporting or to adequately address these safety concerns may result in immediate removal of equipment from PQS listing at the discretion of WHO PQS during, or at any time after, PQS prequalification.

[2] There is limited, directly relevant documentation of requirements for total energy storage for lithium-based appliance batteries based on safety risks. The recommended 300 Wh maximum remains somewhat arbitrary and will be revisited as battery technology and safety advances.

4.2.18 Electromagnetic compatibility

The legal manufacturer shall supply evidence of and declare compliance with the requirements of the latest edition of **IEC 61000-6-1** and **IEC 61000-6-3**.

4.2.19 Shape

For lightweight and medium-weight appliances, the design should consider and promote comfortability for carrying. Sharp edges and corners should be avoided; rounded external corners are preferred. It is also recommended that the design of medium-weight and heavy-weight appliances take into consideration the ergonomics of moving the appliance with multiple people and robust mounting on motorbikes or other modes of transport. The shape and design of appliances that require ventilation should also take into account protection of the ventilation air-flow pathways from accidental blockage, especially if packed in direct contact with other articles during transport. Appliances with such ventilation or other heat dissipation features should be designed (e.g. inclusion of components such as “standoffs”, “spacers”, or “bump stops”) to ensure adequate air circulation. The spacing and design should account for storage or transport on or next to compressible materials, like those often used for seats in vehicles that may inhibit air flow and heat transfer.

4.2.20 Hinges

Hinges, where fitted, should allow the lid to open beyond 90° to give full access to the interior of the appliance. Preferably, the hinges should be recessed so that they are fully protected against damage during transport and storage. Hinges shall be maintenance-free, without need for lubrication and must be secured to the container in a manner which prevents loosening due to vibration.

4.2.21 Carrying components

All carrying components shall be robustly constructed and firmly attached in order to survive rough handling. Both lightweight and medium-weight appliances shall be fitted with at least one carrying component arranged so that the appliance can be comfortably carried in a substantially upright position. Examples include:

- **Carrying handle:** a hinged, sliding or moulded-in handle attached to or forming an integral part of the appliance.
- **Shoulder strap:** an adjustable padded strap arrangement that allows the appliance to be carried over the shoulder.
- **Backpack:** an adjustable padded strap arrangement that allows the appliance to be carried as a backpack.

Heavy-weight appliances shall be fitted with at least two handles designed so that they can be used by multiple people to lift and carry the appliance comfortably when it is fully loaded. Hinge mechanisms, if present, shall restrain the handle in a near-horizontal position when the container is being moved or guided. Preferably, the handles should be recessed so that they are fully protected against damage during transport and storage.

Additionally, both medium-weight and heavy-weight appliances shall include features that facilitate securing, fastening, or otherwise anchoring the appliance to motorbikes or other likely modes of transport to prevent accidental movement during transport.

4.2.22 IP rating

Protection of the appliance with lid or door closed and latched must not be less than that which is stipulated by **IEC 60529: IP54** while operational and allowing no ingress of water into the vaccine storage compartment. The rating includes the entirety of the transportable portion of the device, not just the vaccine storage compartment. It is recommended that any stationary components be capable of meeting at least **IP44**.

4.2.23 Robustness and vibration

The appliance with a full load of vaccine vials and diluent ampoules shall withstand a 0.85 metre drop onto the 11 faces, edges, corners or chimes (circumferential edges) that are most likely to receive impact, and when tested in accordance with **ASTM D5276-09**. At the end of the test there shall be no damage that significantly affects the performance of the appliance and the lid or door must still close and latch correctly although some damage to the appliance or contents is acceptable. The appliance with a full load of vaccine vials and diluent ampoules must also withstand vibration testing typical of unpaved road conditions in accordance with **ASTM D4169-09**, with no damage to either the appliance or contents. Drop and vibration tests will be carried out on each appliance per **WHO/PQS/E003/TS01-VP**.

4.3 Environmental requirements

4.3.1 Material properties at ambient temperatures

Appliance materials and components shall be able to withstand temperatures during transport and storage of -30°C to +70°C when the product is inactivated or turned off.

4.3.2 Ambient humidity range during transport, storage and use

Appliances may be subject to a wide range of uncontrolled ambient humidity up to condensing, 100% RH and should be designed to remain undamaged and fully functional if exposed to these conditions in hot zone temperatures (up to +43°C).

4.4 Physical characteristics

4.4.1 Overall dimensions

To allow for manoeuvring through corners, corridors and doorways, the minimum dimension of the product (length, width, or height) should not exceed 710 mm. The maximum dimension shall not exceed 1700 mm. The maximum diagonal dimension (e.g. corner-to-corner distance in any plane of a rectangular prism) shall not exceed 1850 mm.

4.4.2 Weight

Mechanical lifting equipment will typically not be available at sites. It is recommended that the appliance and any associated components, including stationary components, should be designed for lifting or moving in such a way that no single person is required to carry more than 25 kg, including whilst moving a heavy-weight appliance on their own, or in a group. The maximum loaded mass of the appliance, inclusive of any physically separate components used during transport but excluding any stationary components, shall not exceed the following figures:

- Lightweight appliance: 8 kg
- Medium-weight appliance: 25 kg
- Heavy-weight appliance: 50 kg

4.4.3 Internal Volume

The vaccine net storage capacity shall meet the following minimum requirement based on the type designated by the legal manufacturer:

- Lightweight appliance: greater than 1.5 litres
- Medium-weight appliance: greater than 1.5 litres
- Heavy-weight appliance: greater than 5 litres

4.5 Interface requirements

4.5.1 Voltage stabilizers (if applicable)

Any appliance designed for use with AC mains power shall be provided with either an integrated or a stand-alone voltage stabilizer or protection. The voltage stabilizer or protection must be certified by WHO PQS as complying with **WHO/PQS/E007/VS01**. The design of integrated voltage stabilizers must allow for easy access and repair or replacement by technicians in the event of malfunction. Note that: although DC-powered appliance may still benefit from similar electrical protection, only AC-powered appliances are required to have voltage regulation in full compliance with **WHO/PQS/E007/VS01**.

4.5.2 Solar PV interface (if applicable)

For appliances using solar PV, all electrical components shall be compatible with a solar power system as stipulated in specification **WHO/PQS/E003/PV01**. The appliance is to be equipped with a locking female and male coupler system ("plug and play") that is compatible with the solar array interconnection cable and polarity. If the appliance is intended to be powered by (and/or marketed as powered by) solar power, it shall be supplied with a dedicated, applicable, solar PV system meeting all requirements in **WHO/PQS/E003/PV01**.

The design of the appliance and related system components should account for repeated connection and disconnection by the user to transport the appliance. Disconnecting from a solar PV system or other electricity source while under electrical load using the locking coupler system is generally not recommended for this repeated action. The legal manufacturer shall design the appliance and system to clearly lead the user to connect and disconnect the transportable appliance from the PV system in a safe and robust way.

4.5.3 Power switch

The appliance shall be equipped with a mechanism specifically designed to turn all active cooling on and off (e.g. power switch or button) that is readily accessible to the user but protected from accidental activation during transport or other conditions. If the appliance system includes stationary components with an on and off mechanism, there shall also be an additional mechanism included on the non-stationary components that is readily accessible to the user but protected from accidental activation during transport or other conditions. Cable or cord connectors (i.e. locking female and male coupler system) are not acceptable for switching active cooling components or the appliance itself on and off.

4.5.4 Power lead

If the appliance uses external electrical power, then it shall be supplied with electrical power lead(s) with sealed-on plug(s) that are compatible with the electricity socket standard for the intended country of use and intended power source(s). The plug should be break-proof if dropped. If the appliance is intended to be charged or operated by using a 12-volt "cigarette lighter" plug, it is recommended that the connector seat firmly in the 12-volt port and include a latching or locking mechanism to avoid accidental disconnection or loosening. The connector may also include an LED or other indicator that the plug is correctly electrically connected in the port.

4.5.5 Alerts and alarms

The appliance shall include an alert system. At a minimum, the alert shall include upper and lower settings as noted in **WHO/PQS/E006/TH06** for vaccine refrigerators:

a. *"Low alarm setting*: Exposure to a single temperature event of -0.5°C or below for 60 minutes.
b. *High alarm setting*: Exposure to a single temperature event of +10°C or above for 10 hours."

Note that the minimum sound requirement of 100 dB(A) for optional audible alarms required in **WHO/PQS/E006/TH06** is not required for these portable appliances which may be located very close to users' ears during use. A maximum of 80 dB(A) is recommended. The legal manufacturer should consider this proximity if designing optional, audible alarm systems. It is recommended that both an audible and visual alarm are present and that the alerts should be triggered by the same temperature measurement information that is visible to the user on the display required in *Section 4.2.10* of this specification, in order to avoid apparent discrepancies to the user.

Since appliances are not expected to run and maintain temperatures continuously, provision shall be made for the user to silence or disable the alarms while the appliance is not in use. While in use, the legal manufacturer should consider the implication of simpler vs more difficult ways to silence alarms or alerts. It is recommended that the provision for completely disabling alarms is clearly labelled and either located or programmed in a way that will make it unlikely to be changed inadvertently.

Incorporation of an additional method to alert the user of temperature exceeding +8°C as an early warning is preferred but not required in order to help reduce the frequency of larger excursions that could be caused by users accidentally leaving the appliance door or lid open. Similarly, a door or lid open alert or alarm is also recommended.

Additionally, if the appliance is primarily powered by an electrical battery, the appliance shall have a charge status indicator. This indicator should, at a minimum, give the user some information regarding the amount of remaining energy in the battery. Indications of remaining cooling ability or time may also be included, but the manufacture should consider that due to the circumstantial nature of the estimation, this type of indication may prove difficult to implement accurately.

4.5.6 Dimensional compatibility with vaccine packaging

Lightweight appliances will generally be used to transport mixed loads of vaccine in individual primary containers. The net dimensions of the vaccine storage compartment should accommodate all types of pre-filled vaccine presentation and the complete range of standard vaccine vials and ampoules up to 50 dose size as well as tubes and pre-filled devices.

Medium-weight and heavy-weight appliances may additionally be used to transport secondary cartons (*see Annex 4*). The net dimensions of the vaccine storage compartment (length, breadth, and height) should accommodate the widest possible range of routine vaccines supplied in these forms of packaging. Secondary cartons may be oriented in all three planes – for transport purposes it is not essential that vial caps face upwards.

4.5.7 Compatibility with distribution method

Lightweight and medium-weight appliances shall be designed so that they can be securely strapped, upright, to the luggage rack of a bicycle or motorbike. Medium-weight and heavy-weight appliance design should additionally take into consideration secure transport by larger vehicles in truck beds and on larger roof or tail racks.

4.5.8 Stationary components

Some appliances may include stationary components. As these components of the appliance system are, by definition, not intended for transport, these components are *not* subject to requirements in this specification in sections:

- *4.2.16 Closure and Lock*
- *4.2.19 Shape*
- *4.2.21 Carrying components*
- *4.2.22 IP rating*
- *4.2.23 Robustness and vibration*
- *4.5.7 Compatibility with distribution method*

4.5.9 Intended uses

As identified in the scope, this specification is applicable only for appliances intended for use for temporary storage and transport of vaccines. Use for long-term storage or when powered by systems not intended for the appliance (e.g. health facility solar photovoltaic systems that may not have adequate design capacity) is prohibited. The legal manufacturer shall not design the appliance with the intended use as long-term or permanent storage and shall further warn against such use in both the user manual and in permanent labelling on the appliance. Although specific language is not set for this required labelling, “WARNING: Not for continuous use” or “WARNING: Maximum continuous use = X days” are examples of wording that may be acceptable appliance labels.

As an exception, if the legal manufacturer intends the appliance to be used for long-term storage in addition to use as temporary storage or for transportation as specified herein, they must additionally meet all requirements and pass all tests for another applicable, PQS appliance category (e.g. **WHO/PQS/E003/RF03 -** Refrigerator or combined refrigerator and water-pack freezer: intermittent mains powered,

compression cycle, **WHO/PQS/E003/RF04** - Refrigerator or combined refrigerator and water-pack freezer: Solar powered with rechargeable battery, etc.), and may be listed in both applicable, verified categories.

Additionally, If the appliance could be connected to and directly or indirectly powered or charged by external electrical sources, then the legal manufacturer shall further warn against potential depletion of limited power sources in both the user manual and in permanent labelling on the appliance. This has been confirmed as a risk of using electrically powered, transportable appliances within health systems and at health facilities with limited power resources. Although specific language is not required, the warning language should be relevant to the applicable connection possibilities for example: “WARNING: This appliance may deplete or drain vehicle batteries if connected for extended periods of time” or “WARNING: This appliance may deplete or drain power from facility solar (battery) systems that were not intended or designed for this appliance.”

4.6 Human factors

4.6.1 General design

The appliance shall be usable by the widest practicable range of active health workers, regardless of age, gender, size, or minor disability, including colour-blind users and long-sighted people without glasses, in accordance with the general usability principles laid out in **ISO 20282-1**. Lightweight appliances shall be designed to be comfortable for transport by a similar potential range of health workers for several hours when fully loaded. This includes consideration of individuals wearing traditional dress in intended use regions. Backpack units, for example, may be incompatible with some types of clothing.

4.6.2 Markings and labelling

Compressors, if present, shall be marked with the blue identifying symbol shown in *Annex 2*. In addition, the cabinet shall be permanently marked near the compressor position with the chemical name of the refrigerant or with the refrigerant number, formula or proportion (for blended refrigerants). Appliances operating on R600a shall be marked with the warning symbols shown in *Annex 2*. Appliances not utilizing compressor-based active cooling methods shall be marked identifying any refrigerant and/or heat transfer fluids used including, but not limited to, the chemical name, formula, or proportions (for blended refrigerants).

All appliances containing hazardous materials must be labelled as such and include a Safety Data Sheet. Labels and Safety Data Sheets shall comply with the Globally Harmonized System for the Classification and Labelling of Chemicals GHS Rev.5.

The appliance shall have a non-removable label fixed to the outside, not the bottom, and designed to last the lifetime of the appliance that specifies PQS temperature zone as shown in *Annex 1*. The appliance shall carry the following additional information similarly permanently fixed to the outside, not the bottom, of the appliance: legal manufacturer and model number, serial number, date of manufacture, PQS identification number, applicable service phone number and website URL and applicable required warning statements as described in *Section 4.5.9* of this document. These labels and information shall remain readable for the expected life of the appliance.

4.6.3 Vaccine storage advice

All appliances shall carry a factory-fitted, non-removable label designed to last the lifetime of the appliance that specifies the vaccine storage instructions. The instructions should be fixed internally or externally to either the lid of appliances that open at the top or near the top of the door on appliances that open on a side. Instructions should be in one of the languages specified in *Section 4.11*, as indicated by the purchaser at the time of ordering. If the appliance is graded other than Grade A and removable baskets or other, similar components are supplied, a warning shall be affixed within the appliance instructing users to "*Store vaccine in baskets only"* or other appropriate instruction in the same language.

4.7 Materials

4.7.1 Casing material selection

Some materials are degraded by exposure to ultraviolet radiation. Additionally, certain materials can release toxic halogen gases or other toxins when exposed to sunlight and ultraviolet radiation. Therefore, casing materials that will potentially be exposed to ambient light during use or storage shall resist ultraviolet degradation caused by long-term exposure as well as the release of halogen gases or other toxins. This applies to external surfaces and joints as well as internal surfaces and joints that may be exposed to ambient light during storage if the appliance is left open (e.g. the vaccine storage compartment). Neither chlorinated plastics, nor composites containing epoxy, polyurethane, phenol formaldehyde or urea formaldehyde resins are permitted for these casing materials. Additionally, all joints between moulded components shall be water and vapour proof, easy to clean and selected with environmentally safe end-of-life decommissioning and recycling in mind.

4.7.2 Thermal insulation foaming agents

Any gas complying with the limitations and deadlines set by the Montreal Protocol on the elimination of ozone-depleting chemicals may be used. Insulation materials with a low global warming potential (GWP) are preferred. If foam insulation materials are used, they shall be warranted to have a Long-Term Thermal Resistance (LTTR) no worse than 7% lower

than the rated ‘R’ value at the time of foaming, when subjected to an accelerated ageing test in accordance with **ASTM C1303 / C1303M-12**.

4.7.3 Refrigerant

If refrigerants are used, hydrocarbon (HC) refrigerants such as R600a or other gases with global warming potential (GWP) ≤ 11 and zero ozone depletion potential (ODP) are acceptable. CFC (chlorofluorocarbon) and HCFC (hydrochlorofluorocarbon) gases are not acceptable. The suitability of alternative refrigerants will continue to be assessed and preference will be given to products that use gases with low global warming potential (GWP).

4.7.4 Other restricted materials

The appliance and its constituent components, including batteries, shall not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB), or polybrominated diphenyl ethers (PBDE).

4.7.5 Vacuum panels

Vacuum panel construction is an acceptable alternative to foam insulation provided the panels are warranted to retain an acceptable level of vacuum for a minimum period of 10 years under the intended conditions of use. The panels shall retain their thermal properties well enough that the appliance continues to operate to all performance specifications in this document over the entire period.

4.7.6 PCM

Integrated thermal buffer materials may be used to prevent freezing temperatures from propagating to the vaccine storage compartment or for other thermal purposes. The buffer material may be PCM-based but, if so, the material and container shall comply with **WHO/PQS/E005/PCMC0.1 – Phase change material containers**.

4.7.7 Corrosion resistance

The legal manufacturer shall supply evidence of and declare compliance that the internal and external cabinet, lid, frame, hinges, stays, catches or handles and fixings are protected against corrosion as per **EN ISO 6270-1 / ASTM D2247 / EN 13523-26, EN ISO 6270-2 / EN 13523-25, ISO 6272 / EN 13523-5** and **ISO 2409** as appropriate to the materials used.

It should be expected that the casing and other parts of the appliance may be exposed to condensate when operating in a warm, humid environment. Critical components such as thermostatic controls, electronics, wiring and connections, and displays shall not be located such that condensate or other moisture will flow toward them or accumulate on or near them. All

such components shall not be vulnerable to moisture leading to potential corrosion or other related faults or failures. The susceptibility of modified or combined materials (e.g. after welding, brazing, bending, cutting, etc.) to corrosion should be considered in appliance design, material selection, and for possible post-process treatments or coatings as applicable to avoid corrosion or other related faults and failures. Because the final use location of appliances will often not be known in advance, design and material selection should include the possibility of installation in and exposure to corrosive, coastal, ambient environments.

4.7.8 Chemical resistance

The external and internal surfaces of the appliance shall be resistant to chemicals commonly used for disinfecting (e.g. sodium hypochlorate, 5.25% in water).

4.8 Warranty

The product is to be covered by a minimum two-year replacement warranty in the event of any component failure arising from defective design, materials or workmanship. The legal manufacturer shall state the time period over which the rated independence, holdover time and performance are assured.

4.9 Servicing provision

The product shall be designed, and components selected, with the aim of achieving at least a 10-year life free of repairs or maintenance apart from expected, routine tasks such as de-frosting, cleaning, and replacement of batteries (if any).

4.9.1 Essential spare parts and user maintenance tools and supplies

Based on product design and requirements, the type and quantity of spare parts, basic installation tools/supplies and user and technician maintenance manuals (see *Section 4.11 Instructions*) shall be determined and agreed upon in advance of order placement. As a minimum, each appliance shall be supplied with 10 spare fuses of each fuse size and type used in the appliance. The spare fuses shall be attached within or on the appliance.

Legal manufacturers shall publish a list of spare parts recommended for purchases of 10 and 50 appliances and power systems. Legal manufacturers shall ensure supply of spare parts for a minimum of five years from the time of cessation of the last production of equipment. Spare parts (except batteries if present) shall be provided in kit form for storage in appropriate quantities at national or sub-national level in the purchasing country, as agreed with the purchasing agency.

4.10 Disposal and recycling

The legal manufacturer is to provide information to the buyer on the hazardous materials contained within the system and suggestions for resource recovery/recycling and/or environmentally safe disposal. For legal manufacturers from the European Union WEEE compliance in accordance with European Union Directive **2002/96/EC** is mandatory.

4.11 Instructions

Detailed user and maintenance instructions shall be provided in at least one of the UN languages Arabic, English, French, Mandarin Chinese, Russian, or Spanish, or other language by special order. If only one language is included, it must be the language most appropriate to the country of use. Instructions should include easy to understand visuals whenever possible to avoid reliance on text. The instructions must be written for users and repair technicians and need not repeat the information shown on the permanent labels but shall cover the following topics:

- description of operations and use;
- instructions for safe transport including the recommended use of tie-downs or any other securing mechanisms;
- temperature adjustments (if applicable);
- detailed guide to all warning lights, other indicators and displays;
- prevention of vaccine freezing (if Grade B or Grade C);
- simple daily, weekly and monthly maintenance tasks;
- periodic preventative maintenance checks;
- diagnostic and repair guidance and procedures for minor damage;
- battery replacement (if applicable);
- itemized list of spare parts including part numbers;
- clear warranty terms and conditions; and
- end-of-life resource recovery and recycling procedures.

English versions of all instructions and manuals are required to be supplied at the time of laboratory testing.

A warning shall be included in the instructions that the device is not approved for use as a permanent replacement for a refrigerator, solar powered or otherwise.

4.12 Training

Training is not required although it is recommended that the legal manufacturer or reseller have the capability to provide remote or in-person training in the countries where their product is deployed for appliances with electronic user interfaces; the ability to operate using multiple power sources; or Grade B or C - UDFP.

4.13 Verification

In accordance with PQS Verification Protocol **WHO/PQS/E003/TS01-VP**.

5. Packaging

Legal manufacturers shall be aware that products may be exposed to very high temperatures during shipping and dockside storage and shall take appropriate actions to mitigate associated risks. The packaging is to be a sturdy export quality and of a commercial standard that will provide adequate protection of the goods for carriage by air, sea and/or road to final destinations worldwide, including remote locations under adverse climatic and storage conditions and high humidity. For heavy-weight appliances only, the packaging is to have not less than 17 kN edge crush resistance with minimum 60% remaining with 90% humidity at a temperature of +70°C (tropical conditions).

To avoid destructive unpacking prior to arrival at the final destination legal manufacturers are encouraged to add a resealable observation opening in their packaging to access labelling. Instructions on the packaging alerting inspectors to use of the opening and what information will be revealed are also advised.

Materials used for packaging the finished appliance shall be free of ozone-depleting compounds as defined in the Montreal Protocol. The general specification of shipping containers will be subject to agreement with the individual procurement agencies.

6. On-site inspection and installation

A random visual inspection of each batch of appliances may be conducted by purchasing agencies. This inspection should generally be based upon **WHO/PQS/E003/TS01-VP** Section 5.3.3 (Test 1: Type examination) but may include other tests. There is no requirement for installation.

7. Product dossier

The legal manufacturer or reseller is to provide WHO with a prequalification dossier containing the following:

- Dossier examination fee in US dollars.
- General information about the legal manufacturer, including name and address.
- Unique identification reference for the product type.
- Brand name of the product.
- Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability. Also including the narrative description as applicable and required in Section 4.2.17 regarding product safety.
- Designation of appliance type (lightweight appliance, medium-weight appliance, or heavy-weight appliance) and freeze protection classification (Grade A, B, or C) to be verified by PQS and the testing organization.
- Full details of the required, dedicated, compatible solar power system per specification **WHO/PQS/E003/PV01** (if applicable).
- A comprehensive set of photographs including photographs of the appliance with the door or lid open, the appliance closed, all external surfaces of the appliance, the interior layout, the compressor or cooling system, and close-ups of the thermometer, indicator light(s), control(s),

control panel, securing mechanism (if applicable), and any other special features.

- Certified photocopies of all type-approvals obtained for the appliance. Appliances shall carry the CE mark, UL mark and/or equivalent internationally accepted evidence of conformity assessment.
- Certified photocopies of the legal manufacturer's current **ISO 9001** quality system certification.
- Where relevant, certified photocopies of the legal manufacturer's **ISO 14001** certification, EMAS registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is not mandatory; however, preference will be given to manufacturers who are able to demonstrate compliance with good environmental practice.
- Laboratory test report(s) proving conformity with the product specifications.
- Indicative cost of the product per unit, per 10 units and per 100 units, EXW (Incoterms 2010).

8. On-site maintenance

Routine cleaning and maintenance will be carried out by the end-user and/or their agents. The product is to be designed to be otherwise maintenance-free apart from repair of minor impact damage caused by dropping and the like.

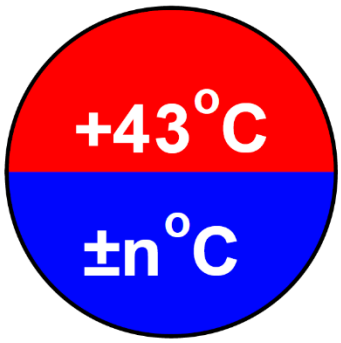
9. Change notification

The legal manufacturer or reseller is to advise WHO in writing of any changes which may affect the performance of the product after PQS prequalification has taken place. Any change that WHO considers would alter the test results obtained against the PQS verification protocol **WHO/PQS/E003/TS01-VP** will result in a request for the product to be retested.

10. Defect reporting

The legal manufacturer or reseller must advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events. This reporting should occur immediately upon the legal manufacturer receiving notification of the complaint or event, and shall occur within 30 days. If requested to do so by WHO/UNICEF, the legal manufacturer shall submit a report to WHO/UNICEF stating the number of affected appliances and the number of component repairs/replacements provided, together with copies of any associated field reports and photographs.

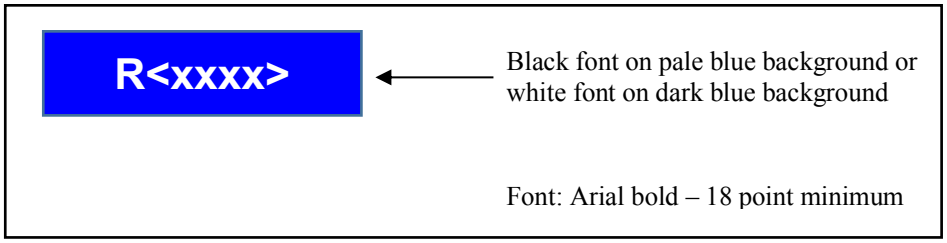
Annex 1 – Temperature zone symbol for refrigerators



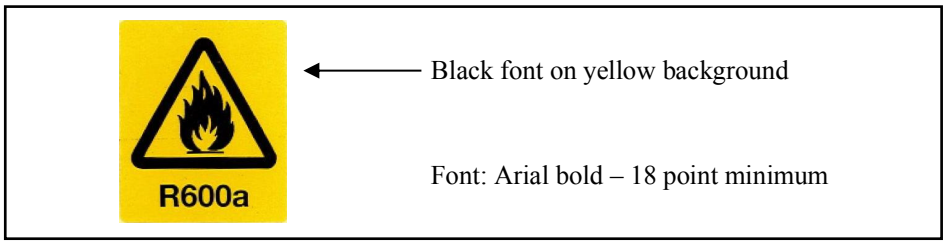
The minimum rated ambient temperature <n> is specified in 5°C increments and shall be between +10°C and -10°C. The symbol shall be between 30 mm and 60 mm in diameter. Font Arial, **bold**.

Annex 2 – Refrigerant symbols

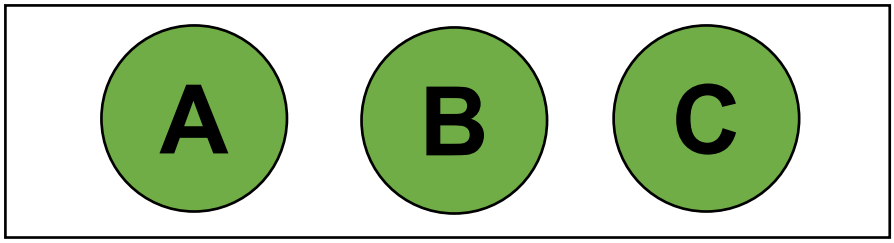
Refrigerant label



R600a warning symbol



Annex 3 – Freeze protection classification symbol



The applicable symbol shall be between 30 mm and 60 mm in diameter. Font Arial, **bold**.

Annex 4 – Table of secondary carton sizes

Secondary carton: This table shows secondary carton dimensions, weights and densities for 99 individual vaccine presentations procured by UNICEF (November 2011 data). The coloured blocks show that there are 16 carton groups that share identical dimensions. Maximum and minimum dimensions, weight and densities are shown at the bottom of the second column. The table is sorted by carton volume.

Vaccine	Width (cm)	Length (cm)	Height (cm)	Weight (grams)	Units per carton	Carton volume (cm^3)	Density (g/cm^3)
MMR	3.0	4.5	3.3	20	1	45	0.4
DTP+Hib	6.1	6.5	3.0	50	1	119	0.4
HepB	3.5	8.5	4.0	61	10	119	0.5
YF	5.5	15.0	1.5	42	10	124	0.3
YF	5.5	15.0	1.5	42	10	124	0.3
bOPV1+3	3.6	7.8	5.1	82	10	143	0.6
mOPV1	3.6	7.8	5.1	82	10	143	0.6
OPV	3.6	7.8	5.1	82	10	143	0.6
OPV	3.6	7.8	5.1	82	10	143	0.6
DTP+Hib	4.9	14.2	2.3	21	1	160	0.1
Hib liq	4.2	8.8	4.4	73	10	163	0.4
HPV	4.1	8.7	4.7	0	10	168	0.0
YF	3.5	9.0	6.5	40	10	205	0.2
DTP-HepB	4.5	11.0	4.3	155	10	213	0.7
Measles	4.4	10.5	4.8	65	10	222	0.3
DTP	4.5	11.0	4.5	155	10	223	0.7
TT	4.5	11.0	4.5	150	10	223	0.7
DTP	4.7	10.6	5.1	184	10	254	0.7
Measles	4.7	10.6	5.1	126	10	254	0.5
MMR	4.7	10.6	5.1	126	10	254	0.5
MV A&C	4.7	10.6	5.1	126	10	254	0.5
YF	4.7	10.6	5.1	126	10	254	0.5
DTP-Hib	4.6	11.2	5.2	178	10	268	0.7
H1N1	4.6	11.2	5.2	178	10	268	0.7
HepB	5.0	11.5	4.8	230	10	276	0.8
YF	5.2	12.7	4.5	140	10	297	0.5
HepB	4.8	11.6	5.4	180	10	301	0.6
DT	5.5	12.5	5.5	200	10	378	0.5
Td	5.5	12.5	5.5	200	10	378	0.5
TT	5.5	12.5	5.5	256	10	378	0.7
Hib lyo	8.5	14.7	3.3	110	10	412	0.3
MMR	8.5	14.7	3.3	110	10	412	0.3
bOPV1+3	11.0	11.0	3.5	390	25	424	0.9
BCG	10.1	15.2	3.0	82	20	461	0.2
DTP-HepB-Hib	8.5	17.0	3.6	315	50	520	0.6
HepB	11.0	11.0	4.3	246	36	520	0.5
bOPV1+3	11.5	11.6	4.0	380	25	534	0.7
mOPV1	11.6	11.5	4.0	460	25	534	0.9
mOPV3	11.6	11.5	4.0	460	25	534	0.9
OPV	11.6	11.5	4.0	460	25	534	0.9
bOPV1+3	8.5	17.0	3.8	415	50	549	0.8
mOPV3	8.5	17.0	3.8	415	50	549	0.8
OPV	8.5	17.0	3.8	415	50	549	0.8
HepB	10.5	14.0	4.0	254	35	588	0.4
DTP-HepB-Hib	8.5	17.0	4.5	36	50	650	0.1
HepB	8.5	17.0	4.5	34	50	650	0.1
HepB	8.5	17.0	4.5	37	50	650	0.1
BCG	8.0	16.7	5.0	390	50	668	0.6
PCV-13	9.2	17.9	4.1	360	50	675	0.5
HepB	11.1	13.0	5.0	33	20	722	0.0
HepB	10.6	14.1	5.3	330	35	792	0.4
Rota liq	8.6	14.6	6.9	305	50	866	0.4
bOPV1+3	11.5	22.6	3.6	835	50	936	0.9
mOPV1	11.5	22.6	3.6	835	50	936	0.9
OPV	11.5	22.6	3.6	835	50	936	0.9
HepB	13.2	13.2	5.4	550	25	941	0.6
HepB	13.2	16.2	4.5	596	30	962	0.6
HPV	14.7	17.8	3.7	585	100	968	0.6
PCV-10	14.7	17.8	3.7	612	100	968	0.6
bOPV1+3	14.7	17.8	3.7	781	100	968	0.8
mOPV1	14.7	17.8	3.7	743	100	968	0.8
mOPV3	14.7	17.8	3.7	743	100	968	0.8
OPV	14.7	17.8	3.7	550	100	968	0.6
OPV	14.7	17.8	3.7	743	100	968	0.8
DTP-HepB	14.9	18.0	3.7	600	100	992	0.6
DTP-HepB+Hib	14.9	18.0	3.7	612	50	992	0.6
DTP-HepB-Hib	9.5	18.5	6.0	360	50	1055	0.3
DTP-HepB-Hib	9.5	18.5	6.0	737	50	1055	0.7
DTP-HepB+Hib	9.5	18.5	6.0	406	50	1055	0.4
Measles	9.5	18.5	6.0	403	50	1055	0.4
Measles	9.5	18.5	6.0	410	50	1055	0.4
MR	9.5	18.5	6.0	405	50	1055	0.4
MMR	9.5	18.5	6.0	405	50	1055	0.4
MMR	9.5	18.5	6.0	405	50	1055	0.4
MMR	9.5	18.5	6.0	405	50	1055	0.4
Men A	9.5	18.5	6.0	405	50	1055	0.4
BCG	9.5	18.5	6.0	374	50	1055	0.4
DT	9.5	18.5	6.0	737	50	1055	0.7
TT	9.5	18.5	6.0	737	50	1055	0.7
Td	9.5	18.5	6.0	737	50	1055	0.7
DTP	9.5	18.5	6.0	740	50	1055	0.7
HepB	9.5	18.5	6.0	268	50	1055	0.3
HepB	9.5	18.5	6.0	737	50	1055	0.7
DTP-HepB	9.5	18.5	6.0	737	50	1055	0.7
TT	13.3	13.3	6.0	707	25	1061	0.7
DTP	13.3	13.3	6.0	707	25	1061	0.7
MV ACWY	10.8	25.3	4.2	700	50	1148	0.6
TT	12.0	15.0	6.5	551	20	1170	0.5
Rota liq	8.4	13.0	11.1	no data	25	1220	no data
HepB	14.0	17.0	5.5	610	30	1309	0.5
TT	14.0	17.0	5.5	610	30	1309	0.5
mOPV1	12.7	14.8	7.5	580	100	1410	0.4
mOPV3	12.7	14.8	7.5	580	100	1410	0.4
OPV	12.7	14.8	7.5	461	100	1410	0.3
OPV	12.7	14.8	7.5	580	100	1410	0.4
BCG	13.3	13.6	8.0	51	100	1447	no data
DTP-HepB	10.8	25.3	5.5	950	50	1503	0.6
MR	10.0	19.5	10.0	840	100	1950	0.4
TT	15.4	16.8	12.0	303	100	3105	0.1
Minimum:	**3.0**	**4.5**	**1.5**	**0.1**	**1**	**45**	**0.0**
Maximum:	**15.4**	**25.3**	**12.0**	**950.0**	**100**	**792**	**0.9**

Revision history			
Date	Change summary	Reason for change	Approved