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भारतीय मानक मसौदा

रेफ्रिजरेटर या संयुक्त रेफ्रिजरेटर और वॉटर-पैक फ्रीजर इंटरमिटेंट मेन्स के लिए विशिष्टता संचालित - संपीडन चक्र - सामान्य आवश्यकताएँ और परीक्षण विधियाँ

Draft Indian Standard

**Specification for Refrigerator or Combined Refrigerator and Water-Pack Freezer
Intermittent Mains Powered — Compression Cycle — General Requirements and
Testing Methods**

Hospital Equipment and Surgical Disposable
Products Sectional Committee, MHD 12

Last date for comments: 15 January 2024

FOREWORD

(Formal clauses will be added later)

This Indian Standard was adopted by Bureau of Indian Standards after the draft finalized by the Hospital Equipment and Surgical Disposable Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2: 2022 'Rules for rounding off numerical values (*second revision*)'.

1 SCOPE

1.1 This Indian Standard specifies the essential requirements for ice-lined compression cycle refrigerators or combined refrigerators and water-pack freezers with an acceptable temperature range of + 2 °C to + 8 °C for storing vaccines.

1.2 This standard covers three temperature zone designations: namely moderate zone, temperate zone and hot zone. This also specifies test methods to establish a minimum rated ambient temperature designation.

2 REFERENCES

The standards listed below contain provisions which, through reference in this text, constitute provision of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreement based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards

IS No./Other Publications	Title
IS 13450 (Part 1) : 2018/IEC 60601-1 : 2012	Medical electrical equipment: Part 1 general requirements for basic safety and essential performance (<i>second revision</i>)
IS 10461 (Part 1) : 1994	Resistance to inter - Granular corrosion of austenitic stainless steels - Method for determination - Part 1 : corrosion test in nitric acid medium by measurement of loss in mass (Huey Test) (<i>first revision</i>)
IS 10461 (Part 2) : 1994	Resistance to intergranular corrosion of austenitic stainless steels - Method for determination: Part 2 corrosion test in a sulphuric acid/copper sulphate medium in the presence of copper turnings (Monypenny Strauss Test) in the presence of copper turnings (Monypenny Strauss Test) (<i>first revision</i>)
IS/IEC 60529 : 2001	Degrees of protection provided by enclosures (IP Code)

3 TERMS AND DEFINITIONS

For the purposes of this standard, the following terms and definitions apply.

3.1 Ice-lined Refrigerator — These are compression-cycle refrigerators, with or without water-pack freezing compartment, powered by mains electricity and are used primarily in areas with an intermittent electricity supply (that is, eight or more hours of reliable electricity per typical day).

3.2 Combined Refrigerator-Water Pack Freezer(if Present) — These are compression-cycle ice lined refrigerators, with water-pack freezing compartment, powered by mains electricity and are used primarily in areas with an intermittent electricity supply (that is, eight or more hours of reliable electricity per typical day).

3.3 Vaccine Storage Compartment — The acceptable temperature ranges for storing vaccine is 2 °C to + 8 °C. However, transient excursions outside this range will be tolerated, within the following limits:

- No excursion must exceed + 20 °C (± 0.5 °C) for any amount of time,
- No excursion must drop below -0.5 °C for any amount of time,

- c) No excursion must drop below 0 °C for longer than 1 h, and
- d) Following an excursion below 0 °C, the appliance must return to safe operating temperature (that is, consistently between + 2 °C and + 8 °C) within two hours. This duration will be measured from the moment the temperature drops below 0 °C and up until it returns to + 2 °C

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

3.4 Water Pack Storage Compartment — The water-pack freezing compartment (if present) shall remain below –3 °C under the same ambient conditions, except during power-off periods of the water-pack freezing test, day-night test and minimum rated ambient temperature test. In these tests, excursions above – 3 °C will be tolerated during the power-off cycles; in addition, in the water-pack freezing test and minimum rated ambient temperature test, the minimum weight of water-packs shall remain fully frozen at the end of the power-off cycle.

3.5 Definitions — For the purpose of this standard, the following definitions apply:

3.5.1 Hot Zone — A steady + 43 °C ambient temperature and over a + 43 °C/+ 25 °C day/night cycling temperature range is defined as hot zone.

3.5.2 Moderate Zone — A steady + 27 °C ambient temperature and over a + 27 °C/+ 10 °C day/night cycling temperature range is defined as moderate zone.

3.5.3 Temperate Zone — A steady + 32 °C ambient temperature and over a + 32 °C/+ 15 °C day/night cycling temperature range is defined as temperate zone.

3.5.4 Overall Dimensions (Door or Lid Closed) — Measurements of the rectangular parallelepiped, whose base is horizontal, within which the Ice lined refrigerator or combined refrigerator-water pack freezer is inscribed to include the complete equipment except for the handle, the protrusion of which, if any, is to be specified separately.

3.5.5 Gross Volume — The total volume within the inside walls of the equipment, without internal fittings, doors or lids being closed.

3.5.6 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.

3.5.7 Minimum Rated Ambient Temperature — All models shall be tested to establish their minimum rated ambient temperature. The minimum acceptable performance rating is achieved if the product passes the day/night test for its nominal temperature zone. The maximum performance rating is achieved if the vaccine load remains within the acceptable temperature range at – 10 °C. A freeze-prevention circuit may be required to protect against freezing at low ambient temperatures.

3.5.8 Water-pack Freezing Capacity — The daily maximum weight and number of water-packs which can be fully frozen, in one batch, during a 24 h freezing cycle.

3.5.9 Holdover Time — The time in hours during which all points in the vaccine compartment remain between + 2 °C and + 8 °C, at the maximum ambient temperature of the temperature zone for which the appliance is rated, after the power supply has been disconnected.

4 REQUIREMENTS

4.1 General (Physical Characteristics)

4.1.1 Ice-lined compression-cycle refrigerators, with or without water-pack freezing compartment are used primarily in areas with an intermittent electricity supply(for example, eight to 20 h of reliable electricity per typical day, less than eight hours of reliable electricity per typical day). It is recommended to be operated in one or more temperature zones as agreed between manufacturer and purchaser.

4.1.2 Overall Dimensions

To allow for manoeuvring through corners, corridors and doorways, the minimum dimension of the product (either length, width or height) shall be minimum 710 mm. The maximum dimension shall not exceed 1700 mm and the maximum diagonal (corner to corner)dimension shall not exceed 1850 mm.

4.1.3 Weight

It is recommended that the refrigerator and any associated components, designed for lifting shall be in such a way that no single worker is required to carry more than 25 kg whilst working on their own, or in a group.

4.1.4 Electrical Safety Rating

The unit shall comply with the requirements of IS 13450 (Part 1) : 2018/IEC 60601-1 : 2012 and IEC 60335-1 : 2010.

4.2 Performance Characteristics

4.2.1 Temperature Requirements

4.2.1.1 Operating temperature range

Three temperature zone designations are described: moderate zone, temperate zone and hot zone. However, all appliances are tested at + 43 °C at minimum. In addition, appliances are tested to establish a minimum rated ambient temperature designation. As indicated on the temperature zone rating sticker attached to the product (*see Annex E*).

4.2.1.2 Refrigeration cycle

Compression-cycle unit operating on alternating current electricity. Compressor type: Compression cycled, CFC/HCFC – Free (both for refrigeration and insulation).

4.2.2 Voltage and Frequency

Direct supply of mains electricity. Options for 220- 240 volt 50/60 Hz is to be offered. Performance is to be identical for all options, regardless of the nominal voltage and frequency rating of the appliance.

4.2.3 Water-pack Freezing Capacity

In combined units with freezer compartment, a minimum of 1.6 kg of water-pack shall be frozen per 24 h whilst maintaining the temperature control specified in **4.2.5.2**. For freezers with at least 50 litres of gross freezer volume a minimum of 2.4 kg of water-pack shall be frozen per 24 h whilst maintaining the temperature control specified in **4.2.5.2**.

4.2.4 Vaccine Freeze Protection

The vaccine freeze protection classification is indicated on the freeze protection classification sticker attached to appliance front (*see Annex E*). The amount of user intervention required to ensure that the vaccines will not be exposed to freezing temperatures when the appliance is used within its nominated temperature range and minimum rated ambient temperature shall be classified and reported as follows.

4.2.4.1 Grade A, user-independent freeze protection (UIFP)

When there is no user intervention required to ensure that the vaccines will not be exposed to freezing temperatures whatever the position of the vaccine in the vaccine storage compartment.

4.2.4.2 Grade B, user-dependent freeze protection (UDFP)

When the user must comply with a procedure provided by the legal manufacturer and requiring one level of user intervention (for example, the requirement to use baskets to avoid vaccine freezing temperatures constitute one level of user-intervention).

4.2.4.3 Grade C, user-dependent freeze protection (UDFP)

When the user must comply with a procedure provided by the legal manufacturer requiring two or more levels of user interventions (for example, a refrigerator that not only requires the use of baskets but also requires use of removable thermal barriers constitutes two levels of user intervention).

4.2.5 Temperature Control

4.2.5.1 Refrigerator compartment

The entire vaccine load shall remain within the acceptable temperature range during any continuous ambient temperature test(s) or day/night cycling temperature test(s). Combined units shall achieve this performance with or without water-packs in the water-pack compartment.

4.2.5.2 Water-pack freezing compartment

The water-pack freezing compartment (if present) shall remain below $-3\text{ }^{\circ}\text{C}$ under the same ambient conditions, except during power-off periods of the water-pack freezing test, day-night test and minimum rated ambient temperature test. In these tests, excursions above $-3\text{ }^{\circ}\text{C}$ will be tolerated during the power-off cycles; in addition, in the water-pack freezing test and minimum rated ambient temperature test, the minimum weight of water-packs described in 4.2.3 shall remain fully frozen at the end of the power-off cycle.

4.2.6 Thermostat

4.2.6.1 The thermostat shall be set to prevent freezing in any part of the vaccine storage compartment. The thermostat shall be effective throughout the ambient operating temperature range (down to the minimum rated ambient temperature, see 4.2.9). 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 (for example, by location within the appliance cabinet). Alternatively, programmable thermostats may be password-protected.

4.2.6.2 Alternatively, in case of programmable thermostat, the temperature controller must be a precision device capable of maintaining control well inside $0.1\text{ }^{\circ}\text{C}$ over time and temperature variations.

4.2.6.3 Finally, the controller must have digital display to show set/controlled temperature values, alarm signals and facility of viewing/editing (with password protection) necessary operational parameters. Additionally, it must be equipped with buzzer element for sounding an alarm in the event of temperature breaches.

4.2.7 Thermometer

4.2.7.1 Option A

Each equipment shall be supplemented with 2 number quantity of externally readable cabinet-mounted gas or vapour pressure dial thermometer or stem alcohol thermometer.

4.2.7.2 Option B

Easily readable electronic thermometer, mounted on the front wall of the equipment shall be there.

4.2.8 Holdover Time

Minimum 20 h at the appliance's maximum rated ambient temperature (Moderate zone: + 27 °C, Temperate zone: + 32 °C, Hot zone: + 43 °C).

4.2.9 Minimum Rated Ambient Temperature

All models shall be tested to establish their minimum rated ambient temperature of + 10.0 °C or lower whilst maintaining the acceptable temperature range. The minimum acceptable performance rating is achieved if the product passes the day/night test for its nominal temperature zone. The maximum performance rating is achieved if the vaccine load remains within the acceptable temperature range at – 10 °C. A freeze-prevention circuit may be required to protect against freezing at low ambient temperatures.

4.2.10 Condensation Management and Defrosting

Condensate and defrost drainage must be provided in all refrigerator and freezer compartments. In non-grade A equipment, the defrost switch (or switches) must be accessible to the user without tools but must be protected from accidental changes in position.

4.2.11 Compressor Starting Voltage

At 22 percent below manufacturers state voltage, 10 out of 10 cold starts and 10 out of 10 hot starts shall all be successful.

4.2.12 Electrical Safety Rating

The legal manufacturer must certify compliance with IEC 60335-1, IEC 60335-2-2.

4.2.13 Indicator Light

A minimum of one green LED indicator light is required to be located on the front or top of the appliance to alert users that the cooling system is actively operating. A constant green LED light is required to indicate that the compressor or cooling system is active and the light is to go off when the compressor or cooling system is off.

4.2.14 Door, Lids and Fittings

4.2.14.1 Hinges and handles shall be strong and resistant to corrosion.

4.2.14.2 Doors and lids shall withstand 100 000 openings and closings without deterioration which, in particular, may be prejudicial to the air tightness when subjected to the durability test.

4.2.14.3 When the door is closed, there shall be no abnormal ingress of air into the interior.

4.2.14.4 The strip of paper shall not slide freely when the door or lid seal is subjected to the air tightness test.

4.2.15 Corrosion Resistance

The legal manufacturer shall certify compliance that internal and external cabinet, lid and frame are

protected against corrosion as specified in IS 10461 (Part 1) and IS 10461 (Part 2).

4.3 Environmental Requirements

4.3.1 Ambient Temperature Range During Transport and Storage

–30 °C to + 70 °C when the product is inactivated.

4.3.2 Ambient Humidity Range During Transport, Storage and Use

Five percent to 95 percent relative humidity, non- condensing.

4.4 Interface Requirements

4.4.1 Voltage Stabilizer Compatibility

All electrical components shall be compatible with voltage stabilizers that use tap-changing technology. A warning shall be affixed to the unit stating the type(s) of voltage stabilizer that may be used and the user's manual and spare parts list shall clearly record this warning.

4.4.2 Power Lead

The product is to be supplied with a power lead with a sealed-on plug compatible with the electricity socket standard in the country where the equipment is to be installed. The power lead shall be at least 1.5 meters and not more than 2.0 meters in length.

4.5 Human Factors

4.5.1 Thermal Insulation and Air Tightness

The thermal insulation shall be efficient and permanently maintained. In particular, the insulating material shall not be subject to shrinkage and shall not allow under normal working conditions an excessive accumulation of moisture.

4.5.2 General

The equipment shall have appropriate mechanism (that is, rotating screw) at its base to balance the weight on uneven floor. The product shall be useable 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 principles laid out in ISO 20282-1 : 2006.

4.5.3 Control Panel and Thermometer

Controls, thermometer and other visual displays may be positioned on the front of the unit; preferably as close to eye level as possible. Alternatively, they may be mounted on top of the unit at a height not exceeding 1.3 metres. If allow level position is essential, the display shall be aligned so that it can easily be read without the user having to squat or kneel down. The on-off and/or defrost switch, if present, shall be recessed or otherwise protected so that it is not possible inadvertently to activate it.

4.6 Materials

4.6.1 General

Equipment shall be constructed in such a manner as to ensure adequate performance and durability in use. Their performance in use is checked by applying a series of relevant tests and this clause defines some characteristics which are not tested but to which the attention of manufacturers is drawn.

4.6.2 Materials and Finishes

All materials used inside the equipment shall not transmit odours. All materials used inside freezers shall not contaminate vaccines stored nor transmit poisonous substances. They shall be resistant to the action of moisture. All surface finishes shall, for the purpose intended be resistant to impact, sufficiently hard,

colour-fast, smooth, easily washable and resistant to damage by moisture and by acids.

4.6.3 Refrigerant

Appliances are preferring to use HC refrigerants such as R600a or other gases with $GWP \leq 11$ and zero ozone depletion potential (ODP).

HFC (hydro fluorocarbon) or HC (hydrocarbon) refrigerant can be used. Refrigerants which are ozone depleting as identified under Montreal protocol shall not be used in the manufacture and operation of these refrigerators. The suitability of alternative refrigerant gases will continue to be assessed and preference will be given to products that use gases with low global warming potential (GWP).

4.6.4 Thermal Insulation Foaming Agents

Any gas complying with the limitations and deadlines set by the Montreal protocol on the elimination of ozone-depleting chemicals.

4.6.5 Other Restricted Material

The product and its constituent components, including batteries, shall not contain lead, mercury, cadmium, hexavalent chromium, poly-brominated biphenyls (PBB) or poly-brominated biphenyl ethers (PBDE). Manufacturing process of the product shall not use or produce hazardous chemicals gases.

5 TEST METHODS

5.1 Test Temperatures

The specific tests listed below apply equally to moderate zone, temperate zone and hot zone appliances. Relevant test chamber temperatures are given in the following format M: <XX °C> for moderate zone; T: <XX °C> for temperate zone and H: <XX °C> for hot zone.

5.2 Test 1 : Cool-down, Initial Stabilization, and Power Consumption

5.2.1 Power: Intermittent

Step 1: Set the test chamber temperature to + 43 °C and leave for 48 h with the appliance empty, the lid or door open, and the power supply switched off.

Step 2: Close the lid or door of the appliance, commence with intermittent power of 20 h of continuous power followed by 4 h with no power per 24 h day and leave it to initially stabilize. Initial stabilization is accomplished when the appliance demonstrates all of the following:

- a) The thermal storage has been cooled for a time period no less than the cool down time period stated in the instructions provided by the manufacturer (for example, if instructions state cool down time is 3 days then at least a 3 day cool down test is required);
- b) The internal temperatures in the vaccine storage compartment are within the acceptable temperature range; and
- c) The cooling system has exhibited consistent on/off operation for the final two days of this test (for example, the same number of on/off cycles per day for the final two days).

Step 3: During stabilization, record temperatures every minute, and continue to do so for 24 h after stabilization. During this period measure the energy consumption and determine the compressor duty cycle. Measure the duty cycle by timing from the end of one cycle to the end of a corresponding cycle approximately 24 h later. Calculate the percentage 'on' time over this period. Measure electricity consumption over the same time scale and report as kWh/day.

5.2.2 Acceptance Criterion

Stabilized internal temperatures between + 2 °C and + 8 °C in the vaccine storage compartment and

below $-3\text{ }^{\circ}\text{C}$ in the water-pack freezing compartment (if present) achieved within the test period (after stabilization). No standard set for the cool-down time but the period shall be reported.

5.2.3 Rejection Criterion

Failure to stabilize within the acceptable temperature range(s). Halt the test if the appliance does not initially stabilize within the period specified by the Legal Manufacturer, plus one day.

5.3 Test 2: Stable Running and Intermittent Power Consumption

5.3.1 Power: Continuous

Step 1: When the internal temperature is stabilized at the end of Test 1 as per **5.2.1**, load the appliance with simulated, pre-conditioned vaccine as described in Annex A. Ensure that the water-pack freezing compartment (if present) is empty.

Step 2: Close the lid or door of the appliance and leave it to stabilize the internal temperatures between $+2\text{ }^{\circ}\text{C}$ and $+8\text{ }^{\circ}\text{C}$ and reach a state where the compressor or cooling circuit is cycling due to thermostat regulation.

Step 3: After temperature stabilization has been achieved, record temperatures every minute for 24 h. During this period measure the energy consumption and determine the compressor duty cycle. Measure the duty cycle by timing from the end of one cycle to the end of a corresponding cycle approximately 24 h later. Calculate the percentage 'on' time over this period. Measure electricity consumption over the same time scale and report as kWh/day.

5.3.2 Acceptance Criteria

Stabilized internal temperatures maintained between $+2\text{ }^{\circ}\text{C}$ and $+8\text{ }^{\circ}\text{C}$ in the vaccine storage compartment and below $-3\text{ }^{\circ}\text{C}$ in the water-pack freezing compartment (if present). No standard set for power consumption but the figure shall be reported.

5.3.3 Rejection Criterion

Failure to meet one or more of the acceptance criteria.

5.4 Test 3: Stable Running and Intermittent Power Consumption

5.4.1 Power: Intermittent

Step 1: Continue the Test 2 conditions but with intermittent power of 20 h of continuous power followed by 4 h with no power per 24 h day and the same temperature monitoring regime, but cycle the power supply intermittently until the temperature has re-stabilized and a minimum of three repeating 24 h temperature profile cycles have been completed.

Step 2: From the start of the next intermittent power-on cycle, measure the energy consumption and determine the compressor or cooling circuit duty cycle. Measure the duty cycle by timing from the start of the power-on cycle to the end of the same cycle (that is, 20 continuous hours). Calculate the percentage 'on' time over this period. Measure and report electricity consumption over the same time scale and report as kWh/day.

5.4.2 Acceptance Criterion

Stabilized internal temperatures maintained between + 2 °C and + 8 °C in the vaccine storage compartment. No standard set for power consumption but the figure shall be reported.

5.4.3 Rejection Criterion

Failure to meet the acceptance criterion.

5.5 Test 4: Water-pack Freezing Capacity, Storage Compartment Capacity and Power Consumption

5.5.1 Application: Combined appliances only.

a) Power: Intermittent.

Step 1: Continue the Test 3 conditions. Commence with intermittent power cycle of 20 h of continuous power followed by 4 h with no power. DO NOT adjust the freezer thermostat.

Step 2: Stabilize water-packs at + 43 °C.

Step 3: Load a minimum of 1.6 kg of water-packs and not less than 2.4 kg per 50 litres of gross freezer volume of water-packs into the freezer compartment. Load the packs in accordance with user instructions including any rack or structure provided. Install the freezer thermocouples, centred as uniformly as possible between the loaded water-packs. The minimum distance between a thermocouple and the lid/door, wall or evaporator should be 30 mm.

Step 4: Record freezer and refrigerator compartment temperatures every minute for the following 24 h. Measure electricity consumption and the cooling system duty cycle over the same duration.

Step 5: At the end of the 24 h test period check that the water-packs are fully frozen (refer to **Annex D** for methodology measurement of ice production). Check that the vaccine load has remained within the + 2 °C and + 8 °C range throughout the 24 h test period. Remove the frozen water-packs.

Step 6: Repeat steps 3 to 5 of 5.4.1.1 introducing larger loads of stabilized water-packs up to the point when one or more of the following conditions occurs:

- The total net weight of fully frozen water-packs has not increased since the previous cycle;
- Until the freezing compartment is full; or
- The temperature of the vaccine load breaches the + 2 °C to + 8 °C range on one or more sensors.

Establish and record the maximum weight of water-packs that can be fully frozen whilst still meeting the requirements of specification 4.2.5.2 (refer to Annex D for the methodology for measurement of ice production). This is the appliance's daily water-pack freezing capacity. Measure electricity consumption over the same time scale and report energy consumption in kWh/day.

Step 7: At the start of the next continuous power phase of a 24 h cycle load water-packs equal to the minimum daily water-pack freezing capacity determined in Step 6 of 5.4.1.1 into the freezer compartment in accordance with user instructions which includes any rack or structure provided for holding water-packs. The process to achieve the maximum freezing capacity must be stated in the user instructions.

Step 8: Record freezer and refrigerator compartment temperatures every minute for the following 24-hours. Measure electricity consumption and the cooling system duty cycle over the same duration. Report energy consumption in kWh/day, percentage on-time over the same time scale and graphically display on/ off cycles.

Step 9: At the end of the next continuous power phase remove all water-packs and quickly determine which are fully frozen and which are not fully frozen per instructions in Annex A. Record each water-pack volume, location and condition (that is, fully frozen or not fully frozen). Replace all packs immediately and add more stabilized water-packs in accordance with user instructions.

NOTE — It must be possible to remove frozen water-packs without any undue force or delay. Defrosting the freezer to enable removal is not acceptable.

Step 10: Repeat Steps 7 to 9 of 5.4.1.1 up to the point when either:

- a) the total net weight of fully frozen water-packs has not increased since the previous cycle;
- b) until the freezing compartment is full; or
- c) the temperature of the vaccine load breaches the + 2 °C to + 8 °C range on one or more sensors.

The number and volume of fully frozen water-packs at the end of Step 10 of 5.4.1.1 are to be reported. This is the appliance's water-pack storage compartment capacity.

5.5.2 Acceptance Criteria (Water-pack Freezing Capacity)

Stabilized internal temperatures maintained between + 2 °C and + 8 °C in the vaccine storage compartment. For freezers of less than 50 litres of gross freezer volume a minimum of 1.6 kg of fully frozen water-packs must remain fully frozen at the end of a 24 h test phase whilst maintaining the temperature control specified in 4.2.5.2. For freezers with at least 50 litres of gross freezer volume a minimum of 2.4 kg of fully frozen water-packs per 50 litres of gross freezer volume must remain fully frozen at the end of a 24 h test phase whilst maintaining the temperature control specified in 4.2.5.2. No standard set for power consumption but report the energy consumption in kWh/day, the percentage on-time during the test time and graphically display on/off cycles.

5.5.3 Acceptance Criteria (Water-pack Storage Compartment Capacity)

Stabilized internal temperatures maintained between + 2 °C and + 8 °C in the vaccine storage compartment. For freezers of less than 50 litres of gross freezer volume a minimum of 3.4 kg of fully frozen water-packs must remain fully frozen at the end of Step 10 of 5.4.1.1 whilst maintaining the temperature control specified in 4.2.5.2. For freezers with at least 50 litres of gross freezer volume a minimum of 4.8 kg of fully frozen water-packs per 50 litres of gross freezer volume must remain fully frozen at the end of Step 10 of 5.4.1.1 whilst maintaining the temperature control specified in 4.2.5.2. No standard set for power consumption but report the energy consumption in kWh/day, the percentage on-time during the test time and graphically display on/off cycles.

5.5.4 Rejection Criterion

Failure to meet one or more of the acceptance criteria.

5.5 Test 5: Holdover Time Test

5.5.1 Power: Intermittent.

Step 1: For appliances without water-pack freezing, continue the Test 3 as per 5.3.1 conditions. For combined appliances, continue the Test 4 as per 5.4.1.1 conditions but with the water-pack freezing compartment empty.

Step 2: Provide intermittent power until the refrigerator and freezer temperatures have re-stabilized.

Step 3: At the end of the next power-on cycle, switch off the power supply. If the compressor has already cycled off at this point record the elapsed time since the end of the previous compressor-on cycle (t).

Step 4: Monitor the temperature of the vaccine load at one-minute intervals. At the moment when the warmest point in the load exceeds + 8 °C record the elapsed time since power supply switch off and add this to the value 't' recorded in Step 3 of 5.5.1. Record the position of the warmest point.

5.5.2 Acceptance Criterion

A minimum of 4 h at a continuous ambient temperature of + 43 °C.

5.5.3 Rejection Criterion

Failure to meet the minimum holdover period.

5.6 Test 6: Freeze Protection Classification

5.6.1 Power: Continuous.

Step 1: At the end of Test 5 as per 5.5.1, immediately switch on continuous power to the appliance and monitor the temperature of the vaccine compartment at one-minute intervals.

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

5.6.2 Acceptance Criteria

To receive a **Grade A** for freeze protection classification, the appliance's cool-down temperatures:

- a) Must not drop below 0 °C for longer than 1 h.
- b) Must not reach -0.5 °C for any amount of time.
- c) Following any excursion below 0 °C, within 2 h the appliance must return to the acceptable temperature range (that is, consistently between + 2 °C and + 8 °C).

5.6.3 Rejection Criterion

Failure to maintain acceptable temperature range during cool-down and stabilization.

5.7 Test 7: Door Opening

5.7.1 Power: Continuous.

Step 1: Continuing from Test 6 as per 5.6.1, after an additional 1 h of continuous power, open all compartment lids/doors of the appliance. This must include primary as well as secondary lids/doors, since some appliances have secondary lids/doors. Allow the compartment to stay fully open for 10 min.

Step 2: Once 10 min have passed, close the lid/door and monitor temperatures of the vaccine compartment for at least 2 h as the appliance cools down and internal temperatures stabilize.

5.7.2 Acceptance Criteria

To receive a Grade A for freeze protection classification, the appliance's cool-down temperatures:

- a) Must not drop below 0 °C for longer than 1 h.

- b) Must not reach $-0.5\text{ }^{\circ}\text{C}$ for any amount of time.
- c) Following any excursion below $0\text{ }^{\circ}\text{C}$, within 2 h the appliance must return to the acceptable temperature range (that is, consistently between $+2\text{ }^{\circ}\text{C}$ and $+8\text{ }^{\circ}\text{C}$).

5.7.3 Rejection Criteria

Failure to maintain acceptable temperature range during cool.

5.8 Test 8: Day/Night Test

5.8.1 Power: Intermittent as Test 8.

Step 1: Stabilize the test chamber at M: $+27\text{ }^{\circ}\text{C}$, T: $+32\text{ }^{\circ}\text{C}$, H: $+43\text{ }^{\circ}\text{C}$. Load the appliance with simulated, pre-conditioned vaccine as described in **Annex A**. Ensure that the water-pack compartment (if present) is empty.

Step 2: Switch the appliance on, initially with continuous power, and stabilize the vaccine load temperature between $+2\text{ }^{\circ}\text{C}$ and $+8\text{ }^{\circ}\text{C}$ and the water-pack freezing compartment (if present) below $-3\text{ }^{\circ}\text{C}$. Allow to run for a further 24 h.

Step 3: Start the intermittent power cycle by disconnecting the power for the next 16 h. Simultaneously begin the day/night cycle by reducing the temperature of the test chamber to M: $+10\text{ }^{\circ}\text{C}$, T: $+15\text{ }^{\circ}\text{C}$, H: $+25\text{ }^{\circ}\text{C}$ over a 3 h period. Hold this temperature for 9 h. Raise the temperature to M: $+27\text{ }^{\circ}\text{C}$, T: $+32\text{ }^{\circ}\text{C}$, H: $+43\text{ }^{\circ}\text{C}$ over a 3 h period. Hold at M: $+27\text{ }^{\circ}\text{C}$, T: $+32\text{ }^{\circ}\text{C}$, H: $+43\text{ }^{\circ}\text{C}$ for a further 9 h. Reduce again to M: $+10\text{ }^{\circ}\text{C}$, T: $+15\text{ }^{\circ}\text{C}$, H: $+25\text{ }^{\circ}\text{C}$ again over a further 3 h period. Repeat this simulated day/night temperature and 16 h power-off, eight-hour power-on cycle five times. Record the vaccine load temperature every minute.

Step 4: Review the data and calculate the MKT for each sensor over the five-day period. Record the highest and lowest temperatures reached during the test.

5.8.2 Acceptance Criteria

Vaccine load temperatures shall remain within the acceptable temperature range throughout the test. The MKT of the worst case sensor shall not be outside the range $+2\text{ }^{\circ}\text{C}$ to $+8\text{ }^{\circ}\text{C}$.

5.8.3 Rejection Criteria

Failure to maintain the vaccine load within the acceptable temperature range throughout the test, and/or the MKT of the worst-case sensor is outside the range $+2\text{ }^{\circ}\text{C}$ to $+8\text{ }^{\circ}\text{C}$.

5.9 Test 9: Compressor Starting Test

5.9.1 Power: Continuous.

Step 1: Empty the appliance.

Step 2: Switch on the appliance using a starting voltage 20 percent lower than the nominal voltage of the compressor.

Step 3: Repeat Step 2 of 5.9.1 ten times from cold with the compressor at M: $+27\text{ }^{\circ}\text{C}$, T: $+32\text{ }^{\circ}\text{C}$, H: $+43\text{ }^{\circ}\text{C}$.

Step 4: Repeat Step 2 of 5.9.1 ten times with the compressor at its normal stable running temperature.

Step 5: Reduce the voltage to -22 percent of the nominal voltage, repeating steps 2 to 4 of 5.9.1 for each voltage.

Step 6: If there is a test failure at or before the -22 percent voltage test, establish the likely cause of the problem and include the diagnosis in the test report.

5.9.2 Acceptance Criterion

Ten out of ten starts shall be successful in both cold start and hot start tests at a minimum of 22 percent

below the manufacturer's nominal voltage.

5.9.3 Rejection Criterion

One or more start failures.

5.10 Test 10: Minimum Rated Ambient Temperature Test

5.10.1 Power: Intermittent.

Step 1: Continuing from Test 7 as per 5.7.1, stabilize the test chamber at + 10 °C or at a lower temperature specified by the manufacturer rounded up or down to the nearest 5 °C. At the same time, for combined appliances, stabilize the minimum specified water-pack freezing capacity load at the current ambient temperature.

Step 2: Load the appliance with simulated, pre- conditioned vaccine as described in Annex A.

Step 3: Switch the appliance on with intermittent power and stabilize the vaccine load temperature between + 2 °C and + 8 °C and the water-pack freezing compartment (if present) below – 3 °C. At the same time, for combined appliances, stabilize the minimum specified water-pack load at the current ambient temperature.

Step 4: Load the stabilized water-packs (combined appliances only) and leave the appliance to run for 24 h.

Step 5: Run the appliance for a minimum of 72 h at test chamber ambient of + 10 °C or at a lower temperature if specified by the manufacturer. Record temperatures every minute. At the end of every 24 h period, remove the water-packs from the freezing compartment (if applicable) and check that they are fully frozen to the minimum water-pack freezing capacity established in Test 4 as per 5.10.1. Return the packs to the freezer immediately.

Step 6: After a minimum of 72 h of operation determine which of the two conditions apply.

a) **Condition 1:** The vaccine load has remained within the + 2 °C to + 8 °C range and (in combined appliances only) water-packs are fully frozen as defined in Step 5 of clause 5.10.1. Conclude the testing.

b) **Condition 2:** The vaccine load has not remained within the + 2 °C to + 8 °C range and/or (in combined appliances only) water-packs are not frozen as defined in Step 5 of 5.10.1. Raise the temperature of the test chamber by 5 °C or to a maximum of + 10 °C and repeat steps 1 to 5 of 5.10.1. Halt the test cycle if the appliance fails at + 10 °C.

Step 7: Report and graphically display the test chamber ambient temperatures, appliance temperatures and condition of water-packs through the entire test starting with Step 1 of 5.10.1 through the completion of Step 6 of 5.10.1. If the appliance passes the testing report the minimum rated ambient temperature.

5.10.2 Acceptance Criteria

Record the lowest temperature increment at which the vaccine load temperature remains within the + 2 °C to + 8 °C range throughout the 24 h cycle and the minimum water-pack load (if applicable) is fully frozen by the end of the cycle. This temperature is the minimum rated ambient temperature for the appliance and this figure, if not 0 °C or any multiple of 5 °C, is then rounded up to the nearest 5 °C and must be + 10 °C or lower. The result will be printed in the blue sector of the temperature zone symbol as per Annex F.

5.10.3 Rejection Criterion

Failure to pass the test at a simulated temperature of + 10 °C or lower.

6 ACCESSORIES

6.1 Vaccine storage basket/tray allowing free circulation of air, having the size to be able to

accommodate 4 to 6 of them in the unit and suitable to match the net volume requirement.

6.2 Baskets and similar components shall have adequate mechanical strength. Those used for storing.

6.3 Baskets which are intended shall allow free circulation of air/easily removable and match the net volume requirement.

6.4 Stem alcohol thermometer for temperature monitoring (Annex H).

7 MARKING AND INFORMATION

7.1 Each ice lined refrigerators or combined refrigerator-water pack freezer shall have the following information marked in a permanent and eligible manner on one or several locations where it is readily visible either when the ice lined refrigerator is away from a wall or after the removal, without the help of the tools, of the small door or ventilating grating:

- a) The manufacturer's name or trade-mark,
- b) The model (or commercial designation) of the ice lining refrigerator and serial number,
- c) The rated gross volume in litres,
- d) The name of the refrigerant used in system and its quantity,
- e) Voltage range,
- f) Supply characteristics,
- g) Wiring diagrams,
- h) Rated energy consumption,
- j) Water packs freezing time,
- k) Overall dimensions, and
- m) Rated storage volume.

7.2 Each ice lining refrigerator or combined refrigerator-water pack freezer shall be accompanied on delivery by instructions for its use and maintenance printed on strong paper, cardboard, or similar material. These instructions shall at least contain information on:

- a) Installation requirements (in particular levelling of equipment);
- b) Conditions of operation (starting, stopping);
- c) Use of various control devices (temperature controller, etc.);
- d) Maintenance and cleaning; and
- e) A paper copy of user/operator manuals to be supplied in English.

8 PACKING, LABELLING AND STANDARD MARK

8.1 Packing and Labelling

8.1.1 Materials used for packaging the finished product are to be free of ozone depleting compounds as defined in the Montreal protocol.

8.1.2 A vertical arrow shall be marked at the all sides of packages to ensure transportation of equipment in vertical position. TOP and BOTTOM shall also be written.

8.1.3 To put label and signage's for HANDLE WITH CARE ON ALL SIDES OF THE CRATES as per packing and shipment norms.

8.1.4 The name of the manufacturer or supplier, model number and date of manufacture/serial number.

8.1.5 Compressors shall be marked with the blue identifying symbol shown in Annex 7. 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 G.

8.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act, 2016* and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

9 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.

ANNEX A

(Clauses 5.2.1, 5.4.1.1, 5.8.1 and 5.10.1)

A-1 GENERAL TEST CONDITIONS

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

A-1.1 Test Conditions

- a) Carry out tests in a test chamber in which temperatures can be controlled to ± 1 °C and humidity within the range of 45 percent to 75 percent unless otherwise stated below. Measure test chamber temperatures in accordance with IEC 62552-1, IEC 62552-2, IEC 62552-3.
- b) Maximum test chamber temperatures of H: + 43 °C is required for the tests.
- c) Minimum test chamber temperatures down to –15 °C may be required for the minimum ambient temperature rating test. The actual minimum required for a specific appliance should be discussed with the appliance manufacturer before the test commences.
- d) Temperatures within the appliance must be continuously monitored to an accuracy of ± 0.5 °C without the presence of the sensors influencing the test in any way. Thermocouples that are sealed within the appliance are most commonly used. Up to 16 simultaneous temperature measurements may be required for a single appliance. The suggested temperature sensor locations are shown in Annex B. See Annex C for temperature sensor specifications.
- e) Position the test appliance in the test chamber with its back face 50 mm clear of one of the chamber walls. Ensure that it is accurately levelled.

A-1.2 Stabilization Times

A-1.2.1 Initial stabilization is accomplished when the appliance demonstrates all of the following:

- a) The thermal storage has been cooled for a time period no less than the cool down time period stated in the instructions provided by the manufacturer (for example, if instructions state cool down time is 3 days then at least a 3 day cool down test is required);
- b) The internal temperatures in the vaccine storage compartment are within the acceptable temperature range; and
- c) The cooling system has exhibited consistent on/off operation for the final two days of this test (for example, the same number of on/off cycles per day for the final two days).

A-1.2.2 Before measuring the performance of a refrigerator or freezer under normal running conditions, internal temperature conditions in the vaccine storage compartment must be stable. This is normally assumed to have occurred when either:

- a) The thermostat has been cycling for 24 h, or
- b) The temperature at each of corresponding points during successive operating cycles varies by less than ± 1 °C and there is no marked trend away from the mean temperature at that point over 24 h.

A-1.3 Vaccine Net Storage Capacity Measurement

- a) Measure vaccine storage capacity using cardboard boxes, plastic foam or wooden blocks, 100 × 100 × 100 mm, 100 × 100 × 50 mm, and 50 × 50 × 50 mm.
- b) Fill the appliance up to the maximum loading line recommended by the manufacturer.
- c) Where baskets and shelves are supplied, these should be used to hold the dummy load. Do not place any boxes outside the zone designated by the manufacturer for vaccine storage.

- d) Do not place the dummy load in the fast freeze compartments of vaccine freezers.

A-1.4 Recording Temperatures

- a) Test appliances, either loaded or empty, as described above in the verification protocol.
- b) Take temperature readings once per minute.

A-1.5 Sensor Placement

- a) Place sensors in contact with the surfaces of the vaccine storage compartment and at the centre of the vaccine load as well as at other positions which are likely to experience extremes of temperature. Such positions might be near door seals or where air circulation is restricted by the appliance design. See the Annex B for sensor position diagrams and notes.
- b) For non-grade A appliances and where vaccine storage baskets are required to avoid freezing temperatures, fix sensors within the volume(s) defined by the internal faces of the basket(s).
- c) Fix the sensors in position so that they cannot be displaced during the course of the tests. Sensors may be fixed in position using thin rigid wire, tape or similar materials which do not affect the thermal performance of the appliance.
- d) After initial setup, do not alter the position of sensors during subsequent tests.
- e) Monitor all sensors so that an overall picture of the temperature distribution can be obtained.

A-1.6 Dummy Vaccine Load

- a) Make up a dummy vaccine load using partially filled water-packs.
- b) Measure the chosen water-packs to establish their nominal unit volume in litres (length × width × thickness in cm/1 000).
- c) Select the number of empty water-packs required to build a dummy load whose nominal volume is equal to the measured vaccine net storage capacity in litres divided by five, ± 5 percent.
- d) Partially fill the water-packs with equal volumes of water so that the mass of the load is equal to the nominal load volume × 0.4 kg (0.4 kg per litre).
- e) Pre-condition the dummy load at + 8 °C and place in the appliance as follows so that it does not interfere with the sensor positions already established.

A-1.7 Front-opening Appliances

Stack the partially filled water-packs evenly on the shelves designated for vaccine storage.

A-1.8 Top-opening Refrigerators

- a) The dummy load described below is intended to approximate the minimum vaccine load in a well-managed refrigerator holding a 25 percent safety stock.
- b) Stack the partially filled water-packs evenly on the bottom of baskets supplied for vaccine storage.
- c) If baskets are not required to keep vaccine away from the base and walls of the appliance, stack the partially filled water-packs evenly on the base of the appliance.

A-1.9 Top-opening Freezers

Stack the partially filled water-packs evenly on the base of the appliance.

A-1.10 Water-packs

Tests which require water-packs must use 0.3, 0.4 or 0.6-liter water-packs.

A-1.11 Dual Compressor or Multiple Cooling Circuit Appliances

Both compressors should be switched on during all tests.

ANNEX B

[*Clauses A-1.1 (d), A-1.5 (a)*]

B-1 TEMPERATURE SENSOR POSITIONS

B-1.1 Approximate sensor positions are indicated by the figures provided in **Annex B**. Except for ambient sensors placed centrally in a compartment the surface sensors are positioned in direct contact with the vaccine storage compartment. If baskets are used to define the vaccine storage compartment, all sensors are to be located inside the basket(s) and the surface sensors are to be in contact with the basket material and as shown in the figures provided in Annex B.

B-1.2 The surface sensors that are to be placed in direct contact with the walls of the vaccine storage compartment are not to be inserted into brass or tin-covered copper mass, as required in the previous version of this protocol. These surface sensors must be directly in contact with the walls of the vaccine storage compartment. However, the ambient sensors that are placed in more central locations in the vaccine storage compartment are to remain in a brass or tin-covered copper mass.

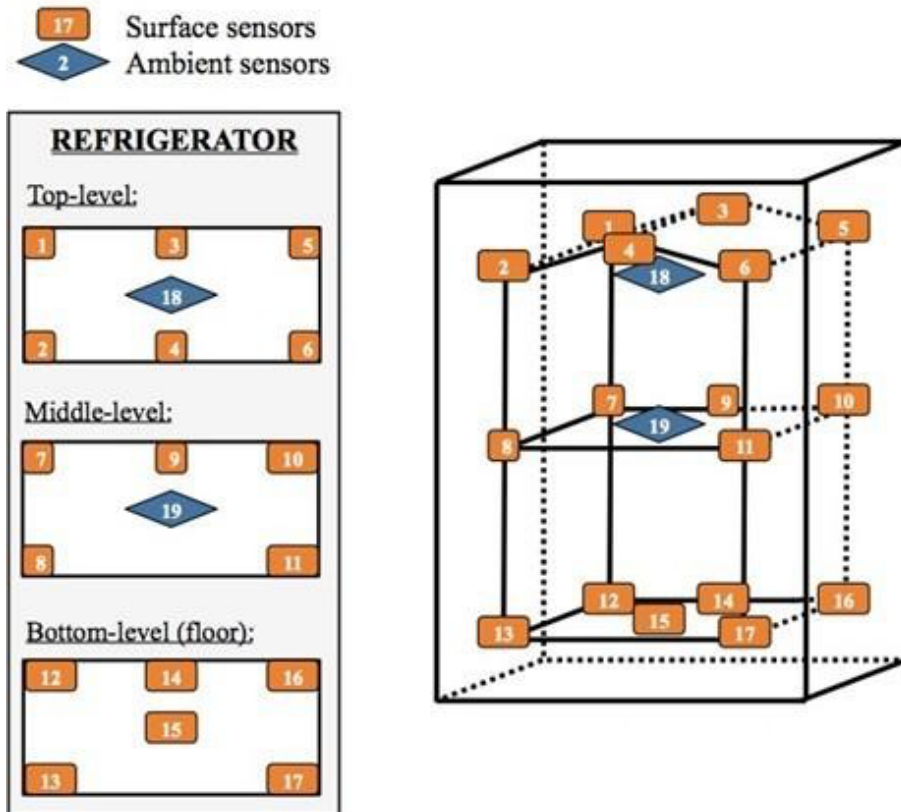


FIG. 1 UPRIGHT COMPARTMENT

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

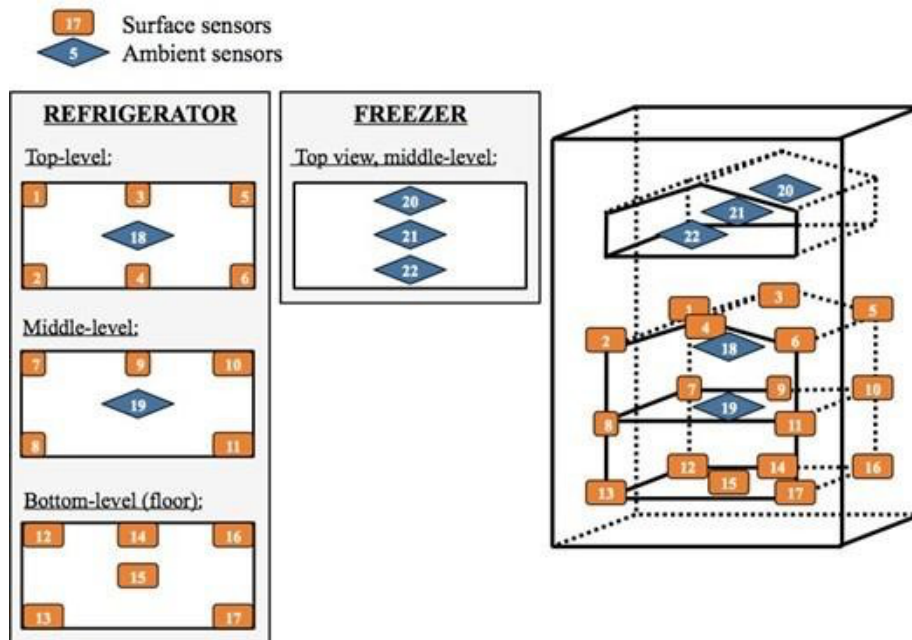


FIG. 2 UPRIGHT COMPARTMENT – WITH FREEZER

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

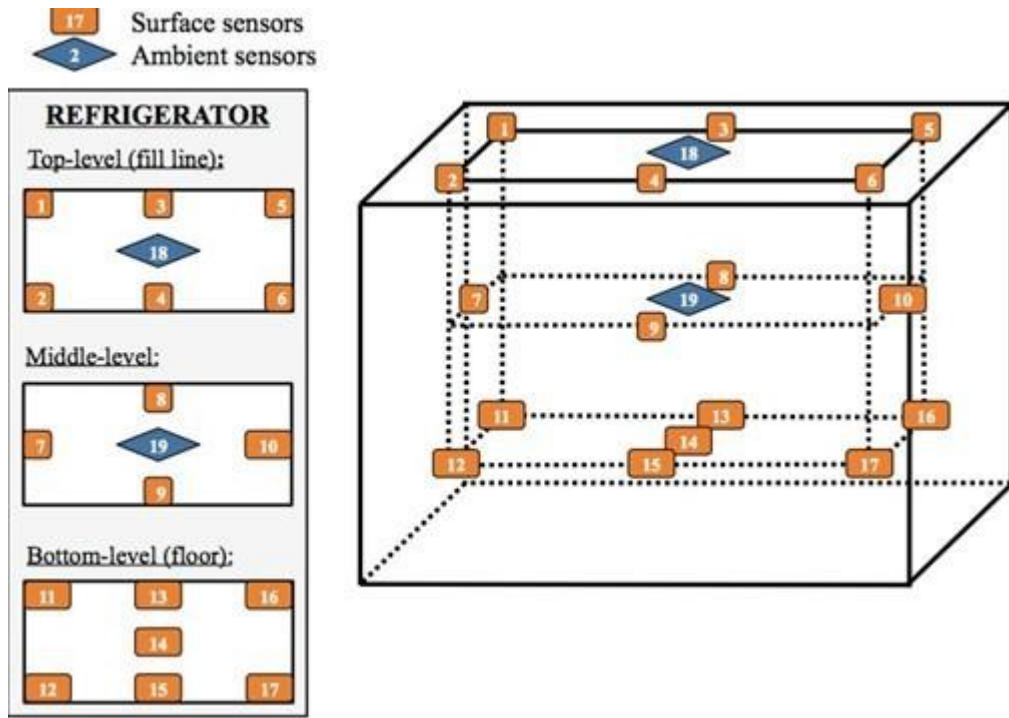


FIG. 3 CHEST COMPARTMENT – NO STEP

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

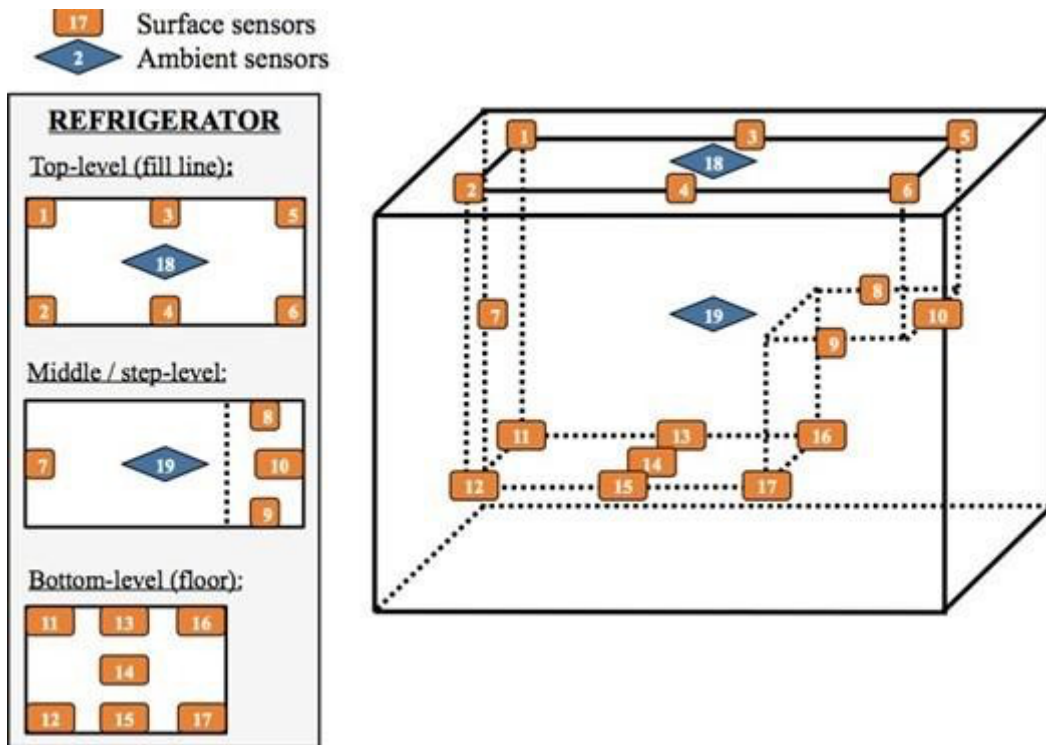


FIG. 4 CHEST COMPARTMENT – WITH STEP

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

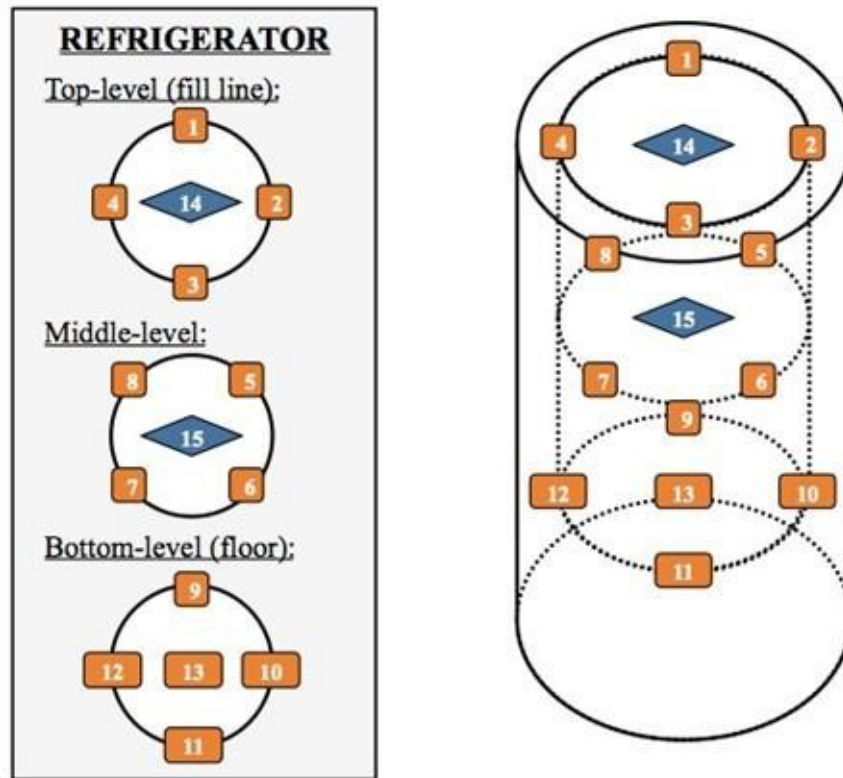
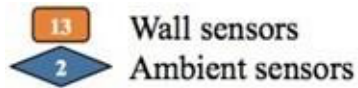


FIG. 5 CHEST COMPARTMENT – WITH FREEZER

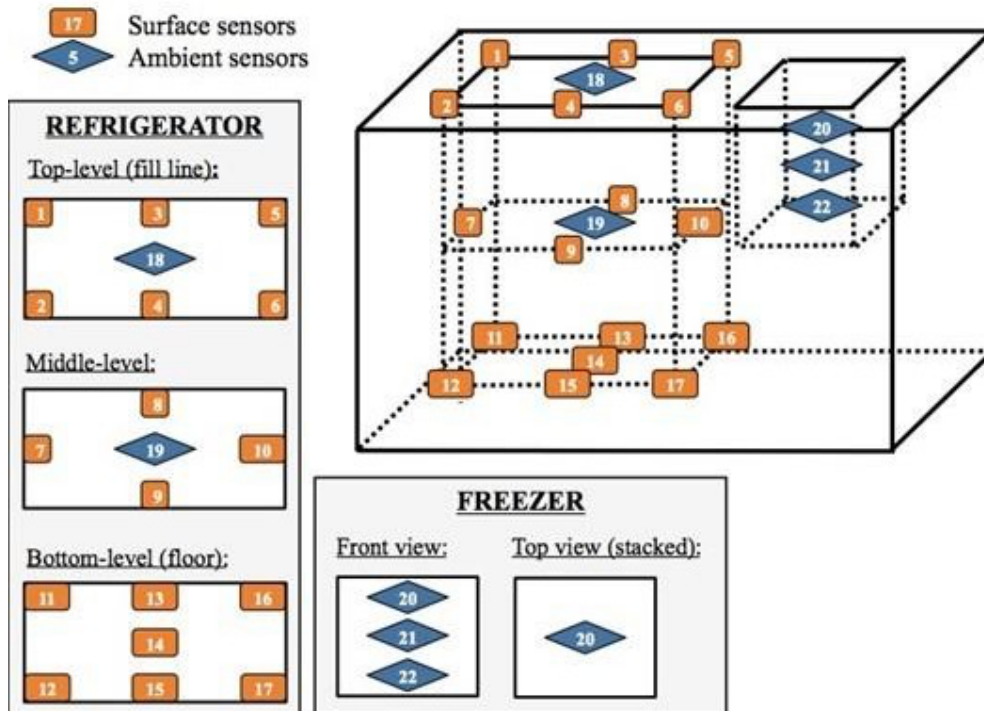


FIG. 6 CYLINDRICAL CHEST COMPARTMENT

ANNEX C

[Clause A-1.1, (d)]

TEMPERATURE SENSOR SPECIFICATION

Surface sensors in contact with the vaccine compartment surfaces must comply with IEC 62552-1, IEC 62552-2 and IEC 62552-3 with probe accurate to ± 0.5 °C but are not to be inserted into brass or tin-covered copper mass of $25 \text{ g} \pm 5$ percent. Ambient sensors not in contact with the vaccine storage compartment are to comply with IEC 62552-1, IEC 62552-2 and IEC 62552-3 with sensor, accurate to ± 0.5 °C, inserted into brass or tin-covered copper mass of $25 \text{ g} \pm 5$ percent and of minimum external area (diameter = height = about 15.2 mm).

ANNEX D

(Clause 5.4.1.1)

D-1 METHODOLOGY FOR MEASUREMENT OF ICE PRODUCTION

D-1.0 The following tests are used to determine whether a water-pack is fully frozen, partially frozen, or unfrozen. While the assessment is not 100 percent accurate, misclassifications are usually conservative in nature, water-packs that are fully frozen are sometimes classified as partially frozen rather than partially frozen water-packs being classified as fully frozen. A fully frozen water-pack contains only ice. A partially frozen water-pack contains both ice and water. An unfrozen water-pack contains only water.

D-1.1 Perform the all of the following tests on the water-pack.

D-1.1.1 *Shake Test*

Shake the water-pack while holding the water-pack near the assessor's ear. If the sound of water sloshing in the water-pack is heard, then the water-pack fails the shake test.

D-1.1.2 *Tilt Test*

Tilt the water-pack back and forth while looking for the movement of air or water in the water-pack. If the movement of air or water is observed, then the water-pack fails the tilt test.

D-1.1.3 *Bulge Test*

Water expands when it freezes. Examine the water-pack for localized bulging near the centreline of the water-pack when viewing the water-pack from the side. If localized bulging is not present, then the water-pack fails the bulge test.

D-1.1.4 *Classify the Water-pack as Follows*

- a) If the water-pack passes all three tests, then the water-pack is fully frozen.
- b) If the water-pack fails one or more tests, then the water-pack is partially frozen or unfrozen and fails the test.

ANNEX E

(Clauses 4.2.1.1 and 4.2.4)

E-1 METHODOLOGY FOR FREEZE PROTECTION ANALYSIS AND GRADING

E-1.0 All data collected and interventions implemented, with the exception of data from Test 2 cool-down, must be evaluated to assign a freeze protection grade according to the definition of freezing temperatures and the below intervention chart in Table 1.

Table 1 Intervention Chart

(Clause E-1.0)

User- Intervention	Evaluation Criteria	Result
Basket storage	Any need to utilize baskets to protect vaccines from freezing.	add 1 user-intervention
Compartment covers	Any need to utilize vaccine compartment covers to protect vaccines from freezing.	add 1 user-intervention
Knob adjustment	Any adjustment of temperature knob or fuel regulator required to protect vaccines from freezing.	add 1 user-intervention

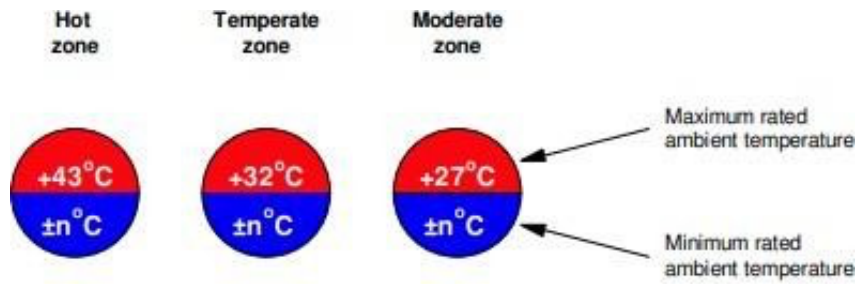
NOTES

- 1 This list of interventions is representative and does not include all possible user-interventions.
- 2 Freeze protection grading criterion: The refrigerator's grade must be evaluated based on the number of user-intervention required to maintain safe storage within the 2-8 °C compartment temperature range.
 - a) Grade A, user-independent freeze protection (UIFP): zero (0) interventions required.
 - b) Grade B, user-dependent freeze protection (UDFP): one (1) user-intervention required.
 - c) Grade C, user-dependent freeze protection (UDFP): greater than one (>1) user-interventions required.
- 3 If at any point during testing, the appliance fails to meet the criteria for "A" grade freeze protection, the testing must be stopped, a manufacturer prescribed intervention implemented and the testing restarted from Test 2. These intervention must be implemented one at a time so as to differentiate between single-intervention "B" grades and multi-intervention "C" grades.

ANNEX F

(Clause 5.10.2)

TEMPERATURE ZONE SYMBOL FOR REFRIGERATORS



Cold climate tolerance rating is specified in 5°C increments:

- *Hot zone:* <n> must be between +25 °C and -10 °C
- *Temperate zone:* <n> must be between +15 °C and -10 °C
- *Moderate zone:* <n> must be between +10 °C and -10 °C

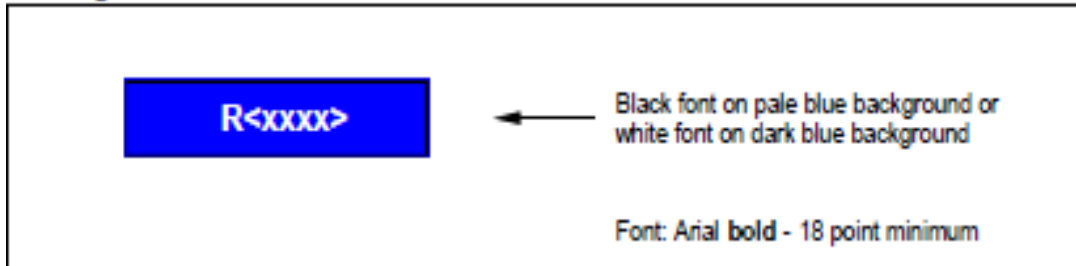
All circles are to be 100mm diameter. Font Arial **bold**.

ANNEX G

(*Clause 8.1.5*)

REFRIGERANT SYMBOLS

Refrigerant label



R600a warning symbol

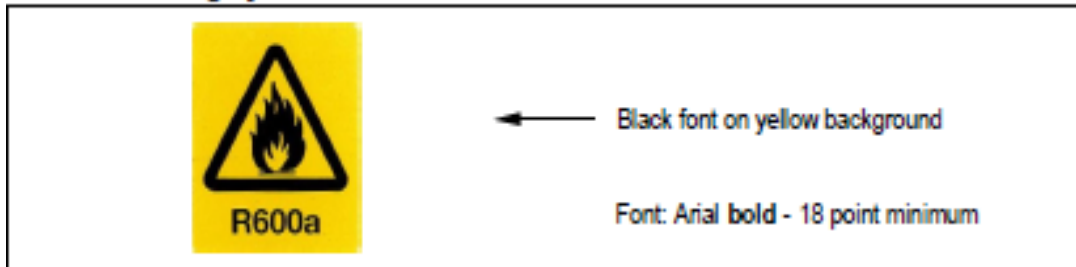


FIG. 8 REGRIGERANT SYMBOLS

ANNEX H

(Clause 6.4)

H-1 ALCOHOL STEM THERMOMETER

H-1.0 Portable alcohol thermometer suitable for monitoring storage temperature in vaccine refrigerators and freezers.

H-1.1 Power Source: None.

H-1.2 Sensor: Coloured alcohol in glass column.

H-1.3 Physical Characteristics

H-1.3.1 Overall Dimensions: Maximum 200 × 25 × 25 mm.

H-1.3.2 Weight: Not critical, provided the product is fully portable.

H-1.4 Temperature Ranges and Accuracy

- a) Upper limit: + 50 °C;
- b) Lower limit: –30 °C; and
- c) Accuracy: + 1 °C.

H-1.5 Scale Markings (Temperature Display)

- a) Easily readable centigrade scale with a minimum space of 1 mm between each line.
- b) Long lines (with numbers) for each 10 degrees.
- c) Short lines for even numbered degrees.
- d) Shorter lines for odd numbered degrees.
- e) Safe zones for ranges of + 2 °C to + 8 °C and –15 °C to –25 °C to be marked with a green bar.
- f) Numeral size: 2 mm high minimum.
- g) Font: high-legibility font.
- h) Below zero temperature range indicated with a minus sign.
- j) Above zero temperature range indicated with a plus sign.
- k) Unit of measurement: Temperatures must be displayed in degrees centigrade only.
- m) Reading angle: between 80 and 100° to the plane of the support plate.
- n) Colour of markings: dark blue or black on a white background.

H-1.6 Environmental Requirements

H-1.6.1 Ambient Temperature Range During Transport: –50 °C to + 55 °C.

H-1.6.2 Ambient Humidity Range During Transport and Use: 0 to 95 percent RH.

H-1.6.3 Maximum Relative Humidity: 90 percent.

H-1.7 Resolution: Resolution: ± 0.5 °C or better within the range –30 °C to + 20 °C.

H-1.8 Casing Specification: Non-corrodible, sealed mechanism.

H-1.9 Vibration Test: Product should stand 30 min on a programmable vibrating table without physical damage or calibration.

H-1.10 Impact Resistance: Product to withstand 5 drops from 1 metre onto a concrete floor without physical damage or loss of calibration.

H-1.11 Construction: The glass column must be protected against break age and strongly supported so, that the column cannot be displaced more than 0.5 mm vertically with respect to the scale.

H-1.12 Mounting Specification

- a) Hook to suspend (Hanging hook with minimum 8.0 mm throat to hook over the rim of a refrigerator/freezer basket).
- b) Rubber sucker. The position of the mounting device must not prevent the temperature scale from being clearly visible in a suitable reading plane.
- c) WHO Specification reference: E06/TH03.1.
- d) Applies to procedures: E06/TH03.VP.1.

H-1.13 IP Rating: Protection of the product not less than IEC 60529: IP67.