*भारतीय मानक*
*Indian Standard*

**IS 17547 : 2021**

# वैक्सीन फ्रीजर या संयुक्त वैक्सीन फ्रीजर एवं जल-पैक फ्रीजर संपीड़न चक्र की विशिष्टि — सामान्य अपेक्षाएं एवं परीक्षण विधियां

# Specification for Vaccine Freezer or Combined Vaccine Freezer and Water-Pack Freezer Compression Cycle — General Requirements and Testing Methods

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भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
मानक भवन, 9 बहादुरशाह ज़फर मार्ग, नई दिल्ली – 110002
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI-110002
www.bis.gov.in www.standardsbis.in

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## FOREWORD

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.

This Indian Standard specifies the general requirements and test methods for vaccine freezer used for vaccine and water–packs storage.

The technical committee responsible for the preparation of this standard has reviewed the provisions of the following International Standards/Other Publications and has decided that they are acceptable for use in conjunction with this standard:

| *International Standard* | *Title* |
|---|---|
| ISO 20282-1 : 2006 | Ease of operation of everyday products — Part 1: Context of use and user characteristics |
| IEC 60335-2-24 : 2007 | Household and similar electrical appliances — Safety — Part 2-24: Particular requirements for refrigerating appliances. |
| IEC 62552 : 2007 | Household refrigerating appliances characteristics and test methods |

In preparation of this standard, assistance has been drawn from specifications received from Technical Specifications Development Group (TSDG) for Cold Chain Equipment, National Cold Chain and Vaccine Management Resource Centre (NCCVMRC), Department of Health and Family Welfare.

The composition of the Committee responsible for the formulation of this standard is given in Annex H.

In reporting the result of a test or analysis made in accordance with this standard, if the final value, observed or calculated, is to be rounded off, it shall be done in accordance with IS 2 : 1960 ‘Rules for rounding off numerical values ( *revised* )’.

*Indian Standard*

# SPECIFICATION FOR VACCINE FREEZER OR COMBINED VACCINE FREEZER AND WATER-PACK FREEZER: COMPRESSION CYCLE — GENERAL REQUIREMENTS AND TESTING METHODS

## 1 SCOPE

**1.1** This Indian Standard describes general requirements and test methods for deep freezers for vaccine and water pack storage. Vaccine freezers maintain temperatures of –15 °C to –25 °C, to store vaccine and prepare ice packs required for passive cooling in vaccines carriers and cold boxes.

**1.2** This standard defines the requirements and procedure for verifying the performance of compression-cycle vaccine freezers or compression-cycle combined vaccine and water-pack freezers. Three temperature zone designations are described: moderate zone, temperate zone and hot zone.

## 2 REFERENCE

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 agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

| *IS. No/Other Publication* | *Title* |
|---|---|
| IS 302 (Part 1) : 2008 | Safety of household and similar electrical appliances: Part 1 General requirements (*sixth revision*) |
| 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) (*first revision*) |
| 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) (*first revision*) |
| IS/ISO/IEC 17025 : 2017 | General requirements for the competence of testing and calibration laboratories (*second revision*) |
| 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 Vaccine Freezer** — These are compression-cycle vaccine freezer or combined vaccine and water packs freezer, powered by mains electricity and are used primarily in areas with a reliable electricity supply (that is, 20 or more hours of continuous electricity per typical day). Freezers maintain temperatures –15 °C to –25 °C, to store vaccine and prepare ice packs required for passive cooling in vaccines carriers and cold boxes.

**3.2 Holdover Time** — The time in hours during which all points in the vaccine or water-pack freezing compartment of the freezer remains below –5 °C after the power supply has been disconnected.

**3.3 Hot Zone** — Hot zone appliances shall operate at a steady +43 °C ambient temperature and over a +43 °C/+25 °C day/night cycling temperature range.

**3.4 Moderate Zone** — Moderate zone appliances shall operate at a steady +27 °C ambient temperature and

over a +27 °C/+10 °C day/night cycling temperature range.

**3.5 Temperate Zone** — Temperate zone appliances must operate at a steady +32 °C ambient temperature and over a +32 °C/+15 °C day/night cycling temperature range.

**3.6 Vaccine Storage Capacity** — The net capacity in an appliance available for the storage of vaccines. It is measured in liters in the following manner:

**3.6.1** *Freezers* — Load the vaccine storage compartment up to the manufacturer's loading markings with boxes or blocks measuring 100 × 100 × 100 mm or 100 × 100 × 50 mm, packed so that there is minimal air space between each, column of packets or between the packets and any adjoining wall. The total volume of the dummy load, in liters, represents the net volume available for the storage of vaccines.

**3.6.2** *Refrigerators* — Load the vaccine storage compartment up to the manufacturer's loading markings with boxes or blocks measuring 100 × 100 × 100 mm or 100 × 100 × 50 mm, packed so that there is a minimal air space between each column of packets or between the packets and any adjoining wall. If baskets are provided, load the boxes or blocks into the baskets in the same manner. The total volume of the dummy load, in litres, represents the net volume available for the storage of vaccines.

**3.7 Water–pack** — Flat plastic container filled with water.

**3.8 Water–pack Freezing Capacity** — The maximum weight of water-packs which can be frozen, in one batch, during a 24 h freezing cycle. During this period the temperature of the vaccine storage compartment shall not exceed –15 ºC, except during the actual freezing process after unfrozen water-packs have been loaded when a rise to a maximum of –5 °C is permitted.

## 4 REQUIREMENTS

### 4.1 General (Physical Characteristics)

Compression-cycle vaccine freezers or combined vaccine and water-pack freezers, powered by mains electricity, are used primarily in areas with a reliable electricity supply (that is, 20 or more hours of continuous electricity per typical day). Manufacturers may offer products suitable for one or more temperature zones.

### 4.2 Overall Dimensions

To allow for manoeuvring through corners, corridors and doorways, the minimum dimension of the product (either length, width or height) should not exceed 710 mm; exceptionally a minimum dimension up to 830 mm can be accepted, but this will restrict the number of sites where the appliance can be installed. The maximum dimension shall not exceed 1700 mm and the maximum diagonal (corner to corner) dimension shall not exceed 1850 mm.

### 4.3 Weight

Mechanical lifting equipment will typically not be available at the installation sites. It is recommended that the refrigerator and any associated components should be designed for lifting 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.

### 4.5 Electrical Safety Rating

Manufacturer to certify compliance with IS 302 (Part 1) : 2008.

### 4.6 Performance

**4.6.1** *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 as specified in Annex E.

**4.6.2** *Refrigeration Cycle*

Compression-cycle unit operating on alternating current electricity.

**4.6.3** *Voltage and Frequency*

Direct supply of mains electricity. Options for 220-240 volt 50/60 Hz and 100-127 volt 50/60 Hz are to be offered. Performance is to be identical for all options, regardless of the nominal voltage and frequency rating of the appliance.

**4.6.4** *Water-pack Freezing*

In combined freezers, not less than 7.2 kg of water-packs must be frozen per 24 h whilst maintaining the temperature control specified in **4.6.7**.

**4.6.5** *Areas not Suitable for Vaccine Storage*

Areas of an otherwise acceptable appliance which are too warm must be excluded from use by design.

**4.6.6** *Vaccine Storage Advice*

All units must carry a factory-fitted non-removable label, designed to last the lifetime of the appliance, carrying the following information:

**4.6.6.1** *Vaccine freezers*

Vaccine storage instructions and the appropriate temperature zone symbol as per Annex E.

**4.6.6.2** *Combined freezers*

Vaccine storage instructions, water-pack freezing instructions and the appropriate temperature zone symbol as per Annex E.

**4.6.6.3** The instructions should be fixed to the lid of chest freezers and near the top of the door on upright freezers. Instructions may be specified in one of the languages as agreed by the purchaser and the manufacturer.

**4.6.7** *Temperature Control*

**4.6.7.1** *Vaccine compartment*

**4.6.7.1.1** *All freezers*

The vaccine load must remain below –15 °C during any continuous ambient temperature test(s) or day/night cycling temperature test(s). Combined units must achieve this performance with no water packs in the water-pack compartment.

**4.6.7.1.2** *Combined freezers only*

While freezing a quantity of water-packs equal to its water-pack freezing capacity, the temperature of the full load of vaccines must remain below –5 °C and return to below –15 °C within the 24 h freezing cycle under the maximum continuous ambient temperature test conditions of its rated temperature zone.

**4.6.8** *Thermostat*

**4.6.8.1** The temperature control shall be effective throughout the ambient operating temperature range (down to the minimum rated ambient temperature). The temperature controller must meet some requirements. Most notably, because of ambient temperature variation and operation uncertainties, the controller must be capable maintaining the temperature range recommended.

**4.6.8.2** Alternatively, in case of programmable thermostat, the temperature controller must be a precision device capable of maintaining control well inside 0.1 °C over time and temperature variations.

**4.6.8.3** 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.

**4.6.9** *Thermometer*

**4.6.9.1** *The following are the thermometers that could be used:*

a) *Option A* — Externally readable cabinet-mounted gas or vapor pressure dial thermometer.

b) *Option B* — Externally readable cabinet-mounted electronic thermometer.

**4.6.10** *Holdover Time*

No standard set.

**4.6.11** *Compressor Starting Voltage*

Compressor starting at 172 volts at 22 percent below manufacturers stated voltage, 10 out of 10 cold starts and 10 out of 10 hot starts must all be successful.

**4.6.12** *Power Consumption*

No standard set however, results will be reported.

**4.6.13** *Evaporator Configuration*

If the evaporator is mounted in shelves, the minimum clearance between shelves must be 130 mm.

**4.6.14** *Lock*

**4.6.14.1** The door or lid must be fitted with a lock. Two keys are to be supplied with every unit.

**4.6.14.2** Hinges and handles shall be strong and resistant to corrosion.

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

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

**4.6.15** *Corrosion Resistance*

The internal and external cabinet, lid and frame shall be tested for corrosion resistance as specified in IS 10461 (Part 1) and IS 10461 (Part 2).

## 5 ENVIRONMENTAL REQUIREMENTS

### 5.1 Ambient Temperature Range During Transport and Storage

–30 °C to +55 °C when the product is inactivated.

### 5.2 Ambient Humidity Range During Transport, Storage and Use

5 percent to 95 percent RH, non-condensing.

## 6 INTERFACE REQUIREMENTS

### 6.1 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.

### 6.2 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.

## 7 HUMAN FACTORS

### 7.1 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.

### 7.2 General

The equipment shall have appropriate mechanism (that is, rotating screw) at its base to balance the weight on uneven floor. The product must be useable by the widest practicable range of active health workers, regardless of age, gender, size or minor disability, including colorblind users and long-sighted people without glasses, in accordance with the general principles laid out in ISO 20282-1 : 2006.

### 7.3 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 meters. If a low level position is essential, the display should 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, should be recessed or otherwise protected so that it is not possible inadvertently to activate it.

## 8 MATERIALS

### 8.1 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.

### 8.2 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.

### 8.3 Refrigerant

**8.3.1** 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. 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).

**8.3.2** Refrigerants which are ozone depleting as identified under Montreal protocol shall not be used in the manufacture and operation of these freezers.

**8.3.3** The Refrigerant symbols to be specified as in Annex F.

### 8.4 Thermal Insulation Foaming Agents

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

### 8.5 Other Restricted Materials

The product and its constituent components, including batteries, must 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.

## 9 ACCESSORIES

**9.1** 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.

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

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

**9.4** Stem alcohol thermometer for temperature monitoring (Annex G).

## 10 APPLICABILITY

Type-testing as per test method mentioned in Annex A.

## 11 MARKING AND INFORMATION

**11.1** Each vaccine freezer or combined vaccine freezer and 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.

**11.2** Each vaccine freezer or combined vaccine freezer and 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.

## 12 PACKING, LABELLING AND MARKING

### 12.1 Packing and Labelling

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

**12.1.2** 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.

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

**12.1.4** The refrigerant symbol to be specified as per Annex F.

### 12.2 Marking

**12.2.1** Compressors shall be marked with the blue identifying symbol shown in Annex G. 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.

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

**12.2.3** *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.

## 13 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

( *Clause* 10 )

## TEST METHODS

### A-1 TEST TEMPERATURES

**A-1.0** 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.

**A-1.1 Test 1**

**A-1.1.1** *Cool-down*

a) Set the test chamber temperature to M: +27 ºC, T: +32 °C, H: +43 °C and leave for 48 h with the appliance empty, the lid or door open and the power supply switched off.

b) Close the lid or door of the freezer, switch the appliance on and leave it to stabilize with the thermostat/fast freeze switch on its maximum setting.

c) After stabilization, 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 hlater.

d) Calculate the percentage 'on' time over this period. Measure electricity consumption over the 24-hour period in kWh/day.

**A-1.1.2** *Acceptance Criterion*

Stabilized internal temperatures maintained at or below –15 ºC.

**A-1.1.3** *Rejection Criterion*

Failure to stabilize at or below –15 ºC.

**A-1.2 Test 2**

**A-1.2.1** *Stable Running and Power Consumption Test*

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

b) Close the lid or door of the freezer and leave it to stabilize below –15 °C with the thermostat/fast freeze switch on its maximum setting.

c) 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 24 h period in kWh/day.

d) If the internal temperatures are not correct, adjust the thermostat, if it is possible to do so, and repeat step 3. If successful, the newly established setting is referred to as the revised optimum. Record all thermostat settings and the outcomes for each setting. Once the revised optimum is established DO NOT adjust the thermostat during subsequent tests.

**A-1.2.2** *Acceptance Criteria*

Stabilized internal temperatures at or below –15 °C. Power consumption at the revised optimum to be reported.

**A-1.2.3** *Rejection Criteria*

Failure to stabilize at or below –15 °C within the test period.

**A-1.3 Test 3**

**A-1.3.1** *Water-pack Freezing Capacity* (*Combination Units Only*)

a) Continue the Test 2 conditions.

b) Stabilize 12 no. 0.6 kg water-packs at M: +27 °C, T: +32 °C, H: +43 °C.

c) Load the water-packs into the freezer compartment, if possible in a row and with the edges perpendicular to the evaporator surface. Install the freezer thermocouples (minimum 8 no.), centered 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.

d) Turn on the fast-freeze switch (if present). DO NOT adjust the thermostat.

e) Record water-pack and vaccine load temperatures every minute for the following 24 h.

f) As soon as the water-packs are frozen (to –3 °C or below) AND the vaccine load has returned to –15 °C or below, they can be removed. Check that the vaccine load has stayed below –5 °C throughout the test period. Check that the water-packs have been fully frozen within the 24 h test period.

g) Repeat steps 2 to 6 introducing additional water-packs up to the point when one or more of the following conditions occurs:

1) One or more of the water-packs do not fully freeze within the 24 h period;
2) The temperature of the vaccine load exceeds –5 °C during the freezing process; and
3) The temperature of the vaccine load does not return to –15 °C or below by the end of the 24 h test period.

h) Establish and record the maximum weight of water–packs that can be frozen whilst still meeting the requirements of specification **4.2.4**.

**A-1.3.2** *Acceptance Criteria*

A minimum of 7.2 kg of water-packs must be frozen within 24 h. The vaccine storage temperature must return to –15 °C or below by the end of the 24 h cycle and the vaccine storage temperature must not exceed –5 °C on one or more sensors at any time during the test period.

**A-1.3.3** *Rejection Criterion*

Failure to meet one or more of the acceptance criteria.

**A-1.4 Test 4**

**A-1.4.1** *Holdover Time*

a) For units without water-pack freezing, continue the Test 3 conditions. For combined units, continue the Test 3 conditions but with the water-pack freezing compartment empty.
b) Stabilize the vaccine load temperature below –15 °C on all sensors. Once the temperature has stabilized, record temperatures every minute.
c) Switch off the power supply at the start of a compressor ON phase. Record the length of the preceding compressor OFF period (t).
d) Monitor the temperature of the vaccine load at one minute intervals. At the moment when the warmest point in the load exceeds –5 °C, record the elapsed time since power supply switch off and add this to the value 't' recorded in Step 3. Record the position of the warmest point.

**A-1.4.2** *Acceptance Criterion*

No standard set. Performance data will be published in the data sheet.

**A-1.5 Test 5**

**A-1.5.1** *Day/Night Test*

a) Stabilize the test chamber at M: +27 °C, T: +32 °C, H: +43 °C. Load the appliance with simulated, pre-conditioned vaccine as described in test 2. Ensure that the water-pack compartment (if present) is empty.
b) Switch the appliance on and allow the temperature of the vaccine load to stabilize below –15 °C on all sensors. Allow to run for a further 24 h.
c) Over a 3 h period reduces the temperature of the test chamber to M: +10 °C, T: +15 °C, H: +25 °C. Hold this temperature for 9 h. Raise the temperature to M: +27 °C, T: +32 °C, H: +43 °C over a 3 h period. Hold at M: +27 °C, T: +32 °C, H: +43 °C for a further 9 h. Reduce again to M: +10 °C, T: +15 °C, H: +25 °C again over a further 3 h period. Repeat this simulated day/night cycle five times. Record the vaccine load temperature every minute.
d) Review the data and establish the highest and lowest temperatures recorded during the test.

**A-1.5.2** *Acceptance Criterion*

Vaccine load temperatures must remain at or below –15 °C throughout the test.

**A-1.5.3** *Rejection Criterion*

Vaccine load temperature exceeds – 15 °C.

**A-1.6 Test 6**

**A-1.6.1** *Maximum water-pack Freezing Load*

a) Set the test chamber temperature to M: +27 °C, T: + 32 °C, H: +43 °C and with the appliance empty, the power supply switched on and the freezer temperature between – 15 °C and – 25 °C. Stabilize the water-packs to be used for the test at M: + 27 °C, T: + 32 °C, H: + 43 °C.
b) Load the freezing compartment, including the fast-freeze zone, with water-packs at M: + 27 ºC, T: + 32 °C, H: + 43 °C with a combined volume of one third of the manufacturer's stated gross volume. Instrument the water pack load in accordance with Fig. 1 and 2 for E003/FZ–01 under points7 to 10 and 5 as in Annex C.
c) Turn on the fast–freeze switch (if present). DO NOT adjust the thermostat.
d) Monitor internal and water-pack temperatures every minute for 24 h. The load is assumed to be completely frozen when the temperature of the warmest water-pack reaches – 3 °C. Next introduce additional water packs up to the point when one of the water-packs does not fully freeze within the 24 h period;
e) Record the weight of water-acks frozen within the 24 h test period.

**A-1.6.2** *Acceptance Criterion*

No standard set. Performance data will be published on the data sheet.

**A-1.7 Test 7**

**A-1.7.1** *Compressor Starting Test*

a) Empty the freezer.
b) Switch on the appliance using a starting voltage

20 percent lower than the nominal voltage of the compressor.

c) Repeat step 2 ten times from cold with the compressor at M: + 27 °C, T: + 32 °C, H: + 43 °C.

d) Repeat step 2 ten times with the compressor at its normal stable running temperature.

e) Reduce the voltage to – 22 percent of the nominal voltage, repeating steps 2 to 4 for each voltage.

f) 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.

**A-1.7.2** *Acceptance Criterion*

Ten out of ten starts must be successful in both cold start and hot start tests at a minimum of 22 percent below the manufacturer's nominal voltage.

**A-1.7.3** *Rejection Criterion*

One or more start failures.

**A-1.8 Test Criteria for Qualification**

**A-1.8.1** A final report must be issued after all testing is complete. The report of the tests must contain the following data and analyses.

**A-1.8.1.1** *Summary*

Conclusions and recommendations, including confirmation of the temperature zone(s) for which the product is suitable:

a) Comments on samples received, tabulated data on the type examination test and relevant photographs.

b) Results of cool-down test, including temperature graphs.

c) Results of stable running and consumption test, including temperature graphs.

d) Results of water-pack freezing capacity test (if relevant), including temperature graphs.

e) Results of holdover time test, including temperature graphs.

f) Results of day/night test, including temperature graphs.

g) Results of maximum water-pack freezing load test, including temperature graphs.

h) Results of compressor starting test.

**A-1.8.2** *Annexes*

Description of the test apparatus. Test chamber temperature records. Copy of reference thermometer calibration certificate(s). Diagrams showing the location and identification codes for temperature sensors, clearly distinguishing between sensors measuring vaccine, water-pack freezer and evaporator temperatures. Additional supporting documentation requested and received from the Legal Manufacturer or Reseller during the course of the type-testing.

**A-1.9 Quality Control Standard**

All testing and reporting must be carried out in accordance with the requirement of IS/IEC/ISO 17025 : 2017.

## ANNEX B

**(** *Annex A*-1.2 **)**

**B-1 GENERAL TEST CONDITIONS**

**B-1.0** The following conditions are applicable to all refrigerator and freezer tests.

**B-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, **8.2**.

b) Maximum test chamber temperatures of M: + 27 °C, T: + 32 °C and H: + 43 °C are 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 product manufacturer before the test commences.

d) Temperatures within the appliance must be continuously monitored to an accuracy of ± 0.5ºC without the presence of the sensors influencing the test in any way. Thermocouples that are sealed within the appliance are most commonly used. Up to 15 simultaneous temperature measurements may be required for a single appliance. The suggested temperature sensor locations are shown in Annex C and Annex D 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.

## B-2 STABILIZATION TIMES

**B-2.1** Before measuring the performance of a refrigerator or freezer under normal running conditions, temperature conditions inside the appliance must be stable.

**B-2.2** 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.

## B-3 VACCINE STORAGE CAPACITY MEASUREMENT

a) Measure vaccine storage capacity using cardboard boxes, plastic foam or wooden blocks, 100 × 100 × 100 mm and 100 × 100 × 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.

## B-4 RECORDING TEMPERATURES

a) Test appliances, either loaded or empty, as described above in the verification protocol.

b) Take temperature readings once per minute.

## B-5 SENSOR PLACEMENT

a) Place sensors at the centre of the vaccine load compartment and 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 as in Annex C sensor position diagrams and note.

b) 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.

c) After initial setup, do not alter the position of sensors during subsequent tests.

d) Where sensors are located in the vaccine storage compartment place them within the volume designated by the manufacturer for vaccine storage.

e) Where vaccine storage baskets are supplied with the appliance, fix sensors within the volume(s) defined by the internal faces of the basket(s).

f) Monitor all sensors so that an overall picture of the temperature distribution can be obtained.

g) Where applicable, the following points should also be monitored:

1) Surface temperature of evaporator plates;

2) Flue temperature; and

3) Condenser fins or outer skin temperatures.

## B-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 liters (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 storage capacity in liters 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 liter).

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.

### B-6.1 Front-opening Appliances

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

### B-6.2 Top-opening Refrigerators

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

b) 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.

### B-6.3 Top-opening Freezers

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

### B- 6.4 Water-packs

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

### B-6.5 Dual Compressor Units

Both compressors should be switched on during all tests.

# ANNEX C

( *Annex A*-1.6, *Annex B*-1.1, *Annex B*-5.0 )

## TEMPERATURE SENSOR POSITIONS

Approximate sensor positions are indicated by the figures. Except for sensors placed centrally in a compartment, the center of sensors should be placed 50 ± 10 mm away from the lining of the water-pack freezing compartment or vaccine storage compartment. If baskets are used for vaccine storage, the sensors should be located inside the basket(s) but not touching the basket material.

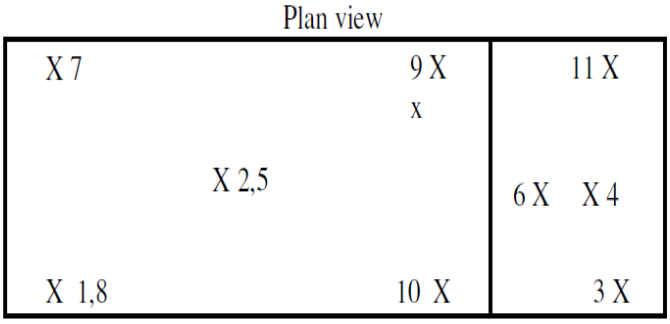


*Figure 2: Chest freezers*

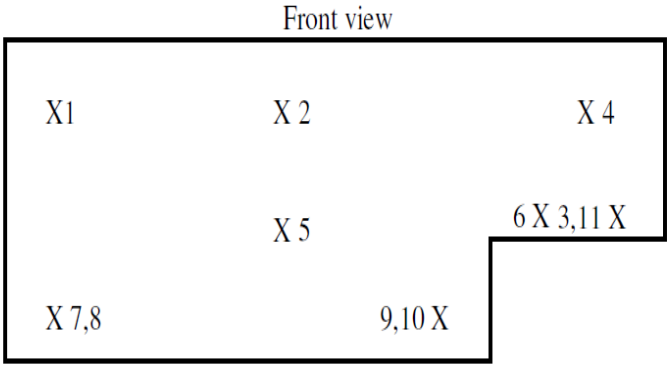


*Figure 3: Water-pack fast freezers*

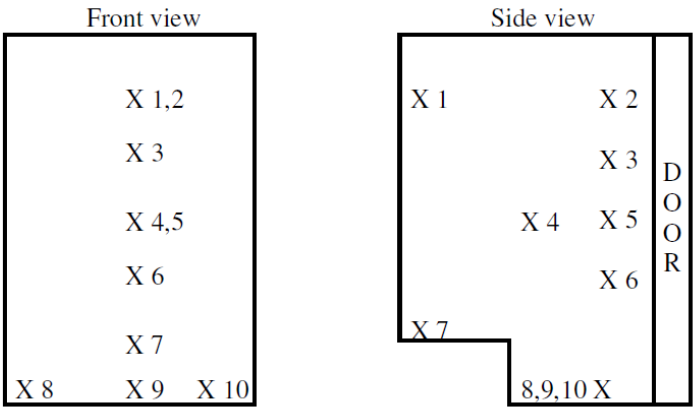


FIG. 1 POSITON OF TEMPERATURE SENSORS

# ANNEX D

( *Annex B*-1.1 )

## TEMPERATURE SENSOR SPECIFICATION

Probe, accurate to ± 0.5 °C, inserted into brass or tin-covered copper mass of 25 g ± 5 percent and of minimum external area (diameter = height = about 15.2 mm).

# ANNEX E

(*Clauses* 4.6.1, 4.6.6.1 *and* 4.6.6.2 )

## TEMPERATURE ZONE SYMBOL FOR FREEZERS

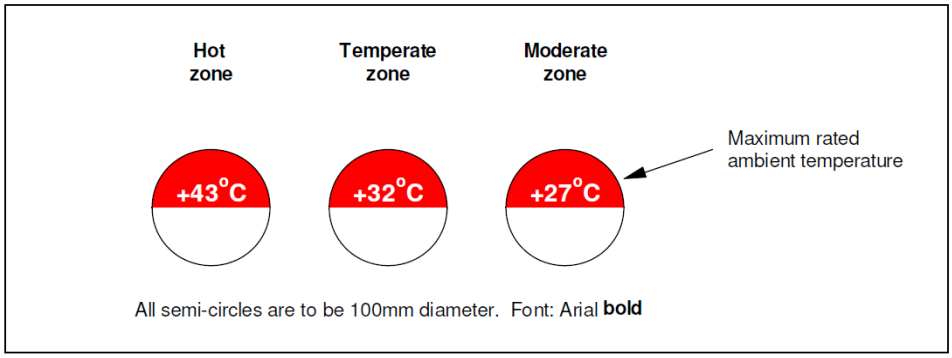


FIG. 2 SYMBOLS OF TEMPERATURE ZONES

# ANNEX F

( *Clauses* 8.3.3 *and* 12.1.4 )

## REFRIGERANT SYMBOLS

**Refrigerant label**

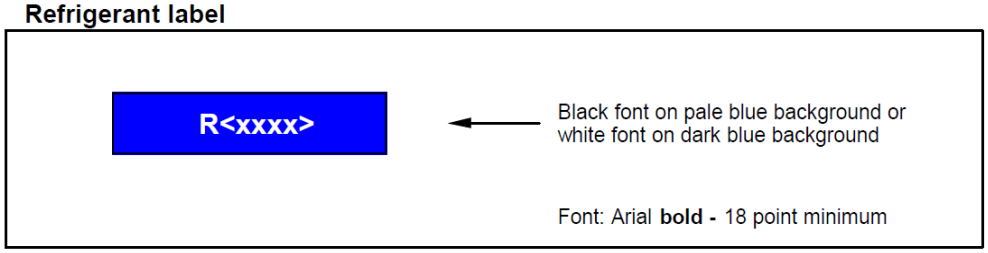


FIG. 3 REFRIGERANT LABEL

**R600a warning symbol**

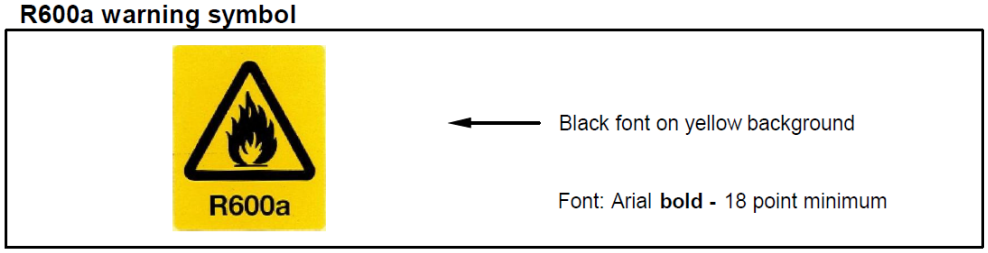


FIG. 4 REFRIGERANT WARNING SYMBOL

# ANNEX G

( *Clauses* 9, *Clause* 12.2.1 )

## G-1 ALCOHOL STEM THERMOMETER

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

### G-1.1 Power Source

Sensor: Coloured alcohol in glass column.

### G-1.2 Physical Characteristics

**G-1.2.1** *Overall Dimensions*: Maximum 200 × 25 × 25 mm.

**G-1.2.3** *Weight*: Not critical, provided the product is fully portable.

### G-1.3 Temperature Ranges and Accuracy

Upper limit: + 50 °C; Lower limit: – 30 °C; Accuracy: + 1 °C

### G-1.4 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; and

n) Colour of markings: dark blue or black on a white background.

### G-1.5 Environmental Requirements

**G-1.5.1** *Ambient Temperature Range During Transport*: – 50 °C to + 55 °C.

**G-1.5.2** *Ambient Humidity Range During Transport and Use:* 0 to 95 percent RH.

**G-1.5.3** *Maximum Relative Humidity*: 90 percent.

**G-1.5.4** *Resolution*: Resolution: ± 0.5 °C or better within the range – 30 °C to + 20 °C.

**G-1.5.5** *Casing Specification*: Non-corrodible, sealed mechanism.

**G-1.5.6** *Vibration Test*: Product should stand 30 min on a programmable vibrating table without physical damage or calibration.

### G-1.6 Impact Resistance

Product to withstand 5 drops from 1 metre onto a concrete floor without physical damage or loss of calibration.

#### G-1.6.1 *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.

#### G-1.6.2 *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.

#### G-1.6.3 *IP Rating*

Protection of the product not less than IS/IEC 60529 : 2001.

# ANNEX H

( *Foreword* )

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