

PQS performance specification

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1. Scope:

This specification defines the requirements for voltage stabilizers suitable for alternating current (ac) powered electric refrigerators and freezers.

2. Normative references

Use the most recent version of these standards. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EMAS: European Union Eco-Management and Audit Scheme.

IEC 60068-2-6 (2007): Environmental testing – Part 2-6: Tests – Test Fc: Vibration (sinusoidal)

IEC 60335-1:2010+AMD1:2013+AMD2:2016 CSV: Household and similar electrical appliances - Safety - Part 1: General requirements.

IEC 61000-6-3 Edition 2.1 (2011): Electromagnetic compatibility (EMC) - Part 6-3: Generic standards - Emission standard for residential, commercial and light-industrial environments.

IEC 61000-6-1 Edition 3 (2016): *Electromagnetic compatibility (EMC) – Part 6-1:* Generic standards - Immunity for residential, commercial and light-industrial environments.

IEC 61000-3-2 Edition 4.0 (2014): Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current \leq 16 A per phase)

ISO 9001 (2015): Quality Management Systems – Requirements.

ISO 14001 (2015): Environmental management systems - Requirements with guidance for use.

ISO/IEC 17025 (2005): General requirements for the competence of testing and calibration laboratories.

ISO 20282-1 (2006): Ease of operation of everyday products - Part 1: Context of use and user characteristics.

IEC 60417-5017 (2002): Graphical symbols for use on equipment – Ground label

IEC 60947-4-1:2009+AMD1:2012 CSV: Low-voltage switchgear and control gear-Part 4-1: Electromechanical contactors and motor-starters.

IEC 60898-1 (2015): Electrical accessories – Circuit-breakers for overcurrent protection for household and similar installations – Part 1: Circuit-breakers for A.C. operation

Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC.

IEC 60085 (2007): Electrical insulation – Thermal evaluation and designation.

3. Terms and definitions:

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

<u>Legal Manufacturer</u>: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

<u>Reseller</u>: A commercial entity, licensed to act on behalf of a <u>Legal Manufacturer</u>, and which carries product liability and warranty responsibilities no less onerous than those carried by the <u>Legal Manufacturer</u>.

<u>Under-voltage</u>: An abnormal decrease in the root mean square value of the input voltage from the nominal value for a period longer than half a cycle of the nominal input waveform.

Over-voltage: An abnormal increase in the root mean square value of the input voltage from the nominal value for a period longer than half a cycle of the nominal input waveform.

<u>Electrical withstand</u>: The root mean square value of the maximum input voltage that the device is able to continuously tolerate without any form of electrical or mechanical damage.

<u>Impulsive transient</u>: A sudden, non–power frequency change in the steady-state condition of voltage, current, or both that is unidirectional in polarity – either primarily positive or negative. Often characterized by extremely high voltages that can drive high levels of current into an electrical circuit for periods ranging from a few millionths to a few thousandths of a second.

Overload: A situation where an electrical device is subjected to a greater electrical load than what it was designed for. Results in larger than design electric current passing through conductors, leading to excessive generation of heat, and the risk of fire or damage to equipment

<u>Short circuit</u>: An accidental electrical circuit in a device with no or low resistance when compared to that of the normal circuit, especially one resulting from the unintended contact of components and consequent accidental diversion of current.

4. Requirements:

4.1 General:

A voltage stabilizer is designed to reduce fluctuations in input voltage and frequency, and to thereby ensure a stable electricity supply for refrigerators and freezers in situations where the supply voltage is subject to wide fluctuations. The device must be compatible with compression cycle, electric-gas absorption cycle and thermoelectric equipment. Alternative supply voltage and frequency combinations are also covered.

4.2 <u>Performance:</u>

4.2.1 Mode of operation:

Both electronic and tap-changing technologies may be offered, but the device must be substantially maintenance-free. Products that incorporate cooling fans are not acceptable because of the maintenance issues involved in keeping the airways clear.

4.2.2 Nominal input and output voltage and frequency:

The device must provide one or more of the following three output voltage and frequency combinations when connected to an electric supply with one or more of the following nominal supply frequencies and voltage ranges. Note that the "230/50-60: Extended" type is required to tolerate a wider range of input voltages (see Section 4.2.3). This type is recommended for countries with wider input voltage fluctuations.

Туре	Nominal supply (input)	Nominal output voltage & frequency (stand-alone)	Nominal output voltage & frequency (integrated)
120/50-60	110, 115, 120, 127 volt; 50-60 Hz	120 volt; 50-60 Hz	
230/50-60	220, 230, 240 volt; 50-60 Hz	230 volt; 50-60 Hz	To be specified by the manufacturer
230/50-60: Extended	220, 230, 240 volt; 50-60 Hz	230 volt; 50-60 Hz	

The purchaser should preferably be able to specify the nominal supply voltage within one of these three voltage/frequency bands so that the manufacturer can optimize the product before delivery.

4.2.3 Input voltage fluctuations:

The device must correct (i.e., continue supplying nominal output voltage and frequency, as specified in Section 4.2.2) within the following minimum ranges of input voltage fluctuation:

Туре	Minimum input voltage regulation range
120/50-60	82-159 volt
230/50-60	173-278 volt
230/50-60: Extended	110-278 volt

Note: The actual voltage range within which the device is able to supply nominal output voltage and frequency, as specified in Section 4.2.2, may be larger than the minimum voltage range specified above.

4.2.4 Voltage Protection:

Under or Over-voltage:

The device output must be isolated (i.e. switched to 0 volt) at the limits of the manufacturer specified input voltage regulation range within which nominal output voltage and frequency, as specified in Section 4.2.2, can be supplied. When the input voltage is restored to a value within the applicable input voltage regulation range as specified by the manufacturer, the output supply of 120 or 230 volt must be restored automatically after a delay of three to six minutes.

Electrical withstand:

The device must be able to withstand (i.e., without suffering any form of electrical or mechanical damage or failure) the following minimum ranges of continuous input voltage levels:

Type	Minimum continuous input voltage range
120/50-60	40-220 volt
230/50-60	100-415 volt
230/50-60: Extended	60-415 volt

Note: The actual voltage range that the device is able to continuously withstand may be larger than the minimum voltage range specified above.

After an under or over voltage event, output power must automatically be restored (i.e. with no user intervention needed) when supply voltage is returned to within the manufactured specified input voltage regulation range within which nominal output voltage and frequency, as specified in Section 4.2.2, can be supplied.

Impulsive Transients:

The device must be equipped with an impulsive transient protection system capable of protecting the system to the following minimum specifications, allowing the device to continue operating after a maximum rated impulsive transient event without any form of mechanical or electrical failure, damage or arc flash between conductors and/or components:

Туре	Maximum continuous operating voltage (MCOV)	Nominal Discharge Current (I _n , 15 x impulses, tested with a 8/20µs pulse current waveform)	Maximum Discharge Current (I _{max} , 1 x impulse, tested with a 8/20μs pulse current waveform)
120/50-60	220 volt or above	2kA or above	8kA or above
230/50-60	415 volt or above	2kA or above	8kA or above
230/50-60:	415 volt or above	2kA or above	8kA or above
Extended			

All residual voltage impulsive transients, after passing through the voltage stabilizer and onto the load under full boost condition, must have peak amplitudes less than the following when tested with a nominal discharge current (I_n) impulsive transient (waveform 8/20µs):

Type	Maximum residual voltage
120/50-60	600 volt or below
230/50-60	1000 volt or below
230/50-60: Extended	1000 volt or below

Overload:

The device must disconnect from mains power within the following maximum disconnect time when connected to a load that exceeds the maximum rated capacity of the device by the corresponding overload factor (rated capacity x overload factor):

Maximum disconnect time	Overload factor
120 seconds	1.5
10 seconds	7.2

Note: This is an adapted version of similar guidance according to IEC 60947-4-1 Class 10A

It must be possible to manually reconnect to mains power when the overload condition has been resolved, with the requirement that a minimum of three to six minutes should have elapsed since disconnection from mains power. Automatic reconnect is not allowed.

Short Circuit:

The device must disconnect from mains power within 100ms in the event of a short circuit occurring downstream from the device, with instantaneous tripping current characteristics corresponding to Type C circuit protective devices as stipulated in IEC 60898-1.

It must be possible to manually reconnect to mains power when the short circuit has been resolved, with the requirement that a minimum of three to six minutes should have elapsed since disconnection from mains power. Automatic reconnect is not allowed.

4.2.5 Capacity rating:

Stand-alone devices must be rated at a minimum of 1.0 kVA peak load. Integrated devices (i.e., with the voltage stabilizer fully integrated into the design and manufacture of the refrigerator) no minimum rating is specified and this is left to the manufacturer to decide what rating best suits the equipment. Under fully rated load conditions there must be 10 successful starts out of 10.

4.2.6 Input frequency fluctuations:

The device must tolerate mains input frequency fluctuations up to \pm 3.0 Hz continuously, \pm 4.0 Hz up to an hour, \pm 5.0 Hz for 10 minutes. This is an adapted version of similar guidance from EN 60950 standards.

4.2.7 Output voltage accuracy:

Maximum plus (+) 10% or minus (-) 15% of the nominal output voltages set out in the table in clause 4.2.2, zero to full load, over the full input voltage regulation range specified by the manufacturer within which nominal output voltage, as specified in Section 4.2.2, can be supplied. This is to be tested in accordance to the EN 60950 standards.

4.2.8 Corrosion resistance of enclosure:

Legal Manufacturer to certify compliance that internal and external cabinet, lid and frame are protected against corrosion as appropriate to EN ISO 6270-1 / ASTM D2247 / EN 13523-26 Determination of resistance to humidity – Part 1: Continuous condensation, EN ISO 6270-2 / EN 13523-25 Determination of resistance to humidity - Part 2: Procedure for exposing test specimens in condensation-water atmospheres, ISO 6272 / EN 13523-5 Impact resistance

– external cabinet, and ISO 2409: 2013: Paints and varnishes – cross cut test (external cabinet).

4.2.9 Insulation materials:

Legal manufacturer to certify that electrical insulation materials used in device construction complies with Class 180 (H) or higher, as specified in IEC 60085.

4.2.10 Electrical safety:

Manufacturer to certify compliance with IEC 60335-1.

4.2.11 Electromagnetic compatibility:

To ensure product meets EMC emissions requirements, Legal Manufacturer must certify compliance to the latest version of IEC 61000-6-3.

To ensure product meets EMC immunity requirements, Legal Manufacturer must certify compliance with the requirements of the latest version of IEC 61000-6-1.

To ensure product meets EMC harmonic distortion requirements where appropriate, Legal Manufacturer must certify compliance with the requirements of the latest version of IEC 61000-3-2.

4.2.12 Robustness:

Electrical:

The device must reliably operate under a 100% (or continuous) duty cycle.

Mechanical:

The device, when packaged in the manufacturer's standard packaging material, must withstand the vibration tests specified in IEC 60068-2-6 as well as the mechanical strength tests specified in IEC 60950-1 (Clause 4.2) and thermal requirements specified in IEC 60950-1 (Clause 4.5) without suffering mechanical damage or functional failure.

4.2.13 Protection against dust and water ingress:

A stand-alone device that is not part of the refrigerator design may be installed in dusty environments. The design of the enclosure should ensure that the device is not damaged by dust penetration. A minimum of IP21 rating is required. This IP rating requirement does not apply for devices that are integrated into the refrigerator design (i.e., within the body of the refrigerator).

4.2.14 Markings:

For all stand-alone devices that are not part of the refrigerator design, the device enclosure must be clearly marked to show the following:

- Nominal input voltage and frequency.
- Nominal output voltage and frequency.
- kVA rating.

The top of the device enclosure must also carry a waterproof label carrying the

following user information in minimum 18-point lettering and in the language requested in the order:

- 'Voltage stabilizer for compression cycle, electric-gas absorption cycle and thermoelectric refrigerators and freezers'.
- 'DO NOT connect more than one appliance'.

In case of metal enclosed devices, all grounding terminals on the enclosure must be identified with symbol IEC 60417-5017.

<u>Note</u>: These markings are not necessary for integrated devices (i.e., incorporated into the body of the refrigerator).

4.3 Environmental requirements:

4.3.1 Ambient temperature range during transport, storage and use:

-30°C to +70°C when the product is inactive.

-5°C to +43°C during use.

4.3.2 Ambient humidity range during transport, storage and use:

5% to 95% RH, non-condensing.

4.4 Physical characteristics:

4.4.1 Overall dimensions:

No restrictions.

4.4.2 Weight:

No restrictions.

4.5 <u>Interface requirements:</u>

4.5.1 Compatibility with electronic circuits:

Vaccine refrigerators and freezers may contain non-adjustable electronic thermostats and electronic thermometers. The voltage stabilizer must not allow supply disruptions and/or voltage fluctuations which could damage such components to pass through to the refrigerator or freezer.

4.5.2 Power lead:

The product is to be supplied with a power lead with a sealed-on plug. The power lead must be at least 1.5 meter in length. Both the plug and the output socket mounted on the device must be compatible with the electricity socket standard in the country where the equipment is to be installed.

4.6 Human factors:

4.6.1 *Generally:*

The product must be designed for use by untrained personnel, in accordance with

the general principles laid out in ISO 20282-1. In particular, indicator lights and indicator light labelling must be designed so that interpretation is not confusing for colour blind users.

4.6.2 Control panel:

The device must incorporate an LED that conveys when the input voltage is within the ranges specified in Clause 4.2.2. Voltmeters or indicator lamps should be positioned on the front or top of the unit.

4.7 Materials:

4.7.1 Restricted materials:

The product and its constituent components must not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated biphenyl ethers (PBDE).

4.8 Warranty:

The product is to be covered by a two year replacement warranty in the event of any component failure arising from defective design, materials or workmanship.

4.9 <u>Servicing provision:</u>

The product is to be designed to achieve a maintenance-free life of not less than 10 years, apart from occasional cleaning and the replacement of user-accessible fuses, if any.

4.10 Disposal and recycling:

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

4.11 <u>Instructions:</u>

User and maintenance instructions are required to be available in Arabic, Mandarin Chinese, English, French, Russian and Spanish. The instructions are to be written for users and repair technicians and are to cover the following topics:

- installation procedures;
- interpretation of indicator lamps or LEDs;
- routine maintenance tasks;
- diagnostic and repair procedures, including replacement of accessible fuses, if any;
- itemized list of spare parts including part numbers;
- end-of-life resource recovery and recycling procedures.

4.12 <u>Training:</u>

Not required.

4.13 Verification:

In accordance with PQS Verification Protocol E07/VS01-VP.4.

5. Packaging:

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

6. On-site installation:

Not required.

7. Product dossier:

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

- Dossier examination fee in US dollars.
- General information about the legal manufacturer, including name and address.
- Unique identification reference for the product type.
- Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability.
- Photographs of the product clearly showing all sides of the device, including indicator lights and product identification labelling.
- Certified photocopies of all type-approvals obtained for the product, including CE marking and the like.
- Certified photocopies of the legal manufacturer's ISO 9001 quality system certification.
- Where relevant, certified photocopies of the legal manufacturer's ISO 14001 certification, EMAS registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is not mandatory; however preference will be given to manufacturers who are able to demonstrate compliance with good environmental practice.
- Certified photocopies of the testing laboratory's ISO/IEC 17025 certification.
- Where available, laboratory test report(s) proving conformity with the product specifications.
- Indicative cost of the product per unit, EXW (Incoterms 2010).

8. On-site maintenance:

Maintenance will be carried out by the end-user and/or his agents.

9. Change notification:

The legal manufacturer or reseller is to advise WHO in writing of any changes which adversely affect the performance of the product after PQS prequalification has taken place.

10. Defect reporting:

The legal manufacturer or reseller is to advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events.

Revision history:

Date	Change summary	Reason for change	Approved
September 2017	4.1 Inclusion of requirement to be compatible with thermoelectric equipment	To cover new technology type recently allowed by PQS	IG
	4.2.3 Format of table changed to more concisely reflect fluctuation range. Inclusion of note to clarify that wider range is acceptable.		IG
	4.2.4 Removal of "Spikes" clause	Feedback from the field and input from manufacturers	IG
	4.2.4 Renaming of "Surges" clause to "Under or Over-voltages"	To better reflect IEC conventions for electrical events	IG
	4.2.4 Inclusion of electrical withstand requirement to specify reliable operation under extreme under and over-voltages	Feedbackfrommanufactures	IG
	4.2.4 Inclusion of impulsive transient protection requirement to specify minimum level of protection against such transients	Feedback from manufacturers	IG
	4.2.4 Inclusion of overload protection requirement to specify minimum level of protection against such events	Feedback from manufacturers	IG
	4.2.4 Inclusion of short circuit protection requirement to specify minimum level of protection against such events	Feedback from manufacturers	IG
	4.2.7 Additional nomenclature added to better describe voltage accuracy requirement		IG
	4.2.9 Inclusion of minimum requirement for electrical insulation materials	To better reflect minimum temperature resistance requirements	IG
	4.2.12 Inclusion of 100% duty cycle requirement	To better reflect minimum electrical robustness requirements	IG
	4.2.13 Inclusion of ground label requirement for devices with metal enclosures	To better reflect minimum grounding safety requirements	IG
	4.3.1 Modified ambient temperature from 45°C to 43°C	To be in line with maximum ambient operating temperatures required for refrigerators/freezers	IG
	4.5.2 Removal of maximum cable length limit	To allow manufacturers to determine optimal cable length independently	IG

	4.11 Inclusion of requirement to clarify indicator lamp or LED interpretation in user instructions		IG
October 2016	4.2.2 Referral to number of frequency bands changed from four to three		IG
	4.2.3 Change in minimum and maximum input voltages	Feedback from manufacturers	IG
	4.2.4 Change in wording to reflect spike and surge protection modes. Wording updated to refer to manufacturer's input voltage range.	To better reflect practical situation	IG
	4.2.7 Change in output voltage accuracy. Updated wording to refer to manufacturer's input voltage range.	Feedback from manufacturers and to better reflect the minimum protection standard specified by this document	IG
	7. Additional clause requiring submission of copies of ISO/IEC 17025 certification.	Quality verification of testing laboratory	IG
December 2015	4.1 Language changed to reflect both the purpose and the functioning of voltage stabilizers		IG
	4.2.2 Number of output voltage and frequency combinations reduced from 4 to 3. Addition of the extended type	Feedback from the field and input from manufacturers	IG
	4.2.3 Change in the output voltage/frequency combinations from 4 to 3	Feedback from the field and input from manufacturers	IG
	4.2.4 Change in the wording to reflect compliance with IEC 61643-1Standards	Feedbackfrommanufactures	IG
	4.2.5 Change of wording to cover separate requirements for both standalone and integrated devices	To better reflect practical situation	IG
	4.2.6 Additional clause to reflect the duration sensitivity to frequency changes	Feedback from manufacturers	IG
	4.2.12 Additional clause to include minimum accepted IP rating for standalone voltage stabilizers	Feedback from manufacturers	IG
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