

TITLE: Single-phase voltage protection for ac and dc powered refrigerators and freezers	
Specification reference:	E007/VS01.6
	E_{007}/V_{001} VD ϵ

Protocol reference:	E007/VS01-VP.6	
Issue date:	July 10, 2022	
Date of last revision:	March 5, 2018	

Contents

_

1.	Scope	
2.	Norma	tive References
3.	Terms	and definitions
4.		ements
	-	ements
-		rformance
Т	4.2.1	Mode of operation
	4.2.2	Nominal input and output voltage and frequency
	4.2.3	Input voltage fluctuations
	4.2.4	Voltage Protection
	4.2.5	Capacity rating
	4.2.6	Input frequency fluctuations
	4.2.7	Output voltage accuracy
	4.2.8	Fuses
	4.2.9	Load power factor effect
	4.2.10	Waveform and distortion
4	.3 Ma	aterials and construction
	4.3.1	Corrosion resistance of the enclosure
	4.3.2	Insulation materials
	4.3.3	Restricted materials
	4.3.4	Electrical safety 11
	4.3.5	Electromagnetic compatibility
	4.3.6	Robustness11
	4.3.7	Protection against solids and water ingress 11
	4.3.8	Markings
	4.3.9	Efficiency
4	.4 En	vironmental requirements
	4.4.1	Ambient temperature range during transport, storage, and use
	4.4.2	Ambient humidity range during transport, storage, and use
4		ysical characteristics
	4.5.1	Overall dimensions
	4.5.2	Weight
4		erface requirements
	4.6.1	Compatibility with electronic circuits

	4.6.2	Power lead	13
	4.6.3	Power output	13
4	.7 H	Iuman factors	14
	4.7.1	Generally	14
	4.7.2	Control panel	14
4	.8 V	Varranty	14
4	.9 S	ervicing provision	14
4	.10 S	pare parts	14
4	.11 D	Disposal and recycling	14
4	.12 In	nstructions	15
4	.13 T	raining	15
4	.14 V	verification	15
5.	Packa	aging	15
6.	On-si	te installation	15
7.	Produ	ıct dossier	15
8.	On-si	te maintenance	16
9.	Chan	ge notification	16
10.	Defec	t reporting	16
Rev	vision I	History	17

1. Scope

This specification defines the requirements for single-phase voltage stabilizers suitable for protecting alternating current (AC) powered electric refrigerators and freezers. Alternative supply voltage and frequency combinations including AC-to-DC switched-mode power supplies (SMPS) are also covered.

Both voltage stabilizers and SMPS may be built into appliances they are intended to protect or may be provided as standalone devices. Relevant requirements for standalone, integrated and dedicated stabilizer solutions are noted within this specification.

For integrated protection devices, the legal manufacturer or reseller of a voltage stabilizer or SMPS may obtain prequalification for that protection device. Appliance manufacturers wishing to integrate prequalified protection devices may rely on this prequalification and are not required to conduct the testing described herein.

2. Normative References

Use the most recent version.

CISPR 14-1: 2020 Electromagnetic compatibility - Requirements for household appliances, electric tools, and similar apparatus - Part 1: Emission CISPR 14-2: 2020 Electromagnetic compatibility - Requirements for household appliances, electric tools, and similar apparatus - Part 2: Immunity - Product family standard

EMAS: European Union Eco-Management and Audit Scheme.

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

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

IEC 60335-1: 2015 Household and similar electrical appliances - Safety - Part 1: General requirements.

IEC 60417-5017: 2006 Graphical symbols for use on equipment – Ground label IEC 60898-1: 2015 Electrical accessories – Circuit-breakers for overcurrent protection for household and similar installations – Part 1: Circuit-breakers for A.C. operation IEC 60947-4-1: 2018 Low-voltage switchgear and control gear - Part 4-1: Contactors and

motor-starters - Electromechanical contactors and motor-starters IEC 61000-3-2,3: 2018 Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current \leq 16 A per phase); Part 3-3: Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current \leq 16 A per phase and not subject to

conditional connection

IEC 61000-4-5: 2014 Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge immunity test

IEC 61000-6-1: 2019 Electromagnetic compatibility (EMC) – Part 6-1: Generic standards - Immunity for residential, commercial, and light- industrial environments.

IEC 61000-6-3: 2020 Electromagnetic compatibility (EMC) - Part 6-3: Generic standards - Emission standard for residential, commercial, and light-industrial environments.

IEC 61204-3: 2018 Low-voltage switch mode power supplies - Part 3: Electromagnetic compatibility

IEC 61204-7: 2016 Low-voltage switch mode power supplies - Part 7: Safety requirements

IEC 62321-8: 2017 Determination of certain substances in electrotechnical products - Part 8: Phthalates in polymers by gas chromatography-mass spectrometry (GC-MS), gas chromatography-mass spectrometry using a pyrolyzer/thermal desorption accessory (Py-TD-GC-MS)

ISO 2859: 2020 Sampling procedures for inspection by attributes

ISO 3951: 2013 Sampling procedures for inspection by variables

ISO 9001: 2015 Quality Management Systems – Requirements.

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

ISO/IEC 17025: 2017 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.

RoHS 3: Restrictions on Hazardous Materials Directive 2015/863

3. Terms and definitions

Appliance: Cold-chain equipment (CCE), e.g. refrigerators or freezers, intended to be protected by voltage stabilizers.

Dedicated voltage stabilizer: A stabilizer model integrated into the appliance for use with a specific product. The stabilizer cannot be removed from the appliance and therefore

must be tested with the complete appliance. See Integrated and Standalone voltage stabilizers.

Electrical withstand: The root mean square (RMS) value of the maximum input voltage that the device can continuously tolerate without any form of electrical or mechanical damage.

Impedance: The effective resistance of an electric circuit or component to alternating current, arising from the combined effects of ohmic resistance and reactance.

Impulsive transient: 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 milliseconds to a few microseconds.

Integrated voltage stabilizer: A stabilizer model integrated into the appliance for general use or for use with specific products. The stabilizer can be removed from the appliance and be operated separately from the appliance for testing. See Dedicated and Standalone voltage stabilizers.

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

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

Over-voltage: Root mean square voltage greater than or equal to 110% of the nominal value for a period longer than a half cycle of the nominal input waveform.

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.

Reseller: A commercial entity, licensed to act on behalf of a legal manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the legal manufacturer.

Rated current: Maximum continuous current at which the device is intended to safely operate.

Rated frequency: The nominal design frequency for safe operation of the device. Rated voltage: The nominal design voltage for safe operation of the device.

Short circuit: 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. SMPS: Switched mode power supply.

Standalone voltage stabilizer: A stabilizer model external from the appliance for general use or for use with specific products. See Dedicated and Integrated voltage stabilizers. Under-voltage: Root mean square voltage less than or equal to 90% of the nominal value for a period longer than a half cycle of the nominal input waveform.

4. Requirements

4.1 General

A voltage stabilizer is designed to reduce fluctuations in input AC voltage and frequency, and to thereby ensure a stable electricity supply for refrigerators and freezers in environments without reliable, safe power. A switched mode power supply (SMPS) serves a similar purpose but converts AC to DC power for a DC-powered appliance. Both types of devices shall be compatible with compression cycle, electric-gas absorption cycle, Stirling, and thermoelectric equipment.

4.2 <u>Performance</u>

4.2.1 Mode of operation

Both electronic and tap-changing technologies may be offered, but the device shall be substantially maintenance-free. AC-to-AC voltage stabilizers and SMPS that incorporate cooling fans are not acceptable because of the maintenance issues involved in keeping the airways clear. Devices that incorporate a SMPS to convert voltage and current from an AC source to a DC load are permitted.

4.2.2 Nominal input and output voltage and frequency

The device shall provide one or more of the following output voltage and frequency combinations when connected to an electric supply with one or more of the following nominal supply frequencies and voltage ranges. All devices shall operate with rated frequencies of 50-60 Hz. No devices are allowed that operate at only 50 or 60 Hz. Note that the "230/50-60: Extended" type is required to correct a wider range of input voltages (see Clause 4.2.3). This type is recommended for countries with wider input voltage fluctuations. Devices capable of operating at both 120 V and 230 V, 50-60 Hz nominal inputs are allowed, but verification testing shall be conducted at both these inputs for all tests.

Туре	Nominal supply (input)	Nominal output voltage and frequency (standalone)	Nominal output voltage and frequency (integrated and dedicated)
120/50-60	110, 115, 120, 127 V	120 V ac	
	50-60 Hz	50-60 Hz	
230/50-60	220, 230, 240 V	230 V ac	To be specified by the
	50-60 Hz	50-60 Hz	Legal Manufacturer
230/50-60:	220, 230, 240 V	230 V ac	
extended	50-60 Hz	50-60 Hz	
SMPS*	100 V to 240 V	12, 24, 36, or 48 V	
	50-60 Hz	dc	

*Specific, allowable DC voltage outputs are listed. Legal manufacturer to specify the specific nominal output at the time of prequalification.

4.2.3 Input voltage fluctuations

The device shall continue supplying acceptable output voltage as specified in Clause 4.2.7 within the following ranges of input voltage fluctuation.

Туре	Input voltage regulation range
120/50-60	82-159 V ac
230/50-60	173-264 V ac
230/50-60: Extended	110-264 Vac
SMPS	85-264 V ac

<u>Note</u>: The device may supply acceptable output voltage as specified in Clause 4.2.7 for a broader range of input voltages than is specified above.

4.2.4 Voltage Protection

Under or Over-voltage:

Overvoltage is most likely to cause rapid damage and should be removed as fast as practicable. The device output shall be isolated (i.e. switched to 0 volt) at the limits of the range at which its output is maintained within the regulation range as specified in Clause 4.2.7. While a response time is not specified, the intent is that stabilizers prevent damage to loads, which may be robust motors, or may include more sensitive electronic power supplies.

When the input voltage is restored to a value within the applicable input voltage regulation range as specified by the legal manufacturer, the AC or DC output supply shall be restored automatically after a delay of three to six minutes. This delay requirement may be waived if the legal manufacturer or reseller of an integrated or dedicated voltage stabilizer or SMPS demonstrates via evidence and written explanation that a delay is unnecessary for the appliance it is intended to protect.

Electrical withstand:

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

Туре	Continuous input voltage withstand
	range
120/50-60	40-220 V ac
230/50-60	100-500 V ac
230/50-60: extended	60-500 V ac
SMPS	60-500 V ac

For all devices:

When exposed to voltages over the ranges in the table above, the surface temperature of a standalone stabilizer or SMPS tested in a 43°C ambient shall be limited to the lesser of 68°C and the operating temperature limit of the enclosure material. The first

limit is to prevent skin burns to users and the second limit is to ensure enclosure integrity. For integrated and dedicated stabilizers or SMPS, the exterior surfaces of the appliance containing the stabilizer shall likewise respect the same limits, and the temperature of any internal enclosures must stay below the operating temperature limit of the enclosure material.

For **SMPS**, also a dielectric strength test:

- I/P-O/P (Input to Output): 1.5 kV ac / 1 min
- I/P-F/G (Input to Protective Earth or "Ground"): 1.5 kV ac / 1 min
- O/P-F/G (Output to Protective Earth or "Ground"): 0.5 kV dc / 1 min

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

Impulsive transients:

The device shall be equipped with an impulsive transient suppression system capable of protecting the system from impulsive transients as described in **IEC 61000-4-5**. The device shall continue operating without any form of mechanical or electrical failure, damage, or arc flash between conductors and/or components. The device shall be tested to Installation Class 4:

- A single impulsive transient of ±4 kV applied line-to-neutral, with a source impedance of 2 ohms.
- Multiple impulsive transients of ±2 kV applied line-to-neutral, with a source impedance of 2 ohms.
- Multiple impulsive transients of ±4 kV applied line-to-ground, with a source impedance of 12 ohms.
- Multiple impulsive transients of ±4 kV applied neutral-to-ground, with a source impedance of 12 ohms.

All residual voltage impulsive transients, after passing through the voltage stabilizer and onto the load under full boost condition for ac stabilizers, shall have peak amplitudes less than the following during the ± 2 kV line-to-neutral test:

Туре	Maximum residual voltage
120/50-60	400 V peak or below
230/50-60	750 V peak or below
230/50-60: extended	750 V peak or below
SMPS	No greater than 3 times the set output
	voltage and return to the set output
	voltage within 2 milliseconds

Overload:

The device shall disconnect its output within the following disconnect times when connected to a load that exceeds the rated continuous output current capacity of the device by the corresponding overload percentages. The voltage stabilizer shall remain undamaged.

% of rated capacity (overload)	Shall disconnect within
150%	120 seconds
720%	10 seconds

Note: This is an adapted version of similar guidance according to **IEC 60947-4-1** Class 10A overload breaker tripping characteristics.

It shall be possible to reconnect manually or automatically to supply power when overload conditions less severe than a short circuit have been resolved. For automatic reconnection functionality, a delay of three to six minutes shall elapse between disconnection from supply power and automatic reconnection.

Dedicated stabilizers can be exempted from this disconnect requirement, provided that the legal manufacturer can demonstrate that the device contains safeguards to prevent overloading the dedicated stabilizer in the event of a malfunction or operation outside the designed operating environment.

Short Circuit:

For AC voltage stabilizers and SMPS, "short circuit" is defined as a load current greater than or equal to 1000% of the rated load current. The device shall disconnect its output within 100 msec in the event of a short circuit occurring at the output of the device, with instantaneous tripping current characteristics corresponding to Type C circuit protective devices as stipulated in **IEC 60898-1**.

It shall be possible to reconnect automatically or manually via the device to supply power when the short circuit has been resolved. Unplugging the device and plugging it back in is not an acceptable means of manually reconnecting for standalone stabilizers. Unplugging the appliance is an acceptable means of reconnecting for integrated and dedicated stabilizers because clearing a short circuit likely requires servicing the appliance, which is only safely accomplished by unplugging from mains. For automatic reconnection functionality, a delay of three to six minutes shall elapse between disconnection from supply power and automatic reconnection. Circuit breakers either on input side or the output side are acceptable. This delay requirement may be waived if the legal manufacturer of the voltage stabilizer or SMPS demonstrates via evidence and written explanation that a delay is unnecessary for the appliance it is intended to protect.

4.2.5 Capacity rating

Minimum continuous capacity ratings are specified for standalone AC and DC output devices. No minimum rating is specified for integrated and dedicated devices, and this is left to the legal manufacturer to decide what rating best suits the application. The voltage stabilizer shall be able to provide the fully rated load in 10 out of 10 simulated compressor start events.

Туре	Minimum continuous capacity rating (standalone)	Minimum continuous capacity rating (integrated and dedicated)
120/50-60	1000 VA (refrigerators and freezers)	To be specified by the legal
230/50-60	5 kVA (Cold/Freezer rooms only)	manufacturer
230/50-60:	10 kVA (Cold/Freezer rooms only)	
extended	15 kVA (Cold/Freezer rooms only)	
SMPS	200 watts	

4.2.6 Input frequency fluctuations

For AC devices, the device shall tolerate input frequency fluctuations between 47 and 63 Hz. The device shall cut off its output when the input frequency is less than 47 Hz or greater than 63 Hz unless it is of a type that can have a different output frequency than input frequency, in which case no frequency outside the range of 47-63 Hz should be detected at the output.

For SMPS, the device shall tolerate input frequency fluctuations between 45 and 65 Hz. Wider ranges are acceptable. The device shall cut off when the frequency is outside the legal manufacturer's specified frequency range.

For all devices, the output shall be automatically restored with an optional delay of three to six minutes when the frequency returns within the acceptable range.

When exposed to frequencies in the ranges above, the surface temperature of a standalone stabilizer or SMPS tested in a 43°C ambient shall be limited to the lesser of 68°C and the operating temperature limit of the enclosure material. The first limit is to prevent skin burns to users and the second limit is to ensure enclosure integrity. For integrated and dedicated stabilizers or SMPS, the exterior surfaces of the appliance containing the stabilizer shall likewise respect the same limits, and the temperature of any internal enclosures must stay below the operating temperature limit of the enclosure material.

4.2.7 Output voltage accuracy

For AC devices, the output voltage shall remain between plus (+) 10% and minus (-) 15% of the nominal output voltage in the table in Clause 4.2.2, when loaded from zero to full load, over the full input voltage regulation range specified by the legal manufacturer within which nominal output voltage, can be supplied.

For SMPS, the output voltage shall remain between plus (+) or minus (-) 5% of one of the nominal output voltages set out in the table in Clause 4.2.2, when loaded from zero to full load, over the full input voltage regulation range specified by the legal manufacturer within which nominal output voltage, as specified in Clause 4.2.2, can be supplied.

Dedicated voltage protection, both AC voltage stabilizers and SMPS, shall provide a way for test laboratories to measure the device's output voltage. If the legal manufacturer feels that its design should be exempt from output protection testing requirements due to the nature of the design, it may provide design information and data to justify that claim.

4.2.8 Fuses

Fuses may not be used as a means of protection because they require spare parts and enable protection to be defeated with improper fuses.

4.2.9 Load power factor effect

AC voltage stabilizers shall be designed in such a manner that they have no effect on system power factor (PF).

For **SMPS**, the device shall be equipped with a PF correction circuit to keep the magnitude of the power factor greater than or equal to 0.8.

4.2.10 Waveform and distortion

An AC-output voltage stabilizer shall have an output voltage waveform with less than 3% total harmonic distortion when supplied with a sine wave input voltage.

4.3 <u>Materials and construction</u>

4.3.1 Corrosion resistance of the enclosure

For standalone voltage stabilizers and SMPS, the legal manufacturer shall declare compliance that the external cabinet 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 – crosscut test (external cabinet). Evidence for compliance to this clause shall be demonstrated.

For integrated and dedicated voltage stabilizers and SMPS, the hardware and any enclosure material shall comply with the required performance specifications of the appliance within which it is integrated.

4.3.2 Insulation materials

Legal manufacturer to declare that electrical insulation materials used in device construction complies with Class 180 (H) or higher, as specified in **IEC 60085**. Evidence for compliance to this clause shall be demonstrated.

4.3.3 Restricted materials

The device shall comply with the Restrictions on **Hazardous Materials Directive 2015/863 (RoHS 3)**. The device and its constituent components shall not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated biphenyl ethers (PBDE).

4.3.4 Electrical safety

For AC voltage stabilizers, the legal manufacturer shall declare compliance with **IEC 60335-1**. Evidence for compliance to this clause shall be demonstrated in the form of a report from an accredited laboratory.

For SMPS, the legal manufacturer shall declare compliance with IEC 61024-7.

Evidence for compliance to this clause shall be demonstrated.

4.3.5 Electromagnetic compatibility

For AC voltage stabilizers, the legal manufacturer shall declare compliance with the requirements of the latest version of **IEC 61000-6-1** for EMC immunity requirements and **IEC 61000-6-3** for EMC emission requirements. Evidence for compliance to this clause shall be demonstrated.

For SMPS, the legal manufacturer shall declare compliance with the requirements of the latest version of **IEC 61204-3** and **CISPR 14-1** for EMC emission requirements and **CISPR 14-2** for EMC immunity requirements. Evidence for compliance to this clause shall be demonstrated.

4.3.6 Robustness

Electrical:

The device shall reliably operate at 100% of rated continuous capacity.

Mechanical:

The device, when packaged in the legal manufacturer's standard packaging material, shall withstand the vibration tests specified in **IEC 60068-2-6**. The device shall also withstand the mechanical strength tests specified in in **IEC 60335-1** (Clause 21) and thermal requirements specified in **IEC 60335-1** (Clause 30) without suffering mechanical damage or functional failure.

4.3.7 Protection against solids and water ingress

Voltage stabilizers and SMPS may be installed in environments that are dusty or humid, and enclosures may need to exclude rodents. Standalone devices shall have enclosures with a minimum **IP31** rating. If the solids ingress rating is not **IP5X** (dust

protected) or better, any printed circuit board assembly shall be protected by conformal coating or potting.

Devices intended to be integrated within appliances are not required to have an enclosure with a specific IP rating. However, if the combination of appliance enclosure and stabilizer enclosure does not achieve a solids ingress rating of **IP5X** or better, printed circuit board assemblies shall be protected by conformal coating or potting.

Manufacturers should consider coating guidelines in IPC document IPC-HDBK-830.

4.3.8 Markings

For all standalone devices that are not part of the appliance design, the device enclosure shall be clearly marked to show the following:

- Nominal input voltage and frequency.
- Nominal output voltage and frequency.
- kVA rating.
- Grounding/Earthing terminal marking (for metal enclosures only)
- Electric hazard warning

The top of the device enclosure shall 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 shall be identified with symbol **IEC 60417-5017**.

Note: These markings are not necessary for integrated or dedicated devices.

4.3.9 Efficiency

For SMPS devices, the operating efficiency shall be more than 90% at full rated load.

4.4 Environmental requirements

4.4.1 Ambient temperature range during transport, storage, and use

 -30° C to $+70^{\circ}$ C when the device is inactive. -5° C to $+43^{\circ}$ C during use. 4.4.2 Ambient humidity range during transport, storage, and use

5% to 95% RH, non-condensing.

4.5 <u>Physical characteristics</u>

4.5.1 Overall dimensions

No restrictions.

4.5.2 Weight

No restrictions.

4.6 Interface requirements

4.6.1 Compatibility with electronic circuits

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

4.6.2 Power lead

Standalone stabilizers and SMPS must be supplied with a power lead with a sealed-on plug that is compatible with the electricity socket in the country where the equipment is to be installed, and shall have a protective earth ("ground") connection. The power lead shall be at least 1.5 m in length.

Integrated and dedicated stabilizers and SMPS shall have a protective earth ("ground") connection, unless the appliance in which it is integrated has class II protection against electric shock as described in IEC 60335-1.

4.6.3 Power output

There shall be only one power outlet on the protection device. Devices with two or more outlets are not allowed.

The outlet on standalone ac voltage stabilizers shall be compatible with the electricity socket standard in the country where the equipment is to be installed and shall include a protective earth connection.

The output connection for standalone SMPS shall not be the same output socket used for AC applications. Protective earthing connections are also required.

4.7 <u>Human factors</u>

4.7.1 Generally

The device shall be designed for use by untrained personnel, in accordance with the general principles laid out in **ISO 20282-1**. Indicator lights and labelling shall be designed so that interpretation shall not be confusing for color-blind users.

4.7.2 Control panel

Standalone devices shall incorporate an LED that indicates when the input voltage is within the ranges specified in Clause 4.2.3. Voltmeters or indicator lamps shall be positioned on the front or top of the unit. An indicator is not mandatory for integrated or dedicated voltage stabilizers.

4.8 <u>Warranty</u>

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

If the voltage protection device is part of the appliance it is protecting (either integrated or dedicated), the voltage protection device shall be covered under the same warranty terms & conditions as the protected appliance.

4.9 <u>Servicing provision</u>

The device is to be designed to achieve a maintenance-free life of not less than 10 years, apart from occasional cleaning.

For dedicated and integrated stabilizers, all components providing voltage stabilization or protection functions shall be provided in a modular design that is easily replaceable by a trained technician, and such modules shall be commercially available as spare parts.

4.10 Spare parts

The legal manufacturer or reseller shall provide a list of recommended spare parts as part of the instruction manual, referencing local parts as much as possible. These spare parts shall be made available for purchase at the time of device procurement.

The legal manufacturer or reseller shall make anti-static wrist bands or other tools available to technicians to protect electronics under repair from electrostatic discharges.

4.11 Disposal and recycling

The legal manufacturer or reseller 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 **2012/19/EU** is mandatory. Test certification in compliance to **IEC 62321-8** is also acceptable.

4.12 Instructions

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

- installation procedures.
- interpretation of indicator lamps or LEDs.
- reconnection instructions if applicable.
- protection against electrostatic discharge and use of anti-static tools and/or or techniques.
- routine maintenance tasks.
- diagnostic and repair procedures.
- itemized list of spare parts including part numbers.
- end-of-life resource recovery and recycling procedures.

4.13 <u>Training</u>

Not required.

4.14 <u>Verification</u>

In accordance with PQS Verification Protocol WHO/PQS/E007/VS01-VP.6.

5. Packaging

Materials used for packaging the finished device 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 prequalification dossier containing the following:

- Dossier examination fee in US dollars.
- General information about the legal manufacturer, including name and address.
- Unique identification reference for the device type.
- Full specifications of the device being offered, covering all the requirements set out in this document, including details of device marking and traceability.

- Full specification of the components used, including individual temperature ratings.
- Internal circuit diagram.
- Photographs of the device clearly showing all sides of the device, including indicator lights and device identification labelling.
- Certified photocopies of all type-approvals obtained for the device, including conformity assessment (e.g., CE, UL) marking and the like. If the certifications are not from an independent test lab, then the legal manufacturer shall provide a technical construction file that demonstrates conformity.
- Certified photocopies of the legal manufacturer's **ISO 9001** quality system certification.
- 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 legal manufacturer who are able to demonstrate compliance with good environmental practice.
- Certified photocopies of the testing laboratory's **ISO/IEC 17025** certification.
- Laboratory test report(s) proving conformity with E007/VS01-VP.6.
- Details of the legal manufacturer's internal Acceptable Quality Level (AQL) sampling procedures in respect of **ISO 3951** and **ISO 2859** or other internally recognized AQL standards.
- Indicative cost of the device per unit, EXW (Incoterms 2020).

8. On-site maintenance

Maintenance shall be carried out by trained technical professionals.

9. Change notification

The legal manufacturer or reseller is to advise WHO in writing of any changes in the device 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 device recalls, component defects and other similar events.

Revision History

Date	Change summary	Reason for change	Approved
May 2022	4.2.4 Overload and short circuit	Industry feedback on difficulty of	11
	requirements reverted to language of VS01.5.	proposed changes.	
	4.2.8 Fuses: fuses not permitted	Expert feedback	
April 2022	3. Terms and definitions: add	Simplify references to different	
	appliance and dedicated, integrated and standalone	types	
	4.1 General: Add Stirling cycle to compatibility requirements	Expert feedback	
	4.2.4 Electrical Withstand: Add surface temperature requirement. Change to absolute temperature limit rather than 5°C temperature rise. Limit based on IEC 60335-1 enclosure temperature limit.	Was previously tested in the VP, but had no matching requirement.	
	4.2.4 Overload: Add provision for exempting dedicated stabilizers from reconnect requirements.	Expert and industry feedback	
	4.2.4 Short Circuit: Allow integrated/dedicated stabilizers to be reset by unplugging.	Industry feedback	
	4.2.5 Capacity rating: Consolidate table to single continuous capacity rating more akin to table in VS01.5, but with cold rooms and SMPS added.	Clarification, and "peak" rating not tested.	
	4.2.6 Input frequency. Add surface temperature requirement. Change to absolute temperature limit rather than 5°C temperature rise. Limit based on IEC 60335-1 enclosure temperature limit.	Was previously tested in the VP, but had no matching requirement.	
	4.3.4 and 4.3.5: Require evidence of safety and EMC compliance	Expert feedback	
	4.3.6 Robustness: Clarify language and fix clause number in IEC 60335- 1 reference.	Clarification.	
	4.3.9 Efficiency: Clarify that efficiency is at full load.	Clarification and expert feedback.	
	4.6.3 Power outlet: remove requirement that dc outlet be designed to work with dc appliances.	Vague requirement, expert feedback deems it is sufficient that the outlet be different from ac outlets.	
	7 Dossier: Add specification of components and temperature limits and circuit diagram. Clarify laboratory test report requirements and add AQL.	Expert feedback	
	9 Change notification: remove "adversely affect performance"	Expert feedback: PQS should determine if it could adversely affect performance.	
September 2021 (for Industry Review)	Normative references: Delete CISPR 11. Add IEC 61204 family for EMC and safety for SMPS. Remove IEC 61000-4-x test procedures except '-4-5, which is referenced in the text.	Add standards relevant to SMPS; simplify references list.	
	4.2.4 Under/overvoltage – added provision to waive reconnect delay for integrated stabilizers.	Manufacturer controls both stabilizer and load, and may have other design features making a delay unnecessary.	

	4.2.4 Short Circuit: revert to 1000%	Exmant foodbook	
	overload	Expert feedback	
	4.2.7 Output voltage accuracy: Add requirement for test points for integrated stabilizer output unless exempt from output testing requirements	Ease testing by labs.	
	4.3.4 Electrical safety: Add IEC 61024-7 for SMPS	Relevant standard	
	4.3.5 EMC: Remove CISPR 14 for all; add IEC 61024-3 for SMPS	Reduce duplication and use relevant standard for SMPS	
	4.3.7 Dust and water ingress: Increase IP to IP31, add conformal coating requirement	Increased robustness	
	4.3.8 Markings: Added grounding and electric hazard markings	Expert feedback	
	4.3.9 Efficiency: Added requirement for SMPS	Expert feedback	
	4.6.2 Power lead: Add requirement for grounded lead unless the equipment has class II protection against electric shock	Protection against shock	
	4.6.3 Power outlet: Add requirement for only a single outlet, compatible with the country standard, or dc systems.	Single outlet discourages overloading the stabilizer.	
	4.8: Warranty: Integrated stabilizers to have same warranty as the equipment they protect.	Single warranty terms for an appliance.	
	4.10 Spare parts: Added this section	Alignment with other specifications	
	4.11 Disposal: Add test certification to IEC 62321-8-6	Another option for manufacturers.	
August 2021	Eliminated reference to IEC 60950-1 in favor of IEC 60335-1	Applicability of IEC 60335-1 to voltage protection equipment	IG
	4.2.2. Nominal input frequency required as 50-60Hz range; disallow designs that only operate at 50 or 60Hz nominal.	Given the variety of power supply environments and conditions, voltage protection devices shall robustly perform across a range of input frequencies.	IG
	4.2.3 Reduced maximum correction range upper limit from 278V to 264V	More in line with industry standards. Relatively limited benefit expected from maintaining broader range when considering the technical complexity and cost of creating devices that meet the broader range to 278V.	IG
	4.2.4 Under/Over-voltage - included provision to allow option for automatic reconnect	Industry and expert feedback	IG
	4.2.4 Overload - ac short circuit protection changed from Type C to Type K	Prevent tripping of ac motors that require greater starting current	IG
	4.2.4 Overload - adjusted overload and short circuit levels to replace 1,000% overload with 1,400% short circuit	Industry and expert feedback	IG
	4.2.4 Impulsive transient - revised requirements, setting three separate transient voltage scenarios and corresponding impedance levels.	More closely align to IEC 61000-4- 5 standard	IG

		1	10
	4.2.4 Maximum residual voltage - revised requirements based on technical feasibility assessment.	Industry feedback and expert research into what is technically feasible given common surge suppressant technology e.g., Metal Oxide Varistors (MOVs). See technology note for a detailed description of the analysis that led to this specification.	IG
	4.2.5 Capacity rating – specification verbiage around 'continuous' and 'peak' capacity; adjusted relevant requirements; included requirements for SMPS	Industry and expert feedback	IG
	4.2.6 Input frequency fluctuations - Differentiated tolerable frequency fluctuation limits for VS and SMPS separately; included requirement to cutoff power supply when outside allowable frequency limits; included provision for manufacturers to report whether there the device can rectify frequencies, although this is not required	Industry and expert feedback	IG
	4.2.9 Load Power Factor Effect - Clarified requirements for VS and SMPS.	Industry and expert feedback	IG
	4.2.10 Wave form and distortion - Clarified requirement for allowable distortion	Industry and expert feedback	IG
	4.3.6 Robustness - Clarified requirement to include 500 VA minimum	Industry and expert feedback	IG
	4.7.2 Control Panel - Clarified requirement for standalone and integrated devices	Industry and expert feedback	IG
Mar. 2020	Included provisions throughout for testing ac-to-dc switching devices.	Allow ac-to-dc switching solutions for power protection.	IG
	4.2.4 revised Impulsive transient specification per IEC 61000-4-5	Refined specification of impulsive transient protection.	IG
	4.2.4 revised overload in line with IEC 60950-1	Revised to be more in line with IEC standard	IG
	4.2.6 revised frequency ranges	Revised based on more conventional specifications	
	4.2.9-11 additional performance Clauses	Ensure proper specification of critical protections	IG
	4.3.3 Adjusted normative references 4.3.4-5 Safety and EMC Clauses	Revised normative references in line with industry standards Updating for RoHS 3 requirement	IG IG
	4.2.4 Overload – Verbiage updated to	Feedback from manufacturers	IG
(VS01.5)	allow for the use of an automatic reconnect switch as an alternative to manual reconnect switch		
Sept. 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	Feedback from manufactures	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
	4.2.4 Increase of overvoltage requirement from 415 V to 500 V	Field data on frequency of overvoltage instances and magnitude	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
Oct. 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
Dec. 2015	4.1 Language changed to reflect both the purpose and the functioning of voltage stabilizers		IG
l	1	1	

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	Feedback from manufactures	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