

Medtech mains-operated compressor Nebulizer Electromagnetic Compatibility

Applicable Device-Model Name	Device-Model Number
HANDYNEB PRO	S0H1
HANDYNEB GOLD	S0H2
HANDYNEB SLIM	S0H3
HANDYNEB MINI	S0H4
HANDYNEB NUPRO	S0H5
HANDYNEB CLASSIC	S0H6
HANDYNEB SMART	S0H7
HANDYNEB SUPER	S0H8
HANDYNEB NOVA	S0H9
HANDYNEB NOVA PLUS	S0H10
HANDYNEB PLUS	S0H23

Information for accompanying documents in the scope of EN60601-1-2:2021

Important information regarding Electro Magnetic Compatibility (EMC)

This device conforms to EN60601-1-2:2021 Electro Magnetic Compatibility (EMC) standard. Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified or provided by could result in increased electromagnetic emission or decreased electromagnetic immunity of the device and result in improper operation.
- The use of the device adjacent to or stacked with other device should be avoided because it could result in improper operation. In case such use is necessary, the device and other device should be observed to verify that they are operating normally.
- Portable RF communications device (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by MEDTECH. Otherwise, degradation of the performance of the device could result.
- Refer to further guidance below regarding the EMC environment in which the device is intended for use
- The device is intended to be used in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment

Table 1 - EMISSION Limits and Compliance

EMC EMISSION TEST AND RESULTS

Name of the Tests	Product Standard	Basic Standard	Enclosure/A C/DC/ Signal Port	Specifications	Observations
Conducted Emission	IEC 60601-1-2	CISPR 11 Class B	230V AC, 50Hz Input Power Port	<p>Quasi-peak limit: 150 kHz – 500kHz : 79 dBμV 500 kHz – 30MHz : 73 dBμV</p> <p>Quasi-peak limit: 150 kHz – 500kHz : 66 dBμV 500 kHz – 30MHz : 60 dBμV</p>	Within the limits
Harmonic current emission	IEC 60601-1-2	EN 61000-3-2	230V AC, 50Hz Input Power port	Upto 40 th Harmonics, Class A	Within the limits
Flicker Emission	IEC 60601-1-2	IEC 61000-3-3	230V AC, 50Hz Input Power port	<p>Long term flicker Plt : < 0.65, Pst : < 1, Highest dt (%) : < 3.3%, Time (ms) > dt : < 500 ms, Highest dc (%) : < 3.3%, Highest dmax (%) : < 4%</p> <p>Short term flicker Pst : < 1, Plt : < 0.65, Highest dt (%) : < 3.3%, Highest dmax (%) : < 4%</p>	Within the limits
Radiated Emission	IEC 60601-1-2	CISPR 11 Class A	230V AC, 50Hz Input Power port	<p>Quasi-peak limit: 30 MHz – 230 MHz : 30 dBμV 230 MHz – 1000 MHz : 37 dBμV</p>	Within the limits

EMC IMMUNITY TEST AND RESULTS

Name of the Tests	Product Standard	Basic Standard	Enclosure/ AC/DC/ Signal Port	Specifications	Observations
Electrostatic Discharge	IEC 60601-1-2	IEC 61000-4-2	Enclosure	Contact discharge $\pm 8\text{kV}$ Air discharge $\pm 15\text{kV}$	Pass
Radiated susceptibility	IEC 60601-1-2	IEC 61000-4-3	Enclosure	80MHz – 1000 MHz 1GHz – 6GHz, 10V/m 1kHz, 80% AM	Pass
High energy surge	IEC 60601-1-2	IEC 61000-4-5	230V AC, 50Hz Input Power port	$\pm 2\text{kV}$ for Common mode $\pm 1\text{kV}$ for Differential mode	Pass
Electrical Fast Transient	IEC 60601-1-2	IEC 61000-4-4	230V AC, 50Hz Input Power port	Upto $\pm 2\text{ kV}$, 5/50ns	Pass
Conducted RF	IEC 60601-1-2	IEC 61000-4-6	230V AC, 50Hz Input Power port	Continuous Frequency 0.15 – 230 MHz, 3 Vrms 1 kHz, 80%AM Spot Frequencies 6.765 – 6.795 MHz, 13.553 – 13.567MHz, 26.957 – 27.283 MHz, 40.66-40.77 MHz Level: 6 Vrms	Pass
Power Frequency Magnetic Field	IEC 60601-1-2	IEC 61000-4-8	Enclosure	30 A/m for continuous 60 Sec.	Pass
Voltage dips & Interruption	IEC 60601-1-2	IEC 61000-4-11	230V AC, 50Hz Input Power port	0% of mains voltage for 0.5cycle 40% of mains voltage for 10 cycles 70% of mains voltage for 25 cycles & 0% of Short Interruption for 250 cycles	Pass