

OMRON mains-operated compressor Nebulizer (NE-C***-series)

Information for Accompanying Documents

in the Scope of EN 60601-1-2:2015+A1:2021

Important information regarding Electromagnetic Compatibility (EMC)

This device manufactured by 3A HEALTH CARE S.r.l. conforms to EN 60601-1-2:2015+A1:2021 Electromagnetic Compatibility (EMC) standard. Nevertheless, special precautions need to be observed:

- Install the device well away from other equipment that emits high frequencies (short waves, microwaves, electric scalpels, cell phones).
- The use of accessories and cables other than those specified or provided by 3A HEALTH CARE could result in increased electromagnetic emission or decreased electromagnetic immunity of the device and result in improper operation.
- During 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.
- During operation, 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 3A HEALTH CARE. Otherwise, degradation of the performance of the device could result.
- The device is intended for use in an electromagnetic environment in which radiated RF disturbances are under control. The customer or user can help prevent electromagnetic interference by maintaining a minimum distances between mobile and portable RF communication equipment (transmitters) and the medical device as recommended below, according to the maximum output power of the radio communication equipment.

Rated maximum output power of transmitter (W)	Separation distance (m) in relation to transmitter frequency		
	from 150kHz to 80MHz $d = 1,2 \sqrt{P}$	from 80MHz to 800MHz $d = 1,2 \sqrt{P}$	from 800MHz to 2,5GHz $d = 2,3 \sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters with rated maximum output power not listed above, the recommended separation distance d in metres (m) may be determined using the equation adopted for the transmitter frequency, where P is the maximum rated output power of the transmitter in Watts (W) stated by the transmitter manufacturer.

Notes:

(1) At 80 MHz and 800 MHz the highest frequency range applies.

(2) These guidelines might not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 1 - EMISSION Limits and Compliance

Phenomenon	EMISSION Limits	Compliance
Conducted and radiated RF EMISSIONS	CISPR 11	Group1, Class B The EMISSION characteristics of this device make it suitable for use in industrial areas and hospitals but also residential ones.
Voltage fluctuations and flicker	See IEC 61000-3-3	Complies

Table 2 - IMMUNITY TEST LEVELS

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air for enclosure port
Radiated RF electromagnetic fields	IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz for enclosure port
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See table 3

Electrical fast transients / bursts	IEC 61000-4-4	±2 kV for Input a.c. power port 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV for input a.c. power port
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM between 150 kHz and 80 MHz 80 % AM at 1 kHz for input a.c. power port
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz
Voltage dips	IEC 61000-4-11	0 % U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° for input a.c. power port
		0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycles single phase: at 0° for input a.c. power port
Voltage interruptions	IEC 61000-4-11	0 % U_T ; 250/300 cycle for input a.c. power port
Proximity magnetic fields	IEC 61000-4-39	See table 4
NOTE: U_T is the A.C. mains voltage prior to application of the test level.		

Table 3 - Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications device

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n , RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

Table 4 - Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz	CW	8
134.2 kHz	Pulse modulation 2.1 kHz	65
13.56 MHz	Pulse modulation 50 kHz	7.5