OMRON battery-operated Electronic Nerve Stimulator (ENS) HV-F128

Information for accompanying documents in the scope of IEC60601-1-2:2007

Important information regarding Electro Magnetic Compatibility (EMC)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation.
Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

Medical devices manufactured by OMRON Healthcare conform to this IEC60601-1-2:2007 standard for both immunity and emissions.
Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified by OMRON, with the exception of cables sold by OMRON as replacement parts for internal components, may result in increased emission or decreased immunity of the device.
- The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.
- Refer to further guidance below regarding the EMC environment in which the device should be used.

(Table 1)

Guidance and manufacturer's declaration – electromagnetic emissions		
OMRON ENS HV-F128 is intended for use in the electromagnetic environment specified below. The customer or the user of these OMRON ENS HV-F128 should assure that it is used in such environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The OMRON ENS HV-F128 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The OMRON ENS HV-F128 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Not applicable	

(Table 2)

Guidance and manufacturer's declaration – electromagnetic immunity			
OMRON ENS HV-F128 is intended for use in the electromagnetic environment specified below. The customer or the user of this OMRON ENS HV-F128 should assure that it is used in such environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable	Not applicable
Surge IEC 61000-4-5	Not applicable	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11	Not applicable	Not applicable	Not applicable
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

(Table 4)

Guidance and manufacturer's declaration – electromagnetic immunity			
OMRON ENS HV-F128 is intended for use in the electromagnetic environment specified below. The customers or the users of this OMRON ENS HV-F128 should assure that it is used in such environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	Not applicable 3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the OMRON ENS HV-F128 including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. **Recommend separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to he transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with he following symbol: 
Note1: At 80 MHz and 800 MHz, the higher frequency range applies. Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the OMRON ENS HV-F128 is used exceeds the applicable RF compliance level above, the OMRON ENS HV-F128 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the OMRON ENS HV-F128. [b] Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.			

(Table 6)

Recommended separation distance between portable and mobile RF communications equipment and the OMRON ENS HV-F128			
OMRON ENS HV-F128 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customers or the users of this OMRON ENS HV-F128 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OMRON ENS device as recommended below, according to the maximum output power of the communications equipment.			
Output Power of Transmitter in Watt	**Separation distance according to frequency of transmitter in meter**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	***80 MHz to 800 MHz*** $d = 1.2\sqrt{P}$	***800 MHz 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 rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note: At 80MHz and 800MHz, the separation distance for the higher frequency range applies Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Note:
EMC tests conducted including attached electrode cord of 1 m length