Guidance & Manufacturer's Declaration

EMC – Diagnosys E3 and Profile

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60601-1-2 Required Information

Electromagnetic Emissions		
The E3 and Profile system is intended for use in the electromagnetic environment specified below. The customer or user of the E3 and Profile system should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electro-magnetic Environment - guidance**
RF Emissions CISPR 11	Group 1	The E3 and Profile system uses RF 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 A	The E3 and Profile system is suitable for use in all establishments other than domestic 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	Class A	
Voltage Fluctuation\flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity			
The E3 and Profile system is intended for use in the electromagnetic environment specified below. The customer or user of the E3 and Profile system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	Contact: ±2kV, ±4kV, ±6kV, ±8kV Air: ±2kV, ±4kV, ±8kV, ±15kV	Contact: ±2kV, ±4kV, ±6kV, ±8kV Air: ±2kV, ±4kV, ±8kV, ±15kV	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Table should be non-metallic.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	± 2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5kV, ± 1kV, ± 2kV	± 0.5kV, ± 1kV, ± 2kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U_T for 1 cycle at 0° 70% U_T for 25 cycles at 0° 0% U_T for 250 cycles at 0°	0% U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U_T for 1 cycle at 0° 70% U_T for 25 cycles at 0° 0% U_T for 250 cycles at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the E3 and Profile system requires continued operation during power mains interruption, it is recommended that the E3 and Profile system be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Monitor system performance for abnormal noise levels and consult Troubleshooting section of User Guide if abnormal noise levels are experienced.
Immunity to proximity magnetic fields IEC 61000-4-39	65 A/m at 134.2 kHz 7.5 A/m at 13.56 MHz	65 A/m at 134.2 kHz 7.5 A/m at 13.56 MHz	
U_T is the a.c. mains voltage prior to application of the test level.			

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Doc: 16566 **Rev:** B ECN 1864 **Date:** 2022/10/04

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Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6Vrms ISM 150 kHz to 80 MHz 80% AM at 1 kHz	3 Vrms 150 kHz to 80 MHz 6Vrms ISM 150 kHz to 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the E3 and Profile system including cables than the recommended separation distances calculated from the equation applicable to the frequency of the transmitter Recommended separation distance: $d = 1.17 * \sqrt{P}$ 80 MHz to 800 MHz $d = 2.33 * \sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m) Field strength 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 the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people			
a Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur 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 E3 and Profile system is used exceeds the applicable RF compliance level above, the E3 and Profile system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or re-locating the E3 and Profile system. b Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3V\m.			

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Electromagnetic Immunity – Wireless Communications						
The E3 and Profile system is intended for use in the electromagnetic environment specified below. The customer or user of the E3 and Profile system should assure that it is used in such an environment. The enclosure port of E3 and Profile system was tested as specified in Table 9 of IEC 60601-1-2:2014 using the test methods specified in IEC 61000-4-3, as summarized below.						
Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum Power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**
385	380 - 390	TETRA 400	Pulse 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460; FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710, 745, 780	704 - 787	LTE Band 13, 17	Pulse 217 Hz	0.2	0.3	9
810, 870, 930	800 - 960	GSM 800/900; TETRA 800; iDEN 820; CDMA 850; LTE Band 5	Pulse 18 Hz	2	0.3	28
1720, 1845, 1970	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse 217 Hz	2	0.3	28
2450	2400 - 2570	Bluetooth; WLAN 802.11 b/g/n; RFID 2450; LTE Band 7	Pulse 217 Hz	2	0.3	28
5240, 5500, 5785	5100 - 5800	WLAN 802.11 a/n	Pulse 217 Hz	0.2	0.3	9

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