Additional sheet to the Instructions for Use

For EMC Class B applications only

Edition: 01A-2024
Date of issue: 2024-02
Part no.: F50020710

The additional sheet provides additional information for the Instructions for Use. In addition, the affected Instructions for Use remain valid.

The additional information relates to the chapter “Information on electromagnetic compatibility”.

Information on electromagnetic compatibility

Specifications refer to the requirements of IEC 60601-1-2.

At the time of production, the device complied with an applicable edition of IEC 60601-1-2.

Guidance and manufacturer's declaration on EMC

Warning

Patient hazard from a device malfunction

The device is not suitable for use in the following environments:
- Use in the vicinity of radio-frequency surgical equipment
- In the vicinity of CT devices or X-ray machines
- In the context of emergency medical services
- In the vicinity of transmission equipment

- **Electromagnetic emissions**

Regardless of the following EMC specifications, the specification of use must be taken into account and followed.

Guidance and manufacturer's declaration – electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1 Class B	The device 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. The device 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	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

- **Electromagnetic immunity**

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ±2 kV, ±4 kV, ±8 kV and ±15 kV air	± 8 kV contact ±2 kV, ±4 kV, ±8 kV and ±15 kV air	Floors 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	± 2 kV for power supply lines ± 1 kV for input/output lines 100 kHz repetition rate	± 2 kV for power supply lines ± 1 kV for input/output lines 100 kHz repetition rate	Supply voltage quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV and ±1 kV differential mode ±0.5 kV, ±1 kV, and ±2 kV common mode; line(s) to earth	±0.5 kV and ±1 kV differential mode ±0.5 kV, ±1 kV, and ±2 kV common mode; line(s) to earth	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T for 0.5 cycles (at 0, 45, 90, 135, 180, 225, 270 and 315 degrees) 0 % U_T for 1 cycle 70 % U_T for 25 cycles at 50 Hz or 30 cycles at 60 Hz 0 % U_T for 250 cycles at 50 Hz or 300 cycles at 60 Hz	0 % U_T for 0.5 cycles (at 0, 45, 90, 135, 180, 225, 270 and 315 degrees) 0 % U_T for 1 cycle 70 % U_T for 25 cycles at 50 Hz or 30 cycles at 60 Hz 0 % U_T for 250 cycles at 50 Hz or 300 cycles at 60 Hz	In the event of short power supply interruptions, the device will turn off.[1] In the event of power supply interruptions, the rechargeable battery of the device temporarily takes over the supply for parts of the system without delay.[2] Mains power quality should be that of a typical commercial or hospital environment. [1] Applies to devices without rechargeable battery [2] Applies to devices with rechargeable battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 or 60 Hz	30 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz 80 % AM at 1 kHz 6 V_{rms} in ISM bands between 150 kHz and 80 MHz 80 % AM at 1 kHz	3 V_{rms} 150 kHz to 80 MHz 80 % AM at 1 kHz 6 V_{rms} in ISM bands between 150 kHz and 80 MHz 80 % AM at 1 kHz	Portable high-frequency telecommunication devices (radio equipment including its accessories such as antenna cables and external antennas) should not be used any closer than 30 cm (or 12 inches) to the device. Failure to comply with this may impair the performance characteristics of the device.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz 9 V/m 704 to 787 MHz 5100 to 5800 MHz Modulation: PM; 217 kHz 27 V/m 380 to 390 MHz Modulation: PM; 18 kHz 28 V/m 430 to 470 MHz Modulation: FM; 1 kHz sine wave 28 V/m 800 to 960 MHz Modulation: PM; 18 kHz 28 V/m 1700 to 1990 MHz 2400 to 2570 MHz Modulation: PM; 217 kHz	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz 9 V/m 704 to 787 MHz 5100 to 5800 MHz Modulation: PM; 217 kHz 27 V/m 380 to 390 MHz Modulation: PM; 18 kHz 28 V/m 430 to 470 MHz Modulation: FM; 1 kHz sine wave 28 V/m 800 to 960 MHz Modulation: PM; 18 kHz 28 V/m 1700 to 1990 MHz 2400 to 2570 MHz Modulation: PM; 217 kHz	
Radiated fields in close proximity according to IEC 61000-4-39	30 kHz Modulation: CW, 8 A/m (for home care only) 134.2 kHz Modulation: PM, 2.1 kHz, 65 A/m 13.56 MHz Modulation: PM, 50 kHz, 7.5 A/m	30 kHz Modulation: CW, 8 A/m (for home care only) 134.2 kHz Modulation: PM, 2.1 kHz, 65 A/m 13.56 MHz Modulation: PM, 50 kHz, 7.5 A/m	The influence of radio equipment on magnetically sensitive components or circuits should not impair the performance characteristics.
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			