

Guidance and manufacturer's declaration – electromagnetic immunity		
Braun ME equipment is intended for use in the electromagnetic environment specified below. The customer or the user of Braun ME equipment is should ensure that it is used in such an environment.		
Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS
		HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields ^{a)}	IEC 61000-4-3	10 V/m ^{f)} 80 MHz – 2,7 GHz ^{b)} 80 % AM at 1 kHz ^{c)}
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See RF wireless communication equipment immunity table below
RATED power frequency magnetic fields ^{d) e)}	IEC 61000-4-8	30 A/m ^{g)} 50 Hz or 60 Hz
<p>a) The interface between the PATIENT physiological signal simulation, if used, and the ME EQUIPMENT or ME SYSTEM shall be located within 0,1 m of the vertical plane of the uniform field area in one orientation of the ME EQUIPMENT or ME SYSTEM.</p> <p>b) ME EQUIPMENT and ME SYSTEMS that intentionally receive RF electromagnetic energy for the purpose of their operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. This test assesses the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.</p> <p>c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.</p> <p>d) Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.</p> <p>e) During the test, the ME EQUIPMENT or ME SYSTEM may be powered at any NOMINAL input voltage, but with the same frequency as the test signal (see Table 1).</p> <p>f) Before modulation is applied.</p> <p>g) This test level assumes a minimum distance between the ME EQUIPMENT or ME SYSTEM and sources of power frequency magnetic field of at least 15 cm. If the RISK ANALYSIS shows that the ME EQUIPMENT or ME SYSTEM will be used closer than 15 cm to sources of power frequency magnetic field, the IMMUNITY TEST LEVEL shall be adjusted as appropriate for the minimum expected distance.</p>		

Guidance and manufacturer's declaration – electromagnetic emissions		
Braun ME equipment is intended for use in the electromagnetic environment specified below. The customer or the user of Braun ME equipment should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment – guidance
RF Emissions CISPR 11	Group 1	The ME equipment 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	Complies
Harmonic emissions IEC 61000-3-2	Not Applicable	The ME equipment is solely battery powered.
Voltage fluctuations/ flicker emissions	Not Applicable	

Guidance and manufacturer's declaration – RF wireless communication equipment immunity

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0,2	0,3	9
5 500						
5 785						

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.