

## ELECTROMAGNETIC COMPATIBILITY

### EN 60601-1-2

#### AEROSOL THERAPY DEVICES:

The device complies with the rules about the electromagnetic compatibility currently in force and is suitable for use in all the establishment, residential and domestic included. The RF emissions of the device are very low and they don't cause any interference in nearby devices. However, it's advisable not place it over or near other devices. If it emitting interferences to nearby electronic devices, move it or connect it to another electrical socket. Radio communication devices can affect the device operating, keep them at least 3 m. distance.

With device we mean the instrument used by the final user.

#### ELETTROMAGNETIC EMISSION

Emissions test	Compliance	Environment
Emissions RF CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Emissions RF CISPR 11	Class B	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

Immunity test	ICE 60601-1-2 test level	Compliance level	Electromagnetic environmental
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 15 kV air	IEC 60601-1-2 test level	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic transient/burst IEC 61000-4-4	2kV for power supply lines 1 kV for input/output lines >3m	IEC 60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5 MO-03	1kV/0.5 kV differential mode 2kV/1kV/0.5 kV common mode	IEC 60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variation IEC 61000-4-11	0% Ut for 0.5 cycles 70%Ut for 25 cycles 0% Ut for 5 sec	IEC 60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment. If the user requests that the device works constantly, we recommend to use it under an UPS.
Network frequency magnetic field (50/60 Hz) IEC 61000-4-8	30 A/m	IEC 60601-1-2 test level	The network frequency magnetic field should be the typical of a commercial or hospital environment.
			<b>NOTE: Ut is the voltage supply value before the test level application.</b>

<p>Radiated RF IEC 61000-4-3</p>	<p>3 V/m 80 MHz ÷ 2.7 GHz</p> <p>27 V/m 380 MHz ÷ 390 MHz</p> <p>28 V/m 430 MHz ÷ 470 MHz</p> <p>9 V/m 704 MHz ÷ 787 MHz</p> <p>28 V/m</p> <p>800 MHz ÷ 960 MHz</p> <p>28 V/m 1700 MHz ÷ 1990 MHz</p> <p>28 V/m 2400 MHz ÷ 2570 MHz</p> <p>9 V/m 5100 MHz ÷ 5800 MHz</p>	<p>IEC 60601-1-2 test level</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the device H4001, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:  <math>d = 1,2 \sqrt{P}</math> from 80 MHz to 800 MHz  <math>d = 2,3 \sqrt{P}</math> da 800 MHz to 2,7 GHz</p> <p>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 metres (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site monitoring, a should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>Conducted RF IEC 61000-4-6</p>	<p>3V from 150 kHz ÷ 80 MHz</p> <p>6V from 6.765 ÷ 6.795 MHz 13.553 ÷ 13.567 MHz 26.957 ÷ 27.283 MHz 40.66 ÷ 40.70 MHz</p>	<p>IEC 60601-1-2 test level <math>d=1,2 \sqrt{P}</math></p>	

**NOTE 1** At 80 MHz and 800 MHz, applies in the higher frequency range.

**NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

**Recommended separation distance:**

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications transmitting equipment and the device as recommended below, according to the maximum output power of the transmitter.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	From 150 kHz to 80MHz d = 1,2√P	From 80 MHz to 800 MHz d = 1,2√P	From 800 MHz to 2,7 GHz d = 2,3√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 metres (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.

## Electromagnetic Compatibility Information for blood pressure monitor BP-500

The device satisfies the EMC requirements of the international standard IEC 60601-1-2. The requirements are satisfied under the conditions described in the table below. The device is an electrical medical product and is subject to special precautionary measures with regard to EMC which must be published in the instructions for use. Portable and mobile HF communications equipment can affect the device. Use of the unit in conjunction with non-approved accessories can affect the device negatively and alter the electromagnetic compatibility. The device should not be used directly adjacent to or between other electrical equipment.

**Table 1**

Guidance and declaration of manufacturer-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
Radiated emission CISPR 11	Group 1, ClassB	The device uses RF energy only for its internal function. Therefore, its emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted emission CISPR 11	N/A	
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

**Table 3**

Guidance and declaration of manufacturer-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 test level	Compliance level	Electromagnetic environment -guidance
Conducted RF IEC 61000-4-6	3V for 0.15-80 MHz; 6V in ISM and amateur radio bands between 0.15-80MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  Recommended separation distance $d = \left[ \frac{3.5}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[ \frac{7}{E_1} \right] \sqrt{P}$ 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 metres (m).
Radiated RF IEC 61000-4-3	385MHz, 27V/m 450MHz, 28V/m 710MHz, 745 MHz, 780MHz, 9V/m 810MHz, 870 MHz, 930MHz, 28V/m 1720MHz, 1845 MHz, 1970MHz, 28V/m 2450MHz, 28V/m 5240MHz, 5500 MHz, 5785MHz, 9V/m	385MHz, 27V/m 450MHz, 28V/m 710MHz, 745 MHz, 780MHz, 9V/m 810MHz, 870 MHz, 930MHz, 28V/m 1720MHz, 1845 MHz, 1970MHz, 28V/m 2450MHz, 28V/m 5240MHz, 5500 MHz, 5785MHz, 9V/m	
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.  Interference may occur in the vicinity of equipment marked with the following symbol: 

**Table 2**

Guidance and declaration of manufacturer-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 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 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 %.
Electrostatic transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	N/A	
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	N/A	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle <5% UT (>95% dip in UT) for 5 secondary	N/A	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m; 50Hz or 60Hz	30 A/m; 50Hz or 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

**Table 4**

Recommended separation distances between portable and mobile RF communications equipment and the device		
The device is intended for use in an electromagnetic environment in which radiated therefore disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.		
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m	
	80 MHz to 800 MHz $d = \left[ \frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2.7 GHz $d = \left[ \frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.  NOTE1 At 80 MHz and 800 MHz, the separation distance for 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.		

# Electromagnetic Compatibility Information for bloode pressure monitor BP-1000

The device satisfies the EMC requirements of the international standard IEC 60601-1-2. The requirements are satisfied under the conditions described in the table below. The device is an electrical medical product and is subject to special precautionary measures with regard to EMC which must be published in the instructions for use. Portable and mobile HF communications equipment can affect the device. Use of the unit in conjunction with non-approved accessories can affect the device negatively and alter the electromagnetic compatibility. The device should not be used directly adjacent to or between other electrical equipment.

**Table 1**

Guidance and declaration of manufacturer-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
Radiated emission CISPR 11	Group 1, class B.	The device uses RF energy only for its internal function. Therefore, its emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted emission CISPR 11	Group 1, class B.	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	

**Table 3**

Guidance and declaration of manufacturer-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 test level	Compliance level	Electromagnetic environment -guidance
Conducted RF IEC 61000-4-6	3V for 0.15-80MHz; 6V in ISM and amateur radio bands between 0.15-80MHz	3V for 0.15-80MHz; 6V in ISM and amateur radio bands between 0.15-80MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	385MHz, 27V/m	385MHz, 27V/m	Recommended separation distance $d = \left[ \frac{3.5}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[ \frac{7}{E_1} \right] \sqrt{P}$ 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 metres (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.  Interference may occur in the vicinity of equipment marked with the following symbol:  
	450MHz, 28V/m	450MHz, 28V/m	
	710MHz, 745MHz, 780MHz, 9V/m	710MHz, 745MHz, 780MHz, 9V/m	
	810MHz, 870MHz, 930MHz, 28V/m	810MHz, 870MHz, 930MHz, 28V/m	
	1720MHz, 1845MHz, 1970MHz, 28V/m	1720MHz, 1845MHz, 1970MHz, 28V/m	
2450MHz, 28V/m	2450MHz, 28V/m		
5240MHz, 5500MHz, 5785MHz, 9V/m	5240MHz, 5500MHz, 5785MHz, 9V/m		

**Table 2**

Guidance and declaration of manufacturer-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 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 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 %.
Electrostatic transient/burst IEC 61000-4-4	± 2 kV, 100kHz, for AC power port	± 2 kV, 100kHz, for AC power port	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5kV, ± 1kV (differential mode)	± 0.5kV, ± 1kV (differential mode)	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 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°  0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°  0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°  0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°  0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m; 50Hz or 60Hz	30 A/m; 50Hz or 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

**Table 4**

Recommended separation distances between portable and mobile RF communications equipment and the device		
The device is intended for use in an electromagnetic environment in which radiated therefore disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.		
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m	
	80 MHz to 800 MHz $d = \left[ \frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2.7 GHz $d = \left[ \frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.		
NOTE1 At 80 MHz and 800 MHz, the separation distance for 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.		

## Electromagnetic Compatibility Information for all digital thermometers

The device satisfies the EMC requirements of the international standard IEC 60601-1-2. The requirements are satisfied under the conditions described in the table below. The device is an electrical medical product and is subject to special precautionary measures with regard to EMC which must be published in the instructions for use. Portable and mobile HF communications equipment can affect the device. Use of the unit in conjunction with non-approved accessories can affect the device negatively and alter the electromagnetic compatibility. The device should not be used directly adjacent to or between other electrical equipment.

Table 1

Guidance and declaration of manufacturer-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	The device uses RF energy only for its internal function. Therefore, its emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	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	N/A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	N/A	

Table 2

Guidance and declaration of manufacturer-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 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 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 %.
Electrostatic transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	N/A	
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	N/A	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (>95% dip in UT) for 0.5 cycle  40% UT (60% dip in UT) for 5 cycle  70% UT (30% dip in UT) for 25 cycle	N/A	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m; 50Hz or 60Hz	30 A/m; 50Hz or 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3

Guidance and declaration of manufacturer-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 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 Mhz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 Ghz	10 V/m	Recommended separation distance $d = \left[ \frac{3.5}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[ \frac{7}{E_1} \right] \sqrt{P}$ 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 metres (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. Interference may occur in the vicinity of equipment marked with the following symbol: 
RF Wireless Communication Equipment IEC 61000-4-3	380MHz, 27V /m 450MHz, 28V /m 710MHz, 745 MHz, 780MHz 9V/m 810MHz, 870 MHz, 930MHz 28V/m 1720MHz, 1845 MHz, 1970MHz 28V/m 2450MHz, 28V /m 5240MHz, 5500 MHz, 5785MHz 9V/m	380MHz, 27V /m 450MHz, 28V /m 710MHz, 745 MHz, 780MHz 9V/m 810MHz, 870 MHz, 930MHz 28V/m 1720MHz, 1845 MHz, 1970MHz 28V/m 2450MHz, 28V /m 5240MHz, 5500 MHz, 5785MHz 9V/m	

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the device
The device is intended for use in an electromagnetic environment in which radiated therefore disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m	
	80 MHz to 800 MHz $d = \left[ \frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2.7 GHz $d = \left[ \frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

NOTE1 At 80 MHz and 800 MHz, the separation distance for 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.