

Guidance and manufacturer's declaration

Applicable models: Refer to " EMC product reference table for Digital Peak Flow Meters"
Information for accompanying documents in the scope of IEC60601-1-2

Electromagnetic emissions

The Microlife unit is intended for use in the electromagnetic environment specified below.
The customer or the user of the Microlife unit should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Microlife unit 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	
Harmonic emissions IEC 61000-3-2	NA	
Voltage fluctuations / flicker emissions IEC 61000-3-3	NA	

Electromagnetic immunity

The Microlife unit is intended for use in the electromagnetic environment specified below.
The customer or the user of the Microlife unit 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 for enclosure port	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air for enclosure port	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 100 kHz repetition frequency ± 1 kV for input/output lines	NA	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5	$\pm 0.5 \text{ kV}$, $\pm 1 \text{ kV}$ differential mode line-line	NA	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 (100 % dip in U_T) for 0.5 cycle at 0° , 45° , 90° , 135° , 180° , 225° , 270° , and 315° 0 % U_T (100 % dip in U_T) for 1 cycle at 0° 70 % U_T (30 % dip in U_T) for 25/30 cycles at 0° 0 % U_T (100 % dip in U_T) for 250/300 cycle at 0°	NA	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Microlife unit requires continued operation during power mains interruptions, it is recommended that the Microlife unit be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz for enclosure port	30 A/m, 50/60Hz for enclosure port	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 a.c. mains voltage prior to application of the test level.

Electromagnetic immunity

The Microlife unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Microlife unit 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 6 Vrms in ISM and amateur radio bands between 150 kHz to 80 MHz 80% Am at 1kHz	NA	Portable and mobile RF communications equipment should be used no closer to any part of the Microlife unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended 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 2.7 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 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 the following symbol:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 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 strengths 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 Microlife unit is used exceeds the applicable RF compliance level above, the Microlife unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Microlife unit.
- b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Microlife unit

The Microlife unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Microlife unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Microlife unit 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		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
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 1 At 80 MHz and 800 MHz, the separation distance for 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.

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications device

Test frequency (MHz)	Band (MHz) ^{a)}	Service ^{a)}	Modulation ^{b)}	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	28
870				
930				
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	28
1845				
1970				
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	9
5500				
5785				

Note: If necessary to achieve the Immunity Test Level, the distance between the transmitting antenna and the ME Equipment or ME System may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

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.

The Manufacturer should consider reducing the minimum separation distance, based on Risk Management, and using higher Immunity Test Levels that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher Immunity Test Levels shall be calculated using the following equation:

$$E = \frac{6\sqrt{P}}{d}$$

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the Immunity Test Level in V/m.