Electromagnetic compatibility - Guiadance and manufacturer's declaration
DIN EN 60601-1-2:2007 (IEC 60601-1-2:2007)
Medical electrical devices are subject to special precautionary measures in particular regarding the EMV with the installation and the operation.
Portable and mobile HF-communication devices e.g. mobile phone can affect medical electrical devices.
A use of other accessories and lines than the indicated, can lead to a increased sending or a reduced noise immunity of the equipment. The equipment has to be operated exclusively with original accessories.
The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration – electromagnetic emissions		
The INQUA® Inhalator is intended for use in the electromagnetic environment specified below. The customer or the user of the INQUA® Inhalator should assure that it is used in such environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The INQUA® Inhalator 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	The INQUA® Inhalator 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	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Passed	

Guidance and manufacturer's declaration – electromagnetic immunity			
The INQUA® Inhalator is intended for use in the electromagnetic environment specified below. The customer or the user of the INQUA® Inhalator should assure that it is used in such environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 KV contact ± 8 KV air	± 6 KV contact ± 8 KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity shall be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	± 2 KV for power supply lines ± 1 KV for input / output lines	± 2 KV for power supply lines ± 1 KV for input / output lines	Mains power quality should be similar to that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 KV common mode ± 2 KV differential mode	± 1 KV common mode ± 2 KV differential mode	Mains power quality should be similar to that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95% dip of U_T) for 1/2 cylcle 40 % U_T (60 % dip of U_T) for 5 cylcles 70 % U_T (30 % dip of U_T) for 25 cylcles < 5 % U_T (> 95% dip of U_T) for 5 s	< 5 % U_T (> 95% dip of U_T) for 1/2 cylcle 40 % U_T (60 % dip of U_T) for 5 cylcles 70 % U_T (30 % dip of U_T) for 25 cylcles < 5 % U_T (> 95% dip of U_T) for 5 s	Mains power quality should be similar to that of a typical commercial or hospital environment. When the user of the INQUA® Inhalator continued function also calls in the event of disruption of supply, it is recommended the INQUA® Inhalator from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	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 INQUA® Inhalator is intended for use in the electromagnetic environment specified below. The customer or the user of the INQUA® Inhalator should assure that it is used in such environment.			
Immunity test	*IEC 60601 test level*	*Compliance level*	*Electromagnetic environment - guidance*
Conducted RF *IEC 61000-4-6*	*3 Veff* *150 kHz to 80 MHz*	*10 V eff* *150 kHz to 80 MHz*	*Portable and mobile RF communication equipment should be used no closer to any part of the INQUA® Inhalator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.*
Radiated RF IEC 61000-4-3	*3 V/m* *80 MHz to 2,5 GHz*	*10 V/m*	***Recommended separation distance:*** *d = 3,5/3 √P* *d = 3,5/3 √P 80 MHz to 800 MHz* *d = 7/3 √P 800 MHz to 2,5 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[b].* *Interference may occur in the vicinity of equipment marked with the following symbol:*
			

Note 1: *At 80 Hz and 800 MHz, the higher frequency range applies.*

Note 2: *These guidances 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 INQUA® Inhalator is used exceeds the applicable RF compliance level above, the INQUA® Inhalator should be observed to verify normal operation.
If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the INQUA® Inhalator.

b *Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.*

Recommended separation distances for portable and mobile RF communication equipment and the INQUA® Inhalator			
The INQUA® Inhalator is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the INQUA® Inhalator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the INQUA® Inhalator 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	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = 3,5/3 \sqrt{P}$	$d = 3,5/3 \sqrt{P}$	$d = 7/3 \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,69	3,69	7,38
100	11,67	11,67	23,33

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