

Spiro-SP-TrueFlow-Sensor EMC-Declaration

T. Mathis, May 2024

1. General

EMC Conformance

The *Spiro-SP* is EMC-tested in conformity with the requirements of IEC 60601-1-2:2014, 4th edition. The *Spiro-SP* is a medical device that requires special safety precautions. It must be installed and put into operation in accordance with the information given in the tables below.

2. Electromagnetic Emission

2.1 Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The *Spiro-SP* is intended for use in the electromagnetic environment specified below. Users of the *Spiro-SP* must ensure that the device is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The <i>Spiro-SP</i> uses RF energy only for its internal functioning. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	The <i>Spiro-SP</i> 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.

☐ Emissions table for IEC 60601-1-2 4th edition

3. Electromagnetic Immunity

The following tables provide guidelines in accordance with the 4th edition of the medical standard IEC 60601-1-2.

3.1 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Spiro-SP is intended for use in the electromagnetic environment specified below. Users of the *Spiro-SP* must ensure that the device is used in such an environment.

Immunity test standard	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	None
Electrical fast transient/burst IEC 61000-4-4	N/A	N/A	No mains supply
Surge IEC 61000-4-5	N/A	N/A	No mains supply
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	N/A	N/A	No mains supply
Power-frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power-frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 Vrms	Recommended separation distance: $d = 1.17\sqrt{P}$ @ 80 MHz to 800 MHz, $d = 2.33\sqrt{P}$ @ 800 MHz to 2.7 GHz
			Note: At 80 MHz and 800 MHz, the higher frequency range applies.
			Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
			Field strengths from fixed transmitters, such as base stations for radios, (cellular/cordless) telephones, land mobile radios, amateur radios, AM and FM radio broadcasts, and TV broadcasts, cannot be predicted with accuracy. To assess the electromagnetic environment created by fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the <i>Spiro-SP</i> is used exceeds the applicable RF compliance level specified above, the <i>Spiro-SP</i> should be observed to verify normal operation. If abnormal performance is observed, additional measures, such as re-orienting or re-locating the <i>Spiro-SP</i> , may be necessary.

☐ Electromagnetic immunity

3.2 Recommended Separation Distances Between Portable or Mobile RF Communications Equipment and *Spiro-SP*

The *Spiro-SP* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Users of the *Spiro-SP* can help to prevent electromagnetic interference by maintaining a minimum distance between portable or mobile RF communications equipment (transmitters) and the *Spiro-SP* as recommended below, depending on the maximum output power of the communication equipment.

Rated maximum output power of transmitter	Separation distance depending on frequency of transmitter		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 0,35 \sqrt{P}$	$d = 0,35 \sqrt{P}$	$d = 0,35 \sqrt{P}$
0.01 W	0.035 m	0.035 m	0.07 m
0.1 W	0.11 m	0.11 m	0.22 m
1 W	0.35 m	0.35 m	0.70 m
10 W	1.1 m	1.1 m	2.2 m
100 W	3.5 m	3.5 m	7.0 m
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) as specified by the transmitter manufacturer.			
Note: At 80 MHz and 800 MHz, the separation distance recommended for the higher frequency range applies.			
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
Note: An additional factor of 10/3 is used in calculating the recommended separation distance to decrease the likelihood that mobile/portable communications equipment will cause interference if it is inadvertently brought into patient areas.			

☐ Recommended separation distances between portable or mobile RF communications equipment and the *Spiro-SP*