W&H Dentalwerk



Manufacturer's declaration

for the product(s)



DENSPLY FRIOS® Unit S/i SI-923 and SI-915

Electromagnetic compatibility (EMC)

WARNING: The use of cables, power supplies, accessories other than those specified by the • manufacturer may result in increased emission and/or decreased immunity.

cable and accessories	length	reference
Cable (EU)	3.0 m	Manufacturer: Feller GmbH REF: 013437000
Alternate cable (UK)	2.5 m	Manufacturer: Feller GmbH REF: 032127000
Alternate cable (AUS, NZL)	2.5 m	Manufacturer: Feller GmbH REF: 029093000
Alternate cable (CH)	2.5 m	Manufacturer: Feller GmbH REF: 428060
Alternate cable (US)	3.1 m	Manufacturer: Feller GmbH REF: 028214000
Alternate cable (DK)	3.0 m	Manufacturer: Feller GmbH REF: 590180
Motor with cable	1.8 m	Manufacturer: W&H REF: 472000
Foot-control (S-N1)	3.0 m	Manufacturer: W&H REF: 504620

Operate the product in a place with a maximum distance to electrical and magnetic interfering • transmitters. If operation of the product close to other devices or together in a stack is necessary, observe the correct function of the system.

Manufacturer's declaration – Electromagnetic Emission (Table 201, EN 60601-1-2)

The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

Emission Test	Compliance	Electromagnetic Environment Guidance	
RF-emission CISPR 11	Group 1	The product use RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.	
RF-emission CISPR 11	Class B	The product is suitable for use in all establishments, including domestic	
Harmonic emissions IEC 61000-3-2 ^(*)	Class A	establishments and those directly connected to the public low-voltage power	
Voltage fluctuations/ flicker emissions IEC 61000-3-3 ^(*)	complies	supply network that supplies buildings used for domestic purpose.	
^(*) Remark: for devices with power consumption of 75 W to 1000 W only			

Manufacturer's declaration – Electromagnetic Immunity I (Table 202, EN 60601-1-2)

The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

Immunity Test	IEC 60601-	Compliance	Electromagnetic Environment	
······, · · ···	Level	Level	Guidance	
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floor 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/bursts 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 that of a typical commercial and/or hospital environment	
Surge IEC61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial and/or hospital environment	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	$\begin{array}{c} <5\% \ U_T \\ (>95\% \ dip \ in \ U_T) \\ for \ 0.5 \ cycle \\ 40\% \ U_T \\ (60\% \ dip \ in \ U_T) \ for \\ 5 \ cycles \\ 70\% \ U_T \\ (30\% \ dip \ in \ U_T) \ for \\ 25 \ cycles \\ <5\% \ U_T \\ (>95\% \ dip \ in \ U_T) \\ for \ 5 \ sec \end{array}$	$\begin{array}{c} <5\% \ U_T \\ (>95\% \ dip \ in \ U_T) \ for \\ 0.5 \ cycle \\ 40\% \ U_T \\ (60\% \ dip \ in \ U_T) \ for \\ 5 \ cycles \\ 70\% \ U_T \\ (30\% \ dip \ in \ U_T) \ for \\ 25 \ cycles \\ <5\% \ U_T \\ (>95\% \ dip \ in \ U_T) \ for \\ 5 \ sec \end{array}$	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or a battery.	
Power frequency(50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/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 mains (AC) voltage before apply test levels				

Manufacturer's declaration - Electromagnetic Immunity II (Table 204, EN 60601-1-2)

The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

Immunity Test	IEC 60601-	Compliance	Electromagnetic Environment
initiality rest	Level	Level	Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 V _{ms} 150 kHz to 80 MHz	3 V _{ms}	Recommended separation distance: d = $1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.2√P for 80 MHz to 800 MHz
			d = 2.3√P for 800 MHz to 2.5 GHz
			where P is the maximum output power rating of the transmitter in Watt (W) according to the transmitter manufacturer and d is the re-commended 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 ^b in each frequency range
Note 1: At 80 MHz and 80			Interference may occur in the vicinity of equipment marked with the symbol described lateral.

Note 1: At 80 MHz and 800MHz, 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, people and animals.

^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 product is used exceeds the applicable RF compliance level above, the product should be observed, additional measures may be necessary, such as reorienting or relocating the product.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Manufacturer's declaration – Recommended Separation Distances between portable and mobile HFcommunications equipment and the product (Table 206, EN 60601-1-2)

The product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product – according on output power and frequency of the communications equipment – as recommended in the following table.

Rated maximum output power of	Separation distance according to the frequency of transmitter in meter (m)				
transmitter in watts	150 kHz to 80 MHz 80 MHz to 800 MHz 800 MHz to 2.5 GH				
(W)	d = 1.2√P	d = 1.2√P	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 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 800MHz, 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, people and animals.