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ANNEXE - USER MANUAL EVOLUTION 3E

Guidance and manufacturer's declaration :

electromagnetic emissions
electromagnetic immunity
recommended separation distances

ESSENTIAL PERFORMANCE

The essential performance of the EVOLUTION 3e identified are claimed only during the creation of lamellar resection on patient.
During this lamellar resection creation with microkeratomes operated by the EVOLUTION 3e:

- the vacuum level must stay lower than 250mmHg.
- the oscillation and forward function of the electrical handpieces must be active
- the supply pressure of the pneumatic handpieces must be active.

These performances are guarantee if the recommendations mentioned in this annex are followed."

WARNING AGAINST ELECTROMAGNETIC COMPATIBILITY (EMC)

The EVOLUTION 3E needs special precautions regarding EMC.
The EVOLUTION 3E has to be installed and put into service according to the EMC requirements.
The EVOLUTION 3E can be affected by portable and mobile RF communications.

WARNING AGAINST ELECTROSTATIC DISCHARGES (ESD)

Pins of connectors identified with the ESD warning symbol should not be touched and connections of these connectors should not be made unless ESD precautionary procedures are used.

When a cable is connected to a connector identified with the ESD warning symbol, the EVOLUTION 3E shall be switch off. Then, touch the main earth terminal or metal part which is connected the earth in order to unload your body and connected the wished cable. Follow the starting procedure (refer to user manual #65060).

All staff involved must receive an explanation of the ESD warning symbol and a training in ESD precautionary procedure.

The training's content must include :

- the introduction of ESD warning
- a practical example of cable connection when ESD warning is present
- the insurance that the staff has completely understood the procedure and the risk if the staff doesn't apply it.

WARNING AGAINST INTERFERENCE RISK

- The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity EVOLUTION 3E.
- The EVOLUTION 3E should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the EVOLUTION 3E should be observed to verify normal operation in the configuration in which it will be used.
- The use of the accessory, transducer or cable with EVOLUTION 3E other than those specified may result in increased emissions or decreased immunity of the EVOLUTION 3E.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

Table 1 - Guidance and manufacturer's declaration – electromagnetic emissions – for all ME equipment and ME systems

Guidance and manufacturer's declaration – electromagnetic emissions		
EVOLUTION 3E is intended for use in the electromagnetic environment specified below. The customer or the user of EVOLUTION 3E product should assure that it is used in such an electromagnetic environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	**Group 1**	The EVOLUTION 3E 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 A**	The EVOLUTION 3E is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. **NOTE**: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re- orienting the equipment.
Harmonic emissions IEC 61000-3-2	**Class A**	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	**Complies**	

Table 2 - Guidance and manufacturer's declaration – electromagnetic immunity – for all ME equipment and ME systems

Guidance and manufacturer's declaration – electromagnetic immunity			
The EVOLUTION 3E is intended for use in the electromagnetic environment specified below. The customer or the user of the EVOLUTION 3E should assure that it is used in such an electromagnetic 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 should 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 that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	±1 kV mode differential ±2 kV mode common	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	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	0 Vac during 10 ms 92 Vac during 100 ms 161 Vac during 1 s 0 Vac during 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EVOLUTION 3E requires continued operation during power mains interruptions, it is recommended that the EVOLUTION 3E be powered 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 for 50Hz and for 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *UT* is the a.c. mains voltage prior to application of the test level			

Table 3 - Guidance and manufacturer's declaration – electromagnetic immunity – for ME equipment and ME systems that are not life-supporting

Guidance and manufacturer's declaration – electromagnetic immunity			
The EVOLUTION 3E is intended for use in the electromagnetic environment specified below. The customer or the user of the EVOLUTION 3E should assure that it is used in such an electromagnetic environment.			
Immunity test	**Immunity test**	**Immunity test**	**Immunity test**
			Portable and mobile RF communications equipment should be used no closer to any part of the EVOLUTION 3E, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.17 \sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.17 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.33 \sqrt{P}$ 800 MHz to 2,5 GHz
Proximity fields from RF wireless communications equipment	380 - 390 MHz 27 V/m; PM 50%; 18Hz 27 V/m	27 V/m	
	430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz	28 V/m	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).
	704 - 787 MHz 9 V/m; PM 50%; 217 Hz	9 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (1) should be less than the compliance level in each frequency range. (2)
	800 - 960 MHz 28 V/m; PM 50%; 18 Hz	28 V/m	Interference may occur in the vicinity of equipment marked with the following symbol:

	1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz	28 V/m	
	2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz	28 V/m	
	5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	9 V/m	

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.

(1) 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 EVOLUTION 3E is used exceeds the applicable RF compliance level above, the EVOLUTION 3E should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EVOLUTION 3E.

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

Guidance and manufacturer's declaration – electromagnetic immunity

The EVOLUTION 3E is intended for use in the electromagnetic environment specified below. The customer or the user of the EVOLUTION 3E should assure that it is used in such an electromagnetic environment.

	Test Frequency	Modulation	Immunity test level (A/m)
IEC6100-4-39	30 KHz [a]	CW	8
Radiated fields in close proximity	134.2 KHz	Pulse modulation [b] 2.1 KHz	65 [b]
	13.56 MHz	Pulse modulation [c] 50 KHz	7.5[b]

[a] This test is applicable only to ME EQUIPMENT and ME SYSTEM intended for use in the HOME HEALTHSCARE ENVIRONMENT

[b] The carrier shall be modulated using a 50% duty cycle square wave signal.

[c] r.m.s , before modulation is applied.

Table 5 – Recommended separation distances between portable and mobile RF communications equipment and the ME equipment or ME system – for ME equipment and ME systems that are not life-supporting

Recommended separation distances between portable and mobile RF communications equipment and the EVOLUTION 3E			
The EVOLUTION 3E is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EVOLUTION 3E can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EVOLUTION 3E 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 $d = 1.17 \sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17 \sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.33 \sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.37	0.37	0.74
1	1.16	1.16	2.33
10	3.69	3.69	7.37
100	11.6	11.6	23.3
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 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.			