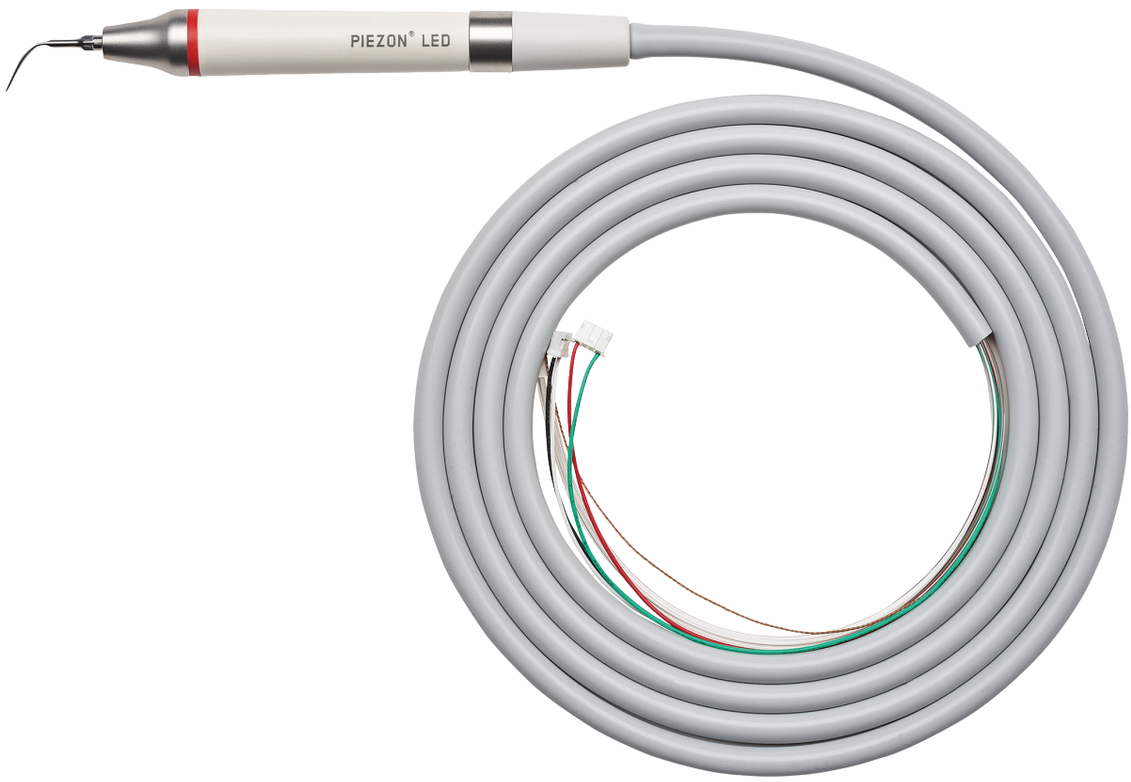
PIEZON® BUILT-IN BIK
PIEZON® BUILT-IN BIK LED

INSTALLATION MANUAL



EMS
ELECTRO MEDICAL SYSTEMS

EN

Contents

About this manual

This manual will assist you in installing the PIEZON® BUILT-IN KIT and PIEZON® BUILT-IN KIT LED scaler. Please read this manual carefully before installing the device and follow the instructions. Always keep this document close at hand. The difference between PIEZON® BUILT-IN KIT LED and PIEZON® BUILT-IN KIT is that the handpiece of the first features integrated light (LED) while the second does not. For simplification purposes and unless specified differently, this manual will use the name PIEZON® BUILT-IN KIT to cover both versions

To prevent injury to people and damage to property, please follow the corresponding directives. They are marked as follows:

Danger
Risk of patient or user injury

Caution
Risk of damage to the device or environmental harm

Please note
Useful additional information and hints

Prohibited

Authorized

Please observe the safety notes to prevent injury to persons or material damages.

We would be happy to assist you for any question you may have. Do not hesitate to contact your local EMS dealer for further information.

EMS reserve the right to carry out changes to technology, accessories and the installation manual, as well as the content of the original packaging in the course of technical development without prior notice.

Note that the English version of this manual is the master from which translations derive. In case of any discrepancy, the binding version is the English text.

Important information

The PIEZON® BUILT-IN KIT is based on an ultrasonic module (EJ-110) that drives the dental handpiece which applies a linear oscillation to the instrument.

The EJ-110 module has no essential performance. The device is only used in dental cabinets which are considered as professional healthcare environment.

The EJ-110 ultrasonic module is compliant with the standards for electromagnetic conformity IEC 60601-1-2:2007 and electrical security IEC 60601-1 (CB-Certificates IEC 60601-1:2005) including electrical security for dental equipment IEC 80601-2-60.

Use of an EN 60601-1 conform power supply as well as the use of EMS approved handpieces and cords are required to retain the conformity with this standard.

Safety notes

The PIEZON® BUILT-IN KIT must be installed in the dental unit by qualified staff who have been authorized by the unit manufacturer.
EMS accepts no liability for direct or consequential injury or damage resulting from improper installation or use arising in particular through non-observance of EMS instructions or improper preparation and maintenance.

The system assembler is responsible for conducting the functional test and measurements on the leakage currents, ensuring that they comply with IEC 60601-1, ANSI/AAMI ES 60601-1, CAN/CSA C22.2 and ensuring that the system is electromagnetically compatible (IEC 60601-1-2:2007).

The system assembler must provide an instruction for use that is specific to the treatment unit allowing to properly and safely control the product, especially regarding the power and the water level regulation. The usability of the selected function and set values must be guaranteed by the system assembler.

The power supply of the dental unit must comply with the following requirements:

- Double insulation for the highest expected supply voltage must be provided between primary and secondary power circuits
- The compliance with leakage currents of the applied part must be guaranteed by the system assembler
- Double insulation for the highest expected secondary voltage must be provided between the secondary voltage and ground (PE)
- The system has to ensure a galvanic separation between all secondary voltages including light supplies
- The secondary circuits must be protected against shorts and overloading

Risk of explosion: Do not use this product in the presence of anesthetics or inflammable gas.

This product must always be connected to the water supply of the treatment unit. The control of the water circuit is under responsibility of the system assembler.

The system assembler is responsible to provide the Operation instructions for Piezon Systems (FB-536/*) and the Reprocessing instructions Dental (FB-358) included with this product to the user.

The use of components other than those listed under Product Components may negatively affect EMC performance.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the PIEZON® BUILT-IN KIT, including cables specified by the manufacturer. Otherwise, degradationof the performance of this equipment could result.

The PIEZON® BUILT-IN KIT needs special precautions regarding installed and put into service according to the EMC information provided.

This product must exclusively be repaired by an approved EMS repair center.

Product component

The PIEZON® BUILT-IN KIT LED and PIEZON® BUILT-IN KIT

The use of accessories, cables and transducers other than those for which the PIEZON® BUILT-IN KIT was designed can significantly degrade emissions and immunity performance. Therefore, a warning on the use of accessories, transducers and cables other than those specified in the accompanying document is necessary to help ensure that the operator will be able to operate the PIEZON® BUILT-IN KIT as intended.

Reference	Description	Picture
EJ-110A/A	Ultrasonic module	
EK-405	Wire harness	
EK-406	LED wire bundle	
EL-463	Set of screws and washers	
EL-457	Potentiometer set (Optional)	
EM-153A/A	Handpiece cord (Length 2.0 m)	
FS-343	Perio Basic System inside SteriBox • Instrument A with CombiTorque • Instrument P with CombiTorque • Instrument PS with CombiTorque	
EN-060/A	Original PIEZON® LED Handpiece (for PIEZON® BUILT-IN KIT LED only)	
EN-061/A	Original PIEZON® Handpiece (for PIEZON® BUILT-IN KIT only)	
FB-606/EN	Installation manual for PIEZON® BUILT-IN KIT for the integrator	
FB-439/*	Operation instruction for PIEZON® Instruments & Systems for the user	
FB-358	Reprocessing instructions Dental for user	

Alternative options:

EK-407	AC wire bundle	

Wiring diagram and electrical integration

⚠ All unused wires of the wire harness must be cut, insulated and tied separately.

Power supply

- For 24 V AC installation: Connect both pin 10 AC1 and pin 11 AC2 of the EJ-110 module to the 24V AC power source of the unit. For this type of use, it is important to do an extra operation on the wire harness to connect pin 12 DCI with pin 2 DCO.
- For 32 V DC installation: If your unit has a DC source providing a voltage of 32 V DC, connect both pin 12 DCI and pin 13 0VP of the EJ-110 module to the power source of the unit.

⚠ Never connect both AC and DC power supplies as this would damage the module.

Ultrasound power ON/OFF

Ultrasound generation can be enabled or disabled in two different ways:

Power ON/OFF method	Modules types	Installation and effects
By activating or deactivating power supply (standard mode)	F, H	Ultrasounds will start immediately when the power supply is turned on. Make sure the Scaler Switch pin 9 ONL is not connected (open)! Impact on LED (only for LED version): The 20 sec LED timer will not work in that mode.
By using the digital Scaler Switch	E, G	This mode allows to use the 20 seconds delay time on the LED handpiece (only for LED version). In that mode, the power supply to the module needs to remain activated. Put pin 9 ONL to 0 VDC to activate the ultrasounds and to 5 VDC or OPEN to switch ultrasounds OFF.

Scaler power control

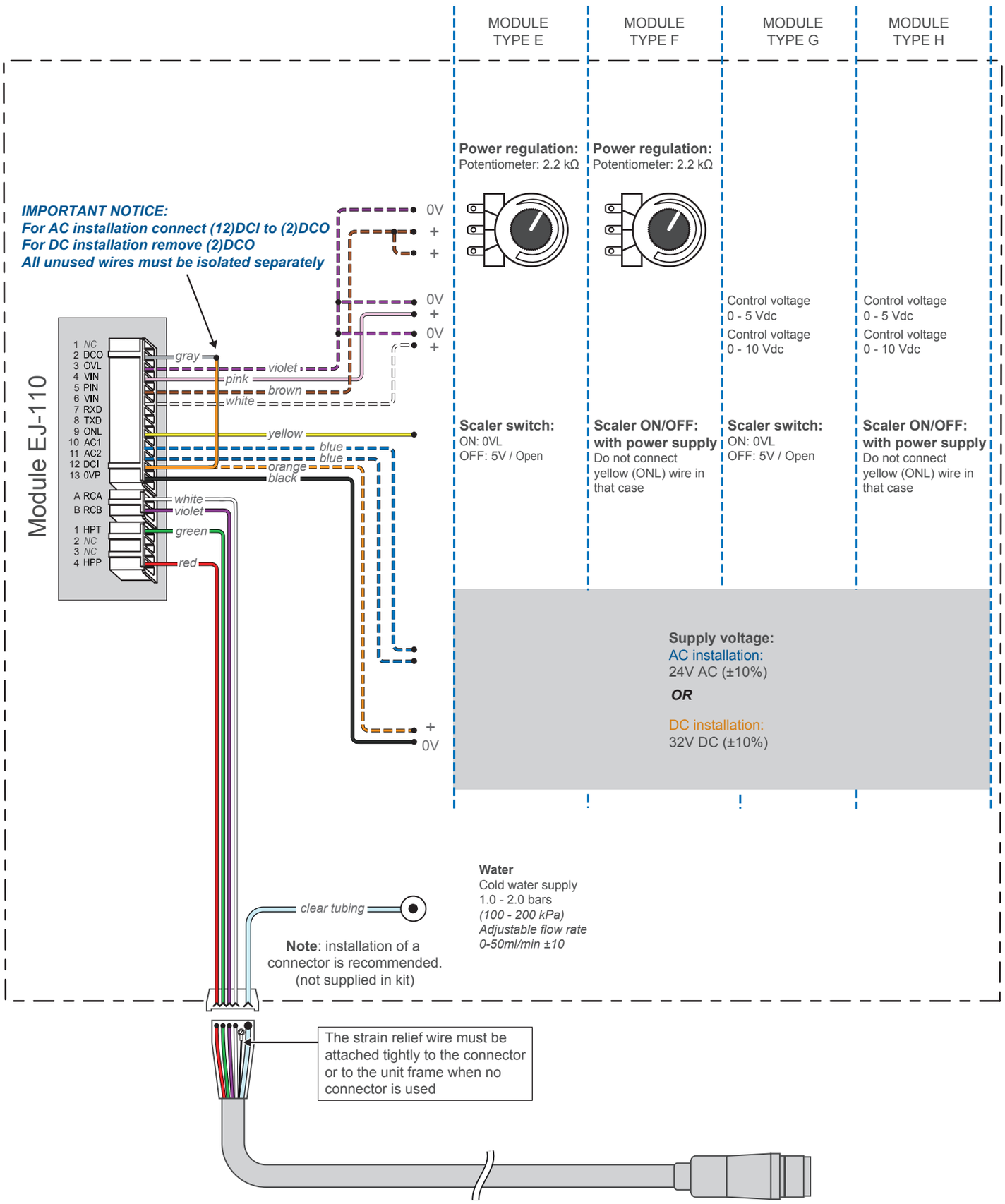
The ultrasonic power of the EJ-110 module can be set using two different modes, either by the use of a potentiometer or via an analogue 0-5 or 0-10 Vdc set-point voltage.

Scaler power control	Modules types	Installation and effects
Potentiometer	E, F	The power regulation using this mode requires a 2.2 kOhm manually operated potentiometer that is delivered with the product. To connect the potentiometer, please refer to the wiring diagram on page 6.
0 – 5 / 0 – 10 Vdc	G, H	The output power can be set with an analog voltage of 0-5Vdc or 0-10Vdc. To connect the EJ-110 module with the dental unit control electronics, please refer to the wiring diagram on page 5.

LED control by the dental unit

It is possible to supply the handpiece LED directly via the dental unit electronics instead of the module. This will require a controlled 5 V DC / 150 mA source. To do so, cut the 2-pin connector from the handpiece cord (white and violet wires) and connect the violet wire to 5 V DC and the white wire to ground.

Wiring diagram



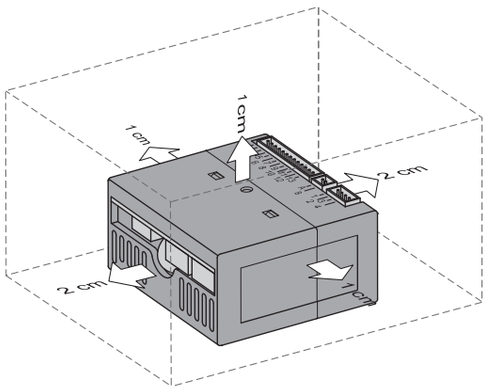
Note: The indicated wire colors for the module control bundle are valid for the universal standard bundle only.

Mechanical integration

Installation of EJ-110 module

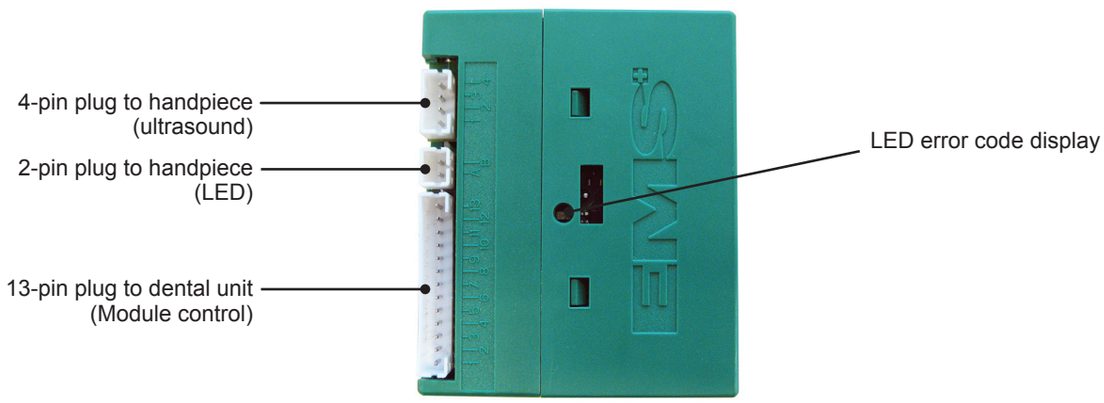
Place the ultrasonic module in a ventilated area and away from any heat source. The ultrasonic module must be installed in a dry zone as its housing does not provide protection against water or liquids. The ultrasonic module has to be installed inside the unit considering a minimum free space as indicated below, this to allow the necessary air circulation for cooling.

⚠ According to the EMC compliance, use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.



For the mounting of the module, a set of screws and washers is supplied with the product.

Description of EJ-110 ultrasonic module



Handpiece cord

It is recommended to integrate a connector between the handpiece cord and the treatment unit. In that case, the strain relief wire must be securely tied up to the connector.

If the cord is mounted to the unit without the use of a connector, the strain relief wire must be tightly attached to the unit frame.

SYMBOL HINT: It is recommended to always connect the 2-pin LED plug even if the current setup does not foresee a use with LED handpiece. This will allow the user to later upgrade its system with a handpiece that is equipped with LED.

Water irrigation

Connect the transparent handpiece cord tube to a cold water supply of 1 – 2 bars (100 – 200 kPa) and allowing an adjustable flow rate between 0 to 50 ml/min ± 10.

Symbols

EMS ELECTRO MEDICAL SYSTEMS	Manufacturer's logo
SN	Serial number
REF	Catalogue number
	Manufacturer
	Applied part, type B
	Read the operating instructions
	Caution!

	Output
	Input
	Disposal of Old Electrical & Electronic Equipment (Applicable in the European Union and other European countries with separate collection systems)
CE 0124	CE marking: Refers to directive 93/42 EEC, including EN 60601-1 and EN 60601-1-2

Trouble shooting

Symptom	Solution
No or intermittent ultrasound power	• Check the connections between module and unit, between module and hand piece cord and between hand piece cord and hand piece • Make sure that the instrument is screwed tightly to the hand piece and not worn off or damaged • Check for error message on EJ-110 module LED error code display (see below) • Check that the ultrasonic module is powered correctly when foot switch activated, respectively when the handpiece is taken out of the tray • Check that the connector between handpiece and handpiece cord is dry • Check the settings and the working mode • Replace the handpiece cord and/or the handpiece to verify if these components are not damaged • Contact an approved EMS repair center

LED error code on ultrasonic module	Error description	Solution
1 pulse (1 sec break)	No handpiece or broken US wires inside hand piece cord	• Replace the handpiece and/or the handpiece cord
5 pulses (1 sec break)	Potentiometer not connected	• Verify connection of potentiometer • Verify input pin of power input regulation

Technical specifications

Manufacturer	EMS Electro Medical Systems SA – 1260 Nyon – Switzerland
Model	PIEZON® BUILT-IN KIT / PIEZON® BUILT-IN KIT LED
Classification	EN 60601-1: Applied part Type B MDD 93/42: Class IIa Humidity protection class: IP X0
Mode	Continuous operation
Power supply	24 VAC ± 10% or 32 VDC ± 10%
Max. power consumption	18 VA
Max. power output	8 W
Frequency range	24 – 32 kHz
Module weight	~ 80 g
Module dimensions in mm	34 x 60 x 50 (without connectors)
Operating conditions	+10°C +40°C 30% – 75% relative humidity Altitude max. 3000 m
Storage and transport conditions	-10°C +40°C 10% to 95% relative humidity 500 hPa – 1060 hPa
Cold water supply	1.0 – 2.0 bar (100 – 200 kPa / 15 – 29 PSI) Adjustable flow rate 0-50 ml/min ±10

Electromagnetic compatibility according to IEC 60601-1-2:2007

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

Guidance and manufacturer's declaration – electromagnetic immunity			
The PIEZON® BUILT-IN KIT is intended for use in the electromagnetic environment specified below. The customer or the user of the PIEZON® BUILT-IN KIT 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	± 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 line(s) to line(s) ± 2 kV line(s) to earth	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 % 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 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % UT (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the PIEZON® BUILT-IN KIT requires continued operation during power mains interruptions, it is recommended that the PIEZON® BUILT-IN KIT 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 (60 Hz)	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.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The PIEZON® BUILT-IN KIT is intended for use in the electromagnetic environment specified below. The customer or the user of the PIEZON® BUILT-IN KIT 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 V rms 150 kHz to 80 MHz	10 V	Portable and mobile RF communications equipment should be used no closer to any part of the PIEZON® BUILT-IN KIT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 0.35 \sqrt{P}$ $d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz $d = 0.7 \sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 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 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:
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 PIEZON® BUILT-IN KIT is used exceeds the applicable RF compliance level above, the PIEZON® BUILT-IN KIT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PIEZON® BUILT-IN KIT.		
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 PIEZON® BUILT-IN KIT			
The PIEZON® BUILT-IN KIT is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PIEZON® BUILT-IN KIT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PIEZON® BUILT-IN KIT 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 $d = 0.35 \sqrt{P}$	800 MHz to 2,5 GHz $d = 0.7 \sqrt{P}$
0.01	0.14	0.04	0.07
0.1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.11	1.11	2.22
100	3.50	3.50	7.00
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.		

EMS Electro Medical Systems SA

Ch. de la Vuarpillière 31
1260 Nyon
SWITZERLAND
Tel. +41 22 99 44 700
Fax +41 22 99 44 701
e-mail: welcome@ems-ch.com

EMS worldwide offices (dental)

CANADA
EMS Canada Inc.
5524 St. Patrick St., Suite 312
Montreal, QC H4E 1A8
Tel. +1 514 736 5066
Fax +1 514 736 5065
e-mail: info@ems-canada.ca

FRANCE
EMS France Sarl
23, Av. Louis Bréguet
Immeuble Santos Dumont, Bâtiment D
F-78140 Vélizy Villacoublay
Tél. +33 1 34 58 03 80
Fax +33 1 34 58 03 90
e-mail: info@ems-france.fr

GERMANY
EMS Electro Medical Systems GmbH
Schatzbogen 86
D-81829 München
Tel. +49 89 42 71 61 0
Fax +49 89 42 71 61 60
e-mail: info@ems-ch.de

ITALY
EMS Italia S.r.l
Via Faravelli 5
I-20149 Milano
Tel. +39 02 3453 8111
Fax +39 02 3453 2778
e-mail: dental@ems-italia.it

SPAIN
EMS Electro Medical Systems España SL
Bernardino Obregón 14 bis
E-28012 Madrid
Tlf. +34 91 528 99 89
Fax +34 91 539 34 89
e-mail: administracion@ems-espana.com

USA
EMS Corporation
11886 Greenville Avenue #120
Dallas, TX 75243, USA
Tel. +1 972 690 83 82
Fax +1 972 690 89 81
e-mail: info@ems-na.com

Manufacturer
Electro Medical Systems SA
Ch. de la Vuarpillière 31
1260 Nyon - SWITZERLAND

EMS - SWISSQUALITY.COM

 FB-609/KR rev. A-01