

USER MANUAL



iMate-II Cordless Endo Motor

- *The unit must be installed by a qualified engineer
- *Only for user by dental professionals
- *Read this manual carefully before installation or operation

CE 0123

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REMARKS:

**The pictures here are for reference only
Real products shall prevail. The parameters and
pictures in this manual are subject to change without
prior notice.**

Thank you for your purchase of our device. Before operating the device, Read this User Manual carefully before use for operating instructions, care and maintenance .Keep this manual for future reference.

DENJOY DENTAL CO., LTD will take the responsibility for the security, reliability, capability under the following conditions:

1. The installation, debugging, maintenance should be adjusted by the approbatory technician by our company or obtained related nation quality level license professions.
2. The power supply shall be in conformity with the relevant provisions of the state and the use requirements of device itself.
3. The device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.The whole operation procedure should follow user manual strictly.

DENJOY DENTAL CO., LTD has right to improve shape and structure of the device, change any information and technical specification of this manual all the time, and no need to notice the user in advance.

CONTACT INFORMATION

The device is manufactured by:

DENJOY DENTAL CO., LTD

Address: F4, Building A4, Lugu Medical Device Park,
No.229 Guyuan Road, Changsha, 410205 P. R. China

Authorized European Representative:

Company name: LANDLINK GMBH

Address: DORFSTRASSE 2/4, 79312 EMMENDINGEN,
GERMANY

Please contact sales representative from whom you have bought this device for user's record and further after-sale service.

SECTION 1: GENERAL INTRODUCTION

Cordless Endo Motor is an endodontic operation instrument. Endo motor function is a kind of endodontic micromotor to drive Ni-Ti instruments, which can assist the dentists to shape more standard root-canal in the process of root-canal treatment based on the micro-electronic control technology. Cordless endo motor can be held in hand to operate and cordless charging. This unit contributes to alleviate the dentist's working intensity.

Product application and intended use

Cordless Endo Motor is applied to dental especially endodontic treatment. It is used for treat the root canal pulp necrosis, chronic pulpitis, chronic apical periodontitis (including meat tooth apical swelling, periapical abscess, periapical cyst), periodontal pulp syndrome and systemic diseases should not be extract but urgent needed to be treat.

Unique advantages

Use endo rotary file to machinery enlarge the root canal , Not only enlarges to the root canal in straight situation, but also works for curved root canal.

- 1, This product is based on ergonomic design, compact body and easy to carry.
- 2, Optional 20:1 mini reciprocating push-style contra angle can be used with universal Hand file
- 3, 6 different programs setting can be preset and saved according the requirement of the operator.
- 4, Auto-reverse and auto-stop function: When torque exceeds the upper limit, the file will automatically reverse or stop.
- 5, It can enable soft start and soft stop, more comfortable operation, avoid breaking when dental root canal files suffered instant heavy impact.
- 6, Contra angle and light support can be 135°C autoclaved.
- 7, Build-in high-capacity lithium battery, greatly resolve the frequent replacement of the battery and the cost of using our equipment.
- 8, If low battery, the machine will alarm to indicate operator.
- 9, With LED fixtures, high brightness, it could help doctors to better observe the root canal environment.

Notice: normal operation, alert tone 1 time; operation confirmation, sound 2 times ; invalid operation or warning, alert tone of 3 times.

SECTION 2: MAIN TECHNICAL INDEX


Model: iMate-II

Trade Name: iM2C

Type of protection against electric shock:

- Class II equipment: 

Degree of protection against electric shock:

- Type B applied part: 

Degree of protection against ingress of water: IPX0

Operation mode: Continuous Operation

Main Unit

Battery voltage: 3.7Vdc Battery capacity: 800mAh

Net weight: 210 g

Adapter

Rated input voltage: AC100-240V 50HZ/60HZ









Output voltage: DC5V Output current: 1A



SECTION 3: SYMBOL

The following symbols may appear in this manual, on the label, or on it's accessories. Some of the symbols represent standards and compliances associated with the endo motor and its use.

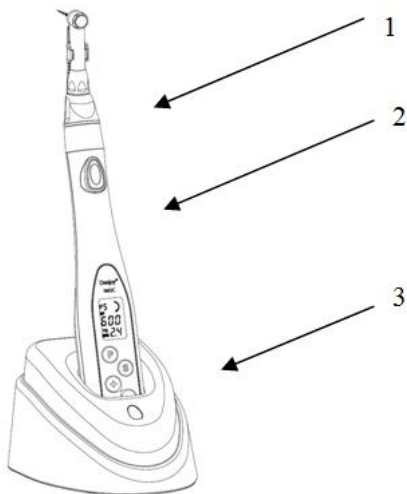


Consult accompanying documents

	Cautions
	Authorized Representative in the European Community
	CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC.
	Date of manufacture.
	Manufacturer
SN	Specifies serial number
	Type B applied part
	Refer to instruction manual / booklet
	The device should not be used after the end of the shown or the day

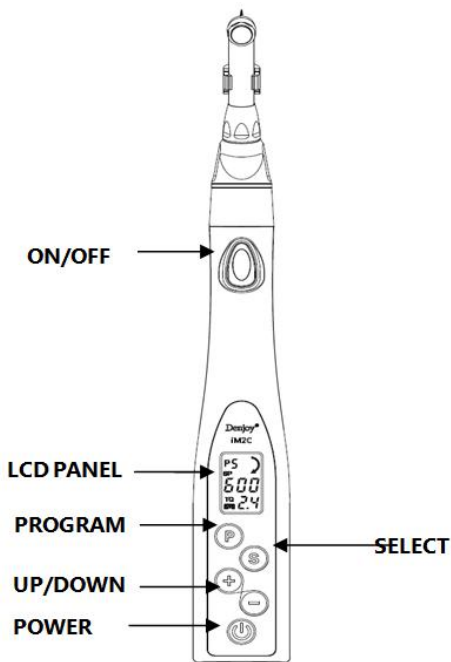
	<p>DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.</p>
	<p>Battery power sign displayed on the LCD screen</p>

SECTION 4: PRODUCT STRUCTURE



1 Contra-angle 2 Handpiece 3 Charging stand

SECTION 5: OPERATION PANEL AND LCD SCREEN OPERATION PANEL



Switch-on and Switch-off the Unit (POWER key



Switch-on

- Holding down the POWER key for more than one second, and the LCD panel lights.

Switch-off

- Holding down the POWER key for more than one second.

Note:

If 5 minutes pass without operation, the power turns off automatically.

Switch-on and Switch-off the Motor handpiece (ON/OFF key)

When the unit is switch-on, press ON/OFF key briefly, the motor handpiece starts, if you re-press the key, it stops.



SELECT

To change Torque (TQ) and Speed (SP).

The torque and speed can be changed while the Motor handpiece works.

Switching sequence: Speed setting (SP) → Press button S → Torque setting (TQ) → Press button S → Speed setting (SP).

The selected items will be flashing.

The speed and torque settings can be changed during operation.

Its switching sequence is same as above (User can not manually set the torque under the program P2 and P4).



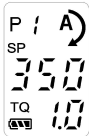
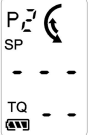
PROGRAM


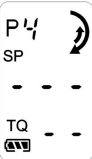
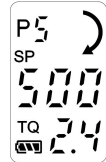

The present program number can be displayed.

The program number is available from 1 to 6.

Tap the button ,

you can choose 6 different programs as below:

	<p>P1: Forward rotation 360° . Auto-reverse when blocked, Recover forward when load moves.</p>
	<p>P2: Exclusive for Denjoy® reverse-reciprocating system. Reverse rotation 150. Forward 30° (Approx.)</p>

 <p>The display shows 'P3' with a counter-clockwise rotation arrow, 'SP' with the value '350', and 'TQ' with the value '10'. A small icon of a file is visible at the bottom left.</p>	<p>P3: Reverse rotation 360° . Auto-forward when blocked. Recover reverse when load moves.</p>
 <p>The display shows 'P4' with a clockwise rotation arrow, 'SP' with dashes '-', and 'TQ' with dashes '-'. A small icon of a file is visible at the bottom left.</p>	<p>P4: Exclusive for Denjoy® forward-reciprocating system. Forward rotation 150° . Reverse rotation 30° (Approx.)</p>
 <p>The display shows 'P5' with a clockwise rotation arrow, 'SP' with the value '500', and 'TQ' with the value '24'. A small icon of a file is visible at the bottom left.</p>	<p>P5: Forward rotation 360° . Stopped when blocked. For manual-file reciprocating contra angle Or taking out broken needle by reverse-blade file.</p>
 <p>The display shows 'P6' with a counter-clockwise rotation arrow, 'SP' with the value '450', and 'TQ' with the value '35'. A small icon of a file is visible at the bottom left.</p>	<p>P6: Reverse rotation 360° . Stopped when blocked. For taking out broken needle by forward-blade file. The torque and speed can be set and adjusted respectively, and the set parameter will be automatic memorized.</p>

Note:

1) For P5 and P6 mode, the torque can be higher than 4.0N.cm. When $TQ - -$ appears, it means that the torque is over 4.0N.cm, it's a special torque for taking out broken file. 2) Definition of forward: clockwise rotation.

**UP/DOWN**

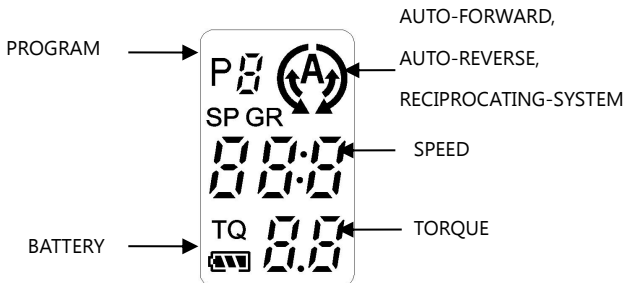
To adjust the set value for each parameter

Speed: rpm, Torque: N.CM

Gear ratio is 20:1

Please use the suitable contra angle based on gear ratio

Speed (rpm)	Gear Ratio	Torque (N.CM)
120-500	20:1	0.6-4.0

LCD PANEL

P 1 means program 1, 2, 3, 4,5, 6.

6 different programs setting can be preset and saved according the requirement of the operator

450 Speed of 450 rpm.

2.4 Torque of 2.4.



Battery remaining

• **MODE DISPLAY**

Display present mode(Torque can not be adjusted when reciprocate-system used, P2 and P4)

A): Forward rotation (reverse rotation when blocked.
recover forward rotation when load moves)



C): Reverse-reciprocating (for reverse-blade one file)

A):Reverse rotation (forward rotation when blocked. cover
reverse rotation when load moves)

↔: Forward-reciprocating

↻: Forward rotation 360° . Stopped when blocked (no reverse)

↺: Reverse rotation 360° . Stopped when blocked.

	<p>Reverse-reciprocating, adjustable speed 200~400. Reverse rotation 150°,forward rotation 30°(approx.).</p>
	<p>Forward-reciprocating, adjustable speed 200~400. Forward rotation 150°,reverse rotation 30°(approx.)</p>

BATTERY REMAINING

Displays the present remaining amount of the battery,The mark is animated when the battery is charging.



:Full charge



: Approximately 30-80% remains



: Less than 30% remains. In this case, the auto reverse function may not activate




: Battery is drained or very low battery voltage. Charge the battery.

Note: It's normal to find that the mark animated during the operation, for safety, the motor will shut down when the battery charged.

Initialization of Program (Factory-set configuration)

The program can be returned to the original state configured at the time of factory shipment, if setup becomes confusing.

1. Turn on the power, and choose P1,P3,P5, or P6.
2. Connect contra angle(no load for the contra angle)
3. Press down the SELECT key  till “**PL**” arises.

4. Click ON/OFF button when “**Li**” appears, subsequently, one “click” will be heard, cancellation begins, after finished, two “click” followed, and return to home screen)

5. Initialization is completed, when LCD panel display normally.

Note: initialization is chose when the LCD screen does not appear in accordance with the selected mode or settings.

SECTION 6: OPERATION

1, Charging the Motor handpiece

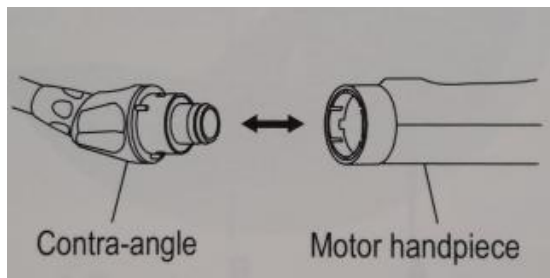
A, connect the power adapter to the charging stand.

B, Put the motor handpiece on the charging stand, during this period, please confirm if a beep is heard and the power display is flashing.

C, If the beep has been heard, and the Power display shows “FUL”, means the battery is full.

2, Connecting and disconnecting the contra-angle

The contra-angle can be connected at 6 adjustable head positions. Align the positioning pins of the contra-angle with the positioning slots of the motor handpiece and insert the head until it clicks, see below:



Disconnecting

When removing the contra-angle, pull it straight out (as above)

Note:

^ When attaching and detaching the contra-angle, turn the power off beforehand.

^ Check that the contra-angle is securely assembled to the motor handpiece.

3, Inserting and Removing the File

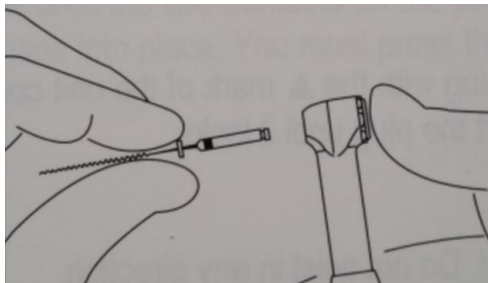
File insertion:

Insert the file into the chuck until it stops.

Lightly turn the file until it engages with the latch mechanism. Push inwards to click.

File removal:

Press the push-button and pull out the file(see blow)



Note:

^ When attaching and detaching the file, turn the power off beforehand.

^ After the file is locked in place, lightly pull out the file to make sure the file is locked.

^ Always clean the shank of the file to be installed. Allowing dirt to enter the chuck could cause deterioration of chucking force.

4. Inserting and removing the LED light

Insert LED light holder to the socket on the main unit, and buckle the upper part to the contra angle firmly; when uninstall, pull out the buckle from the contra angle first. then uninstall the LED light holder upward.



The LED lamp holder can be autoclaved at 135°C.

5, Operation:

Press the Power button to start the machine, press the engine on/off button to start the rotation, and the LED lighted. Press again the engine on/off button to stop the rotation, and the LED light will be off 8 seconds later.

Press the engine on/off without move, it keeps rotation and the LED lights. The engine will stop when moved from the on/off button, and the LED light will be off 8 seconds later.

6, After the operation,

Please press the power button to turn off the machine after the operation.

Auto turn off function

The device will turn off automatically after 5 minutes of no-operation.

Program memory setting.

Because last time you already saved the program setting, this program setting will remain the same until you change the program and save again.

SECTION 7: NOTICE

- Follow the file manufacturer's instructions for use of endodontic files to avoid misusing reciprocating files and continuous rotary files .
- Please do not use improper file because it will cause accident during operation.
- Please use the speed according to the file manufacturer.
- Please avoid putting the machine under high temperature such as sunlight, fire.
- While insert the machine to the charging stand, please make sure to put in the correct position in order to avoid break.
- Please do not lubricate our Motor handpiece or autoclave it.
- The Motor handpiece is not water proof, please keep it away from water or medicine liquid in order to avoid short circuit.
- Please do not fall down the Motor handpiece and

charging stand.

- Please use our power adapter for charge the device.
- Please use the contra-angle we approved to avoid the possible fault .
- Our Motor handpiece will not make electromagnetic interference to other equipment.

Forbidden:

Don't use this device with high-frequency surgical equipment simultaneously,

Used with caution for patients suffered from heart disease

The heart pacemaker patient can't use this device before get the approval from the doctor.

SECTION 8: TROUBLESHOOTING

When trouble is found, check the following again before contacting your dealer. If none of these are applicable or the trouble is not remedied even after action has been taken, the product may have failed. Contact your dealer.

Problems	Cause & Solution
The power is not turned on	The batteries are empty. Charge the batteries or use the AC adapter.

	The press of the power button is short. Please long press the power button
	The POWER button is broken. Contact with your dealer.
The battery can't be charged.	The adapter didn't connect well. Please recheck the connection
	The major machine didn't put on the charger base correctly. Please recheck the connection
	The battery is broken. Contact with your dealer

Fault code	Function	Description
E-1	Overcurrent Protection	The motor will shut off when overcurrent happened during the operation
E-2	Overheating Protection	The motor will shut off when overheating happened during a long time of heavy operation

E-3	Energy consumption Protection	The motor will shut off in 15 minutes if the operation situation without heavy change
E-4	Correcting Protection	Fault Calibration. Exit calibration directly When current over theoretical value

Note:

Relief Measures: For all the fault codes, please press any button to eliminate fault code except the POWER.

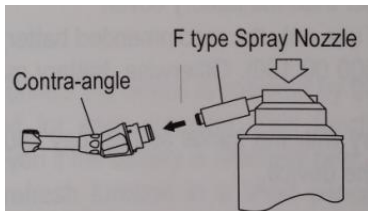
SECTION 9: MAINTENANCE

- 1) Before using the device, Please check if it can runs normally and safely.
- 2) For prolonging the battery operational life span, Please charge the battery one time each month after a long time for no use.
- 3) The device has the life span for about 5 years.
- 4) When the surface of main body is polluted, please wipe the surface with soft cloth ONLY by use Neutral cleanser, and then clean it by wet rag.
- 5) Lubricating the contra-angle
 - ^ Lubricate the contra-angle only with a dedicated

spray.

^ Lubricate after each use and before sterilization.

^ Screw the spray nozzle onto the spray with approx. 10 turns .



^Insert the spray nozzle into the rear part of the contra-angle and lubricate for 2-3 seconds until oil comes out from the contra-angle head.

^Before attaching the lubricated contra-angle to the motor handpiece. Wipe off excess oil. Place it on its end or lean it at an angle for gravity draining. Mount is after excess oil has been drained.

^Do not lubricate the motor handpiece.

^Hold the contra-angle securely to prevent it from detaching with the pressure of the spray.

^Never use a spray can upside down. Only spray gas, and no oil, would be sprayed.

REMARKS: Any liquid lotion like ethanol, banana oil, naphtha are not allowed, For not to cause the battery to explode, please don't put the device under the sunlight or

nearby the fire.

SECTION 10: STERILIZATION

Please note: Please autoclave contra angle, file and LED holder only

Before autoclave contra angle, please use AR spray for cleaning the contra angle.

Don't over 135°C during the autoclave for accessories (121°C for 20 minutes or 132°C for 15 minutes)

Please seal the unused device into the sterilization bag and store it in a clean place.

Remarks:

Please autoclave contra angle, file and LED holder only
Because of the high temperature disinfection stand close to the bottom of the heat source, the local temperature will be very high, so put the vessel in the middle or upper part of the disinfection cabinet

Oxidation potential water, (strongly acidic water super acidic water) or sterilization liquid is strictly prohibited to wash, impregnation the vessel.

SECTION 11: ENVIRONMENTAL REQUIREMENTS

OPERATING CONDITIONS

Ambient temperature: 5°C ~ 40°C

Relative humidity range: ≤80%

Atmospheric pressure: 70kPa~ 106kPa

STORAGE AND SHIPPING CONDITIONS

Ambient temperature: -40°C ~ 55°C

Relative humidity range: ≤80%

Atmospheric pressure: 50kPa ~ 106kPa

Equipment is not suitable for storage in the presence of sunlight, rain, dust, aggressive gas and chemical volatiles, keep it in good ventilation.

Transportation is applicable to all common method.

SECTION 12: Packing List

Motor handpiece	1 pc
Charging base	1 pc
HP contra angle 20:1	1 pc
Adapter	1 pc
LED lamp holder	2 pcs
Motor cover	1 pc
User manual	1 pc

SECTION 13: WARRANTY

The device is maintained free of charge and doesn't require any routine maintenance within warranty period.

Do not modify and disassemble the device.

This instrument described below has been fully inspected and confronts to the current products specification.

This instrument is guaranteed for its designated use, against original defects in materials and workmanship for a period of 12 months from date of purchase.

Products warranty or service will not be extended if (1) the product is repaired, modified, misused, disassembled, or using the parts are not provided by the manufacturer, (2) The serial number of the product is defaced or missing.

The guarantee for accessories is 6 months. All accessories of the device are damaged or needed to be renewed, the user can purchase from the manufacturer.

WARNING

The device is not repairable by user and contains no user serviceable parts. No modification of this equipment is allowed.

The user must check that the equipment functions safely and see that it is in proper working condition before being used. The manufacturer does not require such preventive

inspections by other persons.

Please contact sales representative from whom you have bought this device for user's record and further after-sale service.

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions		
The [iMate-II] is intended for use in the electromagnetic environment specified below. The customer or the user of the [iMate-II] should assure that it is used in such an environment		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The [iMate-II] 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 [iMate-II] is suitable for use in all establishments other

<p>Harmonic emissions IEC 61000-3-2</p>	<p>Class A</p>	<p>than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:</p>
<p>Voltage fluctuations/ flicker emissions IEC 61000-3-3</p>	<p>Complies</p>	<p>Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the [iMate-II] or shielding the location.</p>

Table 2

**Guidance and manufacturer's declaration -
electromagnetic emissions**

The [iMate-II] is intended for use in the electromagnetic environment specified below. The customer or the user of the [iMate-II] 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	Mains power quality should be that of a typical commercial or hospital environment.

			<p>The electrical fast transient burst (EFT) is generated by the switching of inductive loads.</p> <p>Separation between the equipment and other loads shall be considered before installation.</p> <p>Mains filter is required, if necessary.</p>
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)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruption	$< 5\% U_T$ ($> 95\%$ dip in U_T)	$< 5\% U_T$ ($> 95\%$ dip in U_T)	Mains power quality should be that of a

<p>s and voltage variations on power supply input lines IEC 61000-4-11</p>	<p>for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (>95% dip in U_T) for 5s</p>	<p>for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (>95% dip in U_T) for 5s</p>	<p>typical commercial or hospital environment. If the user of the [iMate-II] requires continued operation during power mains interruptions, it is recommended the [iMate-II] be powered from an uninterruptible power supply or a battery.</p>
<p>Power frequency (50/60Hz) magnetic field IEC 61000-4-8</p>	<p>3 A/m</p>	<p>3 A/m</p>	<p>Power frequency magnetic fields should be at levels characteristic of a typical location in a</p>

			typical commercial or hospital environment.
NOTE U _T is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration - electromagnetic emissions			
The [iMate-II] is intended for use in the electromagnetic environment specified below. The customer or the user of the [iMate-II] should assure that it is used in such an environment			
Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the [iMate-II], including cables, than the recommended separation distance

<p>Conducted RF IEC 61000-4-6</p>	<p>3Vrms 150KHz to 80MHz</p>	<p>3V 3 V/m</p>	<p>calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2 \sqrt{p}$ $d=1.2 \sqrt{p}$</p>
<p>Radiated RF IEC 61000-4-3</p>	<p>80MHz to 2.5GHz</p>		<p>80MHz to 800MHz $d=2.3 \sqrt{p}$ 800MHz to 2.5GHz 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</p>

			<p>electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>
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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 [iMate-II] is used exceeds the applicable RF compliance level above, the [iMate-II] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [iMate-II].

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

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the [iMate-II]

The [iMate-II] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [iMate-II] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [iMate-II] 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 $d=1.2\sqrt{P}$	80MHz to 800MHz $d=1.2\sqrt{P}$	800MHz to 2.5GHz $d=2.3\sqrt{P}$
0,01	/	0.12	0.23
0,1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	12	23

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.

WARRANTY REGISTRATION FORM

Item Name: _____

Model Name: _____

Serial No.: _____

Date of Purchase: _____

Name: _____

Address: _____

Phone: _____

Email: _____

Name of Distributor: _____

Authorized Distributors: _____

Stamp and Signature