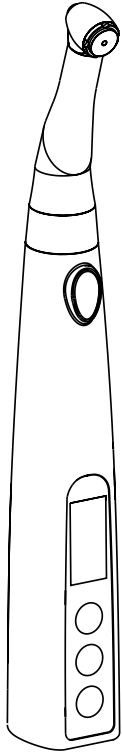
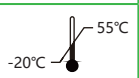
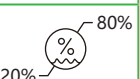
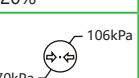


i Motor

Operating manual

Contents

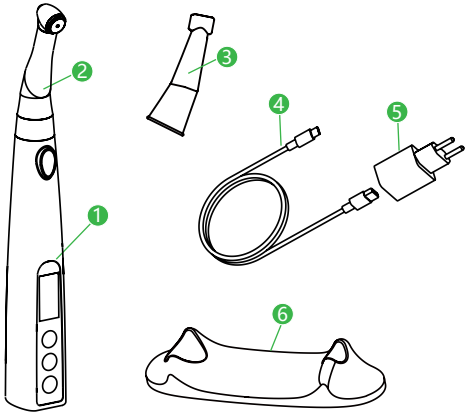
1. Symbols

Warning	If the instructions are not followed properly, operation may lead to hazards for the product or the user/patient.
NOTE	Additional information, explanation of operation and performance.
	Do not dispose of with normal household waste.(WEEE)
SN	Serial number
REF	Catalogue number
	Manufacturer
	Date of manufacturing
	Type B applied part
	Direct current
	Safety class II device
	Store in a dry place
	Can be autoclaved up to a maximum temperature of 135° Celsius
	Temperature limitation
	Relative humidity
	Transport and storage pressure conditions: 70 kPa - 106 kPa

2. Technical Data

Model	**i Motor**
Package Size	193mm x 96mm x 80mm
Package weight	Approx. 510g, ±10%
Power supply	ICR18500, 3.7V 1900mAh ±10%
Charger power supply	5VA
Degree of Protection	IPX 0
Electrical safety class	Class II
Applied part	B
Torque range	10-50N·cm
Speed range	10-50rpm
Contra Angle	Ratio: 20:1
Operation	Forward(Clockwise rotation) ,Reverse(Counter clockwise rotation)
Operating conditions	Use: in enclosed spaces Ambient temperature: 5° C ~ 40 ° C Relative humidity: <80% Operating altitude < 2000m above sea level Atmospheric pressure: 70kPa ~ 106kPa
Transport and storage conditions	Ambient temperature: -20 ° C ~ +55 ° C Relative humidity: 20% ~ 80 % Atmospheric pressure: 70kPa ~ 106kPa

3. Parts Identification



Components and Accessories

1 Main unit	1 (pcs)	2 Contra Angle	1(pcs)
3 Protective Case	2 (pcs)	4 USB Cable	1 (pcs)
5 Adapter	1 (pcs)	6 Base	1 (pcs)
User manual	1 (pcs)		

4. Intended use

i Motor is a cordless motor handpiece system intended for fixing an abutment onto a dental implant in endodontic treatment.

The device must be only used by or under instruction of qualified medical personnel. The personnel who use the device must be trained.

5. Contraindications

This equipment is contraindicated in cases where patient/user carry medical implants such as pace makers or cochlear implants etc.

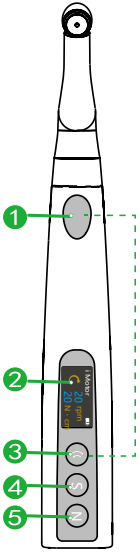
Safety and effectiveness have not been established in pregnant women and children.

⚠Warning

Read the following warnings before use:

1. The device must not be placed in humid surroundings or anywhere where it can come into contact with any type of liquids.
2. Do not expose the device to direct or indirect heat sources. The device must be operated and stored in a safe environment.
3. The device requires special precautions with regard to electromagnetic compatibility (EMC) and must be installed and operated in strict compliance with the EMC information. In particular, do not use the device in the vicinity of fluorescent lamps, radio transmitters, remote controls, portable or mobile RF communication devices, and do not charge, operate or store at high temperatures. Comply with the specified operating and storage conditions.
5. Gloves is compulsory during treatment.
6. If irregularities should occur in the device during treatment, switch it off. Contact the agency.
7. Do not open or repair the device by yourself, otherwise, void the warranty.

6. Use Interface



Turn device on
Press 1 more than 0.8 seconds.

Speed Change
Press "**S**" to change speed

Torque Change
Press **"N"** to change torque

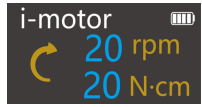
Motion Change
Press " ⌒ " to change Motion

Turn device off
Press 1 for a long time to turn device off.

1 Main switch
2 Display screen
3 ⌒ button
4 **S** button
5 **N** button

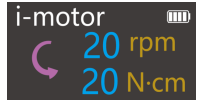
6.1 Display Screen

CW motion



When the motor handpiece reaches the torque limit during its rotation, an alarm sounds (Load alarm).
When the torque limit is exceeded, the rotation automatically stops.

CCW motion



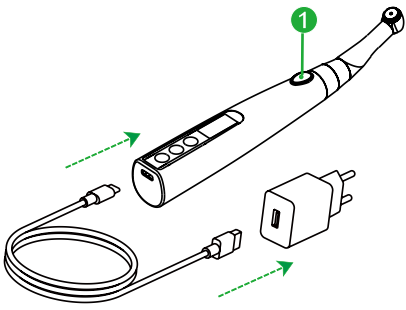
The motor handpiece runs reverse(Counter clockwise rotation) with an alarm sounds , and without torque protection.

NOTE

1. The device shuts down automatically after no operation for 8 minutes.

7. Charging

Turn the device on by pressing the 1 button.



Connect the USB cable to the unit power connector, and plug the other end into a USB adapter.

While charging, the battery symbols on the screen is displayed in sequence as bellow:

Fully charged will take about 4 hours, depending on residual battery power and the battery state.

When charging is completed, the battery symbols displays as below:

If the power is too low, the battery indicator will flash in:

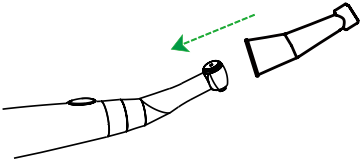
⚠Warning

1. Charge the device for more than 4 hours before using the product for the first time.
2. Only the original adapter and battery can be used.
3. Disposal of waste batteries in accordance with local regulations.
4. Do not use the device while charging.
5. Do not change the battery, only trained technician or distributor can change the battery, the electronic parts will be damaged if use a wrong battery or install with a wrong way.
6. Need to charge immediately if the battery is low.

8. Install accessories

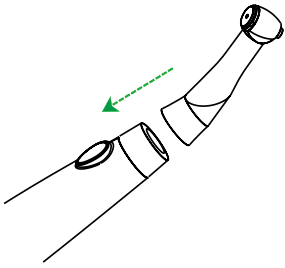
8.1 protective case

It is recommend using an protective case during treatment.

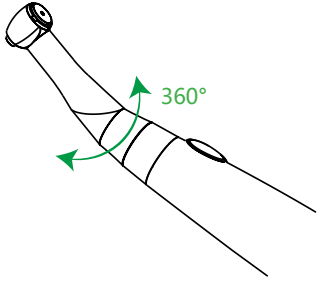


8.2 Install Contra Angle

Insert the Contra Angle into the handpiece until it securely located into the place.



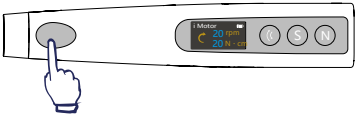
The Contra Angle can be 360° rotated without taking it off , it's easy to use during treatment.



9. Operation

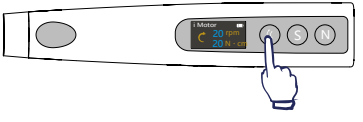
9.1 CW and CCW mode

Press the Main switch to turn device on.

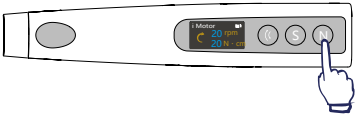


Press the S button to change Speed setting.

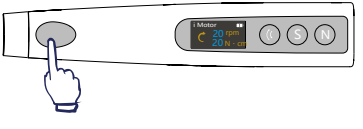
Press the button to change Motion setting.



Press the N button to change Torque setting.

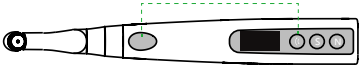


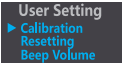
Press the Main switch to start / stop motor during standby status.



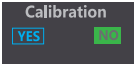
10. User Setting

Holding down "⌒" button and then press main switch to entry User setting during OFF state.

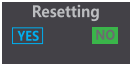




Press Select button to entry "Calibration" in the User Setting Menu,and press "S" and "N" to adjust current selection .

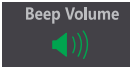


About "Calibration" refer to section **"Calibration"**

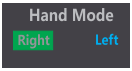


The handpiece can be factory reset and the following parameters restored to the factory defaults:

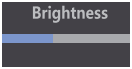
1. Memory program setting.
2. User settings.



Setting the Beep Volume.



Setting the left or right hand operation mode.



Changing the backlight brightness.

11. Maintenance and sterilization

11.1 Foreword

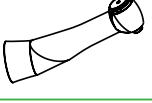
For hygiene and sanitary purpose, the components must be cleaned,disinfected and sterilized before each usage to prevent any contamination. This occurs the first use as well as the subsequent uses.

Comply with your national guidelines,standards and requirements for cleaning, disinfection and sterilization.

11.2 General recommendations

1. The user is responsible for the sterility of the product for the first cycle and each further usage as well as for the usage of damaged or dirty instruments, where applicable after sterility.
2. For your own safety,please wear personal protective equipment.
3. Use only a disinfecting solution which is approved for its efficacy(VAH/DGHM listing,CE marking,and FDA approval) and in accordance with DFU of the disinfecting solution manufacturer.
4. The water quality has to be convenient to the local regulations especially for the last rinsing step or with a washer-disinfector.
5. Thoroughly clean and wash the components before autoclaving.
6. Do not lubricate the motor handpiece.
7. Do not clean the Contra Angle with an ultrasonic cleaning device.
8. Do not use bleach or chloride disinfectant materials.

11.3 Autoclavable Components

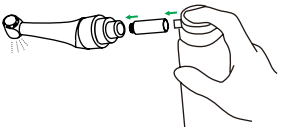
Protective case	Contra Angle
	

Warning

1. Only the components above can be autoclaved.
2. Before first use and after each use,sterilize the above components.

11.4 Cleaning and disinfection

Step	Operation	Processing
1	Preparation	Disconnect the components from the motor handpiece. Store the instruments in a humid surrounding.
2	Transportation	Safe storage and transporation to the reprocessing area to avoid any damage and contamination to the environment.
3	Preparation for decontamination	The device must be reprocessed in disassembled state.
4	Pre-Cleaning	Do a manual pre-cleaning,until the components are visually clean. Submerge the components in a cleaning solution and flush the components with a water jet pistol with cold tap water for at least 10 seconds.Clean the surfaces with a soft brush.
5	Cleaning	Preference is to be given to automated reprocessing methods,especially due to the better standardizing potential and industrial safety. Atuomated cleaning: Carefully put the components into the washer-disinfector on a tray and set the parameters as follows: 1. 4 mins pre-washing with cold water(<40℃); 2. 5 mins washing with a mild alkaline cleaner at 55℃ . 3. 3 mins neutralising with warm water (>40℃); 4. 5 mins intermediate rinsing with warm water(>40℃).
6	Disinfection	Authomated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value(Refer to EN 15883). A disinfection cycle of 5 mins desinfection at 93℃ , has been validated for the device to achieve an A0 value of 3000.

Step	Operation	Processing
7	Drying	Automated Drying: Drying of outside of instrument through drying cycle of washer/disinfector. If needed , additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile conpressed air.
8	Maintenance	Inspect components and sort out those with defects.Dirty components must be cleaned and disinfected again. Lubricate the contra angle: 
9	Packing	Pack washed component in an appropriate packaging material for sterilization.
10	Sterilization	Steam sterilization at 135° C at least 4 mins, or at 121° C at least 35 mins. Minimum drying time after sterilization: 10 mins.
11	Storage	Keep the components in sterilization packaging in a dry and clean environment.

Warning

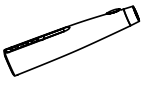
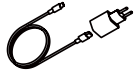
Use only Ethanol for Disinfection (Ethanol 70 to 80% vol.)

Use only approved autoclave devices according to EN 13060 or EN 285. The sterilization procedure must comply with ISO17665. Waiting for cooling before touching.

Check the packaging before using it (packaging integrity, no humidity and validity period), otherwise sterilize again.

Disinfection before first use and after each use.

11.5 Disinfection components

Handpiece	Base	USB cable
		

Wipe all the surfaces with a cloth lightly moistened with Ethanol for Disinfection (Ethanol 70 - 80vol%) at least 2mins, repeat for 5 times.

NOTE

1. Do not use anything except Ethanol for disinfection.

11.6 Battery Maintenance

Charge the battery when the battery icon flashes on the display .

If you do not use the device for a long time, you need to keep the device fully charged at least once a month to ensure that the battery is not too low.

12. Troubleshooting

If trouble occurs during the use of the product, please check the following points before contacting your distributor.

Problem	Cause	Solution	Ref. chap
Cannot turn the device on	The battery is too low	Please charge	/
	Press the main switch button too short time	Press the button more than 0.8 seconds	/
There is no sound	PCB broken	contact your distributor	/
			/
No displays on the screen	PCB broken	contact your distributor	/
Cannot charge	Wrong connect with cable	check connection	/

13. EMC table

Guidance and manufacturer’ s declaration – electromagnetic emissions		
The i Motor is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The **i Motor** 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 **i Motor** is suitable to 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 IEC61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer’ s declaration –electromagnetic immunity			
The **i Motor** is intended for use in the electromagnetic environment specified below. The customer or the user of the **i Motor** 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	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 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 transients/ bursts IEC 61000-4-4	±2kV 100kHz repetition frequency	±2kV 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Line to line: ±0.5kV, ±1kV Line to earth: ±0.5kV, ±1kV, ±2kV	Line to line: ±0.5kV, ±1kV Line to earth: ±0.5kV, ±1kV, ±2kV	Mains power quality should be that of a typical commercial or hospital environment.
Electrostatic discharge (ESD) IEC 61000-4-2	+/8 kV contact +/-2 kV, +/-4 kV, +/-8 kV,+/-15 kV air	+/- 8 kV contact +/-2 kV, +/- 4 kV, +/-8 kV, +/-15 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 %.
Voltage dips, Short interruptions and voltage variations on power supply lines IEC 61000-4-11	0% UT; 0.5 cycle at 0° , 45° , 90° , 134° ,180° , 225° , 270° , and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0° 0% UT; 250/300 cycle	0% UT; 0.5 cycle at 0° , 45° , 90° , 134° ,180° , 225° , 270° , and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0° 0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of devices require continue operation during power mains interruptions, it is recommended that devices be powered form an uninterruptible power supply or a battery

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz or 60Hz	30 A/m 50Hz or 60Hz	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT: rated voltage(s); E.g. 25/30 cycles means 25 cycles at 50Hz or 30 cycles at 60Hz			

Guidance and manufacturer' s declaration –electromagnetic immunity			
The **i Motor** is intended for use in the electromagnetic environment specified below. The customer or the user of the **i Motor** should assure that its used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted disturbances induced by RF fields IEC 61000-4-6 Radiated RF EM fields IEC 61000-4-3 Proximity fields from RF wireless communication equipment IEC 61000-4-3	3 V 0.15 MHz – 80 MHz, 6 V in ISM bands between 0.15 MHz and 80 MHz, 80 % AM at 1 kHz 3 V/m, 80 MHz – 2,7 GHz, 80 % AM at 1 kHz See the RF wireless communication equipment table in "Recommended minimum separation distances"	3 V 3V/m Complies	Portable and mobile RF communications equipment should be used no closer to any part of the **i Motor**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended minimum separation distances. See the RF wireless communication equipment table in" Recommended minimum separation distances".

Recommended minimum separation distances
Nowadays, many RF wireless equipment have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. The **i Motor** has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and the **i Motor** as recommended below.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

NOTE

1.Use of accessories and cable other than those specified or provided by the manufacturer of the **i Motor** could result in increased electromagnetic emissions or decreased electromagnetic immunity of **i Motor** and result in improper operation.

Cable information			
Cable Name	**Cable Length (m)**	**Shielded or not**	**Remark**
Cable	0.5	No	/

14. Warranty

1. The main unit of **i Motor** enjoys a **12-month warranty period**, which starts on the day of our delivery.
2. The host and other parts of the **i Motor** are repaired by authorized repair service partners.
3. If it is proved that the damage is caused by improper daily maintenance by the user, it is not covered by the warranty.

15. Service life

The service life of the i Motor main unit is **5 years**.

16. Declaration

In the following cases, the manufacturer does not assume any responsibility:
1. Use **i Motor** for purposes other than those specified in this manual.
2. The cleaning, disinfection or sterilization operation is not carried out according to the method stated in this manual.
3. Use or maintenance by untrained personnel.
4. If you have any questions, please contact your local dealer.

17. Environmental protection

The package should be recycled. Metal parts of the device are disposed as scrap metal. Synthetic materials, electrical components, and printed circuit boards are disposed as electrical scrap. The lithium batteries are disposed as special refuse. Please deal with them according to the local environmental protection laws and regulation.

18. Right

19. Warranty Card		
Name of customer:	Tel:	Purchase date:
Adress detail:		
Product name:		Model:
Serial number:		
Maintenance record	Date	Fault cause

Thank you very much for using our products;This table is considered as the Protection to fix warranties,so please reserve them carefully,Lose don't repair

1. Calculated from the date of purchase,our company's product warranty period is **_1_ year** .During the warranty period,any problems caused by products' quality or structure,we will be responsible for free repairing if the goods are under normal situation.
2. During the warranty,if there is any breakdown,please return the faulty device and completed warranty card to our company for repair.
3. Those machines that has refitted or added other functions by yourself will not be accepted to repair.

Free maintain won't be given under the following circumstance:

1. Without warranty card or purchase evidence.
2. Failure caused by improper installation,operation,and sterilization (don't comply with the user manual).
3. The breakdown caused by the dismantle movement of non-our-company authorized maintain.
4. The damage caused by customer inappropriate preservation,maintain,breakdown or the usage.
5. Easy damage pieces and present accessories are not concerned.
6. The breakdown and the damage caused by the force majeure.

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