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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 purchasing our device. Before operating the device, please fully read the manual and this manual should be saved for later use.

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 should be operated by licensed dental professionals with medical applied skill. The whole operation process should follow user's 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, EMMENDINGEN, 79312 GERMANY

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

SECTION I. INTRODUCTION

Thank you for purchasing RCTI-DY(I) Endo Motor!

It is a kind of endodontic motor to drive NiTi 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. This unit contributes to alleviate the dentist's working intensity.

SECTION II. MAIN TECHNICAL INDEX

Main Unit

Rated voltage: Max. DC8.4V

Rated current: Max.1.2 A

Power consumption: 10VA

Net weight: 450 g

Charger

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

Rated input current: 0.25A

Output voltage: DC8.7V

Output current: 600mA

Degree of protection against electric shock

---Type B applied part

Degree of Protection from ingress of liquids: None

Foot pedal: (protected against vertically falling water drop)

SECTION III. 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
	Caution: Consult accompanying documents
	Authorized Representative in the European Community
	CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC.
	Sterilizable up to the temperature specified at most
	Date of manufacture.
	Manufacturer
	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>alert indicator displayed on the LCD screen</p>
	<p>battery indicator displayed on the LCD screen</p>
	<p>Rotation direction</p>
	<p>Dynamic display of torque</p>
	<p>After the Endo file exceeds the max preset torque, and then Endo file will stop working automatically.</p>
	<p>After the Endo file exceeds the max preset torque, the Endo file will keep withdraw (reverse) until the removal of resistance, and then the file stop working.</p>
	<p>After the Endo file exceeds the max preset torque, the Endo file will keep withdraw (reverse) until the removal of resistance, and then the file go back to forward rotation again.</p>

SECTION IV. FEATURES

1. 22 settings for adjustable rotational speed ranging from 100 to 650rpm.
2. If the torque exceeds the setting value, the file will auto reverse to avoid the break-off in the root canal when the function of auto reverse is

activated.

3. Adjustable Torque—0.6-5.2 N.cm
4. Auto reverse and manual reverse are available.
5. Saving function—ten groups of program data can be set!
6. Start the rotation of the Ni-Ti files with foot control pedal
7. LCD display
8. When the device needs to be charged, there will be alarm.

SECTION V. SAFETY PRECAUTIONS

1. Before operation, please read the usage manual carefully!
2. Like all of the other electric facilities, this machine has an electromagnetism disturbance. When there is a patient who is now using the cardiac pacemaker, or there is an electronic operation, please don't put the machine around. The cardiac pacemaker sufferer, viz. the serious cardiac pulse abnormality sufferer, is forbidden to use this machine.
3. Equipment not suitable for use in the presence of flammable anesthetic mixture with air or nitrous oxide.
4. Check the product before use by rotating it, paying attention to looseness, vibration, noise and temperature. If any abnormal condition is found even slightly at that time, immediately stop use and contract your dealer.
5. Do not use a bent, damaged, deformed or non-ISO-conforming file. Using such a file may result in personal injury due to its unexpected breaking or "flying way" during rotation.

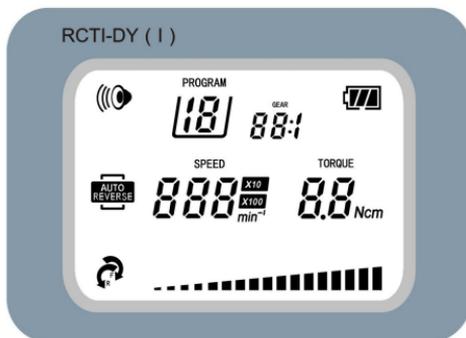
6. Do not expose the unit, motor handpiece, battery or AC adapter to any liquid.
7. Before changing the head or file, turn off the power of the motor handpiece. Changing with the power kept on may cause unintended rotation by accidental touch of the ON/OFF button.
8. ONLY 1:1 contra angle could be connected to motor handpiece.
9. When the reverse rotation is set, the auto reverse function can also be activated.
10. Do not disassemble or alter the motor handpiece.

SECTION VI. PRODUCTS DESCRIPTION

	Main unit		Motor handpiece (Plastics or Metal)
	Foot pedal		Adapter

Operation panel and LCD panel

(The following LCD display is only for reference, NOT actual picture.)



POWER

Holding down the POWER key for more than two seconds turns on the power and the LCD panel lights.

Holding down the POWER key for more than two seconds while the power is on turns off the power and the LCD panel display turns off.



Notice:

Before the root canal treatment operation and after finishing the setting, the dentist could see the corresponding menu flashing on the LCD.

After flash stopped, please switch on the foot pedal, in this situation, root canal treatment operation can be available!

If the dentist does not follow this step order, the unit will not work!

SPEED

The present rotation speed sign is displayed on the lower right corner of LCD.

23 kind of adjustable speed could be adjusted ranging from 100-650rpm (min-1) are available.

Press SPEED "+" key once, speed will increase 25rpm (min-1) every time

Press SPEED "-" key once, speed will decrease 25rpm (min-1) every time

Hold and press SPEED "+" or SPEED "-" key, the speed will keep lasting increase or decrease up to the data dentist want!

TORQUE

Torque range: 0.6-5.2 N.cm

The torque value can be controlled, which is changing when the file is in motion in the root canal!

Press Torque "+" key once, speed will increase 0.1 N.cm every time

Press Torque "-" key once, speed will decrease 0.1 N.cm every time

Hold and press Torque "+" or Torque "-" key, the torque value will keep lasting increase or decrease up to the data dentist want!

**Notice:**

If the torque exceeds the setting value, the file will auto reverse to avoid the break-off in the root canal when the function of auto reverse is activated.

If the torque exceeds the setting value, the file will stop rotating when the function of auto reverse is not activated.

In this situation, the dentist could step off the foot pedal and reset the torque value.

GEAR

The gear ratio not be changed at present.

ONLY 1:1 HP contra angle can be connected to the motor handpiece!

SAVE

Saving function

After setting up the program, if you would like to memorize this setting, please press "SAVE" key. Ten group of program setting data can be set for saving.



Notice: The unit will work under the latest setting program if no other operation is undertaken when the dentist restart the unit.

PROGRAM

"PROGRAM" key is for selecting the proper program from the saving

program data! The numbers 1-10 will be displayed on the top left corner of LCD, if ten groups of program data have been saved!

	<p>Auto reverse switch button</p> <p>After the endo file exceeds the max preset torque, and then Endo file will stop working automatically.</p>
	<p>Auto reverse switch button</p> <p>After the endo file exceeds the max preset torque, the Endo file will keep withdraw (reverse) until the removal of resistance, and then the file stop working.</p>
	<p>Auto reverse switch button</p> <p>After the endo file exceeds the max preset torque, the Endo file will keep withdraw (reverse) until the removal of resistance, and then the file go back to forward rotation again.</p>

Warning:

1. When the torque value is set below 1 N.cm, the speed **MUST** be below 300 rpm for the sake of safety and normal working.
2. When turning on the unit, if the recurring of forward rotation and auto-reverse happen, please enlarge the torque or lower the speed to make it normal working.

REVERSE

The rotation direction of the file can be changed by this key. It can be changed while the file is in motion.



Forward Rotation Reverse Rotation

The motor handpiece starts in reverse. If you want to forward rotation again, just press the REVERSE button on the control panel.

AUTO REVERSE

The auto reverse mode can be selected by this key.



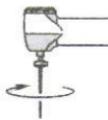
AUTO REVERSE MARK

The auto reverse mark is displayed on lower left corner of the LCD when activated.

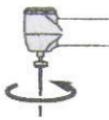
When the function of auto reverse is not activated, this mark will not appear on the LCD alternately.

When the reverse rotation is set, the auto reverse function can also be activated.

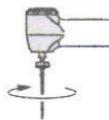
The file starts rotation in reverse. When auto reverse function is activated, the file returns to normal rotation (forward rotation)



Forward Rotation



Reverse Rotation



Forward Rotation


Notice:

When the battery goes down (when the remaining amount of battery

mark indicates  or ) the load may not reach the preset

torque limit value. In this case, the auto reverse function may not be

activated. Please make sure that the battery is not significantly

consumed to ensure the function of auto reverse (When the mark of

battery mark indicates  or ).

BATTERY SIGN

The mark will be flashed when the battery is being charged. The standard charging time is around 5 hours. When the charging has been completed, the mark will stop flashing.

Ensure to charge 8 hours continuously for the first time.

The battery will gradually discharge over time even though the unit is not used. So it is strongly recommended to recharge the battery before reuse.

The charging time varies depending on the use, condition of battery and temperature.

**Notice:**

There will be a sound alarm at every 30s when the battery is

Appro. 30-75% remains like , at every 5s when Less than 30%

like . The unit will be automatically powered off when Low

voltage like .



Full charge



Appro. 30-75% remains



Less than 30%



Low voltage. Charge immediately

FOOT PEDAL

To step on the foot pedal, the endodontic file starts to rotate. To remove from the foot pedal, the file stop rotating.

AC ADAPTER

European plug or American plug is available.

Connect to AC 110-240V power supply.

SECTION VII. CONNECTION

Connect Motor Handpiece

Align the positioning pins of the plug of motor handpiece with the positioning slots of motor handpiece connector and insert the plug in a secure way to ensure that it is fixed properly.



Notice:

To insert the plug, do not do it in a forced way.

To remove the plug, hold the plug ring first, and then pull it out backward.

Connect foot pedal

Securely insert the plug of the foot pedal into foot pedal connector.

Connect AC adapter

Securely insert the jack of AC adapter into the power connector in a proper way.

Connect the contra angle

Align the positioning pins of the contra angle with the positioning slots of motor handpiece and insert the head until they click.

When removing the contra angle, pull it out axially.

SECTION VIII. MAINTENANCE

When the surface of main body is polluted or dirtied, please rub the surface slightly with soft cloth stained with water or non-alcoholic

disinfectant.

Notice: Ethanol, banana oil and light oil are not allowed.

SECTION IX. DISINFECTION

Please wipe the control unit and accessories with the soft cloth stained with ethanol.

Disinfecting the front stainless part by autoclave is preferred

When the instrument is kept nonuse, please make it clean and dry.

SECTION X. STORAGE & TRANSPORT

ENVIRONMENT

Operation environment

Ambient temperature: +5°C ~ +40°C

Relative humidity range: ≤80%

Atmospheric pressure: 86kPa~ 106kPa

Storage environment

Ambient temperature: -40°C ~ +55°C

Relative humidity range: ≤90%

Atmospheric pressure: 50~106 kPa

Equipment is not suitable for storage in the presence of sunlight, rain, dust, and corrosive gasoline and volatile without poor ventilation.

Transportation is applicable to all common method.

SECTION XI. PACKING LIST

Standard accessories:

Control unit	1 pc	Foot pedal	1 pc
Motor handpiece with handpiece cable			1pc
Hnadpiece holder	1pc	Adapter	1 pc
User's manual	1pc		

(Optional Accessory)

The following parts not included in the standard list

1:1 HP contra angle	(low speed 1:1)
Ni-Ti endo file	(K3 Kerr brand recommended)

SECTION XII. WARRANTY STATEMENT

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

The control part of device is guaranteed for its designated use, against original defects in materials and workmanship for a period of 12 months from date of purchase. The guarantee for spare parts is 6 months.

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

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 directly 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 [RCTI-DY (I)] is intended for use in the electromagnetic environment specified below. The customer or the user of the [RCTI-DY (I)] should assure that it is used in such an environment		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The [RCTI-DY (I)] 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 [RCTI-DY (I)] is suitable for use in all establishments other 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: 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 [RCTI-DY (I)] or shielding the location.
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 emissions			
<p>The [RCTI-DY (I)] is intended for use in the electromagnetic environment specified below. The customer or the user of the [RCTI-DY (I)] should assure that it is used in such an environment</p>			
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. The electrical fast transient burst (EFT) is generated by the switching of inductive loads. Separation between the

			equipment and other loads shall be considered before installation. Mains filter is required, if necessary.
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 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 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (>95% dip in	<5% U_T (>95% dip in U_T) 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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [RCTI-DY (I)] requires continued operation during power mains interruptions, it is recommended the [RCTI-DY (I)] be powered from an uninterruptible power supply or a battery.

	U_T for 5s	U_T for 5s	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/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 a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration - electromagnetic emissions			
The [RCTI-DY (I)] is intended for use in the electromagnetic environment specified below. The customer or the user of the [RCTI-DY (I)] 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 [RCTI-DY (I)], including cables, than the recommended separation distance

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150KH z to 80MHz 3 V/m 80MHz to 2.5GHz	3V 3 V/m	<p>calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>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)</p> <p>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</p> <p>Interference may occur in the</p>
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			vicinity of equipment marked with the following symbol: 
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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 [RCTI-DY (I)] is used exceeds the applicable RF compliance level above, the [RCTI-DY (I)] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [RCTI-DY (I)].

^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 [RCTI-DY (I)]
The [RCTI-DY (I)] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the

user of the [RCTI-DY (I)] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [RCTI-DY (I)] 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