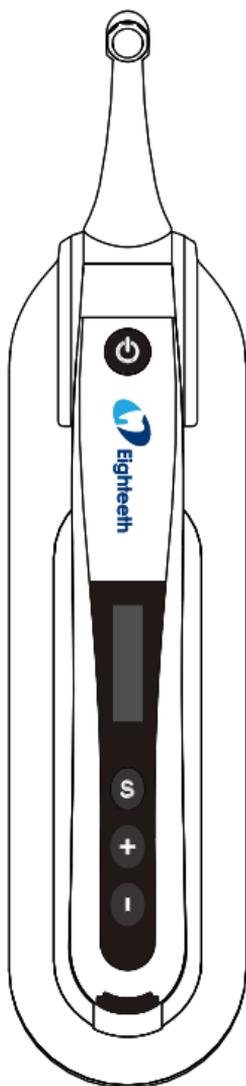




E-xtreme



Endo Motor USER MANUAL

Changzhou Sifary Medical Technology Co.,Ltd.

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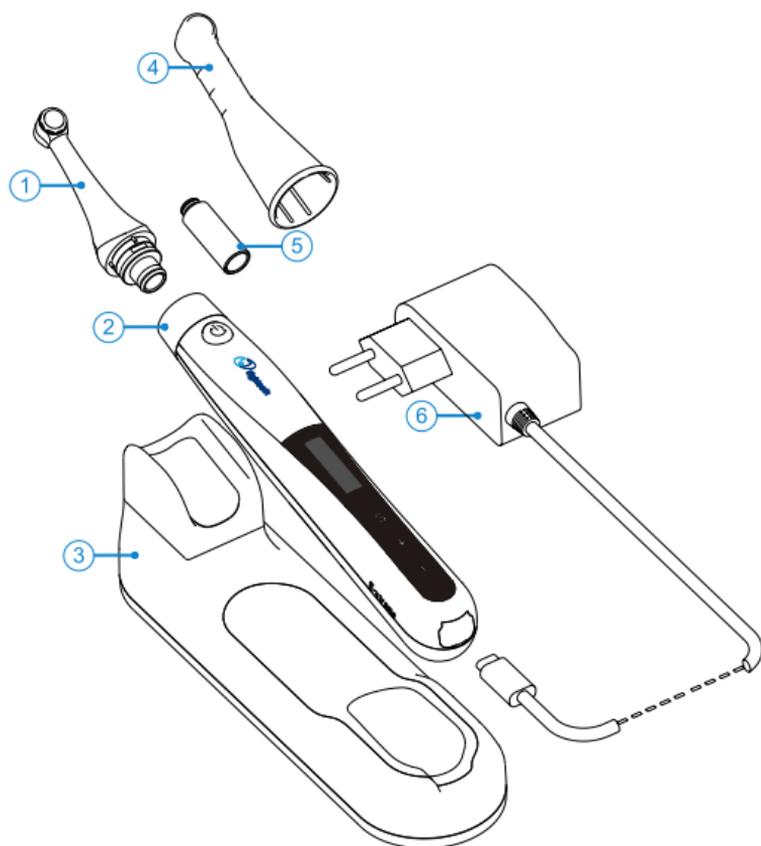
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1. Scope of E-xtreme

1.1 Parts Identification



1. Contra Angle
2. Motor Handpiece
3. Base
4. Insulating Sleeve
5. Spray Nozzle
6. Adapter

Note: This product does not contain root canal file

1.2 Components and Accessories

| | | |
|--|--|--|
| <p>Motor Handpiece (1pcs)</p>  | <p>Base (1pcs)</p>  | <p>Contra Angle (1pcs)</p>  |
| <p>Adapter (1pcs)</p>  | <p>Spray Nozzle (1pcs)</p>  | <p>USER MANUAL (1pcs)</p> |
| <p>Certificate (1pcs)</p> | <p>Warranty card (1pcs)</p> | |

1.3 Options

| | | |
|--|--|--|
| <p>Insulating Sleeve</p>  | | |
|--|--|--|

2. Symbols used in the User Manual

| | |
|--|---|
|  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. |
|  | Serial number |
|  | Catalogue number |
|  | Date of manufacture |
|  | Batch number |
|  | Safety class II device |
|  | Type B applied part |
|  | Direct current |
|  | WEEE (waste of electrical and electronic equipment) directive marking |
|  | Store in a dry place |
|  | Can be autoclaved up to a maximum temperature of 134° Celsius |
|  | Temperature limitation |
|  | Relative humidity limitation |
|  | Atmospheric pressure limitation |
|  | Manufacturer's LOGO |
|  | Be careful! Refer to relevant documents |
|  | Washer-disinfector for thermal disinfection |

3. Before Use

3.1 Intended Use

Use for dental root canal treatment using endodontic instruments in torque controlled continuous rotation and in reciprocating movement.

This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel and not used in the oxygen-rich environment.

3.2 Contraindications

Don't use it with high frequency surgical equipment. Patients with heart disease should use it with caution. It is forbidden to use pacemaker or cochlear implant.

It is forbidden to use this product for implant operation or other non root canal treatment operation.



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. Do not use the equipment in the presence of free oxygen, anesthetic gas or combustible materials. The equipment must be operated, used and stored in a safe environment.
4. This equipment may cause radio interference or interfere with the operation of nearby equipment. At this time, the orientation or position should be readjusted, and shielding should be set near the equipment to minimize the interference effect of the equipment. The electromagnetic radiation emitted by the equipment meets the requirements of relevant regulations (yy0505).
5. 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 and do not use this system near the active HF Surgical Equipment in the hospital. Portable RF communications

equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the E-connect S, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Do not charge, operate or store at high temperatures. Comply with the specified operating and storage conditions.

6. Please do not charge, use or store this equipment at high temperature. Please pay attention to the use and storage conditions.

7. Gloves and a rubber dam are compulsory during treatment.

8. Never open or repair the device yourself, otherwise, void the warranty.

9. If irregularities occur in the device during treatment, switch it off. Contact the agency.

10. Please use the original power adapter when charging; do not use the equipment for treatment during charging.

11. If liquid flows out of the host, it can be judged as battery leakage. Please stop using immediately and contact the local dealer for treatment.

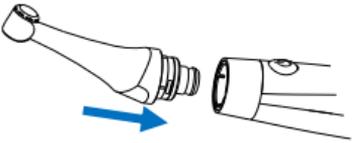
12. Do not dismount the bending head during the operation of the main engine, otherwise the bending head and motor gear will be damaged.

13. Please use the original bending head.

14. Use continuous file in continuous mode; use reciprocating file in reciprocating mode, do not adjust and use, and use according to rotation speed, torque and return angle recommended by the root canal file manufacturer.

4. Installing the E-xtreme

4.1 Installation of the contra angle

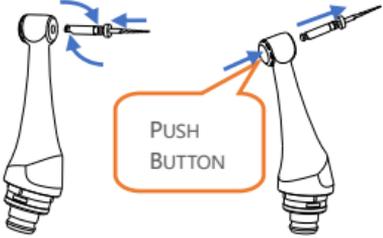
| | |
|---|---|
|  | <p>Make sure 4 pins on contra angle alignment the slots of handpiece, plug them together until it "click" securely into place.</p> |
|  | <p>The contra angle can be 360 degrees rotated without take off, make it easy to watch the LCD in treatment by rotating the contra-angle.</p> |



WARNING

Make sure the assembly is connected properly, otherwise might cause unexpected motor reverse, even hurt the patients
After connecting the contra angle and handle, pull it gently to make sure the connection is good.

4.2 Install the file

| | |
|--|---|
|  <p>Install</p> <p>Remove</p> | <p>Install: insert the root canal file and rotate it slightly from left to right to ensure that the file needle is aligned with the internal bayonet, and then push it in slightly to complete the installation.</p> <p>Remove: press and hold the back cover button on the contra angle to release the internal bayonet and gently pull out the root canal file.</p> |
|--|---|

**WARNING**

Inspect the file head before inserting the file. Do not use the damaged file head.

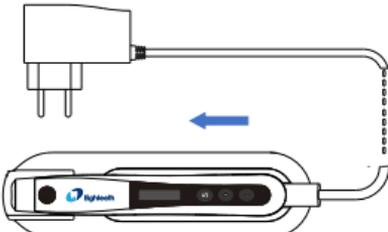
Be careful when inserting and removing files to avoid injury to fingers.

Pull the file gently to make sure that the file is secure in handpiece properly, otherwise it may pop out and hurt the patient.

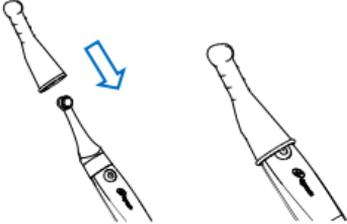
When removing the file, press the button tightly to release the internal bayonet. If the bayonet is not fully released, the bearing will be damaged.

Make sure the motor is stopped when inserting and removing files.

4.3 Charging

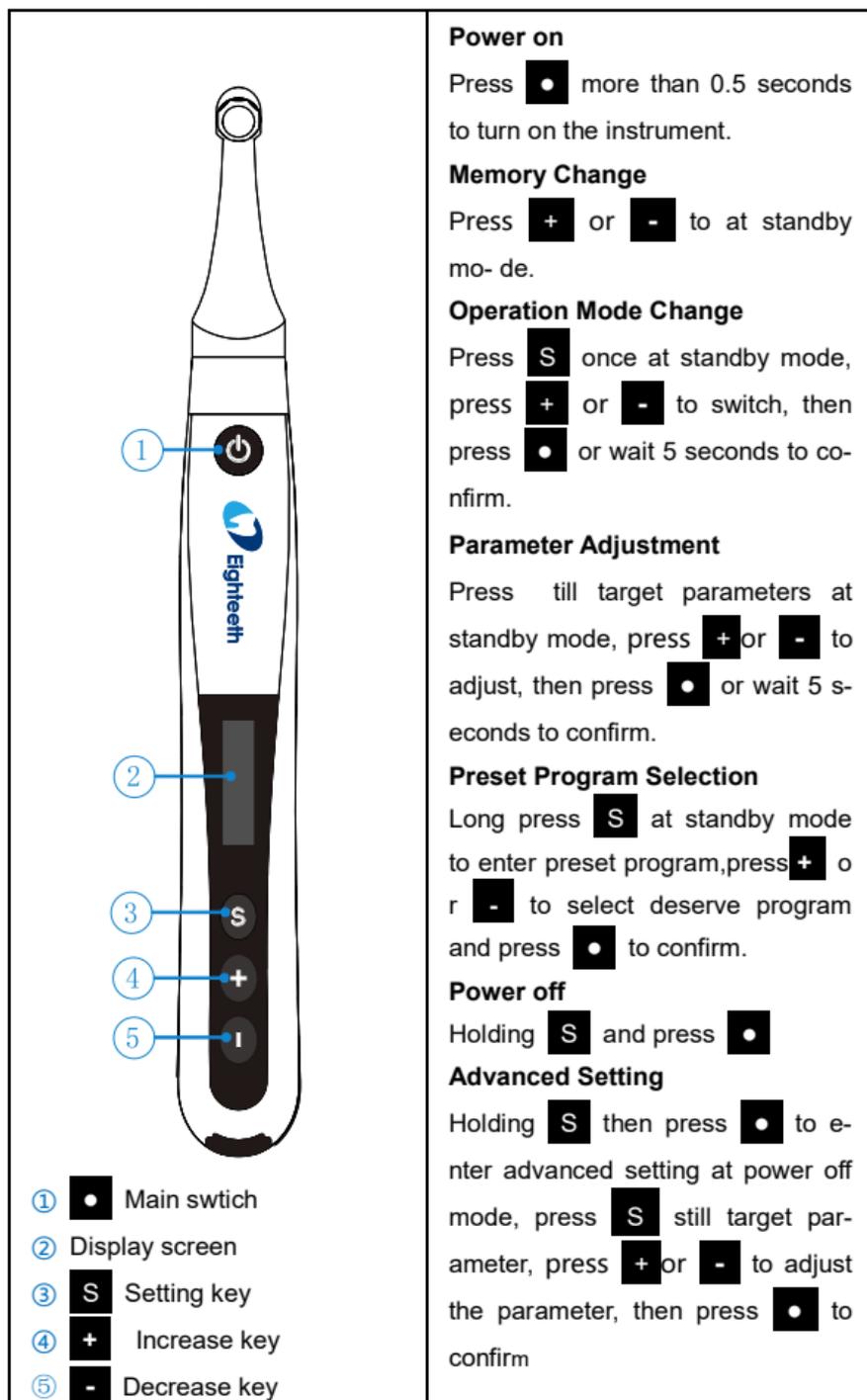
| | |
|---|---|
|  | <p>Show the remaining power. This icon indicates that the remaining power is less than 15%, please charge it in time.</p> |
|  | <p>Connect the power adapter to E-extreme as shown</p> |
| <p> WARNING</p> <p>Do not use the power adapter outside the equipment to charge E-extreme</p> | |
|  | <p>When the power adapter is connected to E-extreme, the screen will display the figure on the left, which indicates charging</p> |

4.4 Install the Insulation Sleeve

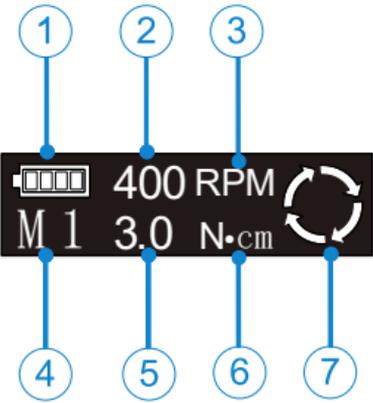
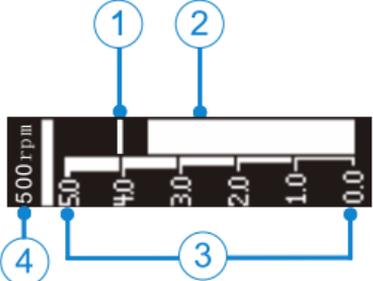
| | |
|--|--|
|  | <p>Install: assemble according to the left figure</p> <p>Remove: pull out the cover in the opposite direction</p> <p> NOTE The head cover is mainly used for secondary isolation to avoid cross infection.</p> |
|--|--|

5. Use Interface

5.1 Panel key



5.2 Screen display

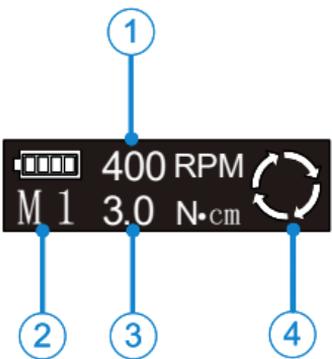
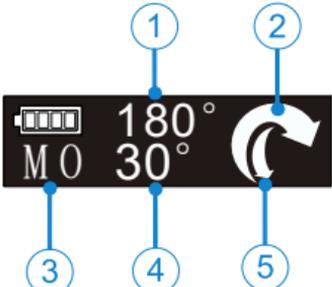
| | |
|---|---|
|  <p>The standby interface screen shows a battery icon with four bars (1), the speed '400 RPM' (2), a circular arrow icon (3), 'M 1' (4), '3.0 N·cm' (5), and a circular arrow icon (7).</p> | <p>Standby interface</p> <ul style="list-style-type: none"> ① Residual battery power ② Speed ③ Unit of speed (Revolutions Per Minute) ④ Memory mode number ⑤ Torque ⑥ Unit of torque (Newton Centimeter) ⑦ Operation mode |
|  <p>The working mode interface screen shows a torque scale from 0.0 to 5.0 (3), a set maximum torque marker at 4.0 (1), a real torque marker at approximately 3.5 (2), and a preset speed marker at 500 RPM (4).</p> | <p>Working mode interface</p> <ul style="list-style-type: none"> ① The set maximum torque ② Real torque ③ Torque display scale ④ The preset speed |

5.3 Terms and definition

| | |
|---------------------------|---|
| Fwd/Fw | Forward (Clockwise rotation) |
| Rev/Rv | Reverse (Counter clockwise rotation) |
| REC | Reciprocation: Be applied to reciprocating file, path file and rotary file protection by setting some special angle |
| Memory mode | Such as M0-M9 |
| Operation mode | Such as Fwd, Rev(set in M1-M9)、 Reciprocation (M0) |
| TRQ | Abbreviation for torque |
| MEM | Abbreviation for Memory |
| R·D | Abbreviation for Rotate Direction |
| DIR | Abbreviation for Direction |
| Separation of instruments | The file used in root canal therapy was broken accidentally. |

6. Setting

6.1 Set memory mode

| | |
|---|--|
|  <p>The LCD display shows the following information: a battery level indicator, 'M 1', '400 RPM', '3.0 N.cm', and a circular arrow icon. Callouts 1, 2, 3, and 4 point to the speed, mode, torque, and operation mode respectively.</p> | <p>The device has 10 memory modes (M0-M9), press + or - at standby mode, memory number (2) will change together. Each memory mode includes its own speed (1), operation mode (4) and torque (3). These parameter can be set separately. (Adjust parameters according to chapter 6.2).</p> |
|  <p>The LCD display shows the following information: a battery level indicator, 'M 0', '180°', '30°', and a curved arrow icon. Callouts 1, 2, 3, 4, and 5 point to the forward angle, reverse angle, mode, forward angle, and reverse angle respectively.</p> | <p>M0 is a separate mode of reciprocating mode. Including forward angle (1) and reverse angle (4). These parameter can be set separately. (Adjust parameters according to chapter 6.2). Figure (2) means Forward, and figure (5) means Reverse. The bigger figure means angle of this direction is bigger than the other one.</p> |

6.2 Set parameters



WARNING

All parameters must be set according to the recommended values of root canal file manufacturer. Before starting the main machine for operation, make sure that all parameters are correct, otherwise there is a risk of instrument separation.

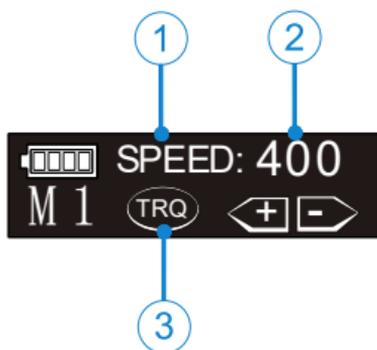
| | |
|--|---|
| | <p>Before starting the main engine, check whether the operation mode (①) is correct. If it is not the expected operation mode, press -S once on the standby mode to enter the operation mode selection, press + or - to switch, and then press • or wait for 5 seconds to confirm the operation mode.</p> |
| | <p>The left figure describes the setting of common functions of the machine (memory mode M1 to M9 are applicable). In standby mode (①) press S to enter the speed setting, press + or - to set the speed value; after the speed value is set, press S again to enter the torque setting, press + or - to set the torque value. After the torque value is set, press S again to enter the rotation direction operation mode (two modes: FWD and Rev), press + or - to set, then press • or S or wait for 5 seconds to confirm the</p> |

operation mode.

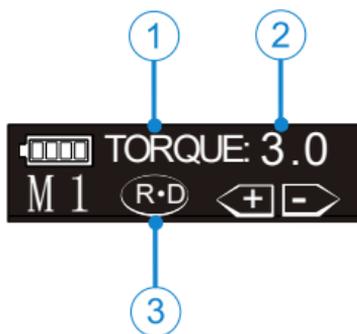


NOTE

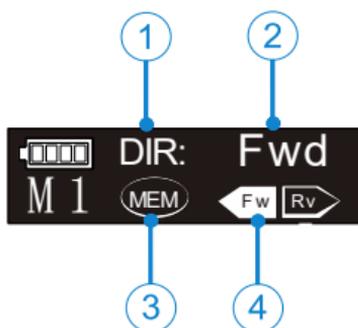
In different operation modes, the values of parameters will be different according to the corresponding logic (**Adjust parameters according to chapter 7.2**).



In M1-M9 memory mode, the speed can be 120rpm-650rpm. Press **S** at standby mode till speed (①②) is displayed, Press **+** or **-** to set, then press **.** or wait for 5 seconds to confirm. The left figure (③) means after pressing **S** again will enter torque (TRQ) setting.



The torque value can be set from 0.5 to 4.0 N·cm. Press **S** at standby mode till torque (①②) is displayed, press **+** or **-** to set, then press **.** or wait for 5 seconds to confirm. The left figure (③) means after pressing **S** again will enter rotate direction- (R.D.) setting mode.

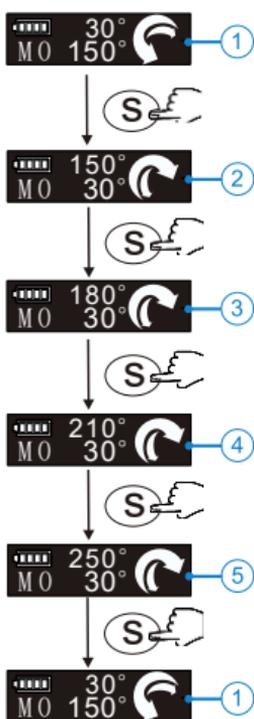


FWD or Rev can be set in operation mode of M1-M9. Press **S** till the operation mode (①②④) is displayed, press **+** or **-** to set, then press **.** or wait 5 seconds to confirm. The left figure(③) means press **S** again will enter memory mode(MEM).



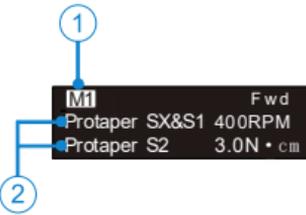
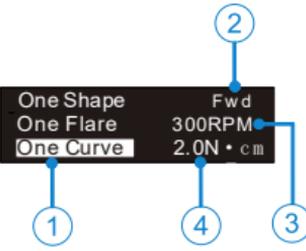
NOTE

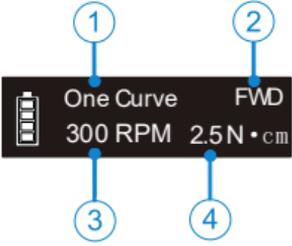
When Rev operation mode is selected, a continuous alarm sound will appear after the host is started to remind the operator that the motor is in the working state of reverse rotation.



The left figure describes the setting of M0(REC mode): Press **S** at M0(①) to switch different reciprocating preset programs. There are altogether 5 sets of preset reciprocating programs.

6.3 Preset programs

| | |
|--|--|
|  | <p>For the convenience of the operator, some common root canal file systems are preset.</p> <p>Long press S at standby mode to enter preset mode, the screen will display as the figure shows on the left.</p> <p>M1(①) means current memory mode, operator can choose preset mode(②) to replace it. Press + or - to switch- (press the key several times to jump to the next page). Then press ● to confirm.</p> |
|  | <p>If you select one of the preset programs, such as "one curve" (①), the corresponding operation mode(②), speed (③) and torque(④) will be automatically set.</p> <div style="background-color: #f0f0f0; padding: 10px;"> <p>NOTE</p> <p>Protaper®, GATES®, Pro.Glider®, and Wave one® is a registered trademark of Dentsply.</p> <p>Mtwo®, Flex.Master®, Reciproc® and R-Pilot® is a registered trademark of VDW.</p> <p>K3XF®, TF® is a registered trademark of SybronEndo.</p> <p>OneG®, OneShape, OneFlare, 2Shape and OneCurve® is a registered trademark of Micro-Mega</p> <p>XPendo.Shaper®, XPendo.Finisher®, Irace®, BT-Race® and BioRace® is a registered trademark of FKG</p> </div> |

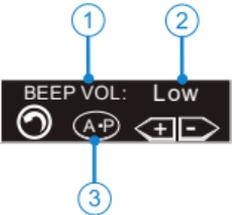
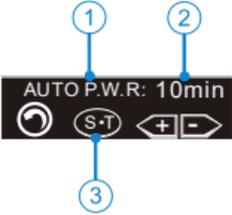
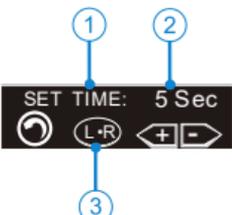
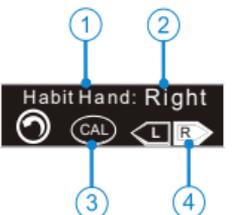


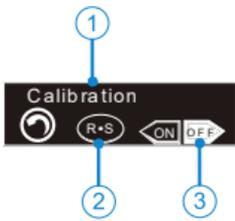
When the preset mode is selected, the memory number(①) will be changed to the preset name, operation mode (②), speed (③) and torque (④) will also be automatically set.

 **NOTE**

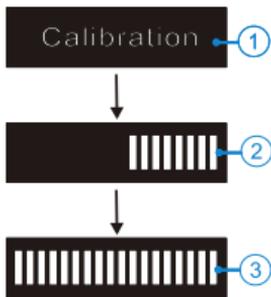
All memory modes (from M1 to M9) can be replaced by preset programs in this way.

6.4 Advanced setting

| | |
|---|--|
|  | <p>Hold S then press . (for about 0.5 seconds) at off mode to enter advanced set mode.</p> |
|  | <p>It will be about 1 second at SET logo and then enter ① "BEEP VOL" (beep volume set). Press + or - to set ② (Mute, Low, Mid, High), then press . to confirm and shut down. The left figure ③ means press S once in this case will enter auto power off time set (A.P).</p> |
|  | <p>Press S again at beep volume set ① will enter "AUTO P.W.R" (auto power off time set), press + or - to set ② (3-15 minutes), then press . to confirm and shut down. The left figure ③ means press S again will enter auto set confirm time (S.T).</p> |
|  | <p>Press S again at auto power off time set ① will enter "SET TIME" (auto set confirm time). Press + or - to set ② (3-15 seconds), then press . to confirm and shut down. The left figure ③ means press S again will enter hand habit set mode (L.R).</p> |
|  | <p>Press S again at auto set confirm time ① will enter "Habit Hand" (hand habit set). Press + or - to set ②④ (Left, Right), then press . to confirm and shut down. The left figure ③ means press S again will enter auto calculation (CAL). After switching to the left-handed habit, the display interface will rotate 180° to facilitate the left-handed operator to observe the display screen</p> |



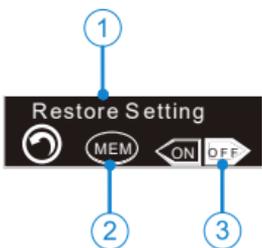
Press **S** again at hand habit set will enter ① "Calibration" auto calibration, press **+** or **-** to set ③ (ON、OFF), Choose "ON" and press **•** or **S** to confirm and the device will auto calibrate. The left figure ② means when choose "OFF" and press **S** again will enter restore settings (R.S).



When the device auto calibrate ①, the screen will display the progress ② (through the bar), after calibrating ③ the bar will be full and the device will beep out.



NOTE
Before automatic calibration, make sure that the original contra angle is installed on the host machine, and the root canal file is not installed on the contra angle. If the contra angle is not installed or non-original contra angle is installed, the torque after calibration may be incorrect, which may bring the risk of instrument separation.



Press **S** again at auto calibration with switch "off" will enter ① "Restore Setting (restore settings). Press **+** or **-** to set ③ (ON、OFF).

Choose "ON" and press **•** or **S** to confirm and restore all settings. Choose "OFF" and press **S** again ② (MEM) to confirm, saving all settings above and return to the memory mode. All parameters will be covered by the factory default parameters. (refer to chapter 7.5 parameter logic).



NOTE
After restoring the factory settings, the parameters set by the customer will be covered by the factory default

6 Setting

| | |
|--|---|
| | parameters. If necessary, please record the parameters before restoring the factory settings. |
|--|---|

6.5 Parameter logic

The factory default parameters of the ten memory modes are shown in the table below. The parameters can be adjusted as needed.

The default advanced settings parameters are shown in the following table. The parameters can be adjusted as needed

| Parameter | M0 | M1 | M2 | M3 | M4 | M5 | M6 | M7 | M8 | M9 |
|-----------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Operation mode | REC | Fwd | Fwd | Fwd | Fwd | Fwd | Rev | Rev | Fwd | Fwd |
| Speed(rpm) | N/A | 350 | 300 | 400 | 400 | 300 | 350 | 500 | 500 | 650 |
| Torque(N·cm) | N/A | 2.5 | 3.0 | 2.0 | 1.5 | 1.5 | 2.5 | 2.0 | 2.5 | 2.0 |
| Fwd angle | 30 | N/A |
| Rev angle | 150 | N/A |

The default advanced settings parameters are shown in the following table. The parameters can be adjusted as needed.

| | |
|-------------------------------------|-------|
| Volume BEEP VOL | Mid |
| Auto power off AUTO P.W.R | 10min |
| Auto set confirm SET TIME | 5s |
| Hand habit Habit Hand | Right |

| | |
|--|-----|
| Auto calibrate Calibration | Off |
| Restore settings Restore Setting | Off |
| / | / |
| / | / |

The **rotational speed (RPM)** varies in different operating modes, as shown in the table below

| Fwd | | Rev | | | REC |
|-----|-----|-----|-----|-----|-----|
| 120 | 150 | 200 | 250 | 280 | / |
| 300 | 350 | 400 | 450 | 500 | |
| 550 | 600 | 650 | | | |

Torque (N·cm) in different operation modes, the torque value can be set differently even in the same operation mode when the speed value is set differently. See the table below for details.

| Fwd | | Rev | | | | | REC | | |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|---|
| 0.5 | 0.8 | 1.0 | 1.5 | 1.8 | 2.0 | 2.2 | 2.5 | 3.0 | / |
| 3.2 | 3.5 | 4.0 | | | | | | | |

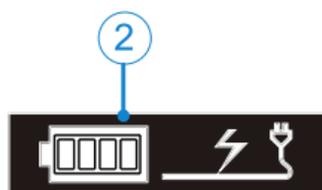
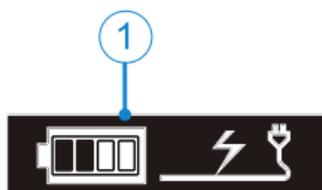
There are 5 fixed values of **reciprocating Angle** in M0 reciprocating mode, and the Angle cannot be changed., as shown in the table below.

| | Fwd | Rev | REC |
|------------------------|-----|-----|---|
| reciprocating Angle | | / | Five sets of fixed values 1. Fwd angle 30°, Rev angle 150° 2. Fwd angle 150°, Rev angle 30° 3. Fwd angle 180°, Rev angle 30° 4. Fwd angle 210°, Rev angle 30° 5. Fwd angle 250°, Rev angle 30° |

7.Operation

7.1 Charge

| | |
|--|--|
|  | <p>Display the remaining power. The remaining charge is less than 15%.</p> |
| | <p> NOTE</p> <ol style="list-style-type: none"> 1. If the battery power is less than 15%, it must be recharged within 30 days, otherwise the battery will be irretrievably damaged due to low power. 2. If you do not use this product for a long time, please charge the product at least once a month. |
|  | <p>If the battery power is lower than 15%, the speed and torque may be lower than the set value. As shown in the left figure, the low power alarm will appear on the display screen with continuous use, and the device will automatically shut down.</p> |
| | <p> NOTE</p> <p>Because the display of the remaining power is based on the voltage level, if a large torque load appears during the operation, the remaining power display may appear a short-term decrease.</p> |



When charging, the charging indicator will appear on the display screen and flicker slowly (①). When the battery is fully charged or in the state of nearly full charge, the display will stop flashing, and the charging indication is shown in the figure (②).

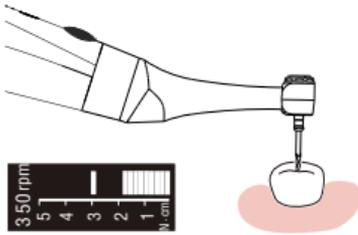
It takes about 4 hours to fully charge the battery. If the remaining charge of the battery is different or the state of the battery is different (such as aging), the charging time will be different.

According to the use state of the battery, the battery can be recharged 300-500 times, and then the battery power will be significantly reduced.



It is forbidden to replace batteries by non professionals or trained personnel. If the wrong battery is used or installed incorrectly, the electronic components will be damaged.

7.2 Motor Operation



In the standby mode, the root canal preparation machine was started by pressing the main switch . After startup, the progress bar will be displayed on the display screen (for details of the progress bar, please refer to chapter 5.2 display screen interface).



WARNING

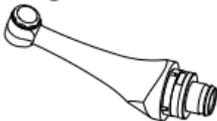
1. Before using in the treatment, please try it out of the mouth to ensure that the function of the device is normal.
2. The root canal file may be damaged suddenly when it enters into the root canal which is too curved or not in good shape. When the user feels that the root canal is abnormal, please stop using the device immediately and confirm the correct operation parameters and methods.
3. Even if the normal parameters are set, due to the metal fatigue of the root canal file, the instrument will be separated. Therefore, when using the root canal file, do not exceed the times recommended by the manufacturer, and replace it in time.
4. When the root canal file is subjected to excessive external force, it may break. When using this equipment, do not apply excessive external force to the root canal file.
5. Do not press the back cover of the bending machine head during the treatment, otherwise the equipment will be damaged, and even the flying needle will hurt the patient.
6. The electromagnetic noise in the surrounding environment may interfere with the normal operation of the equipment. Please do not completely rely on the automatic control of the equipment, and always pay attention to the feedback information on the LCD screen.



NOTE

1. When there is any abnormality, please stop using the equipment. This equipment is not suitable for all types of root canals. It is recommended to use according to the instructions of root canal file.
2. The root canal file is easy to fracture at high speed. Please follow the rotation speed recommended by the manufacturer. Please check the set speed before use.
3. When using this equipment, use the root canal file with materials other than nickel titanium carefully.
4. Please use disposable gloves and rubber barrier for treatment.
5. After the treatment, please take out the root canal file to avoid damage to the root canal file.

8.Maintenance

| | |
|---|--|
| Autoclavable Components | |
| Contra Angle  | Insulating Sleeve  |
|  WARNING Only the components above can be autoclaved. | |
| Autoclavable Procedure | |
| <p>Cleaning: Rinse the components off thoroughly under running water with a soft brush to remove visible contaminations. Use a soft cloth that has been moistened with mild and aldehyde-free cleaning solution to clean all components. Wash the components off in running water and then wipe off the water.</p> | |
| <p>Disinfection: wipe the parts with gauze soaked in alcohol (70-80 vol%) for 2 minutes each time for five times.</p> | |
| <p>Lubrication: Only the contra angle needs to be lubricated</p>  | <p>Before autoclaving, the contra angle must be lubricated. Attaching the spray nozzle to oil can and contra angle, press the oil can button more than 3 seconds, till all the black oil flow out from the head of the contra angle.</p> |
| <p>Packaging: the bending head and head cover are packed in the special bag for high temperature steam sterilization in accordance with EN 868-5.</p> | |
| <p>Sterilization: 134 °C, 0.22mpa high temperature steam sterilization for at least 5 minutes.Dry at least 8 minutes after sterilization.</p> | |
| <p>Storage: the sterilized bending head and head cover are kept in the special sterilization bag and stored in a dry and clean environment. Check the integrity of the package before use and within the validity period of the sterilization bag.</p> | |

**WARNING**

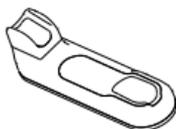
1. Please observe the relevant regulations for disinfection and sterilization.
2. Please be careful in maintenance to avoid cross infection.
3. High temperature steam sterilization must be carried out before and after the first use.
4. Do not oil the main engine, otherwise the internal components will be damaged.

Disinfection components

Handpiece



Base



Adapter



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

**NOTE**

1. Do not use disinfectants other than alcohol for disinfection.
2. Do not use excessive alcohol to prevent alcohol from seeping into the parts and damaging the internal parts.
3. Disinfect before and after each use.

9. Error warnings

| | |
|---|---|
| <p>Overload Restart Motor</p> | <p>This warning will appear on the display screen if the load exceeds the capacity of the standby machine during reversal. Please press the main switch key to restart the standby machine.</p> |
| <p>Low Power Please Charge</p> | <p>Please charge it too low.</p> |

10.Troubleshooting

When trouble is found, check the following points before contacting your distributor. 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 distributor.

| Problem | Cause | Solution | Ref. chapter |
|--|--|--|--------------|
| Cannot power on | Low battery | Charge the handpiece | 7.1 |
| | The duration of pressing the main switch is too short. | Pressing the main switch for more than 0.5 seconds is too long | 5.1 |
| Charging indication does not appear on the host display screen | Wrong power adapter used | Please use the original power adapter | 4.3 |
| | The power adapter is not plugged into the socket | Please check the connection | / |
| | Socket not energized | Please check the connection | / |
| Host display screen does not display | The handpiece is damaged | Long press the main switch to start the machine, | / |

| | | | |
|----------------------------------|--|--|---|
| | | check whether the sound is normal, and press the main switch again to check whether there is the sound of motor rotation. Then contact the dealer. | |
| The motor does not rotate | Bending head stuck | Pull out the bending head and check whether the motor rotates. If it can rotate normally, please clean or repair the bending head | / |
| | The host is protected or damaged by the system | Check according to error warning | 9 |
| The motor cannot stop | There is a short circuit in the internal circuit | Press the "s" key to stop the motor and contact the dealer | / |
| The motor reverses uncontrollabl | The reverse value of the torque setting | Check that the torque limit is too small | / |

| | | | |
|--|---|--|-----|
| y | is reached | | |
| | Rev inversion mode is set | Check settings | / |
| Motor does not reverse | Excessive torque reversal value is set | Check settings | / |
| Frequent switching between forward and reverse rotation of motor | Rec (reciprocating) operation mode is set | If not, switch the operation mode | / |
| No sound | Volume set to "mute" | Set the volume to low, mid, or high | 6.4 |
| The host sends out a continuous alarm. | Rev is set | If the setting is expected, ignore the alarm | / |

11. Technical Data

| | |
|---|--|
| Manufacturer | Changzhou Sifary Medical Technology Co.,Ltd |
| Model | E-xtreme |
| Dimensions | 17.5cm x 10.9cm x 8.4cm±1cm (Outer box) |
| Weight | 0.6kg±15% |
| Contra-angle | Suitable for 2.35mm nickel titanium root canal file according to ISO 1797-2017 and YY / T 0967.1-2015. |
| Power supply | Lithium ion battery: 3.7V, 800mAh, ±10% |
| Charger power supply | AC 100-240 V, ±10% |
| Charger power output | 5V $\overline{\square}$ 1A |
| Frequency | 50/60Hz, ±1Hz |
| Charger nominal power input | 0.4A Max |
| Torque range | 0.5N·cm – 4.0N·cm |
| Speed range | 120-650 rpm |
| Type of protection against electrical shock | Charging, Class II; operating, internally powered equipment |
| Applied part | B |
| Operation mode | Intermittent operation, working for 60 minutes / stopping for 5 minutes |
| Ingress Protection | IPX0 |
| AP / APG equipment | Non AP / APG equipment |
| Application part of defibrillation prevention | / |
| Operation conditions | Ambient temperature: 5°C ~ 40 °C Relative humidity: <80% Operating altitude < 3000m above sea |

11 Technical Data

| | |
|----------------------------------|---|
| | level |
| Transport and storage conditions | Ambient temperature: -20 °C ~ +55 °C Relative humidity: 20% ~ 80 % Atmospheric pressure: 70kPa ~ 106kPa |

12.EMC Tables

The basic performance of E-xtreme: the rotation speed and torque are stable and no maloperation occurs.

Note:

1. The buyer or user of the E-xtreme root canal preparation machine should use the E-xtreme root canal preparation machine under the electromagnetic environment specified in table 201, 202, 204, 206, otherwise, the E-xtreme root canal preparation machine may not work normally.
2. Portable and mobile radiofrequency communication equipment may affect the normal use of E-xtreme root canal preparation machine. Please use E-xtreme root canal preparation machine in the recommended electromagnetic environment.

Warning:

1. In addition to the accessories and cables provided by the manufacturer of E-xtreme root canal preparation machine (the only cable of this product is the power adapter cable, which is fixed to the power adapter), the use of accessories and cables other than those specified may lead to the increase of emission or decrease of immunity of E-xtreme root canal preparation machine.

Cable information:

| Name | Length (m) | Shielded or not | Remarks |
|---------------------|------------|-----------------|---------|
| Power adapter cable | 1.2 | No | / |

2. E-xtreme should not be used close to or stacked with other equipment. If it must be used close or stacked, it should be observed and verified that it can work normally under the configuration used.

Sheet 201

Guidance and manufacturer' s declaration – electromagnetic emission

E-xtreme is expected to be used in the following specified electromagnetic environment, and the buyer or user of **E-xtreme**

| shall guarantee its use in such electromagnetic environment: | | |
|---|---------|---|
| Emission test | Comment | Electromagnetic environment - Guidelines |
| RF emission GB 4824 | Class 1 | E-xtreme uses RF energy only for its internal function. Therefore, its RF emission is very low, and the possibility of interference to nearby electronic equipment is very small. |
| RF emission GB 4824 | Class B | E-xtreme is suitable for use in all facilities, including domestic and residential public low-voltage power supply network directly connected to the household. |
| Harmonic emission GB 17625.1 | Class A | |
| Voltage fluctuation / flicker emission GB 17625.2 | Fit | |

Sheet 202

| Guidance and manufacturer' s declaration – electromagnetic immunity | | | |
|--|--|---|--|
| E-xtreme is expected to be used in the following specified electrom- agnetic environment, and the buyer or user of E-xtreme shall guarantee its use in such electromagnetic 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 floo- rs are covered with synthetic material, the relative humidity should be at lea- st 30 %. |
| Electrical fast transients/bursts IEC 61000-4-4 | ±2kV 100kHz repetition frequency | ±2kV 100kHz repetition frequency | Mains power qual- ity should be that of a typical commerc- ial or hospital env- ironment. |
| 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 quali- ty should be that of a typical comercial or hospital env- ironment. |
| | 0% UT; 0.5 cycle at 0°, 45°, | 0% UT; 0.5 cycle at 0°, 45°, | Mains power qual- ity should be that of a |

| | | | |
|--|--|--|---|
| <p>Voltage dips IEC 61000-4-11</p> <p>Voltage interruptions IEC 61000-4-11</p> | <p>90°, 135°, 180°, 225°, 270°, and 315°</p> <p>0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0°</p> <p>0% UT; 250/300 cycle</p> | <p>90°, 135°, 180°, 225°, 270°, and 315°</p> <p>0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0°</p> <p>0% UT; 250/300 cycle</p> | <p>typical commercial or hospital environment. If the user of devices require continued operation during power mains interruptions, it is recommended that devices be powered from an uninterruptible power supply or a battery</p> |
| <p>Rated Power frequency magnetic field IEC 61000-4-8</p> | <p>30 A/m 50Hz or 60Hz</p> | <p>30 A/m 50Hz or 60Hz</p> | <p>Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.</p> |
| <p>Note: UT refers to the AC network voltage before the test voltage is applied.</p> | | | |

Sheet 204

Guidance and manufacturer's declaration – electromagnetic immunity

The E-xtreme is intended for use in the electromagnetic environment specified below. The customer or the user of the E-xtreme should assure that it is 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 | 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 | Portable and mobile RF communications equipment should be used no closer to any part of the E-xtreme, 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" |
| Radiated RF EM fields IEC 61000-4-3 | 3 V/m, 80 MHz – 2,7 GHz, 80 % AM at 1 kHz | 3V/m | |
| Proximity fields from RF wireless communication equipment IEC 61000-4-3 | See the RF wireless communication equipment table in "Recommended minimum separation distances" | Complies | |
| <p>Note 1: at 80 MHz and 800 MHz frequency points, the formula of higher frequency band is adopted.</p> <p>Note 2: these guidelines may not be suitable for all cases where electromagnetic propagation is affected by absorption and reflection of buildings, objects and human bodies.</p> | | | |

1. The field strength of fixed transmitters, such as the base stations of wireless (cellular / cordless) telephone and mobile terrestrial radio, amateur radio, AM and FM radio broadcasting and television broadcasting, cannot be predicted accurately in theory. In order to evaluate the electromagnetic environment of the fixed RF transmitter, the survey of the electromagnetic field should be considered. If the measured field strength of the root canal preparation machine is higher than the above applicable RF coincidence level, the root canal preparation machine should be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as reorientation or positioning of the root canal preparation machine.
2. The field strength should be less than 3 V / m in the whole frequency range of 150 kHz to 80 MHz.

Sheet 206

Recommended minimum separation distances

Nowadays, many RF wireless equipments have been 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 E-xtreme 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 equipments and the E-xtreme as recommended below.

| Maximum rated output power of transmitter (W) | Isolation distance corresponding to different frequencies of transmitter /m | | |
|---|---|-------------------|-------------------|
| | 150 kHz ~ 80 MHz | 80 MHz ~ 800 MHz | 800 MHz ~ 2.5 GHz |
| | $d = 1.2\sqrt{P}$ | $d = 1.2\sqrt{P}$ | $d = 2.3\sqrt{P}$ |

| | | | |
|------|------|------|------|
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For the maximum rated output power of the transmitter not listed in the above table, the recommended isolation distance D , in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where p is the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watt (W).

Note 1: at 80 MHz and 800 MHz frequency points, the formula of higher frequency range is used.

Note 2: these guidelines may not be suitable for all cases where electromagnetic propagation is affected by absorption and reflection of buildings, objects and human bodies.

13.Statement

Service Life

The service life of E-xtreme series products is 3 years.

Maintenance

MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair.

Disposal

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.

Rights

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