CE 0197

YSDENT®

C-Smart-mini2

Endo Motors

User Manual

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YSDENT®

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands	Portable and mobile RF communications equipment should be used no closer to any part of the model C-Smart-mini2 , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=[3,5/V.]\times\sqrt{P}$ $d=1.2\times\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\times\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter In watts (W) according to the transmitter manufacturer and d Is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur In the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz **385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1:2020)**	10 V/m 80 MHz to 2.7 GHz **385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1:2020)**	

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.

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 model C-Smart-mini2 is used exceeds the applicable RF compliance level above, the model C-Smart-mini2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model C-Smart-mini2.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the model C-Smart-mini2

The model C-Smart -mini2 is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model C-Smart-mini2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model C-Smart-mini2 is 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 $d = 1.2\times\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\times\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 1.2\times\sqrt{P}$
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 transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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) accordable 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.

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1. Safety



Warning:

Please read the safety warning carefully before using this device.
These security warnings will indicate you to use this device better.

1) The equipment must be used within the scope mentioned in the manual, shall not operate or use the equipment for other purposes.

2) When using external power supply, please make sure that the voltage is within the voltage range indicated by the power adapter, otherwise it may cause harm to the operator or the patient.

3) The use of non-original accessories, especially other contra angle, power adapters , may be dangerous to the patient or operator, with damage to the instrument.

4) To avoid electric shock, do not insert other objects into the machine. This may cause electric shock or equipment damage.

5) Avoid cleaning agent from entering the instrument to avoid short circuit and failure.

6) When the instrument is seriously abnormal due to improper use or physical damage, the equipment should be stopped and shut down immediately. If repair is required, please contact the manufacturer or local distributor. Only the manufacturer and distributor can open the device.

7) Please use the ISO 3630 standard and intact root canal expansion file, otherwise it may cause the root canal expansion file to break during operation and cause injury accidents.

8) The device has electromagnetic interference, do not be used in patients with cardiac device or around electronic surgery.

9) Unstable voltage and in the electromagnetic field will interfere with the normal operation of the equipment.

10) For the discarding of batteries and other accessories, please comply with local regulations.

11) Incorrect replacement of lithium batteries causes unacceptable risks, and untrained personnel causes hazards (source) (such as overtemperature, fire or explosion). Users should not replace the battery without authorization.

Guidance & Declaration – electromagnetic immunity			
The model C-Smart-mini2 is intended for use in the electromagnetic environment specified below. The customer or the user of the model C-Smart-mini2 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	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV 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	±2kV for power supply lines ±1 kV for Input/ Output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5kV, ±1kV line to line ±0.5kV, ±1kV, ±2kV line to ground	±0.5kV, ±1kV line to line	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 <5 % U_T (>95% dip in U_T) for 1 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25/30 cycles <5% U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95% dip in U_T.) for 0.5 cycle <5 % U_T (>95% dip in U_T) for 1 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25/30 cycles <5% U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model C-Smart-mini2 requires continued operation during power mains interruptions, it is recommended that the model C-Smart-mini2 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 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.			

Guidance & Declaration - Electromagnetic immunity			
The model C-Smart-mini2 is intended for use in the electromagnetic environment specified below. The customer or the user of the model C-Smart-mini2 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**

15.EMC

This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this instrument can be affected by portable and mobile RF communications equipment.

Caution:

1. **Do not use a mobile phone or other devices that emit electromagnetic fields, near the instrument. This may result in incorrect operation of the instrument.**
2. **This instrument has been thoroughly tested and inspected to assure proper performance and operation!**
3. **This instrument should not be used adjacent to or stacked with other instrument and that if adjacent or stacked use is necessary, this instrument should be observed to verify normal operation in the configuration in which it will be used.**

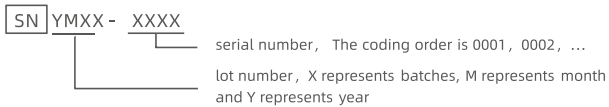
serial number	Name	Cable Length (m)	Whether to shield	Remarks
1	Adapter output line	1.2	No	

Guidance and manufacture's declaration – electromagnetic emission		
The model C-Smart-mini2 is intended for use in the electromagnetic environment specified below. The customer or the user of the model C-Smart-mini2should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The model C-Smart-mini2 uses RF energy only for theirs internal function. Therefore, theirs RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The model C-Smart-mini2 is suitable for used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

2. Symbols

	Thermo-Disinfector		Autoclave
	Warning		Refer to instruction manual
	Type B applied part		Class II equipment
	Vertical up		Keep dry
	Direct current		Fragile
	Special disposal of waste electrical and electronic equipment		Used indoor only
	Date of manufacture		Caution
	Serial number		Manufacturer
	Long press for power on &off; short press for motor on &off		Medical device
	Catalogue number		

Serial number:



3. Intended use

For use in the root canal treatment, the root canal preparation stage is formed and cleaned.

It can only be used by professional dentists in hospitals or dental clinics.

4. Indication

Application disease: Pulpitis, Periapical inflammation.

5. Contraindications

- If the patient has a pacemaker (or other electronic device) and has been warned against small appliances (such as electric razor, hair dryer, etc.).
- This equipment shall not be used for the preparation of severely bent root canals.
- Use it with caution in patients with heart disease, pregnant women and children.

6. List of Accessories

Contra Angle	1
Motor Handpiece	1
Adapter	1
Silicone Base	1
User Manual	1

12.Troubleshooting

If the equipment is not working properly, please check the equipment according to the following table before calling our sales service center.

Fault phenomenon	Analysis of causes	Method of disposition
Can't boot	Battery power is insufficient	Charge in time
Can't charge	The adapter is not reliably connected	Check that the adapter connection is reliable
The battery has short time	Battery charging is insufficient	The charging time is kept for 5 hours or the charge is fully charged

This product can be simple (such as replacing the contra angle) on-site maintenance by professional operators or nursing staff. If damage is found, please contact the company 's after-sales service department for maintenance.

13.Disposal of Medical Instruments



In accordance with the principles, standards and requirement of the country (region) in which you are located, dispose of the old electrical equipment. Ensure that pollution is not produced in the process of waste disposal.

14.Guarantee

1) This equipment does not contain self-repair spare parts, machine maintenance should be designated by the manufacturer of professional personnel.

2) The host warranty is 24 months from the date of purchase, and the accessories of the product are guaranteed for 6 months. Damaged or used up, they can be purchased from our company.

3) The guarantee is valid for normal usage conditions. Any modification or accidental damage will render the guarantee void.

10.Operating, Transport and Storage Environment

Operating environment

Working temperature	+5℃ – +40℃
Working humidity	20% – 80%
ALT	≤2000m

Transport and Storage environment

Storage temperature	-10℃ – +55℃
Storage humidity	≤93%
Atmospheric pressure	50kPa – 106kPa

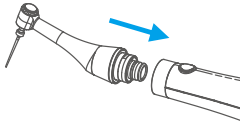
- This equipment should be carefully placed away from the source.
- Do not mix with toxic, corrosive, flammable and explosive items during storage.
- Excessive impact and vibration should be prevented during transportation, and should be carefully released.

11.Technical Specifications

Adapter	100-240V~ 50/60Hz
	Output: 5V ⎓ 2.0A Input: 20VA
Li-ion battery	d.c. 3.7V 800mAh
Degree of Protection against Electric Shock	Type B applied part
Classification of Protection against Electric Shock	Class II (Adapter)
Revolution speed	100-1000 r/min
Torque	0.6N ·cm-3.9N ·cm
Mode of operation	Non-continuous, 5min on,1min off
Degree of Protection (IEC 60529)	IPX0
Applied part	Contra angle
Contra angle speed ratio	16:1
Contra angle material	Copper and stainless steel
Overvoltage category	Class II
Pollution degree	Degree 2

7. Usage

7.1 Connecting and Disconnecting Contra angle

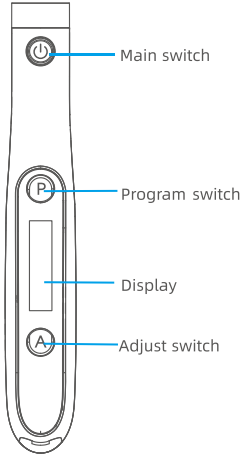


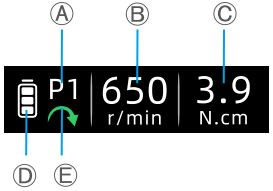
1) Clean, disinfect, and sterilize all components that may come into contact with patients before use.

2) The contra angle is aligned with the handle and installed directly. The contra angle is correctly inserted into the handle. There will be a "click" sound when it is in place.

3) The contra angle can be rotated 360° and inserted directly.

7.2 Operating





Ⓐ Program
Ⓑ Speed
Ⓒ Torque
Ⓓ Battery Power
Ⓔ Direction

7.2.1 Power

Press the power button (⏻) device is turned on, and the information is displayed in the screen. Press the 3s power button (⏻) again to shut the device down, and the display on the screen disappears.

7.2.2 Program

Short press (P) selection program, there are five programs (P1-P5) can be selected and displayed in the screen area Ⓐ.

P1-P3: Continuous rotation mode;
P4: reciprocating mode;
P5: reciprocating mode (OGP).

7.2.3 Set the selection and adjustment

Long press (P) to enter the adjustment interface of the current program, after entering the adjustment interface, short press the button (P) , you can choose between Ⓐ program, Ⓑ speed and Ⓒ torque, the selected parameters will turn blue flashing. Short press button (A) can adjust the value of the selected parameters. After 5 seconds, no operating device will automatically jump out of the set state and return to the standby interface or long press the button (P) to exit the adjustment interface.

- **Rotational speed:**
  The rotational speed value is shown in the area Ⓑ, with the adjustment range: 100 r/min, 150 r/min, 200 r/min, 250 r/min, 300 r/min, 350 r/min, 400 r/min, 450 r/min, 500 r/min, 550 r/min, 600 r/min, 650 r/min, 800 r/min, 1000 r/min.
- **Rotating torque:**
  The torsion value is shown in area Ⓒ, adjustment range: 0.6~3.9N.cm.
- **Rotation angle:** (adjustable parameter in reciprocating mode)
  The angle is shown in the area Ⓒ, and the adjustment range is 150 / 30, 180/ 60, 210 /60, 30 /150, 60 /180 and 60 / 210.

⚠ Caution:

1. **speed, torque, and angle cannot be adjusted while the file is working.**
2. **Do not use files designed for reciprocating motion in Continuous Rotary File Mode.**
3. **The file system shown on the display must always match the file in use.**

	Automated Cleaning: Use a washer-disinfector meeting the requirements of the ISO 15883 series. Put the instrument into the machine on a tray. Connect the instrument with the WD by using suitable adapter and start the program: 4 min pre-washing with cold water (<40°C) emptying 5 min washing with a mild alkaline cleaner at 55°C emptying 3 min neutralizing with warm water (>40°C) emptying 5 min intermediate rinsing with warm water (>40°C) Emptying The automated cleaning processes have been validated by using0. 5% neodisher MediClean forte (Dr Weigert) Note Acc to en ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.
Disinfection	Automated Disinfection: Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0-Value (see EN 15883). A disinfection cycle of 5 min disinfection at 93°C has been validated for the device to achieve an A0 value of 3000.
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 compressed air.
Functional Testing, Maintenance	Visual inspection for cleanliness of the instruments and reassembling. Functional testing according to instructions of use. If necessary, perform reprocessing process again until instrument is visibly clean. Defective accessories should be immediately discarded. The defects include: plastic deformation and corrosion Maintenance is not required. Instruments oil must not be used.
Packaging	Pack the instruments in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607.
Sterilization	Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285 / EN 13060 / EN ISO 17665) under consideration of the respective country requirements. Minimal requirements: 3 min at 134 °C In EU, 5 min at 134 °C is required. Maximal sterilization temperature: 137°C.
Storage	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures refer to label and instructions for use.
Reprocessing validation study information	The above-mentioned reprocessing process (cleaning, disinfection sterilization) has been successfully validated.
Additional Instructions: None	
It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.	

9. Cleaning, Disinfection and Sterilization

Device	Contra angle and Motor handpiece. The procedure for cleaning, disinfection and sterilization applies only to the accessories contra angle.
ADVICE	Reprocessing procedures have only limited implications to a surgical instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. There is no limit of maximum allowable reprocessing cycles. The device should no longer be reused in case of signs of material degradation. In case of damage the device should be reprocessed before sending back to the manufacturer for repair.
Reprocessing Instructions	
Preparation at the Point of Use	Disconnect the contra angle from handpiece. Remove gross soiling of the instrument with cold water (<40°C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process. Store the instruments in a humid surrounding.
Transportation	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.
Preparation for Decontamination	The devices must be reprocessed in a disassembled state. Only contra angle can be cleaned and disinfected with automated methods and sterilized with steam sterilization process. Do not sterilize the Motor handpiece and AC adapter. The Motor handpiece and AC adapter cannot be cleaned and disinfected in a washer/disinfector. For these parts, only general wipe decontamination is possible!
Decontamination of other parts than Contra-angle	After operation, take out the Motor handpiece and AC adapter on the work bench. Soak a soft cloth completely with distilled water or deionized water, Decontamination and wipe all the surfaces of these components, until the surface of the parts the components is visually clean. For decontamination, soak a dry soft cloth with 75% alcohol or other contra-angle, File clip, disinfects which are approved for its efficacy by CE marking, FDA and Health Canada Approval lighting device: Wipe all surfaces of Motor handpiece, AC adapter and other components with the wet soft cloth for about 3 minutes. Please follow the instructions of manufacturer of disinfectant swipe the surface of the component with a dry soft lint-free cloth.'
Pre-Cleaning	**Following instruction are only relevant for Contra-angle!** **Not use automated cleaning, disinfection and sterilization for other parts than Contra-angle in this system!** Do a manual pre-cleaning, until the instruments are visually clean. Submerge the instruments in a cleaning solution and flush the lumens with a water jet pistol with cold tap water for at least 10 seconds. Clean the surface with a soft bristol brush.
Cleaning	Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety.

- **Program schema:**

  The P1-P3 is a continuous rotation:

  1) The file rotates forward at the set speed and automatically reverses when the torque exceeds the set value until the output torque is less than 70% of the set value.The icon  is displayed in the area Ⓔ.

  2) Adjustable parameters: rotational speed, rotational torque.

  P4 reciprocates:

  1) The file is rotated clockwise, then counterclockwise, continuously. The icon  is displayed in the area Ⓔ。

  2) Adjustable parameters: rotation speed, rotation angle.

  The P5 is in a reciprocating mode (OGP):

  1) The file forward rotation 240 ° reverse rotation 240 ° forward rotation 240 ° reverse rotation 330 ° reciprocating cycle.The icon  will be displayed in the area of Ⓔ.

  2) Adjustable parameters: Rotation speed (200-500 r/min, 100 steps).

7.2.4 Select rotation direction

Press the adjustment button Ⓐ can directly switch the rotation direction of the file. The device can only adjust the steering of the file by using the forward and reverse button, and when the file is reversed, the buzzer will ring once every second.

 forward  reversal

7.2.5 Pre-operation check

The equipment needs to be checked before use to ensure that the equipment is not abnormal. Before use,run the instrument outside the oral cavity to make sure it is operating normally.

7.2.6 Start / Stop

Press the start / stop button ⏻ , file for rotation, and press again to stop the rotation.

7.2.7 Motor calibration

Long press the button (P) and the button (A) at the same time to start the calibration. The screen display is as shown in the figure 

The device is automatically calibrated, the successful calibration screen shows "OK", and the buzzer prompts the calibration.

Caution:

1. **Make sure that the machine is inserted and in no resistance.**
2. **The equipment is in the working state and cannot be calibrated.**

7.2.8 Battery capacity

Battery power level is displayed in the battery power area of Ⓓ.

Caution:

1. **Users should not replace the battery without authorization.**
2. **When the battery power is too low, the low voltage alarm is prompted. When the low voltage alarm rings, the battery frame flashes red.The alarm lasts for 5 seconds and the device automatically shuts down; Alarm for 20 seconds during operation, device automatically shuts down.**

7.2.9 Charging

1) Insert the power adapter output line into the charging interface of the host, and connect the adapter plug to the power supply.

2) When charging, the screen dynamically displays the charging status. After charging, the system automatically stops charging, and the battery icon is kept unchanged at the full power level.

 Charging state  Non charging state

 Charging interface when fully charged

3) The equipment must be continuously charged for at least 2.5 hours to prevent the loss of power from causing inconvenience to the user, and the host should often be in the charging state.

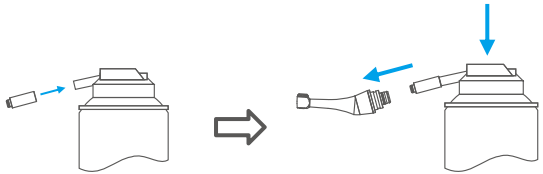
Caution:

1. **Using a non original charger may damage the device.**
2. **Excessive charging time may damage the battery.**
3. **If the user loses the charger, they should purchase a charger of the same specification and comply with IEC 60601-1 standard.**

8. Lubrication

1) Remove the contra-angle from handpiece.

2) Mount the tip nozzle into the spray can port and align the nozzle to the contra-angle, Spray lubricating oil into contra-angle until clean liquid flows out.



Caution:

1. **When the head overflows with clean liquid,the entire cleaning and maintenance steps should be repeated.**
2. **It is recommended to inject lubricating oil before sterilization.**