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C-SMART Mini User Manual

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COXO



Congratulations on your purchase of the endo motor.

Read this operation Manual carefully before use for operating instructions, care

and maintenance. Keep this manual for future reference.

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Recommended separation distances between portable and mobile RF communications equipment and the unit.

The unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the unit as recommended below, according to the maximum output power of the communications equipment.

Rated maximum	Separation distance according to frequency of transmitter			
output power of transmitter (W)	150 kHz to 80 MHz d=1.2×P 1/2	80 MHz to 800 MHz d=1.2×P 1/2	800 MHz to 2.5 GHz d=2.3×P 1/2	
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 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.

Guidance and Manufacture's Declaration – Electromagnetic Immunity

The unit is intended for use in the electromagnetic environment specified below. The customer or the user of unit should assure that it is used in such an environment.

IEC 60601 test level	Compliance level	Electromagnetic environment - guidanc
3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 3 V/m	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 3 V/m 80 MHz to 2.7 GHz 385MHz- 5785MHz Test specifications for ENCLOSURE	Portable and mobile RF communication
		the compliance level in each frequency
		Interference may occur in the vicinity of equipment marked with the following symbol:
	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 3 V/m 80 MHz to 2.7 GHz 385MHz- 5785MHz Test specifications for ENCLOSUNE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-	3 Vrms 150 kHz to 80 MHz 6 Vrms in 15M bands 3 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- of EV 60601-1-

NOTE 2 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 3 These guidelines may not apply in all situations. Flectromagnet

NOTE 3 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 sitesurvey should be considered. If the measured field strength in the location in which the unit is used exceeds the applicable RF compliance level above, the unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the unit.

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

Attention

Do not fail to receive clear instructions concerning the various ways to use this unit as described in this accompanying Operator Manual. Most operation and maintenance problems result from insufficient attention being paid to basic safety precautions and not being able to foresee the possibilities of accidents. Problems and accidents are best avoided by foreseeing the possibility of danger and operating the unit in accordance with the manufacturer recommendations. First thoroughly read all precautions and instructions pertaining to safety and accident prevention; then, operate the unit with the utmost caution to prevent either damaging the unit itself or causing bodily injury.

The following symbols and expressions indicate the degree of danger and harm that could result from ignoring the instructions they accompany:

WARNING	This warns the user of the possibility of extremely serious injury or complete destruction of the instrument as well as other property damage including the possibility of fire.	
A CAUTION	This warns the user of the possibility of mild injury or damage to the instrument.	
Usage Note	This alerts the user of important points concerning operation or the risk of unit damage.	

Disclaimer

The manufacture will not be responsible for accidents, unit damage, or bodily injury resulting from:

- 1. Repairs made by personnel not authorized by the manufacture.
- 2. Any changes, modifications, or alterations of its products.
- 3. The use of products or unit made by other manufacturers, except for those procured by the manufacture.
- 4. Maintenance or repairs using parts or components other than those specified by the manufacture and other than in their original condition.

- Operating the unit in ways other than the operating procedures described in this manual or resulting from the safety precautions and warnings in this manual not being observed.
- Workplace conditions and environment or installation conditions which do not conform to those stated in this manual such as improper electrical power supply.
- 7. Fires, earthquakes, floods, lightning, natural disasters, or acts of God.

Warning and Prohibition

Warning

- 1.This unit must not be connected to or used in combination with any other apparatus or system. It must not be used as an integral component of any other apparatus or system.
- 2. Manufacture will not be responsible for accidents, unit damage, bodily injury or any other trouble which results from ignoring this prohibition.
- 3.A rubber dam should be used when performing endodontic treatment.
- 4.Only fully trained and qualified personnel may operate unit.
- 5. Items to be duly noted when installing unit.
- a. Locate the unit in a place where it will not get wet.
- Install the unit in a location where it will not be damaged by air pressure, temperature, humidity, direct sunlight, dust, salts, or sulfur compounds.
- c. The unit should not be subjected to tilting, excessive vibrations, or shocks (including during shipping and handling).
- d. Do not install the unit where chemicals are stored or where gas may be released.
- e. Follow all electrical specifications.
- 6.Item to be duly noted before use.
- a. Inspect all switch connections, polarity, dial settings, meters etc. to confirm that the unit will operate properly.
- b. Confirm that the ground is connected properly.
- c. Confirm that all cords are connected properly.

Guidance and Manufacture's Declaration - Electromagnetic Immunity

The unit is intended for use in the electromagnetic environment specified below. The customer or the user of unit should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV,±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV,±15 kV air	Floors should be wood, concrete or ceramic tile. If floor 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 ±1 kV for Input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV & ±1 kV differential mode ±0.5 kV, ±1 kV & ± 2 kV common mode	± 0.5 kV & ± 1 kV differential mode ± 0.5 kV, ± 1 kV & \pm 2 kV common mode	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	$100\% U_r$ ($100\% dip in U_r$) for 0.5 cycle $100\% U_r$ ($100\% U_r$) for 1 cycle $30\% U_r$ ($70\% dip in U_r$) for 25/30 cycles $100\% U_r$ ($100\% dip in U_r$) for 25/30 cycles $100\% U_r$ ($100\% dip in U_r$) for 250/300 cycle	100 % U_r (100% dip in $U_{\tau,r}$) for 0.5 cycle 100 % U_r (100% dip in $U_{\tau,r}$) for 1 cycle 30 % U_r (70% dip in $U_{\tau,r}$) for 25/30 cycles 100 % U_r (100% dip in $U_{\tau,r}$) for 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the unit requires continued operation during power mains interruptions, it is recommended that the unit be powered from an unit erruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U₇ is the a.c. mains voltage prior to application of the test level.

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 unit can be affected by portable and mobile RF communications equipment.

⚠ CAUTION

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

Guidance and Manufacture's Declaration-Electromagnetic Emission		
The unit is intended for use in the electromagnetic environment specified below. The customer or the user of the unit should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic Environment-Guidance
RF emissions CISPR 11	Group 1	The unit use 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 emission CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	The unit is suitable for use in all establishments, including domestic establishments directly connected to the public low-voltage power supply network with specific requirement.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	supply network with specific requirement.

- d. Take into consideration that simultaneous use of more than one instrument or device can create a dangerous situation or lead to a mistake in diagnosis.
- e. Reconfirm the safety of external circuits or systems which are connected directly to the patient
- 7. Item to be duly noted during use.
- a. Never use the unit for treatment or diagnosis more than necessary or for longer than necessary.
- Maintain a constant vigilance for abnormal conditions in both the unit and the patient.
- c. Appropriate steps, such as shutting the unit down, should be devised to protect the safety of the patient in case any abnormalities in the unit or the patient are observed.
- d. Make sure the patient does not handle or manipulate the unit.

Prohibition

This indicates when not to use the unit.

- 1.Electromagnetic wave interference could cause this unit to operate in an abnormal, random and possibly dangerous manner. Cellular phone, transceivers, remote controls and all other devices which transmit electromagnetic waves located inside the building should be turned off.
- 2.Instruments which produce considerable electrical noise such as electric scalpels can cause the unit to operate abnormally. Turn the unit off before using any instruments that produce electrical noise
- 3.Do not use this unit on patients who have a pacemaker or an Implantable Cardioverter Defibrillator (ICD).
- 4.This unit must not be connected to or used in combination with any other apparatus or system. It must not be used as an integral component of any other apparatus or system. manufacture will not be responsible for accidents, unit damage, bodily injury or any other trouble which results from ignoring the above prohibitions.
- 5.Do not use this unit in the medical operation room.
- 6.Blocked canals cannot be accurately measured.

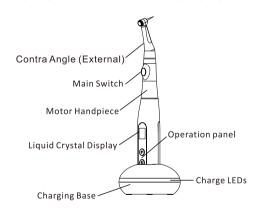
Intended Use

The unit is the supplementary root-canal treatment unit 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.

Adverse Reactions

There are no known adverse reactions.

Parts Identification and Accessories



Adaptor



Battery *Inside motor handpiece

Symbol

Ą	Warning	\wedge	Caution
①	Usage note	C € ₀₁₉₇	CE marked product
	Manufacturer	EC REP	European Union agent
③	Refer to the user manual		Class II Unit
†	Type B applied part	X	Special disposal of waste electrical and electrical equipment
\frac{7}{2}	For indoor use only		Direct current
Ť	For indoor use only	<u> 11</u>	This way up
REF	Catalogue number	Ī	Fragile
1	Temperature limit	SN	Serial number
<u></u>	Atmospheric pressure limit	%	Humidity limit
誉	Avoid the sun	***	Prevent heat source and radiation source

Technical Description

[Specifications may be changed without notice due to improvements.]

Main unit:	
Classification	Safety according to IEC 60601-1, IEC 60601-1-2 European Directive 93/42/EEC IIa
Degree of Protection against Electric Shock	Type B applied part
Degree of Protection (IEC 60529)	IPX 0
Mode of Operation	Continuous
Free running speed of the motor handpiece	125 ~ 625 rpm
Rated Torque	min. 0.06 Nm

Adaptor	
Rated Input voltage	A.C.100 ~ 240 V
Frequency	50 / 60 Hz
Power Consumption	15 W
Output	10V 1.5A

Charge battery	
Voltage	DC 3.7V
Capacity	1200mAh

Usage

Operation Conditions for the main unit and adapter

Temperature: +5°C to +40°C

Relative Humidity: 20% to 80% RH (without condensation)

Atmospheric Pressure: 86 to 106 kPa

Preparation

Charge Battery

- 1. Connect the adaptor cord to the charging base and insert it. The green LED will light up.
- 2.Put the handpiece into the charging base as far as it will go. The yellow Charge LED will light up to show that charging has begun.
- * Charging time is about 300 minutes.
- * Charge the battery as soon as the battery power indicator gets down to its last bar
- * If the yellow charge indicator is off and Green light is on, the battery may be fully charged or the handpiece is not connected to the charging base.

The battery is not charged when the unit is shipped from the factory and must be charged before using the unit.

Do not pull or yank the cord when disconnecting the adapter. Always grip the connectors.

The number of bars shows how much battery power is left. Recharge the battery when there is only one bar left.











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If the battery runs almost completely out, the handpiece turn itself off after about 20 seconds. Recharge the battery as soon as possible.

to inspect and adjust it himself.

* If the user is unable to inspect the unit himself or if the unit fails to work properly after being adjusted or after parts are replaced, contact your local dealer or the manufacture.

If the unit does not seem to be working properly, the user should first try

Troubleshooting

Problem	Check Points	Response
Does not turn on.	Check battery power.	Charge battery.
Bocs not turn on.	Check battery installation.	Install battery properly.
Motor starts but then stops right away.	Did you hold down the Main switch for more than 1 second?	If you hold the Main switch down for more than 1 second, the motor runs only while the switch is held down and stops when it is released. The motor will run without stopping if you release the switch in less than 1 second.
Motor reverses	Check Torque Reverse setting	Increase the torque reverse setting.
rotation too quickly. Motor handpiece will not go in reverse rotation.	Is Torque Reverse setting too high?	Reduce torque reverse value.
	Was the unit no used for a long time?	Auto power off was probably activated. Press the Main switch to turn the unit back on.
Unit turns off on its	The battery is low.	Battery must be charged right away.
own.	This can happen if the battery is very low and a large load is applied to the file.	Battery must be charged right away.
	Check battery installation.	Install battery properly.

If the battery power is very low and a large load is applied to the file, the motor may stop or the unit may turn itself off. This is for safety; there may not be enough power to run the motor with sufficient stability.

Connecting and Disconnecting the Contra angle

a. Connecting

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

b. Disconnecting

When removing the contra angle, pull it straight out.

When attaching and detaching the contra angle, turn the power off beforehand. Check that the contra angle is securely assembled to the motor handpiece.

Inserting and Removing the File.

a. File insertion

Insert the file into the chuck until it stops.

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

b. File removal

Press the push key and pull out the file.

⚠ WARNING

When attaching and detaching the file, turn the power off beforehand. After the file is locked in place, lightly pull out the file to make sure the file is locked.

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

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Disposal of Medical Devices

Any medical devices which could possibly be contaminated must be first decontaminated by the responsible doctor or medical institution and then be disposed by an agent licensed and qualified to handle medical and industrial waste.

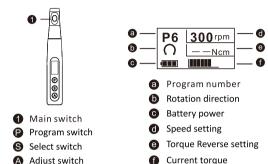
The rechargeable battery should be recycled. Metal parts of the unit are disposed as scrap metal. Synthetic materials, electrical components, and printed circuit boards are disposed as electrical scrap. Material must be disposed according to the relevant national legal regulations. Consult specialized disposal companies for this purpose. Please inquire of the local city/community administrations concerning local disposal companies.

Service

Unit may be repaired and serviced by the manufacture.

Operation

Basic Operation



- 1.Turn unit on: Press Main switch.
- The standby display will appear.
- * The unit turns itself off automatically if it is not used for 3 minutes.
- 2. Select Program: Press Program switch.
- * There are 5 continuous rotary files program and 1 reciprocating rotary files program.
- 3. Follow the file manufacturer's instructions for use of endodontic files.
- 4.Torque and speed values are subject to change by the file manufacturers without notice. Therefore, the preset values must be checked prior to use.
- 5. Torque values shown on the display are accurate and reliable only with contra angle properly maintained and lubricated.

- 6. Start motor: Press Main switch again.
- * When the motor handpiece starts, the torque bar indicates the current torque.
- * If you hold the Main Switch down when you start the motor, it will run only while the switch is held down and stop when the switch is released.
- If, during operation the load reaches the preset torque limit value, the motor handpiece will automatically rotate in the reverse direction.
 When the load is removed, the motor handpiece returns to normal forward rotation automatically.

① Usage Note

In reciprocating motion, the auto reverse function is disabled.

a. Stop motor: Press Main switch again.

b. Reverse: Press Adjust switch

* Press the Adjust switch to change the direction of file rotation (whether the motor is stopped or running), and the current direction of file rotation is displayed. \bigcap indicates forward rotation, \bigcap indicates reverse rotation.

① Usage Note

Only continuous rotary file systems can change the direction; reciprocating file systems cannot change the direction.

Settings

1) Rotation Speed, Torque Reverse

(a) @ @	P1 300 rpm 2.0 Ncm	Select a Program number for the standby display by pressing the Program switch.
<u>a</u> @ @	P1 300 rpm	Press the Select Switch to choose one of the primary functions.
<u>a</u> @ <u>a</u>	P1 150 rpm	Press the Adjust switch to change the setting.

- * The display will go back to the standby display if 2 seconds elapses without a switch being pressed.
- * Speed Settings: 125-625 rpm
- * Torque Reverse Settings: 0.6-3.9 Ncm

Maintenance and Inspection

Regular Inspection

- * Maintenance and inspection are generally consider to be the duty and obligation of the user, but if, for some reason, the user is unable to carry out these duties, he may rely on a qualified medical device serviceman. Contact your local dealer or the manufacture for details.
- * Replace the parts listed in the Parts Lists as necessary depending on degree of wear and length of use.
- * This apparatus should be inspected every 6 months in accordance with the following maintenance and inspection items.

Maintenance and Inspection Items

- 1. Check that the battery is wasting current too quickly.
- Check that pressing the Main Switch turns the unit on. After the unit is on, check that pressing the Main switch turns the motor on and off. Check that the unit turns off when the Main Switch is pressed while the Select switch is being held down.
- 3. Check that pressing the Program switches changes the Program number from M1 through M6.
- 4. Check that the settings for each memory can be changed.
- * For repairs contact your local dealer or the manufacture.

Working-Life

The working-life of this unit is 5 years from the date of shipment provided it is regularly and properly inspected and maintained.

Battery Replacement

* Replace the parts as necessary depending on degree of wear and length of use.

Replace the battery when it starts to lose power relatively quickly after being fully charged.

The battery will last for approximately 1 year under normal circumstances and use.





- 1. Turn power off. Slide the battery cover off.
- 2. Take out the old battery and disconnect it.
- 3. Connect the new battery and put it in.

 Dispose of old lithium ion batteries in an environmentally safe way and in strict accordance with local regulations.
- Replace the cover.
 Be careful not to pinch the battery cord when replacing the cover.

↑ CAUTION

Use only the battery designed for the unit. Other types could cause overheating.

Do not use a battery if it is leaky, deformed, discolored or if its label is peeled off. It might overheat.

Storage

Transport and Storage Conditions for the main unit and AC adapter:

Temperature: -10°C to 55°C

Relative Humidity: less than 93% RH (without condensation)

Atmospheric Pressure: 50 to 106 kPa

- * Do not expose to direct sunlight frequently or for long times.
- * If the unit has not been used for a long time, make sure it works properly before using.
- * Always remove the battery prior to storing or shipping the unit.

⚠ CAUTION

Torque reverse should be set depending on the canal and the file. If the torque reverse seems to be activated too frequently increase its value

- 2) Calibration
- a. Press the Select switch for 2 seconds to enter setting interface,
- b. Press the Select Switch again to choose calibration or screen functions.



- c. While calibration function selected, press Adjust switch to start the calibration process.
- * When the calibration process is completed, the rotation stops and the display returns to standby display.

△ CAUTION

ERROR message indicates that the device is not operating properly. Please contact your local dealer or contact the factory directly for assistance.

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① Usage Note

Should you at any time wish to stop the calibration process, turn the power off.

Calibrate every time the contra angle is lubricated or replaced after sterilizing, or at least once a week (Lubricating the Contra angle, Cleaning, Disinfection and Sterilization see the operation manual of contra angle).

Do not touch or apply a load to the contra angle chuck during calibration.

3) Screen (Right or Left Handed)

While screen function selected, press Adjust switch to set display for right-handed or left-handed user. Display turns upside down for left-handed users.

Sterilization, Replacement Parts, and Storage

Autoclaving the Contra Angle

AWARNING

Autoclave the contra angle after use for each patient.

⚠ CAUTION

Recommended: 134°C (273.2°F) for at least 5 minutes inside a sterilization pouch, or 121°C (249.8°F) for at least 35 minutes inside a sterilization pouch.

Minimum drying time after sterilization: 10 minutes.

ONever autoclave the motor handpiece.

①Autoclaving and drying temperatures must never exceed 135°C/275°F.

①Take the file out of the contra angle before autoclaving it.

OClean everything thoroughly before autoclaving. Any chemicals or foreign debris left on unit could cause them to malfunction or could cause discoloration. Clean and lubricate the contra angle with before autoclaving it.

①For sterilizing files, follow the manufacturer's recommendations.
 Before autoclaving, clean and lubricate the contra angle.
 Take the contra angle off the motor. Put the special nozzle on the spray can.
 Dampen a piece of gauze with ethanol, wring it out and then wipe the contra angle with it.

⚠ WARNING

Do not fail to autoclave the contra angle after use for each patient.

⚠ NOTE

Autoclaving the Contra Angle

Cover the contra angle with a piece of gauze or other suitable cloth. Insert the spray nozzle into the connection end of the contra angle, and spray for 2 or 3 seconds.

Use gauze etc. to wipe excess spray off the outside of the contra angle.

- Always shake the spray can two or three times before using it.
- And use the spray can in an upright position.
- The motor handpiece could be damaged if the contra angle is attached without allowing the excess spray to drain out first.
- After cleaning and lubricating the contra angle, stand it up on a piece of gauze to allow all the excess spray to drain out; then put it in a pouch and autoclave it
- It is highly recommended that unit be autoclaved in a sterilization pouch (wrapped) or similar device.
- Wipe with Ethanol
- Components Sterilized with Ethanol: Motor Handpiece, Charging base.
- Dampen a piece of gauze with ethanol, wring it out and then wipe these components with it.
- Never wipe components with any solution other than ethanol. Other solutions could cause cracking and discoloration.
- Never wipe components with a piece of gauze that is excessively wet with ethanol. It could seep inside the unit and damage it. Be especially careful around the connection jacks for the transmission cable.
- Avoid spilling chemical solutions used for treatment on the motor handpiece, charging base, contra angle or any other components. These chemicals could damage, deform or discolor plastic and metal. Use extra caution to avoid spilling formalin cresol (FC) and sodium hypochlorite as they are quite strong. Wipe up any chemical spills immediately. (Some chemicals may leave traces even if wiped up immediately).

⚠ WARNING

Cover the contra angle's head with gauze to prevent spray getting in your eyes.

Hold both the spray can and the contra angle firmly; otherwise, the pressure from the spray could blow the contra angle out of your hand.

⚠ CAUTION

The unit is extremely hot immediately after autoclaving; do not touch it for at least 10 minutes.