

USER MANUAL

C-PUMA Pro

Dental Electrical Motors



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Safety



Read this manual before proceeding with the installation, use, maintenance, or other operations on the device. Always keep this manual within reach.

- This device is only allowed to be used by professional, trained personnel, such as surgeons. Proper use of the device does not cause side effects; If used improperly, heat will be transferred to tissues, which may lead to tissue damage.
- To avoid the risk of electric shock, the device must be connected to supply mains with protective earth.
- Before using the device, ensure that the voltage is within the specified operating range. Improper input voltage will damage the device and cause harm to the operator and the patient.
- The power plug is used for disconnection in case of problems, it must be easily accessible at all times.
- 5) Please use original accessries (such as motor, power cord and fuses, etc.), otherwise the device may be damagerd or even cause an injury accident. The manufacturer will not be held responsible if the user fails to follow the manual or uses this instrument for other purposes.
- 6) The device is not provided sterile and must be cleaned, sterilized, and sterilized in strict accordance with Chapter 7 before being used for therapeutic purposes.
- 7) Before each use, inspect medical device for damage and loose parts.
- 8) When installing or removing parts from the motor, ensure that the motor is completely stopped.
- 9) Do not make any modifications to this device.
- Main unit and power cord shall not be serviced or maintenance during normal treatment
- Not to position the device to make it difficult to operate the disconnection device.
- 12) Make sure to run tests before each use.
- 13) Do not turn over the main unit to prevent liquid overflow.
- 14) Do not start the foot pedal when the peristaltic pump cover is open.
- 15) Turn off the power switch after use. If the device is not use for a long time, please drain the water in the hose and water tank.
- 16) Avoid cleaning agents entering the machine to prevent short circuits or malfunctions.

- 17) Do not insert any objects into the machine to avoid electric shock or damage.
- 18) If any malfunction occurs (excessive vibration, noise, heat production, etc.), stop the device immediately and contact our after-sales service.
- 19) The device has electromagnetic interference. Do not use it around patients with cardiac pacemakers or electronic surgery.
- Electromagnetic fields and unstable voltages can interfere with the normal operation of the device.
- 21) The motor may exceed 43°C during operation, it is recommended to work for 1min and stop for 10min.
- 22) The product has a service life of 10 years.

) Intended use

Dental surgical motor is for driving dental handpieces for dental surgery, mainly used for dental aesthetics restoration, crown breaking, caries removal, polishing, cutting and separating bone substances mechanically in cranio-maxillo-facial surgery (CMF).

The device is intended for use by suitably qualified and trained medical, technical and specialist staff only.

Contraindication

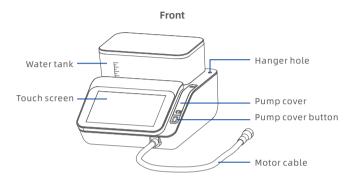
Do not use on the following patients:

- 1) Hemophilia patients;
- 2) The patients and doctors with heart pacemaker;
- Patients with severe systemic infection or systemic diseases such as the diseases of heart, liver, kidney, hematopoietic system, digestive system and endocrine system;
- 4) Pregnant women, children.

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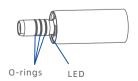
Product description

Control unit

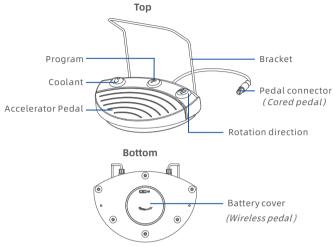


Pedal socket Power socket Fuse holder Power switch

Motor



Foot pedal



Other accessories





See the packing list for detailed.

5 Installation



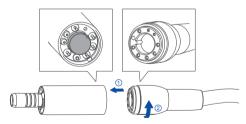
WARNING

- The device cannot operate in environments where anesthetic or flammable mixtures are present.
- Install the device in a place protected against collisions or against accidental sprays of water or liquids.
- Do not install the device above or near heat sources.
- Foresee adequate air circulation around the device when installing it.
 Leave adequate space, especially near the fan placed on the back part of the device.
- Do not expose the device to direct sunlight or to sources of UV light.
- Main unit and power cord shall not be serviced or maintenance during normal treatment.
- Not to position the device to make it difficult to operate the disconnection device.

5.1 Motor

Connect: Fully insert the motor's pins into the holes on the tube connector and tighten the end caps.

Removal: Loosen the end cap and pull the motor outward horizontally.



5.2 Contra angle

Insert the contra angle into the connector on the motor until you hear a click. Rotate the contra angle to confirm the connection is secure.



i NOTE

- All straight and contra-angle handpieces with the motor connection ISO3964 can be attached.
- · Refer to the relevant instructions for the installation of burs and saw blade.

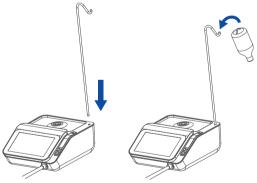


WARNING

Do not connect or disconnect the contra angle until the motor has completely stopped.

5.3 Irrigation hanger and Irrigation tube (for "infusion supply")

Insert the hanger into the hole on the main unit, and hang the saline bottle/bag on the hanger.

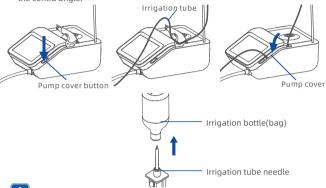


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NOTE

- · Maximum hanging weight for the hanger is 1.5L.
- · Check the stability of the hanger and the saline bottle/bag.

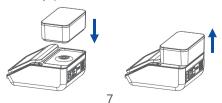
- 1) Press the button to open the pump cover;
- 2) Lay the irrigation tube inside the pump cover;
- 3) Close the pump cover completely;
- 4) Connect the irrigation tube to the saline bottle (bag) and the external nozzle of the contra angle.



- Users need to purchase irrigation tubes (inner diameter: Φ2mm) and saline solution (0.9%) separately.
- Irrigation hanger and Irrigation tube are only used for external contraangles, and the water supply needs to select "infusion supply", refer to "6.4 Irrigation type".
- When installing the irrigation tube, ensure that it is not squeezed and must be laid loosely and without tension.

5.4 Water tank (for "self-water")

Align the tank outlet with the water inlet of the main unit and insert it vertically; to remove it, pull it vertically upwards.





- Do not use saline or sodium hypochlorite. Use purified or distilled water.
- Do not exceed the maximum level of the water tank.
- Transportation or long-term storage may cause water supply problems.
 When using the water tank for the first time, check the water flow as follows:
 Select "self-water" irrigation type and press the pedal until the water flows smoothly. If not, refer to Chapter 8.5 for maintenance.



WARNING

The inner contra-angle handpiece must be used when installing the water tank for "self-water" type. If use the external handpiece, the liquid will enter the device and damage it.

5.5 Foot pedal

The device is suitable for wireless pedal or corded pedal.

5.5.1 Bracket

Insert the bracket into the holes on the back of the pedal and tighten the nut.



5.5.2 Wireless pedal (Optional)

When using the wireless pedal for the first time, you need to install the batteries. Steps:

Unscrew the cover in the direction of the arrow



Put in three



Tighten the cover





- The battery specification is AA*3, please distinguish the positive and negative poles.
- When not in use for a long time, please remove the battery to extend its life.
- · Do not mix new and old batteries or different types of batteries.

5.5.3 Corded pedal (Optional)

Insert the pedal connector into the jack on the back of the main unit, aligning the mark.

5.5.4 Status

At the top of the screen shows the status of the pedal, refer to chapter 6.



NOTE

When both wireless and cored pedals are connected, only the cored pedal is available and the wireless pedal is disabled.

5.6 Power cored

Connect the power cord to the socket on the back of the main unit and the mains power supply.

Turn on the power switch on the back of the main unit to start the machine.

6

Operation

Main page



a Irrigation type:





f Heating status:

Only applicable to the "self-water" type.

Heating function is activated

Water Heating function is disabled

Q Sound status

- b Spray on/off
- C LED light switch
- d Rotation direction switch
- e Gear Ratio select

h Foot pedal status:

(flash) No pedal detected

Corded pedals

Wireless pedal

Wireless pedal battery power:

- Power is low, replace the batteries in time.
- Power is very low, stop working and replace the batteries soon.

Setting page



- Sound on/off
- Screen brightness
- M Status of wireless pedal pairing with main unit:
 - Paired and connected
 - Paired, not connected
 - Not paired

- Heating on/off
- Motor light delay time Switch
- n Factory reset
- O Water supply tube cleaning: Only applicable to the "self-water" type.

Mode 6.1

Click the mode button to select the desired mode.

There are four modes: Extraction, High-speed, Low-speed and Osteotome.

6.2 Program

Each mode contains different programs. Click the program button to select the desired program.

The program can also be switched by pressing the program button (P) on the pedal.

6.3 Speed and Irrigation volume

Drag or click the slider to adjust the motor speed or irrigation volume.

The irrigation volume can also be switched by pressing the coolant button on the pedal.



WARNING

Insufficient cooling may cause overheating of the treatment area. Please ensure sufficient coolant supply when using.

6.4 Irrigation type

Click the water supply button to select the required type.



NOTE

- If there is no water supply, please check: whether the water supply type is correct, whether the water volume setting value is greater than 0, and whether the contra-angle is selected and installed correctly.
- Only Infusion supply type (saline) should be used for Osteotome mode.

6.5 Spray

Click the spray button to turn on or off the spray.

6.6 LED light

Click the light button to change the brightness of the LED on handpiece. There are three levels: High, Low, light off.

6.7 Rotation direction

Click the direction button to switch between forward and reverse rotation of the motor, or you can switch by pressing the direction button on the pedal.

6.8 Gear Ratio

Click the Gear Ratio button and select the same ratio as the connected contra-angle.

6.9 Heating

Click the Settings button to enter the Settings page.

Click the switch button of the Heating option to turn the function on or off. The heating status will be displayed on the main page.



The heating function is only applicable to the "self-water" type (water tank).

6.10 Wireless pedal pairing

Click the settings button to enter the settings page, click the Pairing button, and then follow the prompts.

If pairing fails, you can re-pair follow the prompts.

If already paired, click the button again to disconnect.



NOTE

- The wireless pedal relies on successful pairing with the main unit, they are paired before delivery and can be used directly.
- If the wireless pedal is not detected, in addition to checking the battery, you
 can try to re-pair.
- · After replacing the wireless pedal, you need to re-pair.

6.11 Other settings

On the settings page, you can set the volume, screen brightness, lighting delay, etc.

6.12 Control ranges and default values

Mode	Program	Gear ratio	Speed(r/min)	Coolant	LED
Extraction	Ex1	1:4.2 (D) 1:3/1:3.3/	150000 (D) 9000-168000	5 (D)	High
	Ex2	1:4.2/1:5	150000 (D) 9000-168000		
	Rinsing				
High- speed	Tooth preparation	1:5 (D)	160000 (D) 10000-200000	0 (D)	High
	Crown cutting	1:3/1:3.3/ 1:4.2/1:5	180000 (D) 10000-200000		
Pulp opening			180000 (D) 10000-200000		
	Pulp correction		180000 (D) 10000-200000		

	Caries removal		20000 (D) 10000-200000		
	Fine repair		20000 (D) 10000-200000		
	Other		20000 (D) 10000-200000		
	Rinsing			5 (D)	
Low- speed	Polishing	1:1 (D) 27:1/20:1/16:1/	8000 (D) 2000-40000	0 (D)	High
	Caries removal	10:1/4:1/1:1	20000 (D) 2000-40000		
	Fine repair		20000 (D) 2000-40000		
	Other1		20000 (D) 2000-40000		
	Other2		20000 (D) 2000-40000		
	Rinsing			5 (D)	

Mode	Program	Speed(min-1)	Coolant	LED
Osteotome	Sagittal saw	30000 (D) 10000-40000	5 (D)	Light
	Reciprocating saw	30000 (D) 10000-40000		
	Swinging saw	30000 (D) 10000-40000		
	Surgical handpiece	30000 (D) 10000-40000		
	Other	30000 (D) 10000-40000		
	Rinsing			

(D) = factory setting (default value)

6.13 Working

Press the accelerator pedal to start the motor, which rotates in the set direction.

The speed of the motor depends on the force of pressing the accelerator pedal. When the pedal is completely pressed, the motor reaches the set speed.

Release the accelerator pedal, the motor stops rotating, the coolant stops supplying, and the lighting turns off.

Cleaning, disinfection and sterilization



NOTE -

Please refer to the relevant user manual for the handling steps of the contra angle.

Device:	Main unit and Foot pedal
Warning:	Do not use automatic methods to clean and disinfect the Main unit and Foot pedal. Do not sterilize the Main unit and Foot pedal.
Surface cleaning and disinfection	It is recommended to clean and disinfect the main unit and Foot pedal surfaces with 75% alcohol after use; Soak the cloth in a 75% alcohol container and wring it out to remove excess water. Wipe the surface of the main unit and foot switch at least 3 times with a wet rag, paying special attention to gaps and hidden areas of activity, wipe until it is visually clean.

Device:	Motor, Irrigation hanger and Handpiece stand		
Warning:	Only the Motor, Irrigation hanger and Handpiece stand can be cleaned and disinfected with automated methods. Only the Motor and Handpiece stand need to be sterilized with a steam sterilization process.		
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.		
	The components should be reprocessed after each use.		
Reprocessing Instructions			

Preparation at the Point of Use:	Disconnect the Motor from the motor cable. Remove Irrigation hanger and Handpiece stand. Screw the Motor Cap to the Motor and the protection plug to the Motor connection. Protective plug Motor Cap 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, if required.	
Transportation:	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.	
Pre-Cleaning :	Do a manual pre-cleaning, unitl the instrument are visually clean. Clean the surface of the Motor, Irrigation hanger and Handpiece stand under running water with a soft bristol brush.	
Manual Cleaning for Motor, Irrigation hanger and Handpiece stan d(For US):	Recommend using 3M multi-enzyme cleaning agent at a concentration of 5mL/1L distilled water. Soak the soft cloth in detergent and wring it out. Remove any liquid residue with a lint-free cotton cloth, then dry at 30°C. Checked that if the devices were clean or broken after cleaning. If the cleaning is not good enough, repeat the cleaning procedure. Do not put the Motor into a container containing a cleaning solution. If the internal liquid is not cleaned and the drying is incomplete, theintemal parts may be corroded.	

Automated Cleaning for Motor, Irrigation hanger and Handpiece stan d(For EU):	Use a washer-disinfector meeting the requirements of the IS015883 series. Put the instruments into the machine on a tray and start the program. 1 min pre-washing with cold water (<40°C) emptying 10 min washing with a mild alkaline cleaner at 55°C emptying 1 min rinsing Emptying The automated cleaning processes have been validated by using 0.5% 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.
Manual Disinfection for Motor, Irrigation hanger and Handpiece stand (For US):	Wipe disinfection is recommended to ensure that the disinfectant is used for a limited period of time. Place a lint-free cotton cloth into a container of 75% alcohol and wet it completely, pick it up and twist it gently to dry it. Wipe down the motor and cable at least 3 times, making sure that all surfaces have been wiped down with a damp cloth. Do not soak in disinfectant containers for disinfection.
Automated Disinfection for Motor, Irrigation hanger and Handpiece stand (For EU):	Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to AO-Value (see EN 15883). A disinfection cycle of 5 min disinfection at 93°C has been validated for the device to achieve an AO value of 3000.
Manual Drying for Motor, Irrigation hanger and Handpiece stand (For US):	Use compressed air to blow dry the internal pipes and external surfaces separately.

Automated Drying for Motor, Irrigation hanger and Handpiece stand (For EU):	Dry the outside of instrument through drying cycle of washer/disinfector, if needed, additional manual drying can be performed throuah lint free towel.
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.
Packaging for Motor and Handpiece stand (For US):	Please the sterilization bags which are approved for its efficacy by FDA. Recommended sterilization bag: SlGMASterilization Pouch and Roll 510(k)Number: K202462.
Packaging for Motor and Handpiece stand (For EU):	Pack the instruments in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607.
Sterilization for Motor and Handpiece stand (For US):	Sterilization method: Gravity-Displacement Steam Cycle Sterilization conditions: 135°C, 10 minutes Drying Time: 30 minutes
Sterilization for Motor and Handpiece stand (For EU):	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.
1	

Additional Instructions: None

It is the duty of the user to Make sure 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.

8 Maintenance

8.1 Periodical maintenance

Perform periodical maintenance checks every three months, referring to the checklist below. If any abnormalities are found, contact the manufacture or local dealer.

Point to check	Details
Main unit	Confirm that the touchscreen display and touch are normal.
Foot pedal	Confirm that all the buttons operate normally. Make sure the wireless pedals have sufficient batteries.
Motor	Run for 1 minute and make sure there is no abnormal heating, sound, or vibration. Make sure that the LED of the motor glows normally. Check that the motor O-rings are not broken or deformed.
Irrigation volume	Install the water tank and fill water, step on the foot pedal until the water comes out smoothly.
Contra angle	For the maintenance of the Contra angle, please refer to the relevant instruction manual.
Water tank	Make sure the water tank is not damaged and there is no water leakage. Check that the 0-ring at the bottom of the water tank is not broken or deformed.
Filter	Remove the filter and visually confirm that there are no impurities or dirt on the filter.

8.2 Factory reset

Click the settings button to enter the settings page, click the RESET button, and then follow the prompts.



CAUTION

Factory reset will clear all data set by user and cannot be restored.

8.3 Tube cleaning

The water supply tubes inside the main unit need to be cleaned to eliminate scale and reduce bacterial infection.



- The tube cleaning is only applicable to "self-water" irrigation type.
- It is recommended to run a quick cleaning once a month. If it is not used for a long time, run a deep cleaning before storage.
- The device will prompt if the cleaning has not been run for a long time, and it will disappear automatically after cleaning.

Add more than 100ml of medical alcohol (75% concentration) into the water tank. Remove the contra-angled from the motor handpiece;

Then enter the settings page, click the "clean" button, and follow the instructions.

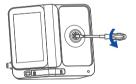
8.4 Cleaning filter



NOTE

If the water supply is low in "self-water" irrigation type, please clean the filter in time.

- 1) Use a flat-blade screwdriver to insert into the filter's groove and unscrew the filter from the main unit.
- 2) Rinse the filter with water and blow dry it.
- 3) Screw the filter back into the main unit.





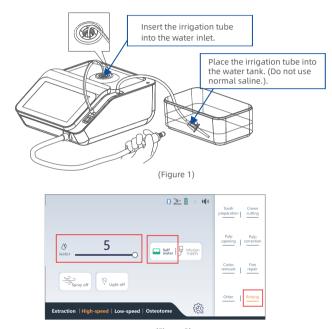
8.5 Unblocking the internal waterway

Impurities in the water can cause the supply components to stick together, and the water supply way may be blocked when the device is not used for a long time.

You can use the external irrigation tube to flush water to unclog the internal supply way, as follows:

- 1) Remove the filter from the main unit, refer to "8.4 Cleaning filter".
- Lay the irrigation tube on the peristaltic pump, place one end in the tank filled with water, and insert the other end into the water inlet of the main unit.(Fig.1)

- 3) Select the "Rinsing" program in any mode. Select the "infusion supply" irrigation type and set the water volume to the highest.(Fig.2)
- 4) Press and hold the accelerator pedal, peristaltic pump will supply water to the internal supplyway until water sprays steadily from the motor outlet.



(Figure 2)

8.6 Replace Fuse



NOTE

- If the main unit does not work, check whether the fuse is blown.
- Fuse specification: F3.15AL 250V 5*20mm.

Use a flat screwdriver to pry open the groove on the side of the fuse holder on the back of the main unit.

Pull out the fuse holder, take out the fuse and replace it with a new one.



8.7 Replace LED



WARNING

Do not touch the LED that has just finished working. Wait for it to cool down.

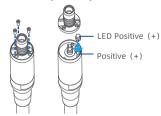


NOTE

LED works depends on the correct installation of positive and negative poles. If the LED emits red light or does not work, try to rotate it 180° and reinstall it.

Unscrew the screws on the motor and remove the damaged LED light;

Insert the new LED into the groove, press it into place, and tighten the screws.



8.8 Replace O-ring



CAUTION

- Do not replace the O-ring when the motor or contra angle working.
- ${}^{\bullet}\,$ Do not use Vaseline or silicone grease on the O-rings.

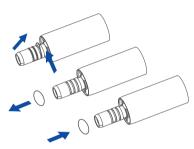


If the contra angle is difficult to connect to the motor, or if you detect an air/water leak, the motor O-ring may be damaged and should be replaced.

Remove the damaged O-ring and replace the new one.

The following three parts of the o-ring can be replaced:

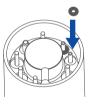
① Motor connector



② Motor inner tube







③ Water tank







Troubleshooting

9.1 Troubleshooting

Malfunction	Possible causes	Solution	
The device does not turn on	Blown fuse	Replace a new fuse	
Touch screen does not respond	The screen is wet or dirty	Clean the screen	
	Battery is low	Replace batteries	
Pedal does not work when pressed	Wireless pedal not connected to main unit	Repair	
pressed	Bad contact of corded pedal	Re-insert	
	Pump cover is not closed	Fully closed	
	Irrigation tube clamp is closed	Open clamp	
No coolant or insufficient	Irrigation tube is kinked	Check and straighten bends	
coolant	Contra-angle nozzle is clogged	Clean and unclog it	
	Internal waterway of the main unit is blocked	Cleaning filter, refer to 8.4 Unblocking the internal supply tube, refer to 8.5	
	Motor connection is loose	Reconnect and check that the connection is in place	
The motor does not run and makes a lot of	Overload	Check whether the straight or contra-angle handpiece is stuck and whether the motor is stuck	
noise	Motor tail cover is not screwed on	Tighten the motor tail cover	
	The motor is not properly installed with contra angle	Reinstall and check for firm installation	
	Water enters the motor	Drying motor	
Motor overheat	The continuous use time of motor is too long or the load is too large	Let the motor cool down before use	
The motor has insufficient torque Transmission ratio setting mismatch		Set the ratio consistent with handpiece used	

	The contra angle resistance is too large	Replace the straight and contra-angle and recalibrate the contra-angle
Speed too fast or too slow	The set ratio does not match the contra-angle	Set the ratio consistent with contra angle used
	LED damage	Replace LED light
No light on the straight or contra-angle	The contra angle is improperly connected	Connect contra angle until it is positioned and locked
	Contra angle without lighting	Use the contra angle with lighting

9.2 Error code

Error description	Possible causes	Solution	
E1:Screen communication failure	Mainframe internal circuit failure. Screen-to-motherboard connection failure.	Turning the device off and on again. If the error message appears again, contact manufacture or local dealer.	
E2: Pedal Bluetooth failure	Bluetooth circuit abnormality Bluetooth communication abnormality	Turning the device off and on again. If the error message appears again, contact manufacture or local dealer.	
E3: Motor failure • Main unit internal circuit fault • Motor operating current fault		Contact manufacture or local dealer.	
E4: Internal water pump failure	Internal water pump fault. Internal water pump drive circuit fault	Contact manufacture or local dealer.	
E5:Motor overheating	Motor working continuously for a long time Motor overload	The motor cools down before continuing to run.	
E6:Heating failure	Heating module abnormality. Thermostat abnormality. The working environment temperature is too high or too low.	Contact manufacture or local dealer.	

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Operating, transport and storage environment

Operating environment

Ambient temperature	+5°C - +35°C
Relative humidity	20%RH - 80%RH
Air pressure	80kPa - 106kPa
ALT	≤2000m

Transport and storage environment

Ambient temperature		-10°C - +55°C	
	Relative humidity	≤93% RH	
	Air pressure	50kPa - 106kPa	

1 1 After-sales service

11.1 Terms and conditions of warranty

The manufacturer provides the final customer with a warranty that the product specified in the delivery note functions properly and is free of defects in the material or workmanship. Main unit, Foot pedal and Motor warranty for 24 months from the date of purchase of the product, manufacturers provide free replacement or repair services for reasonable product defect complaints within the timeframes listed below:

Subject to the following conditions:

- Other claims of any nature whatsoever, in particular with respect to compensation, are excluded. In the event of default and gross negligence or intent, this shall only apply in the absence of mandatory legal regulations to the contrary.
- The warranty does not usually cover bulbs, glassware, rubber parts and the colorfastness of plastics.
- Claims from this warranty can only be asserted when the delivery note of the product has been sent to the manufacturer, and the original can be presented by the operator or user.

The supplier can provide, upon request, circuit diagrams, component lists, notes, calibration specifications, or other information necessary to assist the user's qualified technicians in the repair of parts of the equipment which are designated as repairable by the manufacturer.

11.2 Disclaimer

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

- · Repairs made by personnel not authorized by the manufacture.
- · Any changes, modifications, or alterations of its products.
- 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 programs 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.
- Fires, earthquakes, floods, lightning, natural disasters, or acts of God.

1 Disposal of medical device

The instrument and its packaging are designed to be as environmentally friendly as possible.



Follow your local and country-specific laws, directives, standards and quidelines for disposal.

- > Medical device
- > Waste electrical equipment
- > Packaging

13 Technical specifications

Main unit

Model	C-PUMA Pro
Supply Voltage	100-240V ~ 50Hz/60Hz
Input power	200VA
Fuse	F3.15AL 250V Φ5*20mm
Cooling water	≥50mL/min
Air Supply for Atomization ("self-water" irrigation type with atomization Function)	≥1.5L/min
Dimensions (Without water tank)	L268 * W227 * H114mm
Degree of Protection(IEC 60529)	IPX0(Main unit)
Overvoltage category	Class II
Pollution Degree	Degree 2
Operation mode	Duty cycle: Max.T_ON: 1min, Min.T_OFF: 10min
Classified of protection against Electric Shock	Class I
Degree of protection against Electric Shock	Type BF applied part
Classified by security	Non-AP/APG type

Electrical Motor

Range of speed	2000r/min~40000r/min (1:1)	
Torque output (20:1)	≥2N·cm	
Length of motor cord	2.0m	
Application part	Motor Handpiece: aluminium(6063)	

Foot pedal

Degree of Protection(IEC 60529)	IPX7(foot pedal)
Length of Foot pedal cord	1.8m

Illuminants (LED)

Type of radiation	LED
Typical color temperature	6000K
Rated Voltage	DC 3.2V ±0.4V
Maximal LED current	70mA

14 Symbols

\wedge	Warning	Ţ	Caution
i	Note	\sim	Alternating Current
	Importer	3	Refer to instruction manual / booklet
[Ă]	Thermo-Disinfector	IPX7	Protected against the effect of immersion
†	Type BF applied part	134°C 555	Sterilizable in a steam sterilizer at 134°C
<u> </u>	Vertical up	Ť	Keep dry
SN	Serial number		Fragile,handle with care
I	Power on	Z	Special disposal of waste electrical and electronic equipment
	Date of manufacture	0	Power off
	Protective Earthing		Manufacturer
MD	Medical device	<u>></u>	Foot pedal
类	Keep away from sunlight		General symbol for recovery / recyclable
	Do not walk or stand here	**	Protect from heat and radio-active sources

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Guidance and manufacturer's declaration--EMC



NOTE:

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



WARNING:

Do not use a mobile phone or other devices that emit electromagnetic fields, near the device. This may result in incorrect operation of the device.

This device has been thoroughly tested and inspected to assure proper performance and operation!

This device should not be used adjacent to or stacked with other device and that if adjacent or stacked use is necessary, this device should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacture's declaration - electromagnetic emission

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

Emission test	Compliance	Electromagnetic environment - guidance	
RF emissions CISPR 11	Group 1	The device 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	The device is suitable for use in all establishments, including domestic	
Harmonic emissions IEC 61000-3-2	Class A	establishments directly connected to the public low-voltage power supply network with specific requirement.	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies		

Guidance and manufacture's declaration - electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of device 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, ±8kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8kV, ±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 ±1kV for Input/ output lines	±2kV for power supply lines	Mains power quality should be that of atypical commercial or hospital environment.		
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.		
Voltage dips, short interruptions and voltage variationson 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 70% U _T (30% dip in U _T) for 25/30 cycles <5% U _T (>95 % dip in U _T) for 5 % dip in U _T) for 5 sec	for 0.5 cycle <5 % U _T (>95% dip in U _T) for 1 cycle 70% U _T (30% dip in U _T) for 25/30 cycles <5% U _T	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from a unit eruptible power supply or a battery.		
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields shouldbe at levels characteristic of a typical location in a typical commercial or hospital environment.		
NOTE: U _T is the	NOTE: U _T is the a.c. mains voltage prior to application of the test level.				

Guidance and manufacture's declaration - electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands 10 V/m 80 MHz to 2.7 GHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands 10 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Radiated RF IEC 61000-4-3	385MHz- 5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601- 1-2: 2014)	385MHz- 5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1- 2:2014)	d=[3,5/V1] $\times \sqrt{P}$ 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. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the instrument should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the instrument.
- b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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

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

Rated maximum output power of	Separation distance according to frequency of transmitter				
transmitter(W)	150 kHz to 80 MHZ d=1.2 × √p	80 MHz to 800 MHz d=1.2 ×√p	80 MHz to 800 MHz d=2.3 ×√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) according to the transmitter manufacturer.

NOTE1: At 80 MHz and 800 MHz, the separation distance for the higher frequency rangeapplies.

NOTE2: These guidelines may not apply in all situations. Electromagnetic propagation isaffected by absorption and reflection from structures, objects and people.







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User Manual Ver: 1.0 Software Ver: 1.1 Date: 2025.003.08