stomdevice

SAESHIN

traus SIP10

INSTRUCTION MANUAL



www.saeshin.com

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Traus SIP10

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INTRODUCTION

This product is medical device.

Make sure to read this user manual before using.
This user manual is to assure proper installation and use.
Pay attention to read this user manual in order to making the best use of this product and to assure the prolonged lifespan before using.
Specially, pay attention the contents with marks such as , and .

<User>

- Qualified Professional

<Intended purpose>

- The SIP10 is intended for use in dental surgery, implantology, maxilla-facial surgery and endodontics for treatment of dental hard tissue and mechanical rotating root canal preparation.

<Classification of equipment>

- Type of protection against electric shock: Class I equipment
- Degree of protection against electric shock: Type B applied part
- Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 60529
  - Control Box: IPX 0
  - Foot Controller: IPX 8
- Not suitable product in the atmosphere that exist flammable anesthetic mixture with air or with oxygen.
- User sterile product (non-sterile product at shipment)
- Classification according to mode of operation: Intermittent operation
- Applied part : Bur

<Use time>

- Loading time: 2 minutes
- Resting time: 15 minutes

<Operation & Storage condition>

Operating condition	Temperature (℃)	10~35
	Relative humidity (%)	10~80
	Atmospheric pressure (hPa)	700~1,060
Transport and Storage condition	Temperature (℃)	-20~60
	Relative humidity (%)	10~90
	Atmospheric pressure (hPa)	500~1,060

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USER GUIDELINES

CAUTION

- Please pay attention to the use considering the patient's safety first of all.
- Check condition of the product before use.
- Stop to use and inspect the product when an abnormal sign such as calescence, vibration or noise occurs before or during operation.
- Please contact manufacturer if cannot find reason of problem, or cannot solve the problem.
- Prepare extra consumables before use for safety because blood or physiological saline might flow into the head of angle handpiece.
- Change or insert bur after the motor is completely stopped. Otherwise, inside of the angle could be damaged by bur, and it could cause an accident.
- Please sterilize and lubricate the handpiece right after use. Otherwise, the product could be damaged due to coagulation of blood inside the product.
- The control box and foot controller are not steam sterilization objects
- The input power is available at AC 100-120 V / 220-240 V
  (Check input voltage before connecting the AC power.)
- Dispose the irrigation tube as a medical waste after use.
- Contact manufacturer if incorrect display is on the screen.
- Do not drop or give a strong impact to the product.
- Do not give any damage to irrigation tube, it will not work normally due to the tube is broken or taken off.
- Do not insert oil into BLDC motor. It will damage bearing or cause calescence.
- The product is designed to be used indoor, do not use outdoor.
- Do not use the product in humid or dusty environment.
- Use the regulated products and consumables by manufacturer. Otherwise there might be a risk of an accident or failure.
- Replace the motor cord immediately when it is worn out or damaged to prevent electric shock for user or patient.
- User has responsibility to operate and maintain the product.
- The company did not sterilize the product. Please be sure to sterilize before operation.
  (User sterilization)
- US Federal law restricts this device to sale by or on the order of a dentist.

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WARNING

- Please watch old person, children, or disabled person near the place that the product is installed. If so, do not let them alone.
- Do not drop or damage the handpiece. In case of malfunction, dropping, or dropping in water, do not use it and contact the manufacturer.
  (It may cause vibration of bur, overheating, or damage of the bearings.)
- The equipment is automatically stopped when the machine load is higher than Torque value.
- Do not damage or drop the LCD part of the control box.

PROHIBITION

- Do not use damaged or broken power cord, plug, and outlet. It may cause fire and electric shock.
- When unplug the power cord, hold the plug and do not touch with wet hand.
  Do not use loose power cord, it may cause electric shock and fire.
- Do not damage to power cord (do not bend too hard, do not put heavy objects on it). It may cause electric shock and fire.
- Unauthorized modification and dismantling is prohibited.
- Do not use the solvent such as thinner or benzene for cleaning.
  ※ Be careful not to drop liquid on control box.
  ※ Do not wipe the control box (membrane) with wet fabric.
- Do not place the product near heat equipment, and do not put candles or cigarette on it.
- Please use a grounded plug. Contact to electrician or manufacturer to ask how to grounding.
- Be sure to use designated bur by ISO 1797.
- Follow the instruction manual by manufacturer of bur to use bur.
- Keep the recommended speed limit by manufacturer of bur to use bur. If exceed the speed limit, it might cause an accident.
- The product must be used by specialist or expert. If not, patient might get burn or damage by improper use.
- Do not use the product to patient with cardiac pacemaker because the product may disturb the performance of cardiac pacemaker.
- If patient is taking antibiotics, patient needs to consult with doctor before operation.
- Keep away from fire or heat when using spray containing flammable material.
- Manufacturer does not have any responsibility for defects or loss of property in cases below.
  1. User did not follow the instruction manual to use the product.
  2. Used the product in the place of unregulated wire condition.
  3. Unauthorized person repaired or assembled the product.
  4. Did not follow the instruction manual to keep the product.

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PRODUCT FEATURES & ADVANTAGES

<BLDC motor designed by SAESHIN's own technology and know-how>
- Provide the optimized performance by BLDC motor and standard angle handpiece.
- RPM :

1:4	1:5	1:1	16:1	20:1	27:1	32:1	64:1
160,000rpm	200,000rpm	40,000rpm	2,500rpm	2,000rpm	1,480rpm	1,250rpm	620rpm

The free-running speed of the handpiece shall be in accordance with the manufacturer's instructions at a tolerance of ±10 % as specified. (Refer to ISO 14457)

- Torque :

1:4	1:5	1:1	16:1	20:1	27:1	32:1	64:1
**N·cm	**N·cm	**N·cm	5~50N·cm	5~70N·cm	5~80N·cm	5~80N·cm	5~80N·cm

- Gear Ratio: 1:4, 1:5, 1:1, 16:1, 20:1, 27:1, 32:1, 64:1
- LED: 25,000 Lux

<Program Memory Function>
- Maximum 9 programmable memories for setting Speed, Gear Ratio, Torque, Rotating Direction and Irrigation Pump.

<Automatic Overload Protection Function>
- The motor is automatically stopped and 'Error' sign display on screen when the load is higher than Torque value.
- For releasing the overload function, release the foot controller.

<Realtime RPM, TORQUE View System>
- Actual RPM and Torque value are displayed on the screen. It makes user can do more delicate operation.

<Motor Auto-calibration Function>
- Motor auto-calibration function is that control box check the angle handpiece status to reconcile speed and torque that user wants with angle handpiece for accurate and safe operation.

1. Set the program number at '0'. The program changes to calibration mode.
2. Push the foot controller to the end. The calibration starts and the display show the calibration process.
3. During normal operation, the calibration will be completed after 5~10 seconds with '-CAL-' on the screen and beep sounds.
4. When it is completed, Use the product.

- The function is set up when the product is released by manufacturer and Use the function when user repair or change the product.
- Program 0 is the only for auto-calibration function, so the memory function or other setting value does not work.

<Ergonomic Foot Controller>
- Foot controller is designed ergonomically to control all the functions. And it provides high convenience.

<Optic Function - (option)>

Basic Components	MBP10SX + Non-Optic Angle Handpiece : Except Optic Function
Option	MBP10SL + Optic Angle Handpiece : Optic Function

- LED: 25,000 Lux
- Optic function is only operated by Optic angle handpieces (CRB26LX, CRB27LX, CRB46LN) and Optic micro motor(MBP10SL).

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PRODUCT COMPONENTS

* Please check all components are included. (Some components may be changed by the manufacture.)

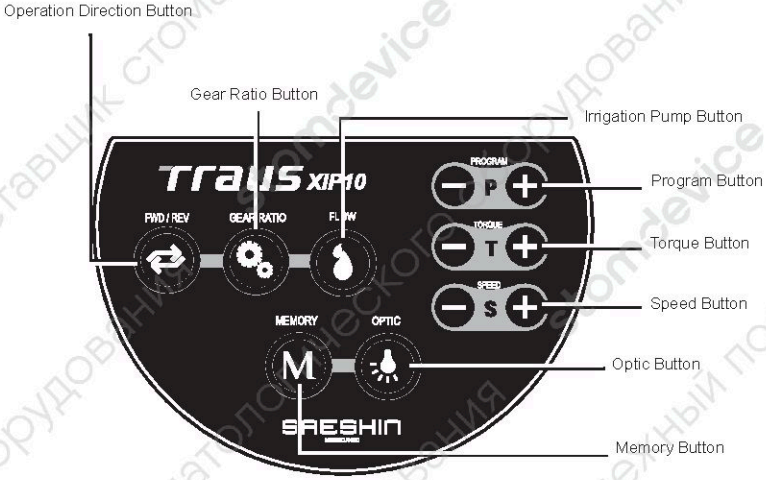
1		8	
2		9	
3		10	
4		11	
5		12	
6		13	
7		14	

No.	Component	No.	Component
1	CONTROL BOX	8	INTERNAL SPRAY NOZZLE (Optional)
2	ANGLE HANDPIECE	9	MOTOR CAP For Autoclave
3	BLDC MOTOR	10	TUBE HOLDER
4	FOOT CONTROLLER	11	TUBE CLAMP
5	MOTOR STAND	12	AC POWER CORD
6	HANGER	13	SPRAY NOZZLE
7	A-SLEEVE	14	

- Saline solution is not included in a set.

PART NAME OF CONTROL BOX





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BUTTONS ON THE OPERATION PANEL



Program Button:
Use for selecting the set program number. (+) button for 1 stage up and (-) button for 1 stage down.



Speed Button:
Use for setting the speed (RPM).
(+) button for 1 stage up and (-) button for 1 stage down. Keep pressing speed button to change the stage rapidly.
* The setting range of speed is different from the gear ratio.



Torque Button:
Use for setting the torque according to the various use such as drilling or tapping.
(+) button for 5 N·cm up and (-) button for 5 N·cm down.
* The setting range of torque is different from the gear ratio.



Memory Button:
Keep pressing Memory button after completed setting. Then the condition is memorized with beep sound.



Gear Ratio Button:
Use for setting the gear ratio of the angle handpiece.

→ 1:4 → 1:5 → 1:1 → 16:1 → 20:1 → 27:1 → 32:1 → 64:1 ↩



Operation Direction Button:
Use for selecting the forward or reverse direction. The beep sound is heard during rotation in reverse direction.



Irrigation Pump Button:
Use for setting the irrigation volume in 5 levels (From 0 to 90ml).

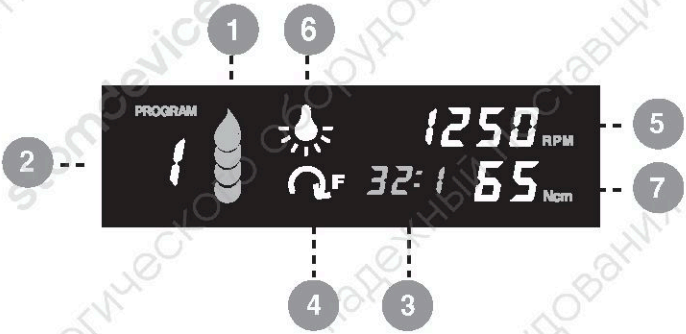
Irrigation Level	Water Pump
0 1 2 3 4	Stage 0: 0 ml/min Stage 1: abt. 40 ml/min ± 20% Stage 2: abt. 55 ml/min ± 20% Stage 3: abt. 70 ml/min ± 20% Stage 4: abt. 90 ml/min ± 20%



Optic Button:
When press the speed control pedal on the foot controller after operating the optic function, LED is turned on at the angle and motor parts.
Release the speed control pedal, turn off the LED after 3 seconds.
Turn off the optic function, LED is not operated regardless pressing the speed control pedal.
Optic function is only operated by Optic angle handpiece and Optic motor .

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LCD WINDOW



1. Irrigation Volume Display
: It shows the selected irrigation level. Level 0 is no volume and level 4 is maximum.

2. Program Number Display
: 9 programmable programs set from 1 to 9. And it shows program 1 at every power on.

3. Gear Ratio Display
: It shows the selected gear ratio number.

4. Operation Direction Display
: It shows the selected direction.

5. Speed Display
: It shows the initial setup RPM when it is on standby. The actual value is displayed in real-time during operation. The number is same as set RPM level when press foot controller to the end.

6. Optic Display (Optic Version)
: The optic function is working when bulb symbol display on the screen.
* Optic function is only operated by Optic angle handpiece and Optic motor.
* When press the speed control pedal on the foot controller after operating the optic function, LED is turned on.

7. Torque Display
: It shows the initial setup torque value. The actual value is displayed in real-time during operation. If an actual load is higher than set torque value, the set torque value is on the screen and the motor is stopped automatically with 'Torque Limit' on the screen and beep sound until user releases foot from the foot controller.

- Impact to device and drop the device may cause breakage of LCD.

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BUTTONS ON THE FOOT CONTROLLER

- FUS10



1. Program Button
: Use the button to select the program. 1 stage increased per each press. 1 stage decreases when press this button above 3 seconds.
(Program decrease function is not operated continuously. If you want to decrease program over the 2 stage, press the button after releasing the button.)

2. Operation Direction Button
: Use the button to change the operation direction.

3. Irrigation Pump Button
: Use the button to select the irrigation volume. 1 stage increased per each press.

4. Speed Control Pedal
: The motor speed is controlled by pressing and releasing the foot controller.

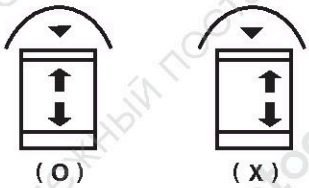
CONNECTION OF EACH PART



- Make sure the power is off before connect each part.
(Otherwise, it might cause a malfunction.)

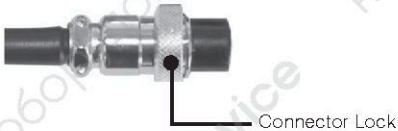
1. Motor Connection
: Please insert the motor plug to the device correctly. (Place the arrow mark on top. See the picture below.)



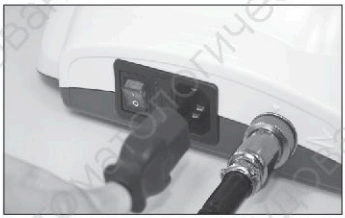


2. Foot Controller Connection
: Please insert the foot controller connector. Check the hole and pins of foot controller connector are in place. Then screw the Connector Lock.





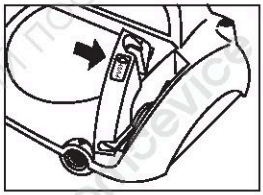
3. Power Cord Connection
: Insert the power cord into the main power inlet of the control box.



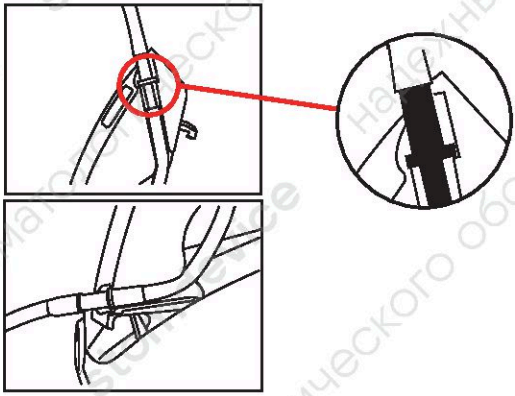
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4. Irrigation Tube Connection to Pump Roller

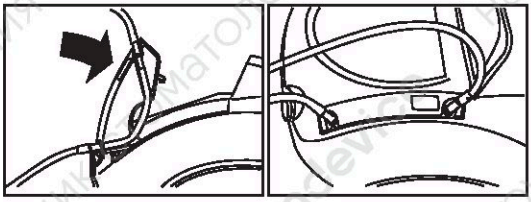
① Please press the PUSH button to open the pump cover.



② Please place the irrigation tube correctly in the pump.



③ Please press the PUSH button to close the pump.



- If you do not use it for long period, please open pump roller cover.
  Otherwise, the irrigation tube might be damaged.

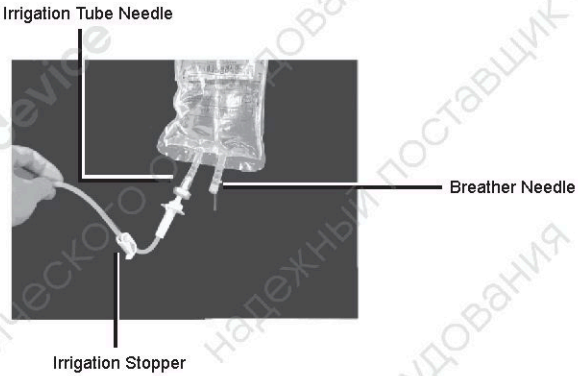
5. Hanger Setting
: Put the hanger into the hanger hole.



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6. Irrigation Tube Insertion

: Lock the irrigation stopper placed between the irrigation tube needle and pack, then insert the irrigation tube needle to the pack in place with the pack downward.



- If pump is operating while the tube is bent or the water does not come out, the tube can be broken or damaged.

7. Irrigation Nozzle Connection

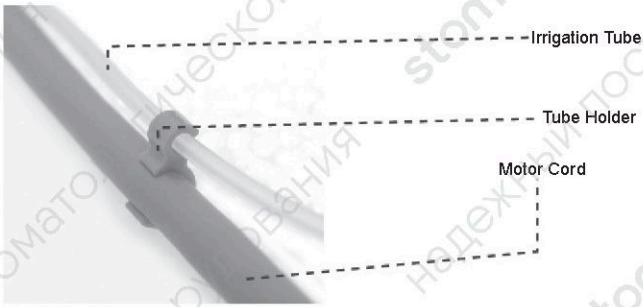
: Insert the irrigation tube to the end of internal spray nozzle pipe and external spray nozzle pipe.



- If user does not remove the internal spray nozzle, and then presses the button or opens the lever when bur replacement, the nozzle may be damaged.

8. Tube Holder Connection

: Put the motor cord and irrigation tube together with holders. Insert the tube holder to the motor cord and then put the irrigation tube for easy work.



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OPERATION PROCESS

(1) Turn the main switch on.
If the product is normal condition, it becomes standby mode with program 1 on the screen like below picture.



(2) Choose the program.
Press the button P on the foot controller or button on the control box, the program changes by 1 stage. Select the program that user want to use.
(Press the button P on the foot controller for 3 seconds, program is decreased the 1 stage.)
The program returns to program 0 after program 9.

(3) Check the setting.
Check the display on LCD box to make sure the setting is correct.

(4) Start the operation.
The motor starts to rotate after press the speed control pedal. It runs at low speed with light press and at high speed with heavy press by the set speed in max. If the irrigation mode is on, the pump operates same as motor operation.

※ **Overload protection function.**
: If the load exceeds the set torque during the operation, the overload protection function works not to generate the extra torque.

(5) Stop the operation.
The operation is stopped when user takes foot off the speed control pedal.

(6) Change the operation direction.
Press the on the foot controller or button on the control box to reverse direction.
In reverse direction mode, the device will sound the beep, and it continues during the operation.
Press the button once more, it returns to forward direction.

- Change the rotary direction after stopping the motor. It causes damage of motor.

Program Setting
: First, select the program number then set Gear ratio, Speed, Torque, Rotating direction, Irrigation volume, and Optic option, and press the memory button (above 2 seconds) to save the setting. (9 programs max.)

Example)

PROGRAM P		SPEED S	TORQUE T				
PRG 1	20 : 1	2,000RPM	10 N·cm	FWD	PMP : 4	ON	Complete
PRG 2	32 : 1	1,250RPM	15 N·cm	FWD	PMP : 2	OFF	Complete

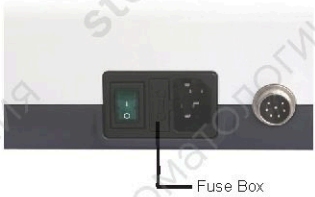
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Error and Remedy

When motor stops due to overload, disconnection or misuse, the error code explanation is below:

Error Display	Cause and Remedy
Err 01	Cause: Foot controller connection is wrong or Foot controller is malfunctioning. Remedy: Check the foot controller connection. Press the speed control pedal on the foot controller. If the remedy does not work, contact the manufacturer.
Err 02	Cause: Motor connection is wrong or Motor is malfunctioning. Remedy: Check the motor connection. Press the speed control pedal on the foot controller. If the remedy does not work, contact the manufacturer.
Err 03	Cause: Running torque exceed preset torque during operation. Remedy: Press the speed control pedal on the foot controller. If the remedy does not work, contact the manufacturer.

Fuse Replacement



Check the fuse if the control box doesn't work.
Contact the manufacturer to change the fuse.

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MAINTENANCE OF THE PRODUCT

1. Cleaning

■ Angle Handpiece

① Rotate the head in a tap water about 10 seconds with maximum speed to remove the remains (blood, physiologic saline solution, etc.) and rinse.
※ Do not put tap water in the motor.
② Disconnect the angle handpiece to the motor.
③ Remove contaminants on the angle handpiece using a nylon brush after soaking for 20 minutes in Enzymatic Detergent.
④ Rinse the angle handpiece using the tap water for 3 minutes to remove Enzymatic Detergent.
⑤ Wash the angle handpiece for 10 minutes in the ultrasonic cleaner containing Enzymatic Detergent.
⑥ Rinse the angle handpiece for 3 minutes in the ultrasonic cleaner containing purified water repeatedly subjected 3 times. (Change the purified water each time.)
⑦ Wipe using dust-absorbent after the product soaked in alcohol(70%) for 30 seconds.

■ Motor

Wipe the surface of motor with alcohol swab or paper towel after removing the dirt.
※ Pay attention to not enter the water into the motor.

- Proteolytic enzyme detergents are recommended as Enzymatic Detergent.
- It is recommended to use ethanol for alcohol (70%).

2. Sterilization

Sterilization Product List

· Angle handpiece
· Motor (Assembling with motor cap)

Sterilization Method

① Dry the applicable products completely after cleaning.
② Put the applicable products in a sterile bag and seal tightly.
※ Make sure to assemble the motor cap for autoclave on the motor.
※ Do not disassemble the motor and motor cord when sterilizing.
③ Put the sterile bag in the sterilizer and sterilization for 4 minutes with 132℃, and let it dry for 30 minutes.



Sterilization	Temperature	Time	Dry
Moist heat sterilization	132℃	4 minutes	30 minutes

- This product is designed to withstand 250 times of re-sterilization process.
- This product recommends the moist heat sterilization (autoclave), other sterile methods are not guaranteed the effectiveness.
- Make sure to use the sterilization bag and seal tightly.
- Make sure to dry the applicable products before sterilization.
- Motor could be damaged in sterilization because of the moisture inflow or else, so should be careful to handle it.
- Sterilizing the angle handpiece with blood or other remains may cause the breakage of the angle handpiece. Therefore, it is necessary to clean the angle handpiece before sterilization.
- Irrigation tube and Y-tube are disposable. Do not re-use.
- Keep dry a connector and socket of the control box.
- Before using, dry the product completely.

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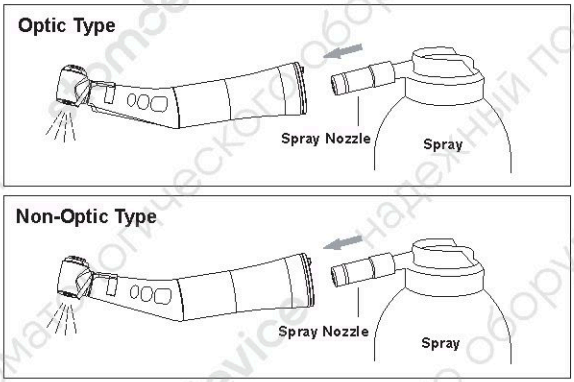
3. Lubrication

Lubrication Product List

· Angle handpiece

Lubrication Method

- Insert the nozzle to motor assembly part(the end part of angle) and spray lubricant 2~3 seconds.



- Do not insert the oil into the motor. It damages the bearing or causes fever.
- If the continuous operation, please put the oil every an hour.
- When lubrication, please hold the angle handpiece firmly because the angle handpiece can go out by the spray pressure.
- Caution: Lubrication spray present combustible hazard.
- Use FDA approved lubricant. (K052700 equivalent lubricant is available.)

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ATTENTION

1. Please read the notice below before operating the product.

1) Check the connection of every cords and correct operation when power-on.
2) Check the earth connection is safe.
3) Make sure to check the contact part to patient.
4) Check the voltage.
5) Check the sterile condition of autoclavable parts.

2. Please read the notice below during the product use.

1) Check the status of product and patient constantly during the surgery.
2) When product or patient has any problem, stop the operation in condition of patient's safety or take proper action.
3) Do not let patient to approach the product.

3. Please read the notice below after operating the product.

1) Do not put any physical pressure on the power cord, motor cord and foot controller cord.

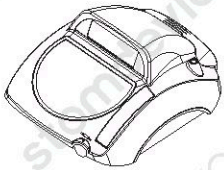
4. Please read the notice below if the product is not used for a long period of time.

1) Turn off and unplug the product. Check the cord regularly and replace it if it has any damage.
2) Clean and sterilize.
3) Keep the product in proper place.

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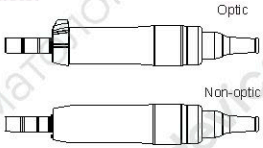
PRODUCT SPECIFICATION

1) Control Box



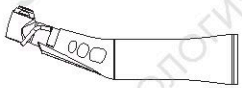
Model Name	XIP10
Input	AC 100-120V / 220-240V, 50/60 Hz
Fuse	5A / 2A
Power Consumption	48 VA
Maximum Irrigation Volume	Max. 90 ㎖ / min ± 20%

2) Motor

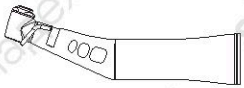


Model Name	MBP10SL	MBP10SX
RPM	40,000	40,000
Optic/Non-optic	Optic	Non-optic
Motor Type	BLDC type	

3) Angle Handpiece



Optic Type



Non-optic Type

Model Name	CRB26LX	CRB26XX	CRB27LX	CRB27XX	CRB46LN	CRB46NN
Gear ratio	20 : 1		32 : 1		20 : 1	
Optic/Non-optic	Optic	Non-optic	Optic	Non-optic	Optic	Non-optic
Bur Replacement Type	Button Type					
Bur Dimension	CA bur (Ø 2.35)					
Coupling Dimension	Standard dimension of dental handpiece (ISO 3964)					

4) Foot Controller



Model Name	FUS10
Classification according to the degree of protection against ingress of water (IEC 60529)	IPX 8

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ELECTROMAGNETIC COMPATIBILITY INFORMATION

In IEC/EN 60601-1-2:2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generate, use and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- **Reorient or relocate the receiving device.**
- **Increase the separation between the equipment.**
- **Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.**
- **Consult the manufacturer or filed service technician for help.**

(1) Electromagnetic Emissions

Emission test	Compliance	Electromagnetic environment - guide
RF emission – CISPR 11 EN 55011	Group 1	SIP10 uses RF energy for internal operation. Therefore, its radiofrequency emissions are very low and are not likely to cause any interference in nearby equipment.
RF emission – CISPR 11 EN 55011	Class A	SIP10 is suitable to use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission – IEC 61000-3-2 EN 61000-3-2	Class A	
Voltage fluctuations Flicker emission – IEC 61000-3-3 EN 61000-3-3	Compliance	

(2) Electromagnetic Immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2 EN 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV 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 transients IEC 61000-4-4 EN 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5 EN 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations IEC 61000-4-11 EN 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 6 cycles 70% UT (30% dip in UT) for 30 cycles <5% UT (>95% dip in UT) for 5s	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 6 cycles 70% UT (30% dip in UT) for 30 cycles <5% UT (>95% dip in UT) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the SIP10 got power from an uninterruptible power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8 EN 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.

(3) ELECTROMAGNETIC IMMUNITY / RADIOFREQUENCY MOBILE EQUIPMENT

Emission test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 EN 61000-4-6	3Vrms 150kHz to 80Mhz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the SIP10 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3 EN 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80MHz to 800MHz $d = 2.3 \sqrt{P}$ 800MHz to 2.5GHz Where 'P' is the maximum output power rating of the transmitter in watt (W) according to the transmitter manufacturer 'd' is the recommended separation distance (m). The electromagnetic field strength of fixed radiofrequency emitters, which is determined by an electromagnetic environment measurement (a), must be less than the compliance level in each frequency range (b). Interference may occur near equipment marked with the symbol below:

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

Note 2: These specifications may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and persons.

(a): The electromagnetic field strength of fixed radiofrequency emitters, such as base stations for mobile telephones (cellular / cordless), mobile radio, AM/FM radio broadcasts and TV broadcasts cannot be determined exactly by theory. To assess the electromagnetic environment due to fixed radiofrequency emitters, an electromagnetic environment measurement must be made. If the measured radiofrequency field strength in the immediate environment where the product is used exceeds the compliance level specified above, the performance of the product must be tested to verify whether it conforms to the specification. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the product.

(b): In the 150 kHz to 80 MHz frequency range, the electromagnetic field strengths must be less than 3V/m.

Cables and accessories	Maximum length	Shield	Complies with	
Micro motor with motor cord	1.7M	Unshielded	RF emissions, CISPR11	Class A / Group 1
			Harmonic emissions	IEC 61000-3-2 EN 61000-3-2
Foot controller with cord	1.7M	Unshielded	Voltage fluctuations / flicker emissions	IEC 61000-3-3 EN 61000-3-3
AC power cord	1.7M	Unshielded	Electrostatic discharge (ESD)	IEC 61000-4-2 EN 610000-4-2
			Electrical fast transient / burst	IEC 61000-4-4 EN 61000-4-4
			Surge	IEC 61000-4-5 EN 61000-4-5
			Voltage dips, short interruptions and voltage variations on power supply input lines	IEC 61000-4-11 EN 61000-4-11
			Power frequency (50/60Hz) magnetic field	IEC 61000-4-8 EN 61000-4-8
			Conducted RF	IEC 61000-4-6 EN 61000-4-6
			Radiated RF	IEC 61000-4-3 EN 61000-4-3

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SYMBOL

	Program Button
	Speed Button
	Torque Button
	Memory Button
	Operation Direction Button
	Manufacturer
	EC Representative
	Serial Number
	Autoclave
	Fuse
	Type B
	This product should not be mixed with other commercial waste for disposal
	Non sterile

	Gear Ratio Button
	Operation Direction Button
	Irrigation Pump Button
	Optic Button
P	Program Button
	Irrigation Pump Button
	Consult Instruction For Use
	General Caution Sign
	General Warning Sign
	General Prohibition Sign
	Alternating Current
CE 1639	CE Marking

WARRANTY

SAESHIN guarantees out product for 1 year from invoice date, and product warranty means that SAESHIN has responsibility of defective material or operation failure. The product warranty does not cover user's misuse, wrong installation, inappropriate maintenance and repair, and normal wear of consumables such as bearings, spindle, gear, and rotator. To check the warranty requires the operating condition, environment information, serial number of the product and stamped invoice. The warranty will be performed as repairs or exchanges by manufacturer's judgement and analysis of product.

Exception of warranty

User's misuse or improper use and treatment
Use the product with incorrect input voltage (AC voltage)
Drop the device during setting, moving, using
Use the not recommended consumables or accessories
Malfunction after repairing the product at the not recommended repair shop
Normal wear of the consumables such as ball bearing, gear, chuck, spindle case assy, rotator etc.
Faulty by Act of God

Foreign Language Manual Support

This manual is basically offered in Korean and English. But, if other countries need manual with their own language, we can offer the manual with relevant language.
1) The translated draft manual will be supplied by manufacturer on demand.
2) We will send the translated draft manual with English version to the import company to check it.
3) After we get the feedback from the import company, we will offer the completed manual.

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stomdevice

SAESHIN

This product is **the medical device.**

1639

Made in Korea

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