SAESHIN

Traus SIP20

USER MANUAL



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traus SIP20

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INTRODUCTION

This product is **medical device.**
(Model name : SIP20)

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 use〉

- SIP20 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: IPX0
  - Foot Controller: IPX8
- 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: : Non-continuous operation
- Applied parts: 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

USER GUIDELINES

CAUTION

- Please pay attention when using to consider the patient's safety most importantly.
- Check the condition of the product before use.
- Stop using and inspect the product when an abnormal sign occurs such as calescence, vibration or noise before or during operation.
- Please contact manufacturer if problem cannot be solved.
- Prepare extra consumables before use for safety.
- 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 angle handpiece right after use. Otherwise, it could be damaged due to coagulation of blood inside the product.
- The control box and foot controller are a not steam sterilization objects.
- The input power is available at AC 100-120V / 220-240V.
  (Check input voltage before connecting the AC power.)
- Dispose the irrigation tube as a medical waste after use.
- Contact manufacturer if an incorrect display appears on the screen.
- Do not drop or bang the product.
- Do not damage the irrigation tube, as it will not work properly due when the tube is broke or dislodges.
- Do not insert oil into the motor. It will damage bearing or cause calescence.
- The product is designed to be used indoors; do not use outdoors.
- Do not use the product in a humid or dusty environment.
- Use only regulated products and consumables by the manufacturer. Otherwise,there could be a risk of an accident or failure.
- Replace the cords immediately when it is worn-out or damaged to prevent electric shock to the user or patient.
- Manufacturer may change specification and design of this product in order to improve the quality.
- User has responsibility to operate and maintain this product.
- The company did not sterilize the product. Please make sure to sterilize before operation. (User sterilization)
- US Federal law restricts this device to sales by or on the order of a dentist.
- Do not sterilize with different methods other than moist heat sterilization. It may cause damage to the product

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 angle handpiece. In case of malfunction, dropping or falling in water, do not use it and contact the manufacturer.
- 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.
- Portable and mobile Radio Frequency communications equipment can affect the product. Do not use Radio Frequency equipment outskirts for the product.
- The system may present a possibility of malfunction when used in the presence of an electromagnetic interference wave. Do not install the system in the vicinity of the device which emits magnetic waves. Turn off the power switch of the Control box when an ultrasonic oscillation device or an electrode knife is located in the vicinity is used.
- For safety, install the control box in a place where the power cord can be easily removed. (It is possible to disconnect the control box from the power source by removing the power cord.)

PROHIBITIED

- Do not use a damaged or broken power cord, plug, or outlet. It may cause fire and/or electric shock.
- When unplugging the power cord, do not touch cord with wet hand.
- Do not damage the power cord (do not bend too hard, or put heavy objects on it). That may cause electric shock and/or fire.
- Unauthorized modification and dismantling is prohibited.
- Do not use a solvent such as thinner or benzene for cleaning.
  ※ Please use an absorbent or alcohol to wipe the controller box. Do not wipe with wet cloth.
  ※ Be careful not to drop liquid on control box.
- Do not place the product near any heated equipment and do not put candles or cigarettes on it.
- Use only a grounded outlet. Please contact electrical technician or manufacturer regarding the ground connection.
- Be sure to use designated bur by ISO 1797.
- Follow the user 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 dentist. If not, patient might get hurt from improper use.
- If patient is taking antibiotics, patient needs to consult with doctor before operation.
- Keep product away from spray containing flammable material.
- Manufacturer does not have any responsibility for defects or loss to property in the following cases:
  1. User did not follow the user manual when using the product.
  2. Used the product in a place of unregulated wire condition.
  3. Unauthorized person repaired the product.
  4. Did not follow the user manual for this product.
- Do not use on the following patients.
  1. Those with medical complications or allergies.
  2. Those who have pre-existing conditions. (E.g. Cardiac, Pulmonary, Renal disturbance or High blood pressure)
  3. Those who are pregnant or lactating.
  4. Patients with cardiac pacemakers and infants.

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 :

Gear Ratio	1:1	1:2	1:5	16:1	20:1	32:1
RPM	1,000 ~ 40,000 rpm	2,000 ~ 80,000 rpm	5,000 ~ 200,000 rpm	30 ~ 2,500 rpm	15 ~ 2,000 rpm	10 ~ 1,250 rpm

- 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 :

Gear Ratio	1:1	1:2	1:5	16:1	20:1	32:1
Torque	-.-	-.-	-.-	5 ~ 50 N·cm	5 ~ 80 N·cm	5 ~ 80 N·cm

- Gear Ratio: 1:1, 1:2, 1:5, 16:1, 20:1, 32:1

〈Program Memory Function〉

- 9 programmable memories for setting Gear Ratio, RPM, Torque, Rotating Direction, Irrigation Pump, Optic.

〈Automatic Overload Protection Function〉

- If the actual loading gets higher than the preset torque value, the motor stops automatically, and the error code is displayed on the screen.
- To release the overload function, release the foot controller.

〈Realtime RPM View System〉

- Actual RPM is displayed on the screen.

〈Motor Auto-Calibration Function〉

- Motor auto-calibration function is that controller check the angle handpiece status to reconcile speed and torque that user wants with angle handpiece for accurate and safe operation.

- The function is set up when the product is released by manufacturer. And use the function when user repair or change the product.

〈Beep Sound Function〉

- When using reverse direction, ring the beep sound for protecting user confusion.

〈Ergonomic Foot Controller〉

- The ergonomically designed Foot Controller with main functions can be used during any surgery for user's convenience.

〈Setting with SETUP Mode〉

- Auto Calibration, Sound Volume Control and Program Reset are available.

〈Optic Function - (Optional)〉

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

- LED: 25,000 lx
- Optic Function is only operated by the optic angle handpieces(CRB26LX, CRB27LX, CRB46LN) and optic micro motor (MBP10SL).

PRODUCT COMPONENTS

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

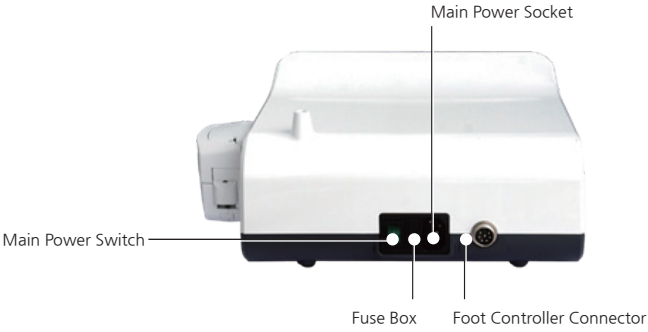
①		⑧	
②		⑨	
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⑥		⑬	
⑦		⑭	

No.	Component	No.	Component
1	Control Box	8	Internal Spray Nozzle (Optional)
2	Angle Handpiece	9	Motor Cap (For Sterilization of motor)
3	BLDC Motor (Optional)	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.
- Irrigation tube and Y-Tube are disposable, Do not use them again.

PART NAME OF CONTROL BOX







BUTTONS ON THE OPERATION PANEL



Gear Ratio Button
: This is used for selecting the gear ratio of the handpiece used during the procedure.

1:1 -> 1:2 -> 1:5 -> 16:1 -> 20:1 -> 32:1



Rotation Direction Select Button
: This is used for selecting the direction of rotation (Forward, Reverse). During reverse operation, it beeps continuously.



Irrigation Button
: This is used for selecting the irrigation volume.
It can control stage 0 to 5 (Max. 90 mℓ/min ± 20%).

Stage	Volume
0 1 2 3 4 5	Stage 0: STOP Stage 1: 35 ml/min ± 25% Stage 2: 50 ml/min ± 25% Stage 3: 65 ml/min ± 20% Stage 4: 80 ml/min ± 20% Stage 5: 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 head part. 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 and Optic motor.



Menu Button
: This is used for selecting the desired menu.
The right menu is selected sequentially per each press the button.

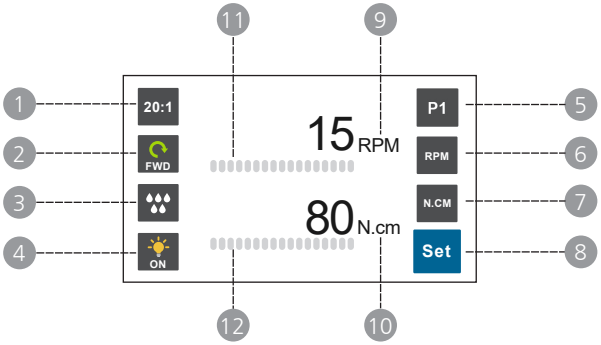


Control Button
: This is used for selecting the program number, SETUP menu and adjusting the rpm, torque.
※ The setting range of rpm and torque are different from gear ratio.



OK Button
: This is used for completing the setting.

LCD WINDOW



1. Gear Ratio Display
: It shows current set of gear ratio.

2. Rotation Direction Display
: It shows the selected direction.

3. Irrigation Volume Display
: It shows selected irrigation stage. The stage is 0 to 5 (Stage 0 = No volume / stage 5 = Maximum volume). Number of Water drop shows the volume stage.

4. Optic Display
: The optic function is working when bulb symbol display on the screen.
* Optic function is only operated with optic angle handpiece.
* When press the speed control pedal on the foot controller after operating the optic function, LED is turned on.

5. Program Number Display
: It shows current set of program number. It display Program 1 to 9 and can save 9 programs. After restart the device, it displays program number 1.

6. RPM Menu Display
: When the corresponding menu is selected, the RPM can be adjusted using the ▲ and ▼ buttons.

7. Torque Menu Display
: When the corresponding menu is selected, the torque can be adjusted using the ▲ and ▼ buttons.

8. SETUP Menu Display
: When the corresponding menu is selected, it can be move to setup menu using the OK button.

9. RPM 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 pressing foot controller to the end.

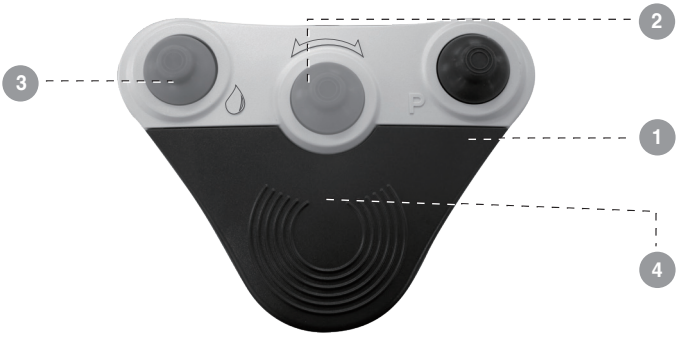
10. Torque Display
: It shows the setup torque value. If an actual load is higher than set torque value, the set torque value is on the screen and the motor is stopped automatically with 'E3' on the screen and beep sound.

11. Foot Controller Gauge Display
: The gauge indicates the degree to which the foot controller is pressed during operation.

12. Torque Gauge Display
: The gauge indicates the actual load value during operation.

- Be careful that the LCD on the control box could be damaged by impacting or dropping.

BUTTONS ON THE FOOT CONTROLLER



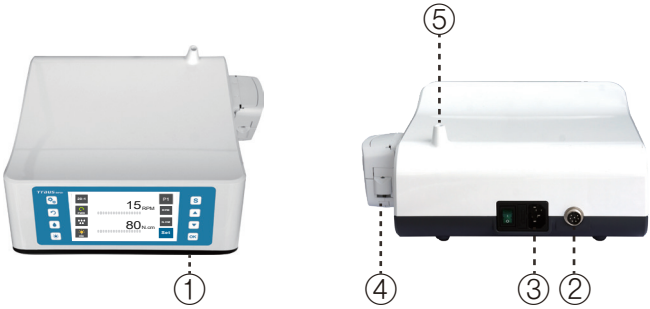
1. Program Button
: Use the button to select the program. 1 stage increases per each press. 1 stage decreases when press this button above 1 second. (Program decrease function is not operated continuously. If you want to decrease program over the 2 stage, press the button after releasing the button.)

2. Operation Direction Button
: Use the button for selecting the operation direction. Press the button, change the rotary direction.

3. Irrigation Pump Button
: Use the button for selecting the irrigation volume. 1 stage increases per each press.
Press the button above 1 second, set the 0 stage (stop condition).

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

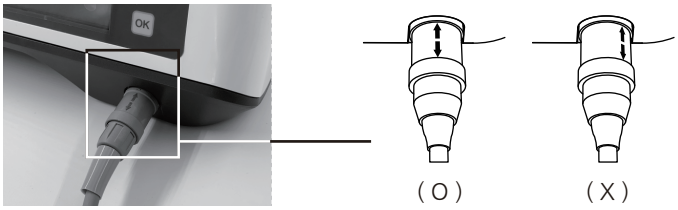
CONNECTION OF EACH PART



- When connecting the motor, foot controller and power cord, please make sure the power is off. (Otherwise, it might cause a malfunction.)

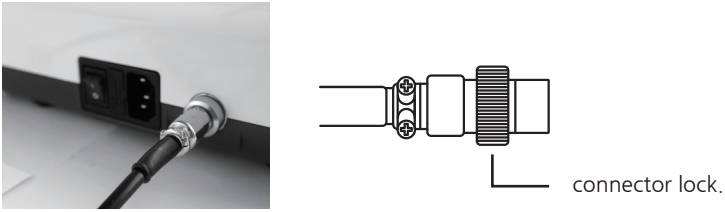
1. Motor Connection

: Insert the motor connector. Check if the holes and pins of motor connector are lined-up. (Place the arrow mark on top. See the picture below.)



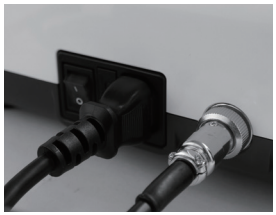
2. Foot Controller Connection

: Insert the foot controller connector. Check if the holes and pins of foot controller connector are lined-up. Then screw the connector lock.



3. Power Cord Connection

: Insert the power cord into the main power inlet of the control box.



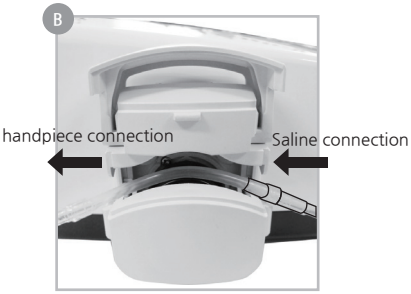
4. Irrigation Tube Connection

A



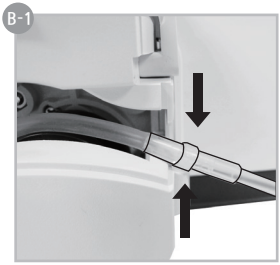
Open the pump roller cover.

B



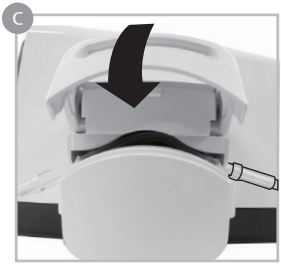
Insert the irrigation tube correctly.

B-1



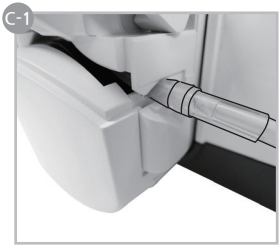
Locate the Irrigation tube correctly when insert the irrigation tube. Otherwise, Irrigation cannot be smoothly.

C



Close the pump roller cover.
(You must close the cover and use it as your fingers may get stuck.)

C-1



Make sure the irrigation tube is located correctly when close the pump roller cover.

D



Make sure the pump roller cover is correctly close.

- When it is not in use for long term, open the pump cover.
  Irrigation tube might change its shape and cause a malfunction.

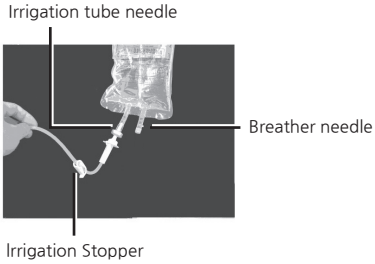
5. Hanger Setting

: Put the hanger into the hanger hole.



6. Irrigation Tube Insertion

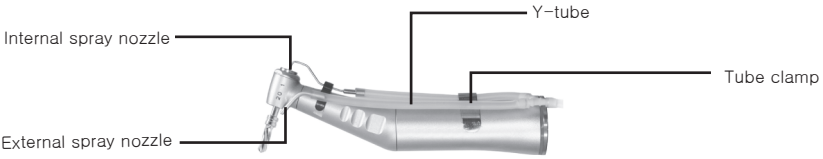
: Insert the irrigation tube needle into the bottle and place with the bottle downward. Lock the irrigation stopper and put it between the irrigation tube needle and bottle.



- If the pump is in operation mode but water does not come out of the handpiece, the tube may be broken or damaged.

7. Irrigation Nozzle Connection

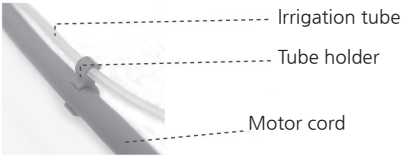
: The internal and external irrigation are available by the Y-tube. Connect the accessories as in the picture according to the bur using and the surgery type.



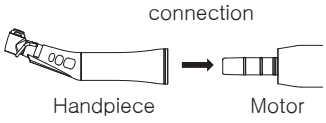
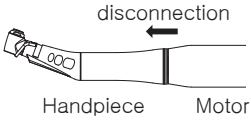
- If the user did not remove the internal spray nozzle and pressed the button or open the lever when replacing the nozzle may get damaged.

8. Tube holder connection

: Put the motor cord and irrigation tube together with the tube holders. Insert the tube holder to the motor cord and then insert the irrigation tube in order to create a better working condition.



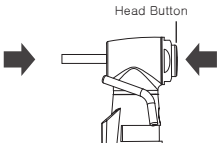
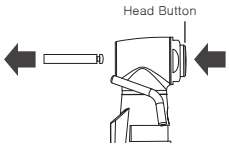
9. Angle Handpiece Connection

Handpiece & Motor connection	Handpiece & Motor disconnection
	

1) Connect : Insert the groove (non-optic) or key (optic) of the angle handpiece into the pin (non-optic) or groove (optic) position of the motor handpiece

2) Disconnect : Hold the motor handpiece and pull the angle handpiece.

10. Dental bur Connection

Connecting the bur	Disconnecting the bur
	

1) Connecting the bur
   ① Insert the bur to the angle handpiece.
   ② Insert certainly the bur while pushing the head button on angle handpiece.
   ③ Release the button
   ④Pull out the bur to check it

2) Disconnecting the bur
   ①Pull out the bur while pushing the head button on angle handpiece.

OPERATION PROCESS

1. Press the Gear Ratio Button ( ) to select the gear ratio to use.

2. Press the Rotation Direction Button ( ) on the control box or Rotation Direction Button ( ) on the foot controller to select the rotation direction. Rotation direction is forward and reverse. During the reverse operation, it beeps continuously. (beeps let the user know the operation direction.)

3. Press the Irrigation Button ( ) on the control box or Irrigation Button ( ) on the foot controller to select the irrigation volume. Irrigation volume per each stage refers to the below.



Irrigation Stop | 35 mℓ/min ± 25% | 50 mℓ/min ± 25% | 65 mℓ/min ± 20% | 80 mℓ/min ± 20% | 90 mℓ/min ± 20%

4. Press the Menu Button (S) to go to the RPM Menu. Set the desired RPM value using ▲ and ▼ button.

Keep pressing speed button to change rapidly. The setting range of rpm is different from gear ratio.

Gear Ratio	1:1	1:2	1:5	16:1	20:1	32:1
RPM	1,000 ~ 40,000 rpm	2,000 ~ 80,000 rpm	5,000 ~ 200,000 rpm	30 ~ 2,500 rpm	15 ~ 2,000 rpm	10 ~ 1,250 rpm

5. Press the Menu Button (S) to go to the Torque Menu. Set the desired torque value using ▲ and ▼ button.

The setting range of torque is different from gear ratio.

Gear Ratio	1:1	1:2	1:5	16:1	20:1	32:1
Torque	-.-	-.-	-.-	5~50 N·cm	5~80 N·cm	5~80 N·cm

6. Press the Optic Button ( ) to use optic function.

7. Use it by pressing the speed control pedal on the foot controller.

8. After the operation is finished, remove the foot from the speed control pedal, stop the product, and turn off the product

- Before operating product, please check the connection of irrigation tube on the angle handpiece. If irrigation tube isn't connected and delivered to bur, there is risk of tissue necrosis or bone damage. Because of the frictional heat between bur and operation site. (Installation method of Irrigation tube: Refer to the connection of each part.)

■ Program Setting

1. Press the Menu Button (S) to go to program number menu.

2. Press the Control Button (▲ , ▼) to select the desired program number.

3. After setting the desired value by referring to the operation method, keep pressing OK Button (OK) for 3 seconds.

4. The 'SAVING' is displayed on LCD, program is memorized with beep sound.

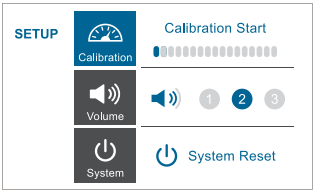
Other Function (SETUP)

Press the Menu Button (S) to go to SETUP Menu and press the OK Button. (OK)

Press the Control Button (▲ , ▼) to the desired item.

Press the OK Button (OK) in SETUP to save and return to main.

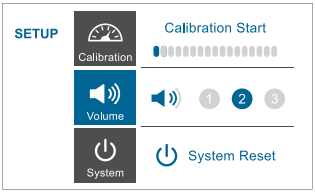
1. AUTO CALIBRATION



After connecting the angle to the motor, hold the motor by hand tightly. Step the foot controller fully in order to start the calibration.
Calibration will be completed with beep sound and display “Calibration Completed”.

- The calibration function sets up for all products from the first delivery or purchasing by the manufacturer. It is recommended to calibrate the motor before using when the motor is replaced or repaired.

2. Sound Volume Control



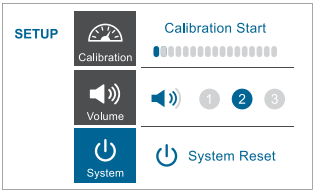
Number of icon bar indicates loudness level of sound.

4 stages, set the sound volume by pressing ▲ or ▼ button.

Press the OK Button (OK) to complete the setting after setting the level of volume.

- Beep sound shuts off in mute mode.

3. Program Reset



By using ▲ , ▼ button, determine the initialization.

Choose “NO” with OK button, the initialization will cancel.

Choose “YES” with OK button, the initialization will start.

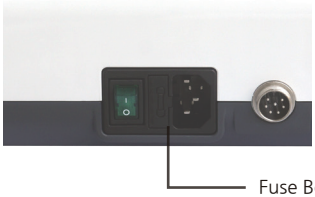
Screen will off for 5-10 sec. And show reset screen with beep sound and message “RESET Completed”.
Then save and return to main.

■ Error and Remedy

: In case of stopping handpiece by not working & using error, each error code may be shown below.

Error code	Cause & Remedy
Warning E1 ⚠ Foot Check!	Cause : The foot controller connection is not proper or the foot controller is defective. Remedy : Make sure that the foot controller is properly connected. Contact the manufacturer if the remedies do not activated.
Warning E2 ⚠ Motor Check!	Cause : The motor connection is not proper or the motor is defective. Remedy : Make sure that motor properly connected. Contact the manufacturer if the remedies do not activated.
Warning E3 ⚠ Torque Limit!	Cause : Torque is overloaded than the setting values during the surgery. Remedy : Press the speed control pedal to release the error. Contact the manufacturer if the remedies do not activated.

■ Fuse replacement



- Check the fuse if the control box doesn't work.
- If necessary contact the manufacturer.

MAINTENANCE OF THE PRODUCT

1. Cleaning

■ Angle Handpeice

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.
⑧ Please visually inspect the angle handpiece in a bright place after cleaning. If the angle handpiece is still soiled after cleaning, the cleaning process must be repeated .

■ Control Box, Foot Controller , 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%).
- If the device is determined not to be visually clean at the end of the cleaning step, the user should either repeat the relevant previous cleaning steps or safely dispose of the device, so that a visibly soiled device is not used again.

2. Sterilization

■ Sterilization Product List

① Angle handpiece
② Motor (Assembling with motor cap)

■ Sterilization Method

① Dry the applicable products completely.
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

* Maximum sterilization number is 250 times.
* Moist steam sterilization only. Otherwise the products might be damaged.
* 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.

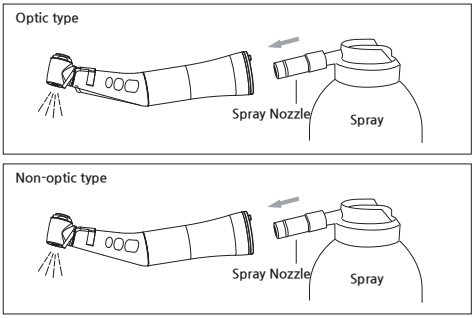
3. Lubrication

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.)

ATTENTION

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

① Check the connection of all cords and correct operation when powering-on.
② Check if the ground connection is safe.
③ Make sure to check any contact part to patient.
④ Check the voltage.
⑤ Check the sterile condition of autoclavable parts. If the packaging of the sterilized product is damaged, discard the product.
- Irrigation Tube
- Y-Tube
- A-sleeve

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

① Constantly check the status of the product and patient during surgery.
② When product or patient has any problem, stop the operation for the patient's safety and take the proper action.
③ Do not let patient approach or touch the product.

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

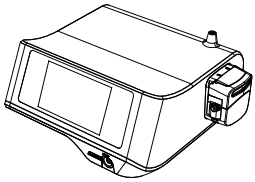
① Do not put any physical pressure on the all cords.

4. When the products are not using for a long term, please be advised to the followings.

① Turn off the power and unplug the cord. Check the cord regularly and replace it when it is damaged.
② Clean and sterilize.
③ Keep the products in the recommended condition.

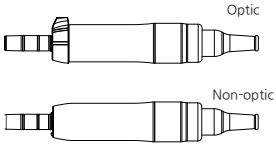
PRODUCT SPECIFICATION

1) Control Box



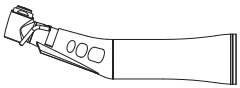
Model Name	BIP20
Input	AC 220-240V
Fuse	2A
Frequency	50/60 Hz
Output	48VA
Irrigation Volume	Max. 90 ㎖ / min ± 20%

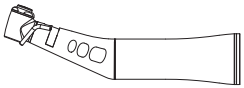
2) Motor



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

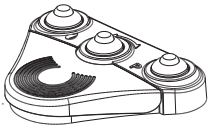
3) Angle Handpiece


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)	IPX8

ELECTROMAGNETIC COMPATIBILITY INFORMATION

In IEC/EN 60601-1-2 4th edition. 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.

<table>
<tr><th colspan="3">Electromagnetic Emissions</th></tr>
<tr><td colspan="3">The SIP20 is intended for use in the electromagnetic environment specified below. The customer or the user of the SIP20 should assure that is used in such an environment.</td></tr>
<tr><td>Emission test</td><td>Compliance</td><td>Electromagnetic environment - guide</td></tr>
<tr><td>RF emission - CISPR 11
EN 55011</td><td>Group 1</td><td>SIP20 uses RF energy for internal operation.
Therefore, its radiofrequency emissions are very low and are not likely to cause any interference in nearby equipment.</td></tr>
<tr><td>RF emission - CISPR 11
EN 55011</td><td>Class A</td><td rowspan="3">SIP20 covers devices for usage in all establishments other than domestic and that are not directly connected to a low voltage power supply network, which supplies domestic environment.

This is a class A product. In a domestic environment this product may cause radio interference in which case the user may be required to take adequate measures.</td></tr>
<tr><td>Harmonic emission -
IEC 61000-3-2
EN 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations
Flicker emission -
IEC 61000-3-3
EN 61000-3-3</td><td>Compliance</td></tr>
</table>

Electromagnetic Immunity			
The SIP20 is intended for use in the electromagnetic environment specified below. The customer or the user of the SIP20 should assure that is used in such an environment.			
Emission test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2 EN 61000-4-2	±8kV contact ±15kV air	±8kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast 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	0 % UT for 0.5 cycle at 8 Φ angles 0% UT for 1 cycle 70 % UT for 25/30 cycles 0 % UT for 250/300 cycle	0 % UT for 0.5 cycle at 8 Φ angles 0% UT for 1 cycle 70 % UT for 25/30 cycles 0 % UT for 250/300 cycle	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 SIP20 got power from an uninterruptible power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8 EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Electromagnetic Immunity

The SIP20 is intended for use in the electromagnetic environment specified below. The customer or the user of the SIP20 should assure that is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 EN 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms In ISM bands from 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz 6 Vrms In ISM bands from 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the SIP20 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	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.7GHz 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.

Recommended separation distances between portable and mobile RF communications equipment and the SIP20

The SIP20 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SIP20 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SIP20 as recommended below, according to the maximum output power of the communications equipment

Rated maximum output Power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ~ 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For 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.

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.

Cables and accessories	Maximum length	Shield	Complies with	
			RF emissions, CISPR11	Class A / Group 1
			Harmonic emissions	IEC 61000-3-2 EN 61000-3-2
			Voltage fluctuations / flicker emissions	IEC 61000-3-3 EN 61000-3-3
			Electrostatic discharge (ESD)	IEC 61000-4-2 EN 61000-4-2
Piezo handpiece cord	1.7 M	Unshielded	Electrical fast transient / burst	IEC 61000-4-4 EN 61000-4-4
Foot controller cord	1.7 M	Unshielded	Surge	IEC 61000-4-5 EN 61000-4-5
AC power cord	1.7 M	Unshielded	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

Description of BASIC SAFETY and ESSENTIAL PERFORMANCE

The SIP20 is intended for use in the electromagnetic environment specified above.
The following essential performance of SIP20 should be running in such an environment.

1) Irrigation volume should be over the 35 ㎖/min ±20% during handpiece is operated.

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 offered in Korean and English. If other languages are needed,
please contact Saeshin for the manual.

1) The translated manual will be supplied by manufacturer on demand.
2) Saeshin will send the translated manual with an English manual to the import company to review the translated manual.
3) After getting feedback from the import company, Saeshin will offer a final version of the manual.

SYMBOL


Gear Ratio Button


Rotation Direction Button


Irrigation Button


Optic Button


Manufacturer



EC Representative



Serial Number



Autoclave


Fuse


Degree of protection against electric shock - Type B


This product should not be mixed with other commercial waste for disposal


Caution hand injury


Rx only



Menu Button


Control Button



OK Button


Consult Instruction For Use


General Caution Sign


General Warning Sign


General Prohibition Sign


Alternating Current

Power On
(Main power switch)

Power Off
(Main power switch)



Non sterile



CE Marking



Medical Device



Catalogue number

SAESHIN

MD This product is **the medical device.**

CE 1639

Made in Korea

SAESHIN

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