

Traus sus10

INSTRUCTION MANUAL



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Traus sus10



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SYMBOL



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 a \mathbf{U} \mathbf{V} and

<User>

· Qualified Professional

<Intended purpose>

• TRAUS SUS10, Piezo Surgery and Implant Engine Unit, is intended for use in dental surgery including: osteotomy, osteoplastic, periodontal surgery and implantation (for ultrasonic surgery), and implantology, maxilla-facial surgery and endodontics for treatment of dental hard tissue and mechanical rotating root canal preparation (for dental implant surgery).

<Classification of equipment>

· Type of protection against electric shock: Class I equipment



* To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth

- 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 parts: Bur, Ultrasonic tip

<Use time>

- Implant mode
- Piezo mode
- Loading time: 2 minutes
- Loading time: 3 minutes
 Resting time: 10 minutes
- Resting time: 15 minutes





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 100-120V / 220-240V

(Check input voltage before connecting the AC power.)

- · 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.
- $\boldsymbol{\cdot}$ 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.
- · Specification and design of product can be changed to improve quality of product.
- · 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.



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.
- TRAUS SUS10 needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information. (Refer to Electromagnetic Compatibility)
- Portable and mobile Radio Frequency communications equipment can affect TRAUS SUS10. Do not use Radio Frequency equipment outskirts for the product.
- For safety, install the control box in a place where the AC power cord can be easily removed. (It is possible to disconnect the control box from the power source by removing the AC power cord.)

- · 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.
- 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.
- · 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

- Provide the optimized performance by BLDC motor (0~40,000rpm) and Angle handpiece of several kinds.
- Provide the piezo function by piezo handpiece (27 ± 3KHz) and ultrasonic tips.

Implant mode>

- 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 handpieces 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

<Piezo mode>

- P-Power : Level 1, 2, 3
- Boost : Level 0, 1, 2, 3

<Program memory function> (Implant / Piezo)

- Maximum 9 programmable memories for setting Speed, Torque, Rotating direction, Irrigation pump, Intensity and Boost.

Automatic overload protection function> (Implant)

- The motor is automatically stopped and 'Error' sign display on screen when the load is higher than Torque value.

Realtime RPM, TORQUE view system> (Implant)

- Actual RPM and Torque value are displayed on the screen. It makes user can do more delicate operation.

Power and vibration function> (Piezo)

- User can set the usage environment for each operation by setting the power and vibration.

(Implant)

- 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.
- 1. Select 'Motor' mode.
- 2. Select the program number '0'
- Program number '0' is the only for auto calibration function, other buttons are not operate except Motor button, Piezo button, Program button, and Program selection button.
- 3. '-CAL-' is on the LCD screen.
- 4. When press the foot controller to the end, Auto-calibration is started.
- 5. Press the foot controller continuously 5 ~ 10 seconds. Then '40,000' is displayed with beep sound, and Auto-calibration is completed. Please press the foot controller until completion
- 6. After Auto-calibration is completed, Torque value is shown as '--' on the screen.
- 7. After Auto-calibration is completed, user can select the other program number to use. (except '0')



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

Kergonomic Foot Controller>

- The foot controller is designed ergonomically to control all the functions. And the foot controller provides high convenience.

<Optic function - (Option)>

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

- LED: 25,000 lx

- Optic Function is only operated by the optic angle handpieces(TRAUS CRB26LX, TRAUS CRB27LX, TRAUS CRB46LN) and optic micro motor (TRAUS MBP10SL).



PRODUCT COMPONENTS

- Check if all components are included.



No.	Component name	No.	Component name
1	Control box	11	Tube holder
2	Angle handpiece	12	Tube clamp
3	Piezo handpiece	13	Torque wrench
4	BLDC motor	14	Tip holder
5	Foot controller	15	Sterilization case
6	Motor stand	16	Power cord
7	Hanger	17	Instruction manual
8	Internal spray nozzle (Option)	18	Spray nozzle
9	A-Sleeve	19	Ultrasonic tip (Option)
10	Motor cap for autoclave		



* Saline solution is not included in a set.





BUTTONS ON THE OPERATION PANEL

Implant mode : The below function runs in implant mode only.



Implant mode select button : Use for switching to implant mode.



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

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





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.



Torgue button : Use for setting the torgue according to the various use such as drilling or tapping. (+) button for 1 stage up and (-) button for 1 stage down. * The setting range of torgue is different from the gear ratio.

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(TRAUS CRB26LX, TRAUS CRB27LX, TRAUS CRB46LN) and Optic motor(TRAUS MBP10SL).

Piezo mode : The below function runs in Piezo mode only.



Common Function : The below function is used jointly in Implant mode and Piezo mode.



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

0 e o o o Memorized program button : Use for selecting the set program number directly. This button is useful to select the frequently used program number.



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



Irrigation pump button : Use for setting the irrigation volume. It is possible to irrigate Max. 90 ml/min ±20% at level 5. Implant mode can select irrigation volume from level 0 to 5. Piezo mode can select irrigation volume from level 1 to 5.



Irrigation stop











35ml / min +25%

50ml / min +25%

65ml / min +20%

5 80ml / min +20%

90ml / min +20%

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Irrigation volume display

: It shows selected irrigation level. In implant mode, the irrigation level is from 0 to 5 (Level 0 = No volume / Level 5 = Maximum volume). In piezo mode, irrigation level is from 1 to 5. Number of Water drop shows the volume level.



Program number display

: It shows selected program number. It shows 0 to 9 in implant mode. User can set a program number from 1 to 9, but the program number 0 is only for calibration which does not have save function. Program number is available to set from 1 to 9 in Piezo mode. After restarted the machine, it displays program number 1 of the latest operation mode (Implant or Piezo).

Gear ratio display

: It shows the selected gear ratio.



Operation direction display

: It shows the selected direction.

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.

Optic display (Optic version)

- : The optic function is working when bulb symbol display on the screen.
- * Optic function is only operated with optic angle handpiece (TRAUS CRB26LX, TRAUS CRB27LX, TRAUS CRB46LN + TRAUS MBP10SL)
- * When press the speed control pedal on the foot controller after operating the optic function, LED is turned on.



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.

Motor display

: Display the implant mode.

Output intensity display

: Show the output intensity of piezo handpiece.

Scan display

: It scans and memorizes the most suitable output for each 'Ultrasonic tip' for operation.



: Display the piezo mode.



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Error display

: Error code will be on the screen in order to show condition of controller and cause of problem when motor is stopped because breakdown, overload, or misuse causes error.

Boost display

: It shows level 0 to 3 of 'Boost'

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Clean display

: It is a function to clean the flow part before and after operation. While press the Clean/Ready button, the 'CLEAN' sign is on the screen.



BUTTONS ON THE FOOT CONTROLLER







Program button

: Use the button to select the program. 1 stage increases 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.)



Operation direction button

: In implant mode, press the button shortly, change the rotary direction. Press the button above 3 seconds, change the mode (implant/piezo).



Irrigation pump button

: Use the button to select irrigation volume. 1 stage increases per each press.



Speed control pedal

: The motor speed is controlled by pressing and releasing the foot controller.



IMPLANT PART



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

1. Motor cord 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.



4. Irrigation tube connection to pump roller





- * See the Fig.1 to install the irrigation tube correctly.
- * If you do not use it for long period, please open pump roller cover. Otherwise, the irrigation tube might be damaged.

For implant mode (Irrigation pump on the left)







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



Insert the irrigation tube correctly.



Close the pump roller cover.



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



Make sure the pump roller cover is correctly close.

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



Irrigation Stopper Breather needle



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.

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. Angle Handpiece Connection



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.

9. Dental bur Connection



1) Connecting the bur

Insert the bur to the angle handpiece.

O 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.



CONNECTION OF EACH PART







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

1. Piezo handpiece connection

: Please insert the piezo handpiece 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.



4. Irrigation tube connection to pump roller





 * See the Fig.4 to install the irrigation tube correctly.
 * If you do not use it for long period, please open pump roller cover. Otherwise, the irrigation tube might be damaged.

For piezo mode (Irrigation pump on the right)





Open the pump roller cover.

Insert the irrigation tube correctly.



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



Close the pump roller cover.



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



Make sure the pump roller cover is correctly close.

5. Hanger setting

: Put the hanger into the hanger hole.



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.

Irrigation tube needle





Breather needle



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

7. Irrigation Nozzle Connection

: Insert the irrigation tube to the irrigation pump pipe placed in the end of piezo handpiece like the image below.



8. Ultrasonic Tip Connection

(1) Screw the ultrasonic tip carefully to clockwise.



(2) Use the torque wrench to tighten the ultrasonic tip.





IMPLANT PART

(1) Turn the main switch on.

It is always selected last used program number 1 of operation mode like below picture. If the mode is piezo mode, press the 'Implant mode select button' to change implant mode.

7	Motor	Program		
GEAR	Å : ;		Г RPM -	- Ncm
TIP	H/F	F /C	TOF	QUE

(2) Choose the program.

Press the program button of the control box or foot controller to change program stage. If press the program button '+' or P-button(Foot controller) when program number 9 on LCD screen, program is returned to program number 0.

(3) Check the LCD screen to make sure the setting is correct.

(4) Start operation.

The motor is worked by pressing the speed control pedal on the center of foot controller. If user presses pedal lightly, the speed will be low, and high speed needs more pressure. Pump will operate as same way in irrigation mode.

* Overload protection system

: If the load exceeds the preset torque and stays more than 2 sec, the overload protection system works to stop generating any more torque and stops the operation.

(5) Change the operating direction.

Press the *button* on the control box or *button* on the foot controller to reverse direction. In reverse direction set, the control box will sound the beeping sound, it continues during in reverse direction operation. Press the button to change the direction again.

(6) Stop the operation.

Operation will be stopped when user stops to press foot controller.

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)

	Ð	0,			¢		X	М
PRG	1	20 : 1	100 RPM	10 N ⋅ cm	FWD	PMP:4	ON	COMPLITION
PRG	2	32 : 1	200 RPM	15 N · cm	FWD	PMP:2	OFF	COMPLITION

Error and Remedy

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

Error display	Cause and Remedy
H/P CHECK	 Defective motor or wrong motor connection * Remedy: Check the motor connection. If the remedy does not work, contact the manufacturer.
F/C CHECK	 Defective foot controller or wrong foot controller connection * Remedy: Check the foot controller connection. Press the speed control pedal. If the remedy does not work, contact the manufacturer.
	 Motor is automatically stopped when running torque exceed preset torque, and warning sign on the screen. * Remedy: Press the speed control pedal. If the remedy does not work, contact the manufacturer.

Fuse Replacement



Check the fuse if the control box does not work.

Contact the manufacturer when replace the fuse.

OPERATION PROCESS

PIEZO PART

- Before operation

(1) Turn the main switch on.

It is always selected last used program number 1 of operation mode like below picture. If the mode is implant mode, press the 'Piezo mode select button' to change piezo mode.



- (2) Insert the ultrasonic tip into the piezo handpiece.
- (3) Range the ultrasonic tip and carefully turn clockwise to tighten.



(4) Use a torque wrench to tighten ultrasonic tip. See the picture below.



(5) Put the piezo handpiece in drainage easy place. Start the irrigation by pressing the () button to clean the flow part.



* Replace the ultrasonic tip when the ultrasonic tip is worn out or bent. Otherwise, it can cause injury and inefficiency of operation.

- * If user uses small diameter of ultrasonic tip or an excessive power, ultrasonic tip might be broken.
- * Check the irrigation at piezo handpiece assembled ultrasonic tip by pressing Clean/Ready button before operation.

- Operation

- (1) Check the mode is piezo mode.
- (2) Select output mode which meet the operating condition by pressing P-power button and Booster button.
- (3) Check the irrigation volume. If the irrigation volume is not proper, control it by using irrigation pump button of the control box or foot controller.
- (4) Select the proper setting about Irrigation volume, P-Power value and Boost value. Select the program number and press the memory button (above 2 seconds) to save the setting. (9 programs max.)
- (5) Please refer the piezo tip reference guide for the manufacturer's setting recommendations.

- After operation

- Clean the product. Refer the 'MAINTENANCE OF THE PRODUCT' in instruction manual.
- (2) Turn the torque wrench counterclockwise to disassemble the ultrasonic tip.



(3) Sterilize the product.

Refer the 'MAINTENANCE OF THE PRODUCT' in instruction manual.

(4) Keep the product in the hygienic environment.

Error and Remedy

When piezo handpiece stops due to disconnection, misuse or etc., the error code explanation is below:

Error display	Cause and Remedy
TIP CHECK	 The ultrasonic tip got loose or damaged and ultrasonic tip is not assembled to the piezo handpiece. *Remedy: assemble the ultrasonic tip. Use a torque wrench to tighten ultrasonic tip. Change the ultrasonic tip when it is breakdown.
H/P CHECK	 Piezo handpiece connection is defective. *Remedy: Make sure the piezo handpiece is properly connected. Press the speed control pedal to release the error. If the remedy does not work, contact the manufacturer.
F/C CHECK	 Foot controller is defective. *Remedy: Make sure the foot controller is properly connected. Press the speed control pedal to release the error. If the remedy does not work, contact the manufacturer.

Fuse Replacement



Check the fuse if the control box does not work.

Contact the manufacturer when replace the fuse.

MAINTENANCE OF THE PRODUCT

1) Cleaning

Angle Handpiece

- 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 the 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.

Ultrasonic Tip

- ① Place the piezo handpiece on the good drainage location to clean the irrigation line with used ultrasonic tip.
- ② When you press the Clean/Ready button on the control box, the pump roller is working and 'CLEAN' sign is on the LCD screen.
- ③ Please keep press the Clean/Ready button to clean more than 35 seconds.
- ④ The ultrasonic tip by using a torque wrench separates from the piezo handpiece.
- ⑤ Remove contaminants using a nylon brush after soaking for 3 minutes in Enzymatic Detergent.
- 6 Rinse using the tap water for 3 minutes to remove Enzymatic Detergent of ultrasonic tip.
- \odot Perform the ultrasonic washing for 10 minutes using the Enzymatic Detergent at 35 ~ 45 $^\circ$ C.
- \circledast Perform the Ultrasonic rinsing repeatedly subjected 3 times for 3 minutes using the purified water at 35 ~ 45 \degree . (However, Purified water is replaced every time.)
- (9) Wipe using dust-absorbent after the ultrasonic tip soaked in alcohol (70%) for 30 seconds.



- * 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.

Motor and Piezo Handpiece

Remove any debris or blood stains by wiping over all surfaces with alcohol towelettes (70% Isopropyl). Repeat wipe over three times.

- * Pay attention to not enter the water into the motor and Piezo Handpiece.
- After use, Clean the handpiece by pressing the "CLEAN" button for 10 seconds.
- Detach the irrigation tube from the saline bag to remove the saline solution remaining inside the handpiece.
- Press the "CLEAN" button to flush out all the saline solution inside the irrigation tube.
- * Please refer to the Cleaning Guide for more information.

2) Sterilization

Sterilization part list

- · Angle handpiece
- · Motor (Assembling with motor cap)
- · Piezo Handpiece
- · Ultrasonic Tip
- · Tip Holder
- · Torque Wrench

Sterilization method

- 1 Dry the applicable products completely.
- 2 Put the angle handpiece and motor in a sterile bag and seal tightly.
 - * Make sure to assemble the motor cap for autoclave on the motor.
 - $\ensuremath{\,\times\,}$ Do not disassemble the motor and motor cord when sterilizing.
- ③ Insert the ultrasonic tip into the tip holder.
- ④ Insert the tip holder inserted ultrasonic tip, piezo handpiece and torque wrench into the sterilization box. And close the sterilization box cover.
- ⑤ Put the sterile bag and sterilization box in the sterilizer and sterilization for 4 minutes with 132℃, and let it dry for 30 minutes.
- (6) To maintain the sterilization status, keep the sterilized products in a sterilized pouch (or wrap) approved by the FDA.

Sterilization	Temperature	Time	Dry	132°C
Moist heat sterilization (pre-vacuum)	132℃	4 minutes	30 minutes	555

* Maximum sterilization number of the angle handpiece, motor and piezo handpiece is 250 times.

- * Moist steam sterilization only. Otherwise the products might be damaged.
- * Make sure to use the sterilization bag and seal tightly when sterilize the angle handpiece and motor.
- * Make sure to dry the applicable products before sterilization.
- * Do not put the piezo handpiece into any kind of liquid. It may damage the ultrasonic resonator.
- * Piezo handpiece and lead wire are inseparable.
- * 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.
- * Keep dry a connector and socket of the control box.
- * Before using, dry the product completely.

3) Lubrication

Lubrication part 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).



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. If the packaging of the sterilized product is damaged, discard the product.
 - A-sleeve

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



PRODUCT SPECIFICATION

1. Control box



2. Motor



3. Piezo handpiece



 Model name
 TRAUS PEZ10XX

 Frequency of Piezo operation
 27 ± 3KHz

TRAUS MBP10SL

40,000

Optic

TRAUS XUS10 AC 100-120V / 220-240V

5A/2A

50 / 60 Hz

48 VA

15~59 VA

Max. 90 ml/min ± 20%

TRAUS MBP10SX

40,000

Non-optic

4. Angle handpiece



Optic Type



Non-optic Type

Model Name	TRAUS CRB26LX	TRAUS CRB26XX	TRAUS CRB27LX	TRAUS CRB27XX	TRAUS CRB46LN	TRAUS 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)					

Model name

Frequency

Output of

piezo mode Maximum

Model name

RPM

irrigation volume

Optic / Non-optic

Output

Input Fuse

5. Foot controller



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: 2009 EN 55011: 2009	Group 1	TRAUS SUS10 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: 2010 EN 55011: 2010	Class A	TRAUS SUS10 is suitable to use in all establishments
Harmonic emission IEC 61000-3-2: 2014 EN 61000-3-2: 2014	Class A	including domestic establishments and those directly connected to the public low voltage power supply network
Voltage fluctuations Flicker emission IEC 61000-3-3: 2013 EN 61000-3-3: 2013	Compliance	that supplies buildings used for domestic purposes.

(2) Electromagnetic Immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2: 2008 EN 61000-4-2: 2008	±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 / Buarst IEC 61000-4-4: 2012 EN 61000-4-4: 2012	±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: 2014 EN 61000-4-5: 2014	±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: 2004 EN 61000-4-11: 2004	<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 TRAUS SUS10 got power from an uninterruptible power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8: 2009 EN 61000-4-8: 2010	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: 2013 EN 61000-4-6: 2014	3Vrms 150kHz to 80Mhz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the TRAUS SUS10 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3: 2006 EN 61000-4-3: 2006	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	Complie	s with
Micro motor with motor cord	1.8 M	Unshielded	RF emissions, CISPR11	Class A / Group 1
Piezo handpiece	1.8 M	Unshielded	Harmonic emissions	IEC 61000-3-2: 2014 EN 61000-3-2: 2014
cord	4 014	Unshielded	Voltage fluctuations / flicker emissions	IEC 61000-3-3: 2013 EN 61000-3-3: 2013
cord	1.8141		Electrostatic discharge (ESD)	IEC 61000-4-2: 2008 EN 61000-4-2: 2009
AC power cord	1.8 M	Unshielded	Electrical fast transient / burst	IEC 61000-4-4: 2012 EN 61000-4-4: 2012
			Surge	IEC 61000-4-5: 2014 EN 61000-4-5: 2014
			Voltage dips, short interruptions and voltage variations on power supply input lines	IEC 61000-4-11: 2014 EN 61000-4-11: 2014
			Power frequency (50/60Hz) magnetic field	IEC 61000-4-8: 2009 EN 61000-4-8: 2010
			Conducted RF	IEC 61000-4-6: 2013 EN 61000-4-6: 2014
			Radiated RF	IEC 61000-4-3: 2006 EN 61000-4-3: 2006

Description of BASIC SAFETY and ESSENTIAL PERFORMANCE

The TRAUS SUS10 is intended for use in the electromagnetic environment specified above.

The following essential performance of TRAUS SUS10 should be running in such an environment.

1) Maximum RPM of hand-piece should be value 40,000 rpm $\pm\,2\%$



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 motor. 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, motor, 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.

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







	MEMO
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This product is the medical device.



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