Dental Implant Unit User manual

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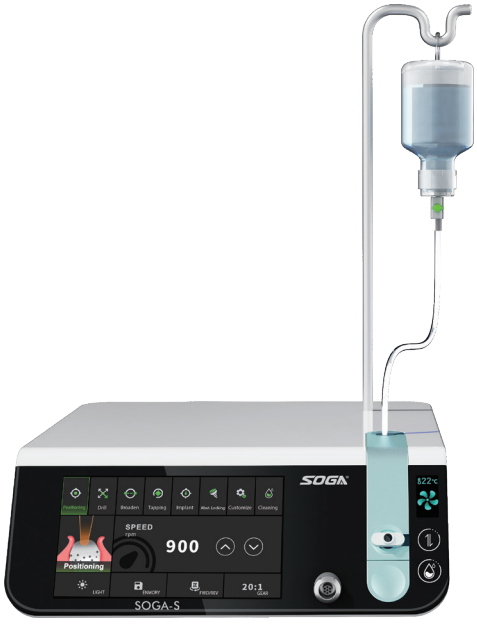

Shenzhen Soga Technology Co., Ltd

SOGA®

Thank you for purchasing SOGA Dental Implant Unit SOGA-S.
In order to guarantee the correct operation, it is recommended to read this user manual carefully before operation.
For convenient reading and to ensure safe and effective use, it is recommended to put it where it is available at any time.

Device Type

1. Type of protection against electric shock: Class I equipment with internal power supply
2. Degree of protection against electric shock: Type B application part
3. Recommended processing method: Refer to section 6 Cleaning, disinfection, and sterilization
4. Waterproof protection Compliant with standard IEC 60529: Mainframe-IPX0, Control pedal-IPX7
5.Safety of use in environments with flammable anesthetic mixtures with air, oxygen or nitrous oxide: This planter is not suitable for use in environments with flammable mixtures of anesthetics with air, oxygen and nitrous oxide.
6.Operating mode: Intermittent

Precautions

1. Please read these precautions before using the device.
2. The following icons are for ensuring safe operation, preventing you or others from being hurt. These icons are classified by the degree of risk, degree of damage, and severity. All indicators should be highly concerned. Please obey the instruction.

Classification	Degree of risk, degree of damage and severity
Dangers	Indicating potential personal injury or bodily injury
Warnings	Indicating potential slight injury or bodily injury
Precautions	Indicating instructions to be observed for ensuring safety

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1. Product introduction

1.1 Precautions

⚠ Danger

1. To prevent electric shock, do not use wet hands to contact the power cord; Be sure to prevent water from entering the control circuit; it shall use a grounded electrical outlet.
2. Keep it away from explosives and combustibles, with special care not to use this device for patients who are narcotized with nitrous oxide.
3. This device may be used only by specialized and suitably trained personnel such as a dental surgeon. The application of the device shall be a dental clinic or hospital. If not used correctly, this device may rise to the transmission of heat to the tissues.

⚠ Warnings

1. To avoid the risk of electric shock, this device shall only be connected to supply mains with protective earth.
2. In the presence of an electromagnetic interference environment, the planter may be malfunctioning. Do not install the Dental Implant Unit near the device that releases magnetic waves. When using ultrasonic vibrating equipment or an electrode knife nearby, close the switch on the control panel.
3. The device requires special precautions for EMC and needs to be installed and put into service according to the EMC environment.
4. The Dental Implant Unit cannot be used in operating rooms containing potentially flammable gas mixtures.
5. To avoid possible injury to human or damage to the device, make sure that the motor handpiece (hereinafter simply referred to as the motor) is completely shutdown when replacing the planting tool. And the replacement shall be conducted by controller of foot control.
6. Severe impact, such as dropping, will lead to damage to the device.
7. During the work of peristaltic pump, the water pipe cannot be excessive bending or knotting, otherwise the pipe may fracture.
8. Do not attempt to disassemble the control panel, foot control or motor.
9. Dental handpieces (hereinafter referred to as handpieces) should be cleaned, lubricated and disinfected immediately after use.
10. Do not lubricate the motor. Lubricating oil can cause overheating, resulting in damage to the motor. Control panel and foot control cannot be disinfected.
11. Do not clean control panel with dissolving solution.
12. The motor cable cannot be removed from motor.
13. Please turn of the device after each use.

⚠ Precautions

1. If you need to repair or purchase spare parts, please contact the authorized supplier.
2. It is recommended to use the original pre-disinfection disposable water pipe combination.
3. The accuracy of torque monitoring depends on the accuracy of the handpiece installed on the micromotor. If the handpiece produced by other manufacturers is used, the actual torque value may not be displayed correctly. To ensure that the actual torque matches the displayed torque, please use the provided handpiece.
4. Please read this user manual before operating and mastering parts of functions.
5. Check the operating status of the Dental Implant Unit before use and confirm that there is no abnormal condition.
6. Test the Dental Implant Unit before operating to ensure correct operation.
7. If there is a permanent malfunction (excessive vibrations, noise, heat production, etc.) on the SOGA-S, please immediately close it and return it to the authorized dealer.
8. Please cut off the power before cleaning the control panel with a damp cloth.
9. Please dispose of used water pipes and other waste according to local medical waste regulations.
10. The operation mode of SOGA-S is Intermittent operation mode, i.e., there will be 10 minutes pause after 3 minutes. It will prevent the patients, users, or third parties from overheating damage.

The user should be responsible for the use and shutdown of the device.
This instruction manual is intended to indicate the safety requirements, installation procedures, proper methods of use, and proper maintenance of the device. If you encounter any unexpected problems, please contact the Service Center of Shenzhen Soga Technology Co., Ltd.
The manufacturer will not be responsible for any personal injury or property damage caused by device tampering or modification conducted by unauthorized persons.
SOGA reserves the right to change the design of the device, the technique, fittings, the instruction manual, and the content of the original packing list at any time without further notice. The pictures are only for reference. The final interpretation rights belong to Shenzhen Soga Technology Co., Ltd.
Shenzhen SOGA Technology Co., Ltd. will continue to update its products, thus bringing changes in device components. If there is any difference between your manual and the description on your product, please contact the authorized distributor or after-sales service center of Shenzhen Soga Technology Co., Ltd. for an explanation.
This manual is strictly prohibited from being used in any way other than installation, use and maintenance of the device.

1.2 Contraindications and precautions

1.2.1 Patients with hemophilia are forbidden to use this device.
1.2.2 Patients and doctors with heart pacemakers are forbidden to use this device.
1.2.3 Patients with Heart disease and children should be cautious to use the device.
1.2.4 Patients with oral and maxillo-facial infection, oral mucosal diseases, periapical disease, gingivitis, periodontitis, or mouth neoplasm should be cautious to use this device.
1.2.5 Patients with an allergic constitution or drug allergy history are forbidden to use this device.
1.2.6 People with mental disorders should be cautious to use this equipment.
1.2.7 Patients with severe systemic infection or systemic diseases such as the diseases of heart, liver, kidney, hematopoietic system, digestive system, and endocrine system should be cautious to use this device.
1.2.8. Pregnant women, lactating women, and women who have a plan of birth should be cautious to use this device.

1.3 Scope of use

This product is intended for use in dental surgery, thus other uses are not allowed. There will be a potential danger if it is used for other purposes!

1.4 Safety requirement

Shenzhen Soga Technology Co., Ltd. will NOT be responsible for any direct or indirect damages and losses under the following conditions:
The device is used for any purpose that is not mentioned in the scope of use.
The operator does not follow the steps and requirements in the user manual to use the device.
The cabling system of the room where the device is used does not meet the appropriate standards and the appropriate requirements. Assemble, operate, and repair the device without the authorization of the manufacturer.
The environment in which the device is located or stored does not meet the requirements mentioned in the technical requirements section of the instruction manual.

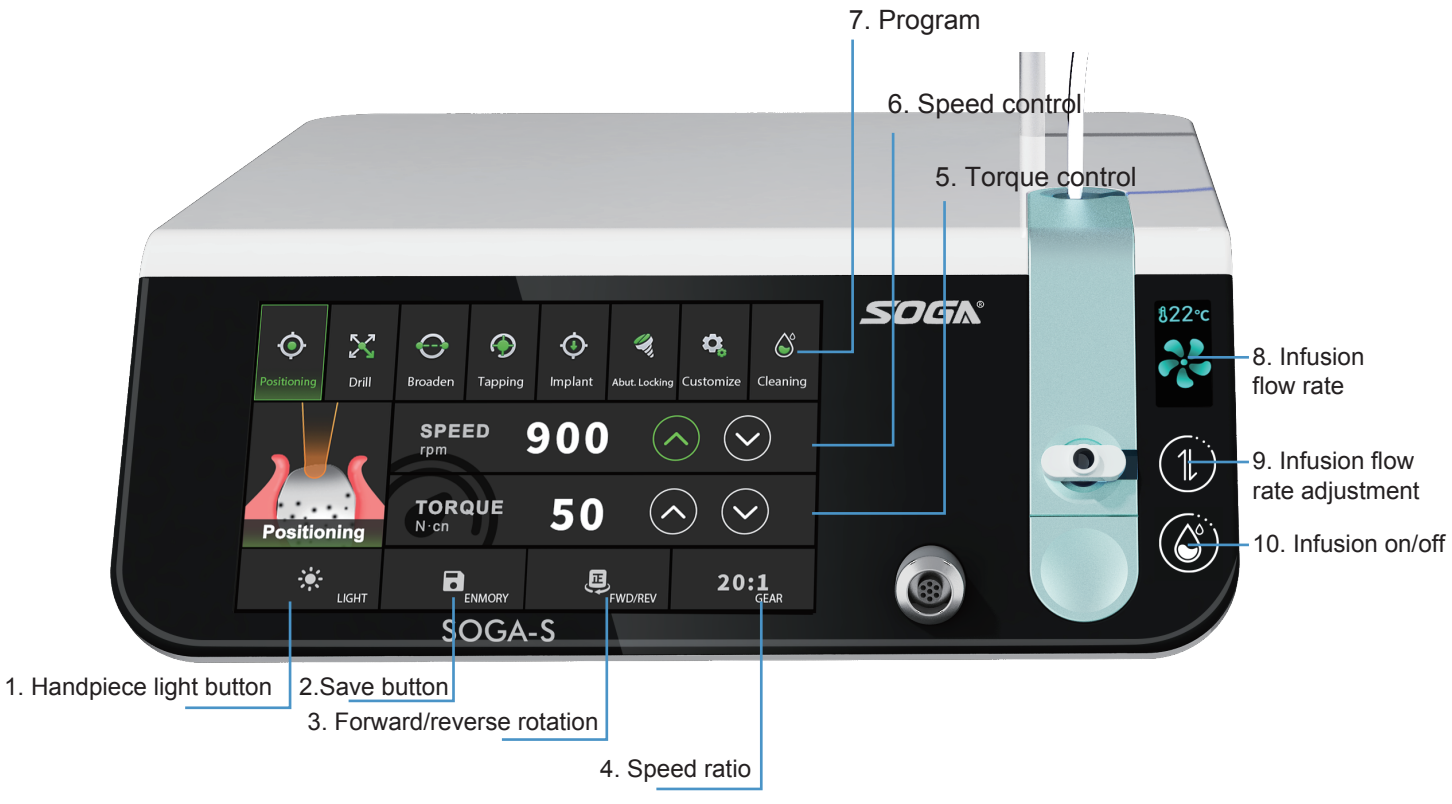
2. Accessories description

Please refer to the packing list for device configuration.

3. Control panel of mainframe and foot control

3.1 Control panel of mainframe

3.1.1 Operation buttons on mainframe interface



1. .Handpiece light button: Touch to switch the motor LED light;

2.Save button: Touch to save program default setting.

3. Forward/reverse rotation: Touch to switch the direction of rotation; direction changes for each pressing.

4. Handpiece gear ratio: Used to align the gear ratio with the connected handpiece.

5. Allow to adjust the torque

6. Allow to adjust the rotation speed

7. Program button: Touch the icons to choose the corresponding programs. Please refer to Clause 5.1 for the functions of each program.

8. Indicating the present infusion flow rate

9. Allow to adjust the infusion flow rate between 6 levels

10. Switch the infusion water function

3.1.2 Error alarm interface

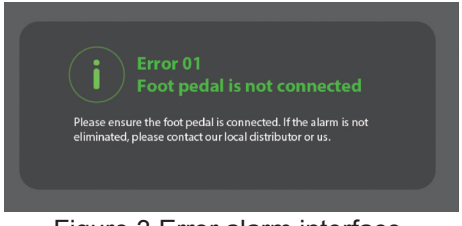
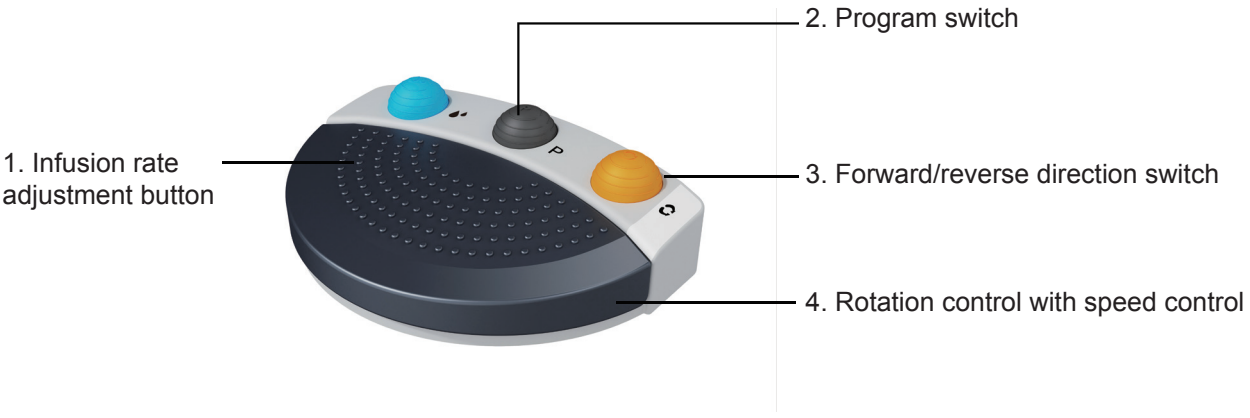


Figure 3 Error alarm interface

As shown in Figure 3, the warning indicates the error number. Please refer to section 7-Error code for solution according to the specific number and the corresponding content.

3.2 Foot control



1. Infusion rate adjustment button

The device has 6 infusion flow rate levels for choosing from.
The infusion flow rate level is incremented each time the button is stepped.
When the level is at the maximum level-100%, pressing once to loops back to level 1.

2. Program switch

Use to choose programs. The program is changed each time the button is stepped. At Program 8, press once to loop back to Program 1. Short press Program switch to move forward to the next program, and long press (>2s) to move back to the last program.

3. Forward/reverse direction switch

Use to change the rotating direction of the handpiece. The direction will change for each step.

4. Speed control pedal

Use to start/stop the motor and control the speed during operation. The operating speed of the motor is controlled by the foot of the operator. The harder the operator step, the faster the motor speed and the preset speed is the maximum speed.

4. Installation

4.1 Safety requirements during installation

⚠ Danger: The Dental Implant Unit is placed on the premise that the placement must meet the appropriate standards and related electrical safety requirements.

⚠ Danger: Never place the device in an explosion-hazardous environment; the device shall not be operated in an environment with flammable gases (anesthetic mixture, oxygen, etc.).

⚠ Danger: The device placement site should be able to protect the device from shocks and splashing of water or other liquids.

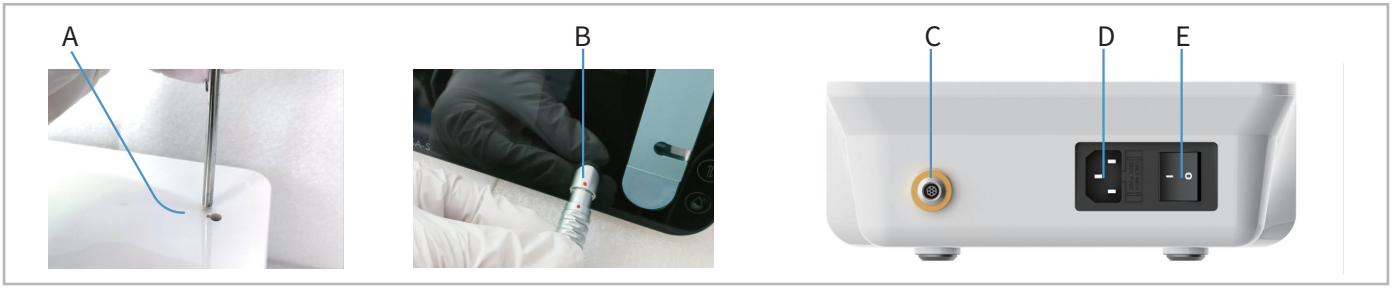
⚠ Danger: Do not place the device near or above a heat source. It must be placed in a well-ventilated environment with sufficient space around it, especially the exhaust fan and back.

⚠ Warning: Do not directly expose the parts to the sun or UV light source.

⚠ Warning: Dental Implant Unit is a portable device. Please be careful while handling it.

⚠ Warning: Before connecting the cord to the device, make sure the connectors are dry. If necessary, dry it with an air gun.

4.2 Accessories connection



4.2.1 Connection of foot control:
Connect the foot control plug to the pedal socket on the back of the mainframe (Figure 4-C)
4.2.2 Power cord connection:
Plug the power cord output into the power supply socket of the device (Figure 4-D)
4.2.3 Connection of infusion bottle holder:
Insert the infusion bottle holder into the fixing hole on the top right corner of the device; (Figure 4 - A)
4.2.4 Hanging of infusion bottle:
Hang the infusion bottle (The infusion bottle contains purchased normal saline injection.) on its holder.

4.2.5 Connection of motor handle:

Plug the tail cord of the motor handle into the output socket on the front of the device (Note: align the red marking point). (Figure 4-B)

Figure 5

4.2.6 Install infusion water line:

A. Press the peristaltic pump chamber button and the chamber will open (Figure 5-A).

B. According to the groove of the opened chamber, the tube is stuck in the groove (Figure 5 - B).

C. Keep the tube in the groove and press the open cavity back to the original state (Figure 5 - D).

4.2.7 Complete machine diagram after installations of all accessories: (Figure 6)

Figure 6

4.2.8 Switch on (Figure 4-E); start to use the device if it displays normally:
Step on the foot control after the parameters such as speed, torque, and infusion rate are set properly. The device starts to work. When the foot control is released, the device stops working.

is released, the device stops working.

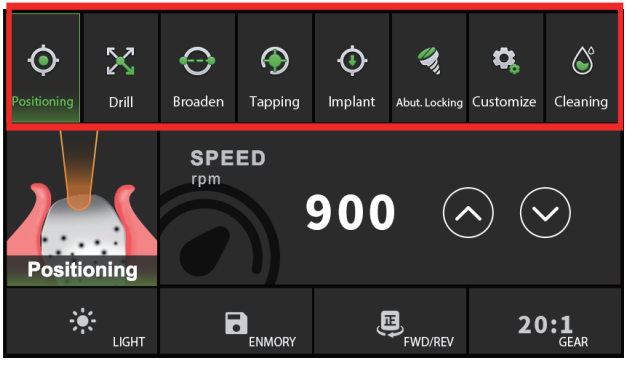
5. Operation

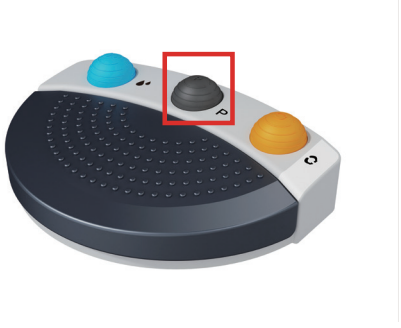
5.1 Program

5.1.1 Choice of programs

SOGA-S owns 5 programs. There are two ways to choose a program:

1. Touch the corresponding icons on the screen.
2. Step on the “Program switch” button on the foot control.





5.1.2 Function description of programs

The function of each program is as shown as follow:

Icon	Function	Description
	Positioning	Accurate positioning on the alveolar bone by using a positioning drill.

	Hole-drilling	Determine the direction and depth of hole-drilling.
	Hole-broadening	Determine the diameter of the hole.
	Tapping	Make a thread on the hole to match the implant.
	Implanting	Implant dental implants into alveolar bone.
	Lock the abutment screw	Screw the nut onto the dental implant.
	User defined mode	A program is used to provide the operator with a parameter setting which able to be customized.
	Cleaning	Water discharging without motor rotation is s convenient for flushing

5.1.3 Factory Setting

Before delivery, several parameters mainly including motor speed, torque, speed ratio, and infusion rate output have been set according to the actual application. These parameters can be changed within the range of parameters specified in the current program.

The range of different parameters and their factory settings are shown in the table below:

Icon	Function	Speed/ rpm	Torque/ N·cm	Speed ratio	Water output/%
	Positioning	200-2500 1000(D)	5-80 35(D)	16:1,20:1, 27:1,20:1(D)	60
	Hole-drilling	200-2500 800(D)	5-80 35(D)	16:1,20:1, 27:1,20:1(D)	60
	Hole-broadening	200-2500 600(D)	5-80 35(D)	16:1,20:1,27:1,20:1(D)	60
	Tapping	15-100 20(D)	5-80 35(D)	16:1,20:1, 27:1,20:1(D)	60
	Implanting	15-100 20(D)	5-80 35(D)	16:1,20:1, 27:1,20:1(D)	0
	Lock the abutment screw	15-100 20(D)	5-15 10(D)	16:1,20:1, 27:1,20:1(D)	0
	User defined mode (Implanter)	15-200000 1200(D)	5-80 45(D)	1:1,1:2,1:3, 1:5,16:1, 20:1,27:1, 20:1(D)	60
	User defined mode	15-200000 1200(D)	5-80 45(D)	1:1,1:3,1:4.2, 1:5,16:1, 20:1,27:1, 20:1(D)	60

	Cleaning	——	——	——	80

Note: the letter “D” stands for default value.

5.2 Default parameter adjustment

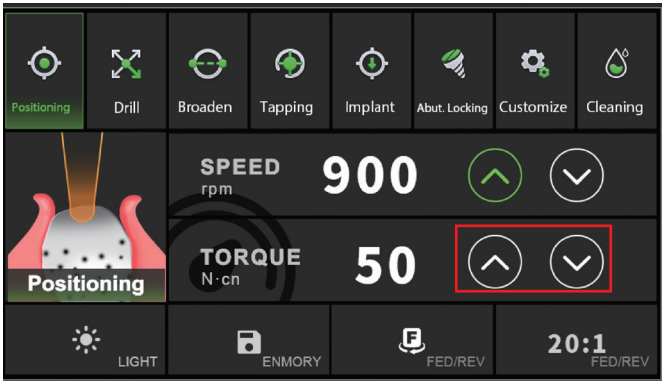
Within the specified range, the adjustable parameters are as follows:

1. Maximum speed
2. Maximum torque
3. Infusion rate
4. Speed ratio

5.2.1 Infusion rate adjustment

Touch the “Infusion rate” button on the screen to adjust. There are 6 Infusion rate levels. The level will change to the next level after each touch.

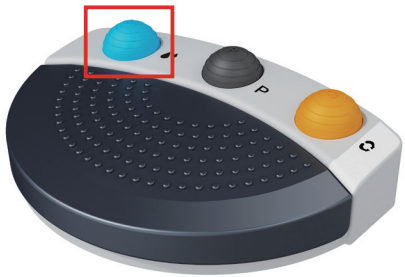
5.2.2 Maximum torque adjustment



Touch the “Torque” (+, -) key to adjust maximum torque output of motor. The torque will change each time after touching the “Torque” key. Long press the “Torque” key to accelerate the change of torque setting value.

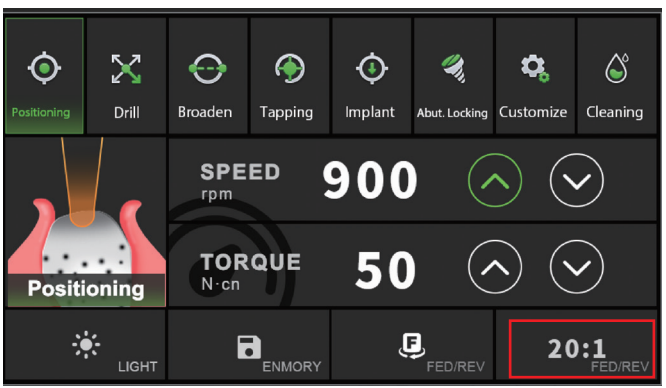
5.2.3 Infusion rate foot control

Touch the “Water volume” key on the screen to adjust. There are 6 water levels. The water level will change to the next level after each touch.



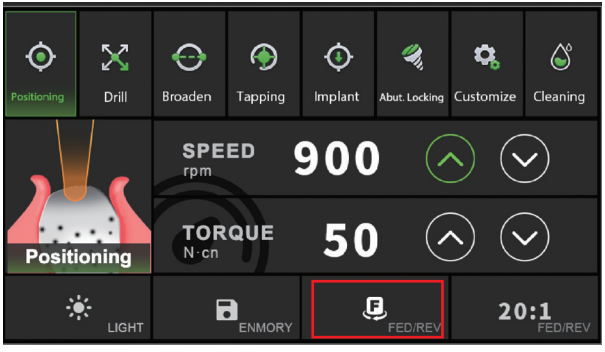
Step on the blue “Water volume adjustment” button to adjust water volume.

5.2.4 Speed ratio adjustment



Adjust by pressing the "Speed Ratio" button to match the gear ratio of the handpiece to be used.

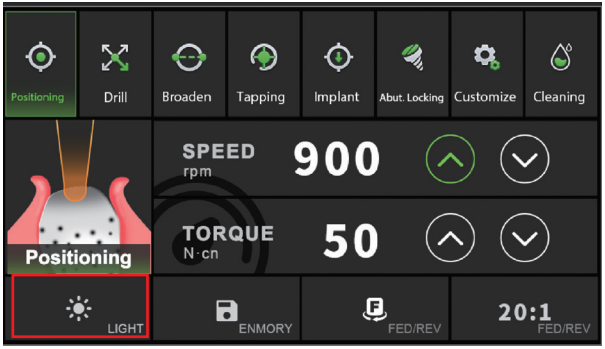
5.3 Motor rotating direction adjustment



Touch the key shown above to change the rotating direction of motor.

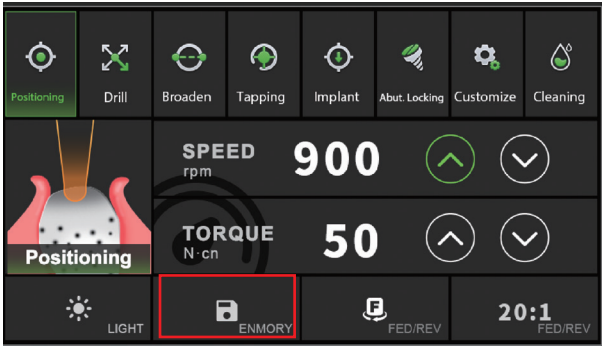
Step on the “Forward/reverse rotation” during operation to change the rotating direction of motor .

5.4 Motor LED adjustment



Touch the 'LED" button to for settin g to determine the on or off state of LE D while stepping on foot pedal. The state of LED will change once after each touch. Only the device with LED owns this function.

5.5 Save the parameters

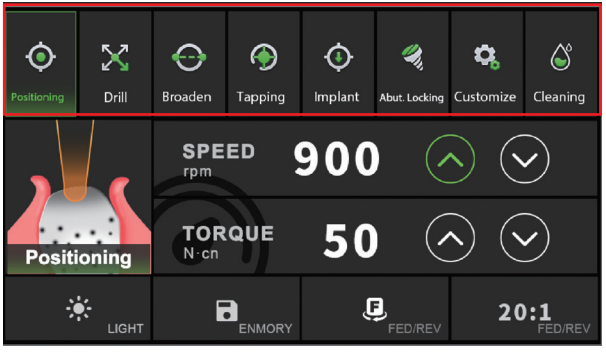


After finishing the above steps, press the “Memory” button. The parameters will be saved.

5.6 Standard operation

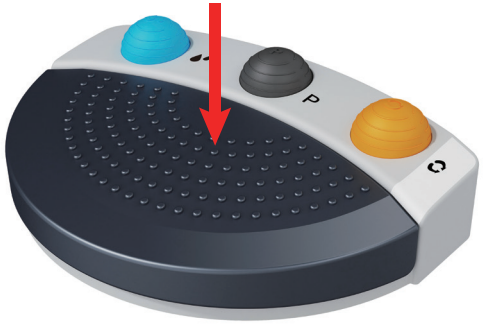
1. After installation of corresponding accessories, connect to the power supply, and turn on the power supply. After booting, the displayed interface is default to be Program 1.

2. Touching the screen or stepping on the “Program switch” button on the foot control to choose the program.



3. Confirm that the motor speed, torque, infusion rate, rotation direction, speed ratio, and other parameters of the corresponding program meet the requirements.

4. Step on the foot control, and then the motor starts to rotate. Step harder to accelerate; the maximum speed value is the current program speed setting value; Lossen to reduce the speed; the minimum trigger speed is 15 rpm (Gear ratio of handpiece: 20:1). When full release the foot control, the speed will slow down to 0.



5. Torque protection will start as the torque reaches the preset value. Meanwhile, the motor slows down to stop, preventing it from generating excessive torque. Release the foot control to remove torque protection. Step again, and the motor will rotate under the preset torque value.

6. Release the foot control, and the motor will stop rotating.

6. Clean, disinfection, and sterilization

If there is blood or salt residue on the mainframe and foot control, unplug the power cord, wipe it off with a water-damped cloth, then and wipe it with a soft cloth dampened with alcohol. The handpiece and the motor handle can be sterilized with heat sterilizers. It shall plug in the motor protector before sterilizing the motor handle!

Warning:

Never place the mainframe and foot control in a washer-disinfector, autoclave, or ultrasonic bath.

Warning:

If you use a disinfectant in the form of a spray, never spray on the devices and accessories directly.

Warning:

Only use surface disinfectants that are certified by officially recognized institutes which do not contain chlorine and have been d eclared aldehyde-free.

Warning:

Clean and disinfect the mainframe and foot control regularly. When cleaning/disinfecting the mainframe or foot control, ensure that the charging cable is not connected and that the power switch is closed.

Warning:

Only the following parts can be sterilized: Handpiece and its kit, motor handle, handle holder, motor protector, pipe clamp, and O-ring.

The processing of the motor handle are as follows.

Unless otherwise stated, they will be hereinafter referred to as “products”.

Warnings:

The use of strong detergent and disinfectant (alkaline pH>9 or acid pH <5) will reduce the life span of products. And in such cases, the manufacturer takes no responsibility.

The products may not be exposed to temperature above 138℃.

6.1 Processing limit

The products have been designed in a way that the performance maintains within sterilization cycles. The materials used in manufacturing were considered accordingly. However, with every renewed preparation for use, thermal and chemical stresses will result in the aging of the products. The maximum number of sterilizations for the motor handle is 250 times.

6.2 Initial processing:

Processing principles:

It is only possible to carry out effective sterilization after the completion of effective cleaning and disinfection. Please ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and product-specific procedures are used for cleaning/disinfection and sterilization, and that the validated parameters are adhered to during every cycle.

Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic,especially with regard to the additional requirements for the inactivation of prions.

6.3 Post-processing operation:

The post-operative treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. The steps are as follows:

1. Wipe all visible surfaces of the device with a water-damped soft cloth, including the motor handle, infusion bottle handle, foot control, and cables. And then dry them after washing;
2. Wipe all visible surfaces of the device including the motor handle, infusion bottle handle, foot control, and cables with a disposable soft cloth dampened with disinfectant to ensure that all surfaces are wet. Let the disinfectant work during a specified period and then dry the surface;
3. Dry all the cleaned and disinfected parts thoroughly in the air indoors.

Cautions:

(1) Do not use automatic cleaning equipment to clean the mainframe.
(2) Do not use metal brushes.

6.4 Preparation before cleaning:

Steps:
Tools: tray, disposable soft cloth, disinfectant, motor protector
1. Remove the motor handpiece from the motor handle and put the motor handpiece into a clean tray.
2. Please plug the motor protector into the motor handle.

6.5 Cleaning:

The cleaning should be performed no later than 24 hours after using the device.
The cleaning can be divided into automated cleaning and manual cleaning. Automated cleaning is preferred if conditions permit.

Automated cleaning:

The parts that can be cleaned automatically are as follow: handpiece, O-ring.
• The cleaner shall be proven to be consistent with EN ISO 15883.
• There should be a flushing connector connected to the inner cavity of the product.
• The cleaning procedure is suitable for the product, and the irrigating period is sufficient.
• Do not clean the product with ultrasound.
It is recommended to use a washer-disinfector in accordance with EN ISO 15883. For the specific procedure, please refer to the automated disinfection section in the next section "Disinfection".

Manual Cleaning:

The component that needs to be cleaned manually is as follows: motor handle.
Manual cleaning steps
1. Wet the soft cloth completely with distilled water or deionized water, and then wipe all the surfaces of the handle and mainframe until the surface of them is not stained.:

2. Wipe the surface of the handpiece and main unit with a dry soft nap-free cloth.
3. Repeat the above steps at least 3 times.
Notes: Use distilled water or deionized water for cleaning at room temperature.
Precautions:
(1) The cleaning agent does not have to be pure water. It can be distilled water, deionized water, or multi-enzyme. But please ensure that the selected cleaning agent is compatible with the product.
(2) In the washing stage, the water temperature should not exceed 45 °C; otherwise, the protein will solidify and it would be difficult to remove.
(3) After cleaning, the chemical residue should be less than 10mg / L.

6.6 Disinfection:

Disinfection must be performed no later than 2 hours after the cleaning process. Automated disinfection is preferred if conditions permit.

Automated disinfection-Washer-disinfector:

The parts that can be disinfected automatically are as follow: handpiece.
• The washer-disinfector is proven to be valid by CE certification in accordance with EN ISO 15883.
• Use high-temperature disinfection function. The temperature does not exceed 134 ° C, and the disinfection under the temperature cannot exceed 20 minutes.
• The disinfection cycle is in accordance with the disinfection cycle in EN ISO 15883.
Cleaning and disinfecting steps by using Washer-disinfector:
1. Carefully place the product into the disinfection basket. Fixation of the product is needed only when the product is removable in the device. The products are not allowed to contact each other.
2. Use a suitable rinsing adaptor, and connect the internal water lines to the rinsing connection of the washer-disinfector.
3. Start the program.
4. After the program is finished, remove the product from the washer-disinfector, inspect (refer to section "Inspection and Maintenance") and packaging (refer to chapter "Packaging"). Dry the product repeatedly if necessary (refer to section "Drying").

Precautions:

(1) Before use, you must carefully read the operating instructions provided by the equipment manufacturer to familiarize yourself with the disinfection process and precautions.

(2) With this equipment, cleaning, disinfection and drying will be carried out together.

(3) Cleaning:

(a) The cleaning procedure should be suitable for the product to be treated. The flushing period should be sufficient (5-10 minutes). Pre-wash for 3 minutes, wash for another 5 minutes, and rinse it for twice with each rinse lasting for 1 minute.

(b) In the washing stage, the water temperat ure should not exceed 45°Cotherwise the proteinv will solidify and it is dificult to remove.

(c) The solution used can be pure water, distilled water, deionized water or multi-enzyme solution, etc., and only freshly prepared solutions can be used.

(d) During the use of cleaner, the concentration and time provided by manufacturer shall be obeyed. The used cleaner is neodisher MediZym(Dr.Weigert).

(4) Disinfection:

(a) Direct use after disinfection: temperature ≥ 90 ° C, time ≥ 5 min or $A0 \geq 3000$;

Sterilize it after disinfection and use: temperature ≥ 90 ° C, time ≥ 1 min or $A0 \geq 600$

(b) For the disinfection here, the temperature is 93 ° C, the time is 2.5 min, and $A0>3000$

(5) Only distilled or deionized water with a small amount of microorganisms (<10 cfu/ml) can be used for all rinsing steps. (For example, pure water that is in accordance with the European Pharmacopoeia or the United States Pharmacopoeia).

(6) After cleaning, the chemical residue should be less than 10mg / L.

(7) The air used for drying must be filtered by HEPA.

(8) Regularly repair and inspect the disinfector.

Manual disinfection:

The parts that need to be disinfected Manually are as follow: motor handpiece.

Manual disinfection steps:

1. Soak the dry soft cloth with 75% alcohol.
2. Wipe all the surfaces of the motor handpiece with a wet soft cloth for at least 3 minutes.
3. Wipe the surface of motor handpiece with a dry soft nap-free cloth.

Notes:

a) The cleaning and disinfection must be performed within 10min before use.

b) The disinfectant used must be used immediately, no foaming is allowed.

C)In aadition to 75% alcohol you can use non -residue disinfectants such as Oxytech from German y, but you must respect the concentration, temperature and time specified byt the disinfectant manufacturer.

6.7 Drying:

If your cleaning and disinfection process does not have an automatic drying function, dry it after cleaning and disinfection.

Methods:

.Spread a clean white paper (white cloth)on the flat table point the p roduct against the white paper(white cloth)and then dry the product with filtered dry compressed air(maximum pressure 3 bar).Unt il no liquid is sprayed onto the white paper (white cloth) the product drying is completed.

2. It can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80℃ ~ 120℃ and the time should be 15 ~ 40 minutes.

Precautions:

(1) The drying of product must be performed in a clean place;

(2) The drying temperature should not exceed 138 °C;

(3) The equipment used should be inspected and maintained regularly.

6.8 Inspection and maintenance:

In this chapter, we only check the appearance of the product. Make sure the inspection is correct.

1. Check the product. If there is still visible stain on the product after cleaning/disinfection, the entire cleaning/disinfection process must be repeated.

2. Check the product. If it is obviously damaged, smashed, detached, corroded or bent, it must be scrapped and not allowed to continue to be used.

3. Check the product. If the accessories are found to be damaged, please replace it before use. And the new accessories for replacement must be cleaned, disinfected and dried.

4. If the service time (number oftimes)of the product reaches the specified service life

6.9 Packaging:

The disinfected and dried product quickly package in a medical sterilization bag (or special holder , sterile box).

Precautions:

(1) The package used conforms to ISO 11607;

(2) It can withstand high temperature of 138°C and has sufficient steam per rmeability;

(3) The packaging environment and related tools must be cleaned regularly to ensure cleanliness and prevent the introduction of contaminants;

(4)Avoid contact with parts of different metals when packaging

6.10 Sterilization:

Use only the following steam sterilization procedures (fractional pre-vacuum procedure*) for sterilization, and other sterilization procedures are prohibited:

1.The steam sterilizer complies with EN13060 or is certified according to EN 285 to comply with EN ISO 17665;

2. The highest sterilization temperature is 138 ° C;

3. The sterilization time is at least 4 minutes at a temperature of 132 ° C / 134 ° C and a pressure of 2.0 bar ~ 2.3 bars.

4. Allow a maximum sterilization time of 20 minutes at 134 °C.

Verification of the fundamental suitability of the products for effective steam sterilization was provided by a verified testing laboratory.

Precautions:

(1) Only products that have been effectively cleaned and disinfected are allowed to be sterilized;

(2) Before using the sterilizer for sterilization, read the Instruction Manual provided by the equipment manufacturer and follow the instructions.

(3) Do not use hot air sterilization and radiation sterilization as this may result in damage to the product;

(4) Please use the recommended sterilization procedures for sterilization. It is not recommended to sterilize with other sterilization procedures such as ethylene oxide, formaldehyde and low temperature plasma sterilization. The manufacturer assumes no responsibility for the procedures that have not been recommended. If you use the sterilization procedures that have not been recommended, please adhere to related effective standards and verify the s uitability and effectiveness.

* Fractional pre-vacuum procedure = steam sterilization with repetitive pre-vacuum. The procedure used here is to perform steam sterilization through three pre-vacuums.

6.11 Storage:

1. Store in a clean, dry, ventilated, non-corrosive atmosphere with a relative humidity of 10% to 93%, an atmospheric pressure of 70KPa to 106KPa, and a temperature of -20 °C to +55 °C;

2. After sterilization,the product should be packaged in a medical sterilization bag or a clean sealing container, and stored in a special storage cabinet. The storage time should not exceed 7 days. If it is exceeded, it should be reprocessed before use.

Precautions:

(1) The storage environment should be clean and must be disinfected regularly;

(2) Product storage must be batched and marked and recorded.

6.12 Transportation:

1. Prevent excessive shock and vibration during transportation, and handle with care;
2. It should not be mixed with dangerous goods during transportation;
3. Avoid exposure to sun or rain or snow during transportation.

The cleaning and disinfection of mainframe are as follows.

• Before each use, wipe the surface of the device and the tail cord of the motor handle with a soft cloth or paper towel soaked in 75% medical alcohol. Repeat the wipe for at least 3 times.

• After each use, wipe the surface of the device and the tail cord of the motor handle with a soft cloth soaked in clean water (distilled or deionized water) or a clean disposable wipe. Repeat the wipe for at least 3 times.

7. Error code and solution (error alarm interface)

When there is a problem with the operation,the display will provide the err or code of the problem diagnosis:Specificallyswitch to the error prompt interface for explanation and solution to the problem:

Error code	Error description	Solution
Error 01	Foot pedal is not connected	Please ensure the foot pedal is connected. If the alarm is not eliminated, please contact our local distributor or us.
Error 02	Motor voltage error	The power supply voltage is unstable. Please ensure that the grid voltage is stable. If the alarm is not eliminated, please contact our local distributor or us.
Error 03	Power-on failure	The motor handpiece is not connected when the machine is turned on. Make sure that the motor handpiece and the main unit are properly connected and then power on again. If the alarm is not eliminated, please contact our local distributor or us.
Error 04	The handpiece is not connected	Please check if the handpiece is in good contact. If the alarm is not eliminated, please contact our local distributor or us.
Error 05	Abnormal signal line	Please contact our local distributor or us.
Error 06	The circuit is abnormal	Please contact our local distributor or us.
Error 07	Operation failure	Please check if the parameter settings are normal.

8. Storage and maintenance

8.1 The device should be handled carefully and lightly. Be sure that it is far from the vibration, and installed or kept in a cool, dry, and ventilated place.

8.2 Do not store the machine together with articles that is poisonous, combustible, caustic, or explosive.

8.3 This device should be stored in a room where the relative humidity is not exceed 93%, and the temperature is-20℃ ~ +55℃.

8.4 Turned off power switch and unplug the power plug when the devic ce is not in use.If it is not used for a long time, please get through to power supply and water for five minutes once per month.

8.5 Check the integrity of cable. If it is damaged, please replace it with original accessories.

8.6 After each operation, the contra-angle shall be cleaned, applied oil, and disinfected as per requirements. If it is not used for a period, please clean it, apply oil to it, and disinfect is at least once a week.

Replacement of fuse

Power supply shall be cut off while intending to conduct the following operations. And disconnect power supply cable and main power supply.(See Figure 7-Refer to B)

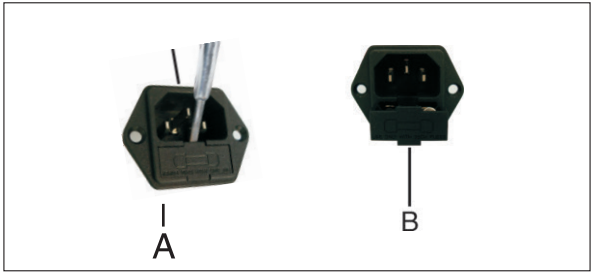


Figure 7

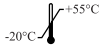
1. Danger: Switch off the apparatus.

2. Insert a flat-blade screwdriver to the groove under the power supp y hole, and then pry it out(Figure 7-ref.A) A);

3. Pull out the fuse compartment (see Figure 7 - Ref. B) and select the appropriate fuse for replacement by following the label on the bottom of the power supply socket.

8.7 The maintenance personnel appointed by the manufacturer can obtain the equipment maintenance-related data (such as circuit diagrams, component lists, etc.) from the manufacturer.

9. Symbols

SOGA®	Mark		Follow Instructions for Use
	Use indoor only		Appliance complies with WEEE directive
	Socket for the foot switch		Temperature limit for storage
	Manufacturer		Date of manufacture
IPX0	No protection	IPX7	Protection against the effects of temporary immersion in water
	Type B applied part		Can be autoclaved
	Caution		Protective earthing
SN	Serial number		Humidity limit for storage

Note: Please refer to product packaging label for production date.

10. Specifications

10.1 Mainframe specifications

Model: SOGA-S
Device for intermittent operation: 3 min ON,10 min OFF
Power supply voltage: 220-230V~
Power supply frequency: 50/60Hz
Software version: Implant-V1
Input power: 60VA
Fuses: 2×F2.0AH 250V
Dimension: 265mm*263mm*119mm
Operation environment:
Environment temperature: +5~40℃
Relative humidity: ≤80%
Device case material: PC+ABS

10.2 Motor handle specifications:

Model: RN-2050
Rotating speed range: 500-40,000 rpm (±10%)
Torque range: 5-90 N•cm (ratio: 20:1)
Input voltage: DC 24V
Tail cord length: 1.5m

10.3 Foot control specifications

Model: P-2
Tail cord length: 1.8m

11. After-sales service

Since the date of sale, the device enjoys one year of free warranty, and our company is responsible for the lifetime maintenance.

Irreparable damage to device caused by non-designated professional maintenance personnel does not belong to the scope of free warranty.

12. Environment protection

The device does not contain any harmful ingredients. It can be handled or destroyed in accordance with the relevant local regulations.

13. Statement

Shenzhen SOGA reserves the right to change the design of the device, the technique, fittings, instruction manual and the content of the original packing list at any time without further notice. The pictures are only for reference. The final interpretation rights belong to Shenzhen SOGA Technology Co., Ltd.

14. Guarantee

14.1 Before being put into the market, all Shenzhen SOGA devices should be thoroughly inspected to ensure proper use.
14.2 Shenzhen SOGA promised that for any new products purchased from authorized distributors or importers of Shenzhen SOGA if an ill function results from a quality problem, you are entitled to free replacement during the warranty period:

- One year since the date of purchasing the device;
- One year from the date of purchasing the motor handle.

4.3 During the warranty period, Shenzhen SOGA will repair or replace the damaged parts of the device for free.

14.4 Shenzhen SOGA will not be responsible for any direct or indirect damage and loss if:

14.4.1 The device is used for any purpose other than the mentioned scope of use.
14.4.2 The operator does not follow the steps and requirements stipulated in the instruction manual to use the device.
14.4.3 The cabling system of the room where the equipment is used does not meet the appropriate standards and the appropriate requirements.
14.4.4 The device is installed, operated, or repaired by unauthorized personnel.
14.4.5 The environment where the device is used and stored does not meet the requirements stipulated in the relevant section of the instruction manual.
14.5 Damage caused by transportation, incorrect use, or negligence will be excluded from the warranty. And if the parts are tempered unauthorized, the warranty card losses effect.

14.5 Damage caused by transportation, incorrect use, or negligence will be excluded from the warranty. And if the parts are tempered by unauthorized, the warranty card losses effect.

14.6 Warnings

14.6 Warnings

To request a warranty, please send your device, warranty card, and invoice for the device to your Shenzhen SOGA distributor/importer within the warranty period. In order to be repaired during the warranty period, the purchaser shall return the repaired product to the distributor/importer at their expense.

14.7 Parts must be properly packaged (or in original packaging) while being sent back.

14.8 All parts must be accompanied by the following information

14.8.1 Buyer information, including phone numbers, etc.;
14.8.2 Distributor or importer information;
14.8.3 A copy of the photo of the goods, date of purchase, problem of part, part name and serial number;
14.8.4 Description of the problem.

14.9Any damage caused during transportation is not under warranty. If the problem is caused by incorrect use, the repair fee should be undertaken by the users.

15. EMC-Declaration of comformity

The device has been tested and homologated in accordance with EN 60601-1-2 for EMC. This does not guarantee in any way that his device will not be effected by electromagnetic interference Avoid using the device in high electromagnetic environment.

Technical Description Concerning Electromagnetic Emission

Table 1: Declaration - electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The model SOGA-S is intended for use in the electromagnetic envi ronment specified below . The customer or the user of the model SOGA-S should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The model SOGA-S uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The model SOGA-S is suitable for used 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 emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Technical Description Concerning Electromagnetic Immunity

Table 2: Guidance & Declaration - electromagnetic immunity

Guidance & Declaration — electromagnetic immunity			
The model SOGA-Sis intended for use in the electromagnetic envin ronment specified below . The customer or the user of the model SOGA-S should assure that It is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±2, ±4, ±8, ±15kV air	±8kV contact ±2, ±4, ±8, ±15kV air	Floors should be woodconcrete or ceramic tile. Iffloorsare covered with synthetic material, the relative humidity should be at least 30 %.

Electrical fast transient/ burst IEC 61000-4-4	±2kV for power supply lines ±1kV for Input/output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5, ±1kV line to line ±0.5, ±1, ±2kV line to earth	±0.5, ±1kV line to line ±0.5, ±1, ±2kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT.) for 1 cycle 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 250 cycles	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT.) for 1 cycle 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models SOGA-Srequires continued operation during power mains interruptions, it is recommended that the models SOGA-S be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table 3: Guidance & Declaration - electromagnetic immunity concerning Conducted RF & Radiated RF

Guidance & Declaration - Electromagnetic immunity			
The model SOGA-S is inte anded for use in.the electromagnetic environ ment specified below. The customer or the user of the model SOGA-S sh hould assure that it is used in such an envi ronment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

Conducted RF IEC 61000-4-6 Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM frequency band 3 V/m 80 MHz to 2.7 GHz	3V 6V 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the models SOGA-S, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.2×P1/2 d=2×P1/2 d=1.2×P1/2 80 MHz to 800 MHz d=2.3×P1/2 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter In watts (W) according to the transmitter manufacturer and d Is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur In the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz end 800 MHz. the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, obiects and people.			
a Field strengths from fixed transmitters, su ch as base stations for radio(cellular/cordles ss) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast o annot be predicted theoretically with accura cy.To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site sur wey should be considered. If the measured f eld strength in the location in which the model SOGA-S. is used exceeds the applic able RF compliance level abovethe mod el SOGA-S. should be observed to verify normal operation. If abnormal performanc e is observed, additional measures may b e necessar. such as reorienting or relocating the model SOGA-S. b Over the frequency range 150 kHz to80 M MHz, field strengths should be less than 3V/ m.			

Table 4: Recommended separation distances between portable and mobile RF communications equipment and the model SOGA-S.

Recommended separation distances between portable and mobile RF communications equipment and the model SOGA-S.

The model SOGA-S. is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model SOGA-S. can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model SOGA 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		
	150kHz to 80MHz d=1.2×P1/2	80MHz to 800MHz d=1.2×P1/2	800MHz to 2,7GHz d=2.3×P1/2
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in 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) accordable to

NOTE I At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.

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

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