Ai-surgery
MANUAL OF USE AND MAINTENANCE

CE 0197

Guilin Woodpecker Medical Instrument Co., Ltd.

Please read this manual before operating

Content

1. Introduction

1.1 Foreword

Before proceeding with the installation, use, maintenance or any other activities on the equipment please read the manual carefully.
Important: To avoid causing personal injuries or damages to property, read all the points concerning “safety requirement” contained in this manual with particular attention.
Depending on the level of risk involved, safety requirements are classed under the following indications:

Danger(always referred to personal injury)

Warning(referred to possible damage to property)

Not to position the device to make it difficult to operate the disconnection device.
In the presence of electromagnetic interference environment, the device may be malfunctioning. Do not install Ai-surgery near equipment that releases magnetic waves.
Warning, all unauthorized device modification may cause danger, please do not try !
Ai-surgery requires special precautions for EMC and needs to be installed and put into service according to the EMC environment.
Device with electromagnetic launcher will affect the normal operation of Ai-surgery , do not run both devices at the same time.
To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
The purpose of this manual is to ensure that operators are aware of the safety requirements, of the installation procedures and of the instructions for correct use and maintenance of the apparatus.
The user is not authorized to tamper with the equipment under any circumstances. If any problems are encountered, please contact a Woodpecker Service Centre.
Any attempts on the part of the user or any unauthorized personnel to tamper with or alter the apparatus will invalidate the warranty and release the Manufacturers from any liability in respect of any harm or damage to persons or property.
The information and illustration contained in this manual are up-dated to the date of publication indicated on the last page.
WOODPECKER is committed to continuous up-dating of the products, which may entail changes to components of the equipment. If there are any discrepancies between the descriptions contained in this manual and your equipment, please contact your dealer or the WOOKPECKER After-sale service for explanations.
Using this manual for purposes other than those relating to the installation, use and maintenance of the equipment is strictly prohibited.

1.2 Description of the Device

Thanks to its controlled three-dimensional ultrasound oscillations, the original Ai-surgery technique rings in a new age for osteotomy and osteoplasty in Implantology, Periodontology, Endodontics and Orthodontic Surgery. Its main features are:
Micrometric cutting: Maximum surgical precision and intra-operative sensibility;
Selective cutting: Maximum safety for the soft tissues;
Cavitation effect: Maximum intra-operative visibility (bloodless field);
The equipment has an automatic tuning circuit that offsets wear of the tips, thus ensuring work in constant conditions of maximum efficiency.

1.3 Intended Use

The Ai-surgery is a piezoelectric device for bone surgery that enables osteotomy and osteoplasty techniques to be applied to in almost any anatomical situation. This equipment can be used in the following fields:
a) Oral surgery;
b) Orthopedic surgery;
c) Maxillofacial surgery;
d) Cosmetic surgery;
e) Neurosurgery;
f) Otolaryngology.

This equipment cannot function in places where there is an inflammable atmosphere (anaesthetic mixture, oxygen, etc).

1.4 Safety requirements

Woodpecker will not accept any liability for direct or incidental personal injury or damage to property in the following cases:
1.4.1 If the equipment is used for purposes other than that for which it is intended;
1.4.2 If the equipment is not used in accordance with all the instructions and requirements described in this manual;
1.4.3 If the wiring system in the room where the equipment is used does not comply with the application standard and appropriate requirements;
1.4.4 If any assembly operations, extensions, settings, alterations or repairs have been carried out by personnel not authorized by Woodpecker;
1.4.5 If the environmental conditions in which the device is kept and stored do not comply with the requirements indicated in the chapter on technical specifications.

Danger: Qualified and specialized personnel.

This equipment may be used only by specialized and suitably trained personnel

such as surgeons. If correctly used, this equipment does not give rise to side effects. Improper use, on the other hand, will give rise to transmission of heat to the tissues.

Danger: Intended use.

Use the equipment solely for the purpose for which it is intended (see point 1.3), failure to comply with this requirement could lead to serious harm to the patient and/or to the operator and/or damage to/failure of the equipment.

Danger: Contraindications.

Do not use the Ai-surgery on patients with pace-makers or other implantable electronic devices. The same requirement applies also to the operator.

Danger: Contraindications.

An electrosurgical knife could interfere with correct functioning of the device.

Danger: Cleaning, disinfection and sterilization of new or repaired products.

All new or repaired products are delivered in no sterile conditions. Before being used for treatments, all new or repaired products should be cleaned, disinfected and sterilization following the instructions provided under point 8 strictly.

Danger: Use only original Woodpecker accessories and spare parts.

Danger: Check the condition of the device before treatment.

Always make sure that there is no water under the apparatus. Before each treatment always check that the equipment is in proper working order and that the accessories are efficient. Do not carry out the treatment if any problems are encountered in operating the device. If the problems concern the equipment contact an authorized technical service centre.

Danger: Breakage and wear of the tips.

The high-frequency vibrations and wear may, very occasionally, lead to breakage of the tip. Tips of which the shape has been changed or which are otherwise damaged are liable to break during use. Any such tips should definitely not be used. It is necessary to instruct the patient to breathe though his nose during the treatment in order to avoid ingestion of the broken off fragment of the tip.

Danger: Do not install this equipment anywhere there is a risk of explosions.

This equipment cannot function in places where there is an inflammable atmosphere. (anaesthetic mixture, oxygen, etc)

Danger: Personnel injury.

The foot switch of the Ai-surgery must not be activated when the door of the peristaltic pump open. (Fig.5—Ref.B).Moving parts could injure the operator.

Danger: Contraindication.

Do not carry out this treatment on metal or ceramic prosthetic artifacts. The ultrasonic vibrations could lead to decrementing of such artifacts.

Danger: Contraindication.

After autoclave sterilizing of the handpiece, wait for it to cool down completely before using itm.

2. Identification data

2.1 Identification data

An exact description of the model including the serial number of the equipment will make it easier for our After-Sale Service to respond quickly and efficiently to your enquiry.

Always provide the above information whenever you contact a Woodpecker Service Centre.

2.2 Data plate of the device

Each device has its own data plate (Fig.1), on which technical specifications and serial number are indicated. The data plate is on the rear of the device. The remaining data are included in this manual (see point 15).

Fig.1

2.3 Data plate of the scaler handpiece

The serial number of the Ai-surgery handpiece is engraved on the ring nut (Fig.2).

Fig.2

3. Testing of the device

All the devices are checked and tested by Woodpecker completely, including all the parts.
When testing, all the parts will work in intermittent operation.
The test emphasized that all the problems are from the failure parts. This procedure ensures the function and reliability of all the parts.

4. Delivery

Avoid the excessive concussion, shake, cover in delivery.
Do not mix with the danger articles.
Avoid the sunlight, rain and snow in delivery.

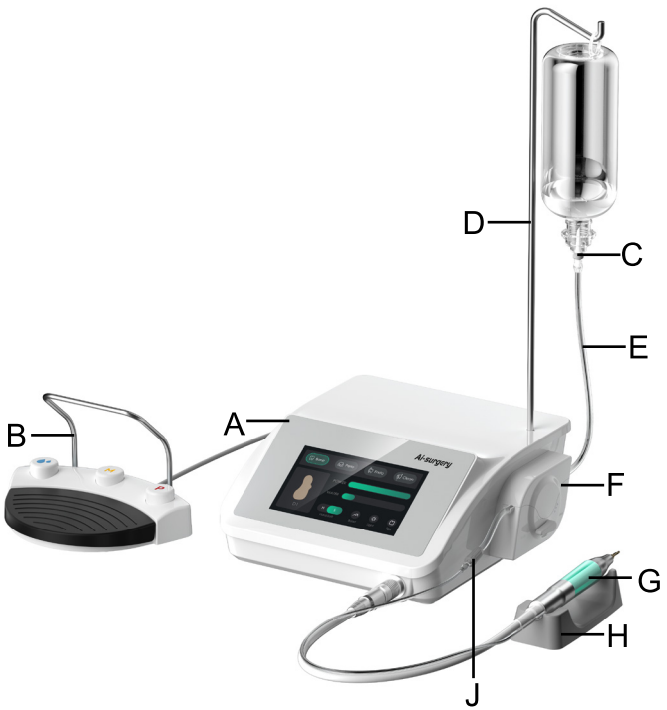
5. List of material included in the supply

The material included in the supply may vary in case of promotional campaigns.

Warning: Handpiece and cord can't be detached.

Name	Quality	Ref
Device	1	Fig.4—Ref.A
Multi-founction foot pedal	1	Fig.4—Ref.B
Normal saline connector	2	Fig.4—Ref.C*
Hook	1	Fig.4—Ref.D
Pump tube	8	Fig.4—Ref.E*
Peristaltic pump	1	Fig.4—Ref.F
Ai-surgery handpiece	2	Fig.4—Ref.G*

Name	Quality	Ref
Silicone handpiece holder	2	Fig.4—Ref.H*
Connection for the cord and tube of the peristaltic pump	4	Fig.4—Ref.J*
Torque wrench	1	Fig.4—Ref.K*
Sterilize box	2	Fig.4—Ref.L*
Tip Holder and Tips	Marked on the packing list	Fig.4—Ref.M*
Power-supply cable	1	Fig.4—Ref.N



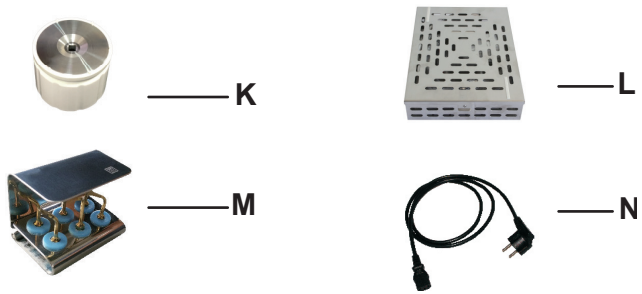


Fig.4

6. Installation

6.1 Safety requirements during Installation

Danger: The wiring system of the premises where the apparatus is installed and used must comply with the applicable standards and the relevant electrical safety requirements.

Danger: Do not install the apparatus in places where there is a risk of explosion. The apparatus may not be used in areas where there are inflammable atmospheres (anaesthetic mixtures, oxygen, etc).

Danger: Install the apparatus in a place where it will be protected from blows and from accidental sprays of water or other liquids.

Danger: Do not install the device on or in the vicinity of sources of heat. Install it such a way that there is an adequate circulation of air around it. Leave sufficient free space around it, in particular with reference to the fan on the rear. (Fig.6)

Warning: Do not expose the apparatus to direct sunlight or to sources of UV light.

Warning: The apparatus is transportable, however it must be handled with care when it is moved.

Warning: Before connecting the cord to the device, make sure that the electrical contacts are perfectly dry. If necessary, dry them with the air syringe.

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

Warning: The capacity of brine bottle hang on brine bottle holder

should not be more than 1000ml, and the weight should not exceed 1Kg.

6.2 Initial installation

To ensure perfect operation of the equipment, it is installed by technical personnel authorized by Woodpecker. The equipment will be installed in a suitable and handy place for it to be used.
The technician must:
6.2.1 Install the device in a suitable place;
6.2.2 Explain the main aspects of correct installation to the user;
6.2.3 Fill in the installation form, including the purchaser's data;
6.2.4 Send the installation form to Woodpecker to ensure traceability and activation of the warranty.

Fig.5

6.3 Connection the accessories

The accessories listed as follow should be connected with the Ai-surgery ：
6.3.1 Insert the silicone tube into the peristaltic pump, proceeding as follows:
a) Open the door(Fig.5—Ref.A)as far as it will go.
b) Position the tube in the impeller(Fig.5—Ref.B,C).
c) Close the door completely(Fig.5—Ref.D).

Danger: personnel injury.

The foot pedal of the Ai-surgery must not be activated when the door of the peristaltic pump open. (Fig.5—Ref.A).Moving parts could injure the operator.
6.3.2 Insert the rod for supporting the bag into the holes provided for it (Fig.6—Ref.A);
6.3.3 Connect the foot pedal to the casting of the device by inserting the plug into the foot pedal socket (Fig.6—Ref.E);
6.3.4 Plug the power cable into the connector on the casting of the device (Fig.6—Ref.D) and then into the power outlet;
6.3.5 Insert the tube of Ai-surgery cord to the cord connector on the device (Fig.6—Ref.B);
6.3.6 Connect end of the tube of the peristaltic pump;
6.3.7 Connect the flow-control system to the bag containing the appropriate liquid for the treatment;
6.3.8 Use the torque wrench to screw the tip (Fig.7) till the clattering voice;

6.3.9 Press the button “on/off” (Fig.6—Ref.C), then can use the device.

Fig.6

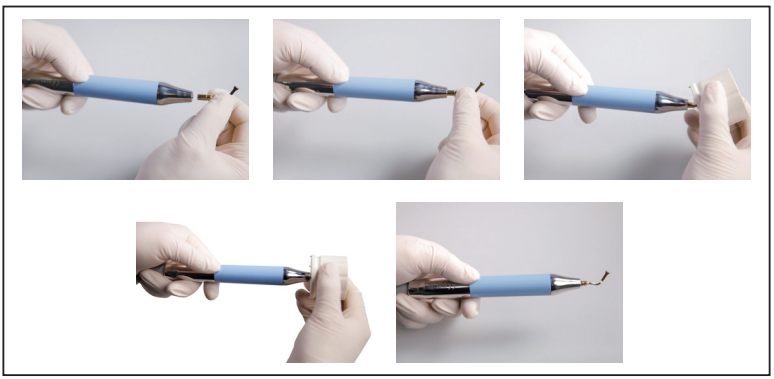


Fig.7

Fig.8

7. Controls

7.1 Description of the controls

This section illustrates the parts of the front panel of the Ai-surgery unit, enabling the controls described in this manual to be located immediately.

7.1.1 Description of bone function:

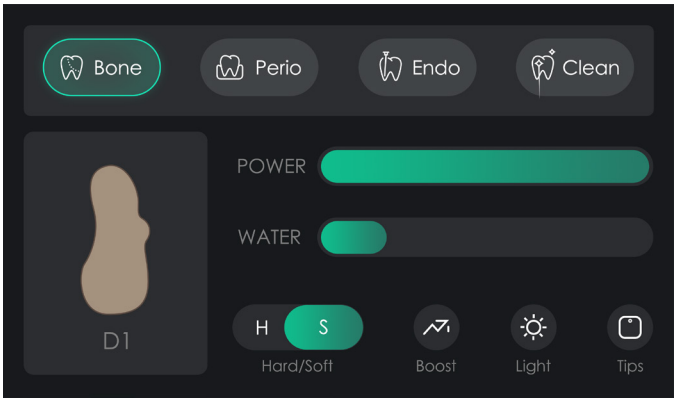


Fig9

As shown in Fig. 9, when the mode name "Bone " is selected in the green frame, the device is in bone cutting mode;In this mode, there are "power" and "water volume" that can be adjusted by sliding;Among them, the “power” in the 1~10 levels respectively correspond to the bone density pictures “D4~D1” on the left. In this interface, there is also the "H/S" key to switch the bone cutting depth: Surface cortical bone and deep cancellous bone;There is an "enhance" button, which can increase the current power by 30% with one button, which is convenient for efficiency improvement;There is a "light" button, which can switch the LED light on the handle;There is a "Settings" button for system settings and function introduction.

7.1.2 Description of perio function:

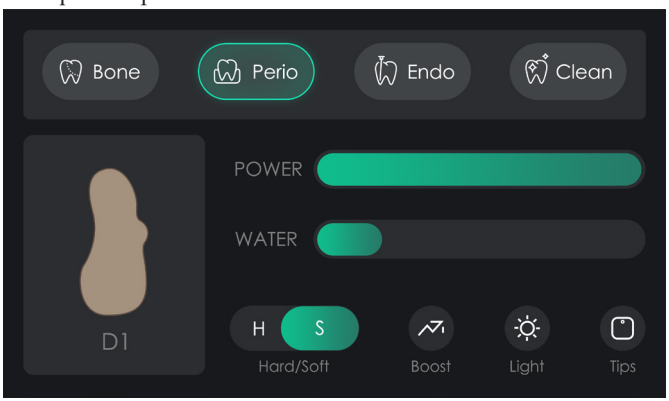


Fig.10

As shown in Fig. 10, when the mode name " perio " is selected in the green frame, the device is in periodontal mode; in this mode, the function buttons are in

the same bone cutting mode

7.1.3 Description of Endo function:

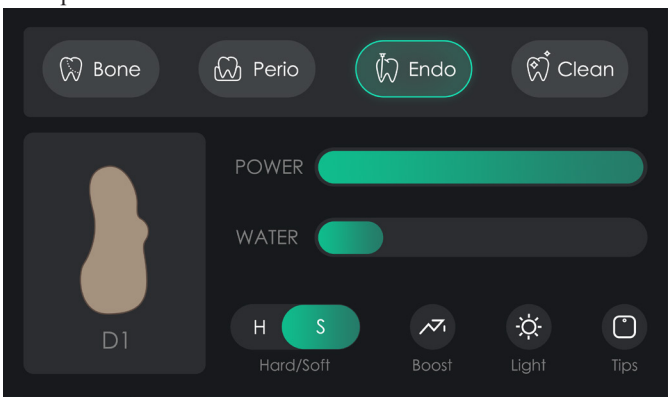


Fig.11

As shown in Fig. 11, when the mode name "Endo" is selected in the green frame, the device is in theEndo mode; in this mode, the function buttons are the same as the bone mode.

7.1.4 Description of clean function:

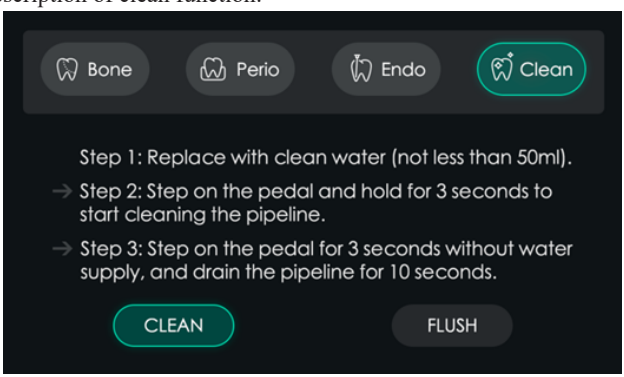


Fig.12

7.1.5 Description of Flush function:

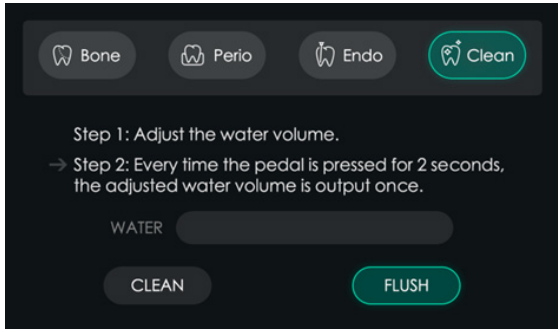


Fig.13

As shown in Figures 12 and 13, when the mode name "Clean" is selected in the green frame, the device is in the cleaning mode; in this mode, the device has only the water output function and no ultrasonic vibration is output; it is divided into the "cleaning mode" "And "Flush Mode". "Clean mode" shown in Figure 12, is used to flush the pipeline with clean water after the operation; "Flush mode" shown in Figure 13, can adjust the output of quantitative water each time you step on the pedal.

7.2 Description of the display and functions

There are three functions of bone root, clean for this Ai-surgery.

7.2.1 BONE function (Fig.8)

In bone function, both the water and power model are available.Ten power levels as follows:

a) Power 9-10: D1,Very high bone density

b) Power 6-8: D2,High bone density

c) Power 3-5: D3,Middle bone density

d) Power 1-2: D4,Low bone density

7.2.2 PERIO function (Fig.9)

In this function, both the water and power model are available, one model as follow:Perio.

7.2.3 ENDO function (Fig.10)

In this function, both the water and power model are available, one model as follow:Endo.

7.2.4 CLEAN function (Fig.11)

In this function, press the foot pedal, the device can clean the tube .(Recommend at least 25 seconds)

7.2.5 FLUSH function (Fig.12)

In this function, Step on the foot pedal once, out of a certain amount of water, water adjustable: The range is 0.5 ~ 5 ml/time .

7.3 Safety requirements during use.

Danger: Contraindications.

Do not use the Ai-surgery on patients with pacemakers or other implantable electronic devices. This requirement also applies to the operator.

Danger: Breakage and wear of the tips.

The high-frequency vibrations and wear may, very occasionally, lead to breakage of the tip. Tips of which the shape has been changed or which are otherwise damaged are liable to break during use. Any such tips should definitely not be used. It is necessary to instruct the patient to breathe through his nose during the treatment in order to avoid ingestion of the broken fragment of the tip.

Danger: Control of infections.

For maximum safety of both the patient and the operator, clean, disinfect and sterilize the piezo electronic handpiece, the tips and the torque wrench after each treatment.

Warning: Contraindication.

Do not carry out this treatment on metal or ceramic prosthetic artifacts. The ultrasonic vibrations could lead to decrementing of such artifacts.

Warning: Contraindication.

After autoclave sterilizing of the handpiece, wait for it to cool down completely before using it.

Warning: The electrical contacts inside the cord connector must be dry.

Before connecting the handpiece to the device, make sure the electrical contacts of the connector are perfectly dry, in particular after the autoclave sterilization cycle. If necessary, dry the contacts by blowing air onto them with the syringe.

Warning: To use the device correctly, it is necessary to press the foot pedal and start it up without letting the tip rest on the part to be treated. This will allow the electronic circuit to detect the point where resonance of the tip is without any interference, thus enabling optimum performance.

If this is not done, contact with the part to be treated or with other surfaces before start-up could cause tripping of the protection systems.

Warning: For spray treatment, use only tips through which liquid is passed.

7.4 Protection systems and alarms.

The device has a diagnostics circuit that is used to recognize tripping of the protection system and of the alarms. These are shown on the display, as follows:

Warning code	Warning description	Solution
Warn 01	The handle is not completely dry or reduced in performance	Please ensure that the handle is completely dry. If the alarm is not removed, replace the handle.
Warn 02	There is no reliable connection in the handle	Please reconnect the handle interface
Warn 03	Fan failure	Please call the Woodpecker service centre immediately.
Warn 04	Pump failure	Please call the Woodpecker service centre immediately.
Warn 05	Abnormal power failure	Please call the Woodpecker service centre immediately.
Warn 06	Abnormal handle or work tip loosening	Please reconnect the handle and tighten the working tips. If the alarm is not eliminated, please contact the local sales or woodpecker company.
Warn 07	Abnormality of bone cutting pattern	Please restart the device, if the problem persists, stop using it and call the Woodpecker service centre immediately.

7.5 Instruction for use

7.5.1 Open the air intake on the drip system;
7.5.2 Screw the chosen tip onto the Ai-surgery handpiece until it is flush against it;
7.5.3 To use the torque wrench correctly (Fig.7) proceed as follow;
a) Hold the body of the handpiece firmly;

⚠ Warning: Do not grip the end part of the handpiece or the cord, only the plastic casting (Fig.7) and do not turn it while fastening the tip in place;

b) Turn the wrench in a clockwise direction until the cultch engages (till making clicking sound);
c) The tip is now properly tightened in place;
7.5.4 Make sure that the Ai-surgery handpiece is correctly connected to the handpiece connector (Fig.6-Ref.B);
7.5.5 Check the display to see the type of power that has been set. If the type of power required different from the type that has been set, use key “M” on Multi-founction foot pedal to switch;
7.5.6 Check the display to see the power level that has been set, if the type of power required differs from the level that has been set, use the key “P”on Multi-

founction foot pedal for selecting, depending on the type of function that has been set;
7.5.7 Check the display to see the delivery rate of the peristaltic pump, if the delivery rate required is other than the level that has been set, use the key "Water"on Multi-founction foot pedal to choose, depending on the type of function that has been set.

7.6 Rules for keeping the device in proper working order

7.6.1 Check the state of wear of the tips periodically and replace any for which a drop in performance is noted;
7.6.2 Do not alter the shape of the tips by bending or filling them;
7.6.3 Replace any tip that has become deformed or damaged by impacts;
7.6.4 Always make sure that any threaded parts and their contact surfaces are perfectly clean;
7.6.5 If an tip becomes too worn, the device will stop working.

7.7 Settings permitted according to insert type

The following table shows the Mode and Power settings permitted for correct use of the device.

Insert	Mode	Power
SS1-SS2-SS3-SS4-SS5-SS6-SS1L-SS1R	BONE	Power1-Power10
SL1-SL2-SL3-SL4-SL5	BONE	Power1-Power10
SC1	BONE	Power1-Power10
SI1-SI2-SI7-SI8-SI9	BONE	Power1-Power10
SP1-SP2-SP3-SP4-SP5-SP6-SP7	Perio	Power1-Power10
SE1-SE2-SE3-SE4	Endo	Power1-Power10

7.8 When the equipment is finished, turn off the power switch, press the button "off" (Fig.6—Ref.C), then remove the power plug.

8. Cleaning, Disinfection and Sterilization

The cleaning, disinfection and sterilization of handpiece, Torque wrench,Pump tube, Brine bottle connector,Connection for the cord and tube of the peristaltic pump,tips,tip holder,Silicone handpiece holder and Sterilize box are as follow. Unless otherwise stated, they will be hereinafter referred to as “products”.

Warning:

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 shall not be exposed to high temperature above 138℃.

Processing limit:

The products have been designed for a large number of sterilization cycles. The materials used in manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products.

The maximum recommended sterilization times for pump tube is 8 times; the maximum allowable sterilization times for handpiece and Silica gel support for the handpiece is 100 times; the maximum allowable sterilization times for tip is 300 times; the maximum allowable sterilization times for connection for the cord and tube of the peristaltic pump, brine bottle connector, support for the handpiece, torque wrench and surgical tray is 300 times.

8.1 Initial processing

8.1.1 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.

8.1.2 Post-operative treatment

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.Ultrasonic bone surgery is operated in flushing mode for 20-30 seconds to flush the handpiece and tip;

2.Remove the handpiece from the Ultrasonic bone surgery, and rinse away the dirt on the surface of the products with pure water (or distilled water/deionized water);

Note:

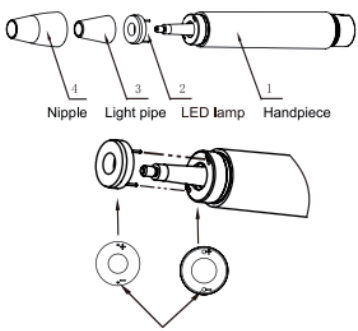
1)The package used conforms to ISO 11607;

2)It can withstand high temperature of 138 °C and has sufficient steam

permeability;
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.

8.2 Preparation before cleaning

Tools: Ultrasonic bone surgery torque wrench, tray, soft brush, clean and dry soft cloth
1.Adjust the machine to the cleaning mode, step on the pedal for 3s to start the cleaning procedure;
Note:
a) Pure water, distilled water or deionized water should be used at this time.
2. Screw the handpiece interface sealing sleeve of the machine into the interface to ensure that the interface is not eroded by water;
3.Remove the tip from product with Ultrasonic bone surgery torque wrench provided by Guilin Woodpecker Medical Instrument Co., Ltd, and then put the tip and torque wrench into a clean tray.
4.Unscrew the nipple at the front end of the handpiece in a counterclockwise direction, remove the light pipe and LED lamp, and put them into the tray.
5.Use a clean soft brush to carefully brush the front thread, horn, nipple, light pipe and LED lamp until the dirt on surface is not visible. Then use soft cloth to dry the handpiece and accessories and put them into a clean tray. The cleaning agent can be pure water, distilled water or deionized water.
Disassembling steps



8.3 Cleaning

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

• The cleaner is proved to be valid by CE certificationin accordance 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 products, and the flushing period is sufficient.
• Do not clean the handpiece 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».
Note:
a)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 products.
b)In washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it would be difficult to remove.
c)After cleaning, the chemical residue should be less than 10mg / L.

8.4 Disinfection

Disinfection must be performed no later than 2 hours after the cleaning phase. Automated disinfection is preferred if conditions permit.
8.4.1 Automated disinfection-Washer-disinfector
• The washer-disinfector is proved 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 products into the disinfection basket. Fixation of products is needed only when the product is removable in the device. The products are not allowed to contact each other.
2.Connect the inner cavity of the product to the flushing connection of the washer-disinfector with a proper cleaning connector.
3.Start the program.
4.After the program is finished, remove the products from the washer-disinfector, inspect (refer to section «Inspection and Maintenance») and packaging (refer to chapter «Packaging»). Dry the products repeatedly if necessary (refer to section «Drying»).
Note:
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 products 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 temperature should not exceed 45 °C, otherwise the protein will solidify and it is difficult 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 ≥ 3000;
Sterilize it after disinfection and use: temperature ≥ 90 ° C, time ≥ 1 min or A0 ≥ 600
(b) The disinfection temperature used here is 93 ℃, 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.

8.5 Drying

If your cleaning and disinfection process does not have an automatic drying function, dry it after cleaning and disinfection.
Methods:
1.Spread a clean white paper (white cloth) on the flat table, point the products against the white paper (white cloth), and then dry the products with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the products 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.
Note:
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.

8.6 Inspection and maintenance

In this chapter, we only check the appearance of the products. After inspection, if there is no problem, the handpiece should be immediately reassembled, installing the LED, light guide, and cone head in sequence to the handpiece, and then tighten the cone head clockwise.
1. Check the products. If there is still visible stain on the products after cleaning/disinfection, the entire cleaning/disinfection process must be repeated.
2. Check the products. 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 products. 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 of times) of the products reaches the specified service life (number of times), please replace it in time.

8.7 Packaging

Install the disinfected and dried products and quickly package it in a medical sterilization bag (or special holder, sterile box).
Note:
1)The package used conforms to ISO 11607;
2)It can withstand high temperature of 138 °C and has sufficient steam permeability;
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.

8.8 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.
Note:
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 suitability 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.

8.9 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.
Note:
1)The storage environment should be clean and must be disinfected regularly;
2)Product storage must be batched and marked and recorded.

8.10 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 main unit are as follows:
• Before each use, wipe the surface of the machine and the tail cord of the handpiece with a soft cloth or paper towel soaked in 75% medical alcohol. Repeat the wiping for at least 3 times.
• Before each use, please let the Ultrasonic Periodontal Treatment Device work under irrigation mode for 20-30s, and then install the handpiece.
• After each use, please let the Ultrasonic Periodontal Treatment Device work under irrigation mode for 20-30s, and then remove the handpiece.
• After each use, wipe the surface of the device and the tail cord of the handpiece with a soft cloth soaked in clean water (distilled or deionized water) or a clean disposable wipe. Repeat the wiping for at least 3 times.

9. Regular maintenance

9.1 handle this device gently, keep away from the shake source, and should

install and store in shade.
9.2 Do not mix with poison, causticity, explosive and combustible things together.
9.3 This equipment should be stored in a room where the relative humidity is 10% ~ 93%, atmospheric pressure is 70kPa to106kPa, and the temperature is -20℃ ~ +55℃.
9.4 If the device is not used for a long time running, it is better to connect the electricity and water one time per month, 5 minutes per time.
9.5 disconnect the device from the power mains.

Danger: Check regularly that the power cable is intact, if it is damaged, replace it with an Woodpecker spare.

10. Replacement of the fuses

Danger: Switch off the apparatus.

Always turn off the apparatus by means of the switch (Fig.5-Ref.B) and disconnect it from the power outlet before carrying out the following maintenance activities.
10.1 Insert the flat tip of a screwdriver into the recess in the fuse compartment below the power socket and use it as a lever (Fig.12-Ref.A);
10.2 Pull out the fuse compartment(Fig.12-Ref.B);
10.3 Danger: Replace the fuses, using fuses of the type indicated on the identification label on the bottom of the apparatus;
10.4 Put the compartment back into place (Fig.12-Ref.B).

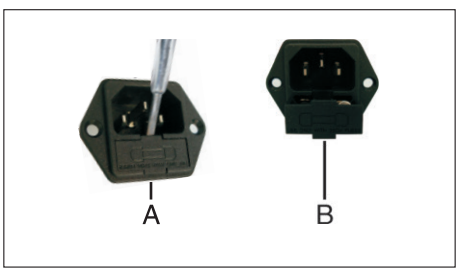


Fig.12

11. Disposal procedures and precautions

Danger: Hospital waste

Treat the following items as hospital waste
- Tips, when worn or broken.
- Tube of the peristaltic pump, after 8 sterilizing cycles.
- Torque wrench for tightening tips, when worn or broken.

12. Tips

12.1 Sharp tips

The sharp edges of these tips can be used to treat bone structures efficiently and effectively. Sharp tips are used in osteotomy and osteoplasty when a fine and well-defined cut in the bone structure concerned it required, there are also tips with sharp edges for osteoplasty techniques and for removing bone fragments.

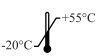
12.2 Smoothing tips

The smoothing tips have surfaces shaped in such a way that they can be used to work the bone structures with precision and in a controlled manner. Smoothing tips are used in osteotomy when it is necessary to prepare difficult and delicate structures such as those for preparing a maxillary sinus window or to complete preparation of the site of an implant.

12.3 Blunt tips

Blunt tips are used for separating the soft tissues, for example for detaching schneider's membrane or for lateralizing nerves. In periodontology, these tips are used to smooth the root surfaces.

13. Symbols

	Follow instructions for use		Use indoor only
	Alternating current		Socker for the foot switch
	Manufacturer	IPX1	Drip-proof
	Can be autoclaved		Date of manufacture
	Protective earthing		Caution mechanical injury
	1.6A, 250V Pwtective tube		Type B applied part
SN	Serial number	CE 0197	CE marked product
	Atmospheric pressure for storage		Temperature limitation for storage

Humidity limitation for storage

Appliance compliance WEEE directive

IPX6

Strong water spraying experiment

100–240V~

Input voltage

EC REP

Authorised Representative in the EUROPEAN COMMUNITY

14. Troubleshooting

If the device does not seem to be working properly, read the instruction again and then check the following table:

Problem	Possible cause	solution
The device does not turn on when the switch it positioned on ON.	The connector on the end of the power cable is plugged into the socket on the rear of the device properly.	Check that the power cable is firmly connected.
	The power cable is faulty.	Check that the power outlet is working properly. Replace the power cable.
	The fuses blew out.	Replace the fuses.
The connector on the end of the power cable is plugged into the socket on the rear of the device properly.	The connector of the foot pedal is not properly plugged into the socket.	Insert the foot pedal connector properly.
	The foot pedal will not work.	Contact the nearest dealer or authorized Woodpecker service centre.
A faint whistle can be heard coming from the Surgery-X Pro handpiece during operation.	The tip is not correctly tightened onto the handpiece.	Unscrew the tip and screw it back into place correctly.

Problem	Possible cause	solution
The device is switched on but does not work, the message WARN appears on the display.	The tip is not fitted correctly into the handpiece.	Unscrew the tip and screw it back into place correctly.
	The tip is worn, broken or deformed.	Replace the tip.
	The connector of the cord is wet.	Dry the connectors.
The device is switched on but will not work, the message WARN appears on the display.	Cord not connected to the device.	Connect the cord to the device.
	Lack of continuity of a lead in the cord.	Contact the nearest dealer or authorized Woodpecker service centre.
	Handpiece failure.	Contact the nearest dealer or authorized Woodpecker service centre.
	Malfunctioning of the tuning circuit.	Contact the nearest dealer or authorized Woodpecker service centre.
No liquid comes out of the tip during operation.	The tip is of the type with no through-flow of liquid.	Use an tip of the type with through-flow of liquid.
	The bag of liquid is empty.	Replace the bag with a full one.
	The cover of pump that connected with the water tube is open.	Close the cover.
	The tubes of the drip system and of the pump have not been correctly installed.	Check the connections of the tubes.
	The tip is clogged.	Free the passage in the tip through which the water passes.

Problem	Possible cause	solution
No liquid comes out of the tip during operation.	The handpiece is clogged.	Contact the nearest dealer or authorized Woodpecker service centre.
The device is working properly, but the pump is being forced.	Too much pressure by the impeller on the tube in the peristaltic pump.	Check that the tube in the peristaltic pump has been correctly inserted.
The pump is running correctly but when it stops liquid comes out of the handpiece.	The door of the peristaltic pump is not closed properly.	Make sure that the door of the peristaltic pump is properly closed.
Insufficient power.	The tip is not correctly fitted to the handpiece (the message WARN appears on the display).	Unscrew the tip and screw it back into place correctly.
	The tip is worn, broken or deformed (the message WARN appears on the display).	Replace the tip.
LCD screen mess or imcomplete display.	Voltage interference.	Stop any operation, change the model then return to the original model or restart the machine.

15. Technical data

15.1 Device in accordance with Directive 93/42EEC.
15.2 According to EN60529: IPX1 (device)
IPX6 (foot pedal)
15.3 Software version: BoneSurgical3-V1.0.0
15.4 Device for intermittent operation: 60s ON, 10s OFF
15.5 Power-supply voltage: ～100V-240V 50Hz/60Hz 170VA
15.6 Fuses: 2×1.6AT 250V
15.7 Working frequency: 24kHz～36kHz
15.8 Flow: 25～110ml/m
15.9Applied parts: Tips
15.10 Protection systems and tripping time of the APC:

No handpiece connected: 10ms
Cord interrupted: 10ms
Tips broken or not correctly tightened: ＜500ms
Protection by discharge to earth: 10ms
15.11 Alarm: Front display show the e (see point 7.3 and 14)
15.12 Operation environment:
a) Environment temperatuer: +5°C～+40°C
b) Relative humidity: 30%～75%
c) Atmosphere pressure: 70kPa～106kPa
d) Temperature in the water inlet of water-cooling equipment is not higher than 25°C
15.13 Delivery and store environment: This equipment should be stored in a room where the relative humidity is 10% ～ 93%, atmospheric pressure is 70kPa to106kPa, and the temperature is -20℃ ~ +55℃.
15.14 Pump tube: less than 8 sterilization cycles is highly recommended
15.15 Size of main unit: 276 mm×267 mm×110mm
15.16 Weight of main unit: 2.8kg
15.17 Type of protection against electric shock: Class Ⅰ equipment
15.18 Degree of protection against electric shock: Type B applied part

16. After service

We offer two year, free repair to the equipment according to the warranty card. The repair of the equipment should be carried out by our professional technician. We are not responsible for any irretrievable damage caused by the non-professional person.
Woodpecker state that the we can provide circuit diagrams, component lists, drawings, calibration details, or other information to help maintenance personnel repair Ai-surgery components that can be repaired by maintenance personnel designated as required.

17. Environmental protection

Please dispose according to the local laws.

18. Manufacturer's right

We reserve the right to change the design of the equipment, the technique, fittings, the instruction manual and the content of the original packing list at any time without notice. If there are some differences between blueprint and real equipment, take the real equipment as the norm.

19.Guarantee

19.1 Before being placed on the market, all WOODPECKER equipment

undergoes a thorough final check to ensure that it is are in proper working order.

19.2 WOODPECKER guarantees its products, purchased new from a WOODPECKER dealer or importer, to be free from manufacturing or material defects for:

-TWO YEAR from the date of purchase for the device;
-ONE YEAR from the date of purchase for the handpiece with its cord.

19.3 Throughout the warranty period, WOODPECKER undertakes to repair (or, at their sole discretion, to replace) free of charge any parts that, in their opinion, are faulty.

Complete replacement of WOODPECKER products is excluded

19.4 Woodpecker cannot accept any liability for direct or incidental damage or personal injury in the following cases:

19.4.1 If the equipment is used for purposes other than that for which it is intended;
19.4.2 If the equipment is not used in accordance with all the instruction and requirement described in this manual;
19.4.3 If the wiring system in the room where the equipment is used does not comply with the applicable standards and appropriate requirements;
19.4.4 If any assemble operations, extensions, settings, alterations or repairs have been carried out by personnel not authorized by Woodpecker;
19.4.5 If the environmental conditions in which the device is kept and stored do not comply with the requirements indicated in the chapter on technical specifications.

19.5 Accidental damages due to transport, incorrect use or carelessness or to connection to power supplies other than as envisaged and damage to the signaling lamps handpiece and all accessories are excluded from the warranty.

The warranty will no longer apply if the apparatus has been tampered with or repaired by unauthorized personnel.

19.6 Warning:

The warranty is valid only if the warranty slip enclosed with the product has been completed in full and returned to us or, if appropriate, to your WOODPECKER dealer or importer within 20 days from the date of purchase, as proven by the consignment note/invoice issued by the dealer/importer.
In order to benefit from the warranty service, the customer must return the apparatus to be repaired to the WOODPECKER dealer/importer from which it was purchased, at his own expense.

19.7 The apparatus should be returned suitable packed (possibly in its original packing material).

19.8 Accompanied by all the accessories and by the following information:

19.8.1 Owner's details, including his telephone number;
19.8.2 Details of the dealer/importer;
19.8.3 Photocopy of the consignment note/purchase invoice of the apparatus issued to the owner and indicating, in addition to the date, also the name of the apparatus and its serial number;
19.8.4 A description of the problem.

19.9 Transport and any damages caused during transport are not covered by the warranty

In the event of failure due to accidents or improper use, or if the warranty has lapsed, repairs to WOODPECKER produces will be charged on the basis of the actual cost of the materials and labour required fro such repairs.

20. Statement

This is to certify that all the functions of the equipment have been tested rigidly. All the functions run normally. In special condition, abnormal phenomenon may happen due to the unavoidable interference.
In the equipment, power network or static interference may make the display screen display white flake. This phenomenon does not influence the operation of normal functions. Solvents: Stop the equipment, press the top-right key-press on the display panel to change the display of screen, then return. Thus the equipment can display normally. Or turn off the power supply, restart the equipment.

WOODPECKER, any copy or fake product must take legal responsibilities.

21.Declaration of comformity-EMC

Guidance and manufacturer's declaration - electromagnetic emissions		
The models Ai-surgrey, Surgic smart are intended for use in the electromagnetic environment specified below. The customer or the user of the models Ai-surgrey, Surgic smart should assure that they are used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**

RF emissions CISPR 11	Group 1	The models Ai-surgrey, Surgic smart use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The models Ai-surgrey, Surgic smart are suitable for used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions lEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions lEC 61000-3-3	Complies	

Guidance & Declara tion — electromagnetic immunity			
The models Ai-surgrey, Surgic smart are intended for use in the electromagnetic environment specified below. The customer or the user of the models Ai-surgrey, Surgic smart should assure that they are used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV 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 transienUburst IEC 61000-4-4	±2kV for power supply lines ±1 kV 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 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	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 % U_T (>95% dip in U_T.) for 0.5 cycle <5 % U_T (>95% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles <5% U_T (>95 % dip in U_T) for 5/6 sec	<5 % U_T (>95% dip in U_T.) for 0.5 cycle <5 % U_T (>95% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles <5% U_T (>95 % dip in U_T) for 5/6 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models Ai-surgrey, Surgic smart require continued operation during power mains interruptions, it is recommended that the models Ai- surgrey, Surgic smart be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance & Declaration - Electromagnetic immunity			
The models Ai-surgrey, Surgic smart are intended for use in the electromagnetic environment specified below. The customer or the user of the models Ai-surgrey, Surgic smart should assure that they are used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

Conducted RF IEC 61000-4-6 Radiated RF lEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands 10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specification s for ENCLOSURE PORT IMMUNITY to RF wireless communicati on equipment (Refer to table 9 of IEC 60601-1-2:2014)	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands 10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specification s for ENCLOSURE PORT IMMUNITY to RF wireless communicati on equipment (Refer to table 9 of IEC 60601-1-2:2014)	Portable and mobile RF communications equipment should be used no closer to any part of the models Ai- surgrey, Surgic smart, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $=[3,5/V_1]\times P^{1/2}$ $d=1.2\times P^{1/2}$ 80 MHz to 800 MHz $d=2.3\times P^{1/2}$ 800 MHz to 2.5 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 and 800 MHz. the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the models Ai-surgrey, Surgic smart is used exceeds the applicable RF compliance level above, the models Ai-surgrey, Surgic smart should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the models Ai- surgrey, Surgic smart.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the models Ai-surgrey, Surgic smart

The models Ai-surgrey, Surgic smart are intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the models Ai-surgrey, Surgic smart can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the models Ai-surgrey, Surgic smart are 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 $d=1.2\times P^{1/2}$	**80MHz to 80MHz** $d=1.2\times P^{1/2}$	**800MHz to 2.5GHz** $d=2.3\times P^{1/2}$
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 the transmitter manufacturer.

NOTE 1 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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for more information

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