WOODPECKER

Surgic Touch（LED）

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 Surgic Touch(LED) near equipment that releases magnetic waves.
Surgic Touch(LED) 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 Surgic Touch(LED) , 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 Surgic Touch (LED) 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 Surgic Touch (LED) 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 Surgic Touch (LED) 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 Surgic Touch (LED) 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).

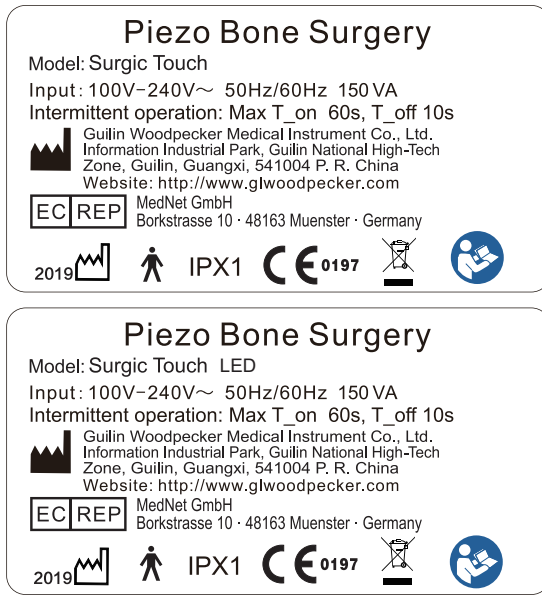


Fig.1

2.3 Data plate of the scaler handpiece

The serial number of the Surgic Touch (LED) 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
Surgic Touch (LED) handpiece complete with cord	2	Fig.4—Ref.G
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

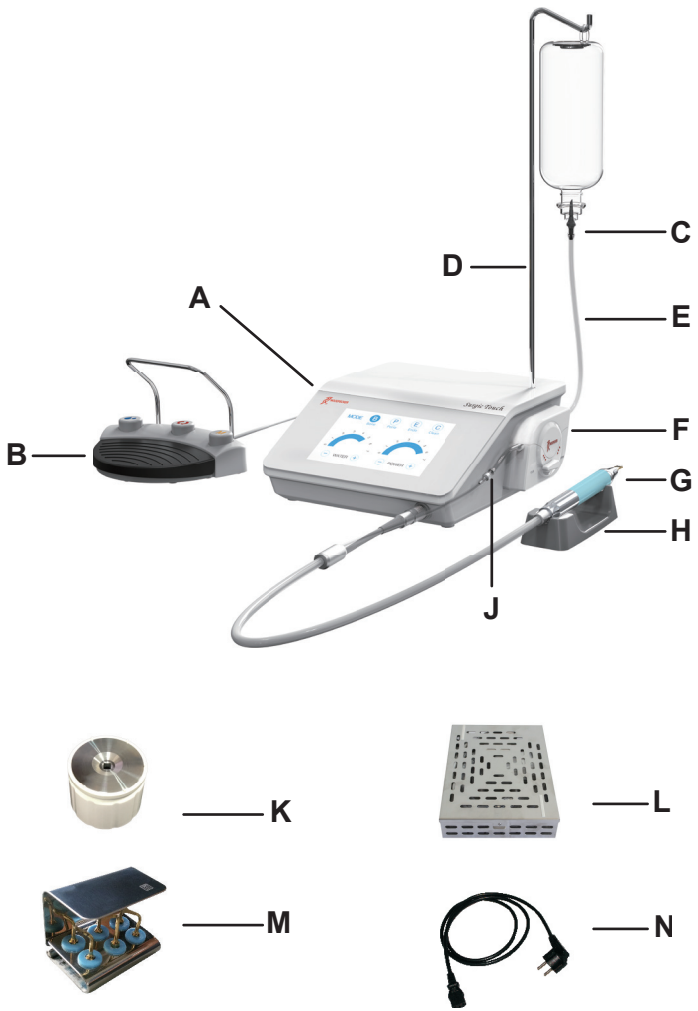


Fig.4

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.

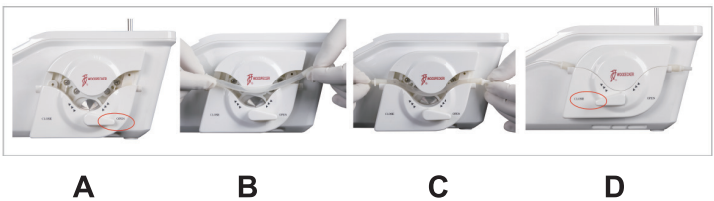


Fig.5

6.3 Connection the accessories

The accessories listed as follow should be connected with the Surgic Touch (LED):
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 footswitch of the Surgic Touch (LED) 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 footswitch to the casting of the device by inserting the plug into the footswitch 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 Surgic Touch (LED) 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.

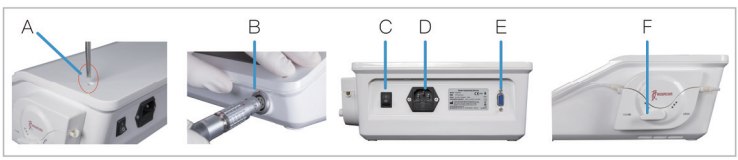


Fig.6

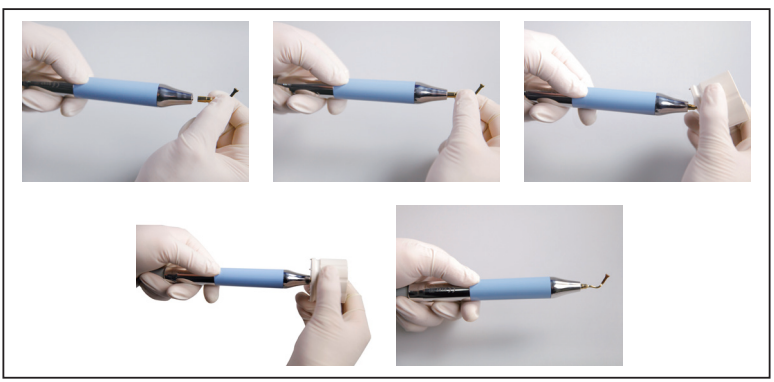


Fig.7

7. Controls

7.1 Description of the controls

This section illustrates the parts of the front panel of the Surgic Touch (LED) unit, enabling the controls described in this manual to be located immediately.

7.1.1Description of bone function:

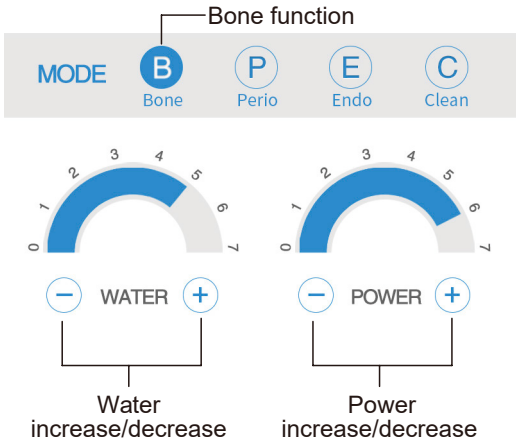


Fig.8

7.1.2 Description of perio function:

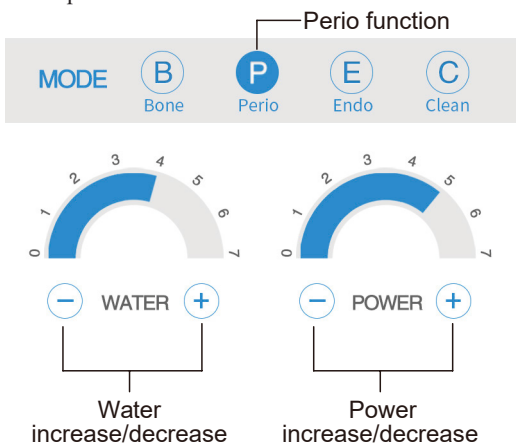


Fig.9

7.1.3 Description of Endo function:

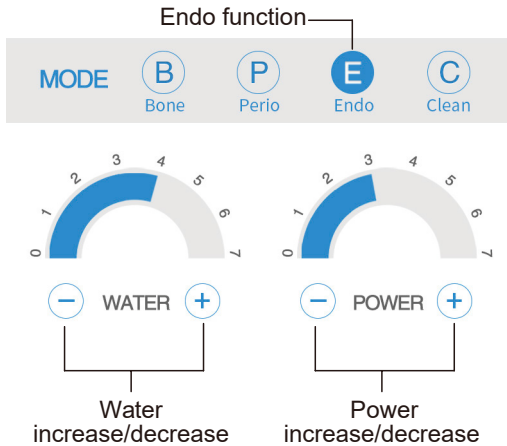


Fig.10

7.1.4 Description of clean function:

Fig.11

7.2 Description of the display and functions

There are three functions of bone root, clean for this Surgic Touch (LED).

7.2.1 BONE function (Fig.8)

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

a)Power 6-7: Very high bone density

b)Power 4-5: High bone density

c)Power 3-4: Middle bone density
d)Power 2-3: Low bone density
e)Power 1: Very 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.
7.2.2 ENDO function (Fig.10)
In this function, both the water and power model are available, one model as follow:Endo.
7.2.3 CLEAN function (Fig.11)
In this function, press the footswitch, the device can clean the tube .(Recommed at least 25 seconds)

7.3 Safety requirements during use.

Danger: Contraindications.

Do not use the Surgic Touch (LED) 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 footswitch 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.

Warning code	Warning description	Solution
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 Surgic Touch (LED) 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 Surgic Touch (LED) 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
US1-US2-US3-US4-US5-US6-US1L-US1R	BONE	Power1-Power7
UL1-UL2-UL3-UL4-UL5	BONE	Power1-Power7
UC1	BONE	Power1-Power1
UI1-UI2-UI7-UI8-UI9	BONE	Power1-Power7
UP1-UP2-UP3-UP4-UP5-UP6-UP7	Perio	Power1-Power7
UE1-UE2-UE3-UE4	Endo	Power1-Power7

8. Cleaning ,disinfection, Sterilization and maintenance

8.1 Preparation

Basic principles

It is only possible to carry out effective sterilization after the completion of effective cleaning . 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 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. This applies especially with regard to the additional requirements for the inactivation of prions.
Our methods of cleaning and sterilization are verified to be effective.The cleaning and sterilization procedure apply to the accessories .

8.2 Cleaning :Automated Cleaning

Notice: tips, tip holder, torque wrench, pump line, handpiece holder, silicone handpiece holder, and pump line connector can be automated cleaning with a washer-disinfector.
Thermal disinfection should be used if this function is available on your washer-disinfector.Use if possible a disinfecting cycle compliant with the standard EN ISO 15883.
Note that there is a risk of disinfectant residue on products when using chemical disinfectants.
Ensure the following criteria are met when selecting a washer-disinfector system:
• Washer-disinfector is proven effective through testing (e.g. FDA approved or CE marked / EN ISO 15883 compliant).
• Washer-disinfector has suitable baskets to hold small fragile products and has rinsing connections for the attachment to product lumina.
• The cleaning program is suitable for products to be processed and the rinsing cycle is sufficient.
• Only low microbe count (<10 cfu/ml) distilled or deionized water is used for all rinsing steps. (E.g. Aqua purificata, as per the specifications of Pharm. Eur. or USP).
Washer-disinfectoris serviced and checked on a regular basis.
8.2.1 Steps for automated cleaning with a washer-disinfector
a. Carefully place the products in the disinfection basket. Fastening of the products is only permissible if they are freely moveable in the fixture. The products are not permitted to make contact with one another.

b. Using a suitable rinsing adaptor, connect the product lumina to the rinsing connections of the disinfector.
c. Start the program.
d. Remove the products from the disinfector and start the inspection (see section Inspection and maintenance) after the program ends.
e. Wrap the products directly fol lowing disinfection and drying (see section Packaging and sterilization). If necessary, repeat drying of the product in a clean place.
Sequence and parameters applicable to the cycle:
- 3 mins., Pre-wash with cold water;
- 5 mins., Washing with 0,5% neutral pH detergent at 45°C;
- 2 mins., Rinsing with tap water;
- 2 mins., Rinsing with cold demineralised water;
- 5 mins., Thermodisinfection at 93°C with demineralised water.
The automated thermodisinfection was not experimentally tested. According to standard ISO 15883-1, Table 2.1 [4] the thermodisinfection at a temperature of 90°C for 5 mins. determines an A0 value of 3000);
WARNING: The automatic cleaning cycle, as described above, must always be preceded by the manual cleaning steps.
8.2.2 Auto Cleaning Mode to clean pipeline
a) Change the bag containing water (demineralized water is recommended);
b) Check whether the water system is connected correctly;
c) Start the CLEAN function (Fig.11);
d) Press the footswitch to start the cleaning cycle, as soon as the peristaltic pump starts up, a status bar will appear on the display to indicate progressively the time remaining to completion of the tempo CLEAN cycle. The cycle lasts for 25 seconds and cannot be stopped;
e) Once the cleaning cycle has been completed, the device exits from the CLEAN function and returns to BONE function (Fig.9);
f) On completion of the cleaning operations, empty the tubes and dry the accessories that have been through the cleaning cycle.

8.3 MANUAL PROCEDURE

When selecting the cleaning agent to be used, ensure that:

• These are fundamentally suitable for the cleaning of the products and compatible with one another,

• The detergent agent holds a tested effectiveness (e.g. DGHM, FDA approval or CE marking),

• The chemicals used are compatible with the products.

It is absolutely essential that the concentrations and contact times specified by the manufacturer of the detergent agent(Medical multienzyme detergent(Protease, phospholipase, etc.)) are adhered to. Only freshly prepared solutions may be used. The detergent solution is not permitted to foam.Only sterilized or low microbe count distilled/deionized water (< 10 cfu/ml) can be used for all rinsing steps. Also ensure the presence of a sufficiently low endotoxin and particle concentration (e.g. Aqua purificata, as per the specifications of Pharm. Eur. or USP).

Steps for manual cleaning

a. Completely disassemble the tip and endochuck from the handpiece , if applicable.

b. Place the products in the cleaning solution for at least the minimum the time and the concentration specified by the manufacturer of the detergent agent.

c. Remove any externally-attached soiling by brushing carefully with a soft brush or a soft cloth.

d. Rinse the products vigorously at least five times, each time with fresh distilled or deionized water (each product lumen with at least 50 ml of water). Repeat the cleaning process if the last rinsing does not run clear, or if stains are still visible on the product.

8.3.1 Cleaning and disinfection of handpiece

Warning:Never place the components in a washer-disinfector, autoclave or ultrasonic bath.

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

Warning:Only use surface disinfectants that are certified by officially recognized

institutes, do not contain chlorine and have been declared aldehyde-free.
Warning:The handpiece to be Cleaned and disinfected before each use.
For cleaning and disinfection proceed follows:

#	Action
1	**Separate the handpiece from the main unit, thoroughly surfaces with a soaked wipe.**
2	**After any pre-cleaning, lightly soak a paper tissue or soft cloth in a mild, aldehyde-free disinfection and cleaning solution (bactericidal and fungicidal) and use it to clean/disinfect all components.**
3	**Thoroughly disinfect surfaces with a soaked wipe (min. 30 seconds), making sure the entire surface is wetted, and allow to act (contact time > 30 minutes). If large surfaces have to be treated, use more than one wipe where necessary.**

8.4 INSPECTION AND MAINTENANCE

If stains are still visible on the product after cleaning, the entire cleaning procedure must be repeated. Products with visible damage, chip/flake loss, corrosion or bent out of shape must be disposed of (no further use is permissible)

8.5 PACKAGING AND STERILIZATION

Warning:Can be cleaned and sterilized by any neutral sterilized liquid ,Do not immerse the handpiece or the cords in a disinfectant solution as this may damage them. Do not sterilize under the high temperature and pressure.
Notice:handpiece: tips, tip holder, torque wrench, handpiece holder, silicone handpiece holder and sterilization box can be sterilized with Steam sterilizer.
Only cleaned and disinfected products are permitted to be sterilized. Prior to sterilization, the products need to be placed in a suitable sterilization container:

- Compliant with EN ISO 11607,
- Resistant to 134°C, with adequate steam permeability,
- Maintained on a regular basis.

If double, single-use sterilization packaging (double bag) is to be used, this

must also comply with EN ISO 11607 and be suitable for steam sterilization (temperature resistant to 134°C with adequate steam permeability).

Use only the following listed steam sterilization procedures for sterilization; other sterilization procedures are not permissible:

• Fractional pre-vacuum procedure*

* Fractional pre-vacuum procedure = steam sterilization with repetitive pre-vacuum.

• Steam sterilizer in accordance with EN 13060 or EN 285 validated in compliance with EN IS0 17665,

• Maximum sterilization temperature 134°C,

• Sterilization time 4 min. at 132/134°C (fractional pre-vacuum procedure),

• Sterilization at 134°C for a maximum of 20 minutes is permissible.

Verification of the fundamental suitability of the products for effective steam sterilization was provided by an independent, accredited testing laboratory for use of the fractionated vacuum procedure.

The hot-air sterilization and radio-sterilization procedure may not be used (as it causes the destruction of products).

The manufacturer assumes no responsibility for the use of other sterilization procedures (e.g. ethylene oxide, formaldehyde and low temperature plasma sterilization). In such cases, please observe the respective valid standards (EN IS0 14937/ANSI AAMl IS0 14937 or the procedure-specific standard) and verify the suitability and effectiveness in principle of the procedure (if necessary, including investigations on sterilizing agent residue), taking into account the specific product geometry as part of the validation.

SERVICE LIFE

The products have been designed for a large number of sterilization cycles. The materials used in their manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products. If the number of permissible re-sterilization cycles is restricted, this will be pointed out in the product specific instructions. The use of ultrasound baths and strong cleaning and disinfection fluids (alkaling pH > 9 or acid pH < 5) can reduce the life span of products. The manufacturer accepts

no liability in such cases.

The products may not be exposed to temperatures above 134°C.

The following sterilization ways for handpiece, torque wrench, pump line, handpiece holder, silicone handpiece holder and pump line connector are forbidden:

a) Soaked in solution.

b) Dip in iodine, alcohol or glutaraldehyde.

c) Torrefy in oven or microwave oven.

Notice: We are not responsible for any damage directly or indirectly made by any way in the above items.

8.6 Cleaning the Main Unit and the Foot Pedal

1) Turn OFF the power and disconnect the AC power cord from the wall power socket.

2) Wipe the surface, first with a moist cloth, then with an alcohol soaked cloth.

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).

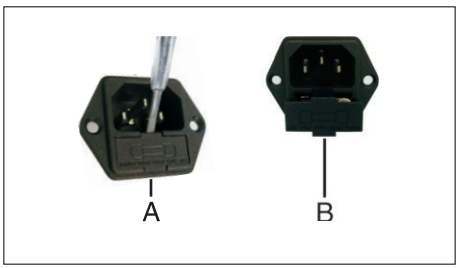


Fig.12

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.

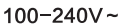
12.3 Blunt tips

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

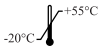
WOODPECKER ®	Mark		Use indoor only
	Follow instructions for use	IPX1	Drip-proof
~	Alternating current		Socker for the foot switch
	Manufacturer		Date of manufacture
	Caution		Caution mechanical injury
134°C	Can be autoclaved		Type B applied part
	Protective earthing	CE 0197	CE marked product
IPX6	Strong water spraying experiment	SN	Serial number

1.6A, 250V Pwtective tube



Input voltage

Atmospheric pressure for storage



Temperature limitation for storage

Humidity limitation for storage

Appliance compliance WEEE directive

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 footswitch is not properly plugged into the socket.	Insert the footswitch connector properly.
	The footswitch will not work.	Contact the nearest dealer or authorized Woodpecker service centre.
A faint whistle can be heard coming from the Surgic Touch (LED) 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 (footswitch)

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 150VA

15.6 Fuses: 2×1.6AT 250V

15.7 Working frequency: 24kHz～36kHz

15.8 Flow: 25～110ml/m

18.9Applied parts: handpiece and 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 Surgic Touch(LED) 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.

21.Declaration of conformity- EMC

Guidance and manufacturer's declaration - electromagnetic emissions		
The models Surgic Touch(LED) are intended for use in the electromagnetic environment specified below. The customer or the user of the models Surgic Touch(LED) should assure that it is used in such an environment.		
Emissions test C	ompliance	Electromagnetic environment - guidance

RF emissions CISPR 11	Group 1	The models Surgic Touch(LED) 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 Surgic Touch(LED) 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 Surgic Touch(LED) are intended for use in the electromagnetic environment specified below. The customer or the user of the models Surgic Touch(LED) should assure that It ,s used ,n 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, ±1 5 kV air	±8 kV contact +2 kV +4 kV ±8 kV, ±1 5 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 ±1kV for interconnecting cable	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line	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 40 % U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T.) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70 % U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models Surgic Touch(LED) require continued operation during power mains interruption s, it is recommended that the models Surgic Touch(LED) be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/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 Surgic Touch(LED) are intended for use in the electromagnetic environment specified below. The customer or the user of the models Surgic Touch(LED)should assure that it is 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 3 V/m 80 MHz to 2.5 GHz	3V d 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the models Surgic Touch(LED), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance =[3,5/V1]×$P^{1/2}$ d=1.2×$P^{1/2}$ 80 MHz to 800 MHz d=2.3×$P^{1/2}$ 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 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, 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 Surgic Touch(LED) are used exceeds the applicable RF compliance level above, the model Surgic Touch(LED) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the models Surgic Touch(LED).

[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 Surgic Touch(LED)

The models Surgic Touch(LED) are intended for use in electromagnetic environment in which radiatedRF disturbances is controlled. The customer or the user of the models Surgic Touch(LED) can helpprevent electromagnetic interference by maintaining a minimum distance between portable andmobile RF communications equipment (transmitters) and the models Surgic Touch(LED) 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 separationdistance d in meters (m) can be estimated using the equation applicable to the frequency of thetransmitter, where P is the maximum output power rating of the transmitter in watts (W) accordableto 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 byabsorption and reflection from structures, objects and people.

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

Scan and Login website
for more information

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