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FDA CE 0197

DS-II and DS-II LED

MANUAL OF USE AND MAINTENANCE



Guilin Woodpecker Medical Instrument Co., Ltd.

Please read this manual before operating

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Content

1. Introduction 1
2. Identification data 5
3. Testing of the device 7
4. Delivery 7
5. List of material included in the supply 7
6. Installation 9
7. Controls 13
8. Cleaning, Disinfection and Sterilization 19
9. Regular maintenance 24
10. Replacement of the fuses 24
11. Disposal procedures and precautions 25
12. Tips 26
13. Symbols 26
14. Troubleshooting 27
15. Technical data 29
16. After service 30
17. Environmental protection 30
18. Manufacturer's right 30
19.European authorized representative 31
20. Declaration of conformity- EMC 31
21. Guarantee 34
22. Statement 36

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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)**

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.

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1.2 Description of the Device

Thanks to its controlled three-dimensional ultrasound oscillations, the original DS-II (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 DS-II (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

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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 DS-II (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.**

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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 DS-II (LED) must not be activated when the door of the peristaltic pump open. (Fig.5—Ref.B).Moving parts could injure the operator.

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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).



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Fig.1

2.3 Data plate of the scaler handpiece

The serial number of the DS-II (LED) handpiece is engraved on the ring nut (Fig.2).



Fig.2

2.4 Data plate of the foot switch

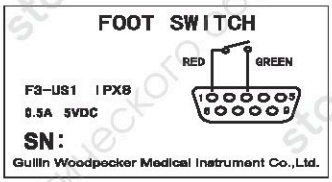


Fig.3

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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
Peristaltic pump	1	Fig.4—Ref.A
Device	1	Fig.4—Ref.B
Torque wrench	1	Fig.4—Ref.C
DS-II (LED) handpiece complete with cord	2	Fig.4—Ref.D
Connection for the cord and tube of the peristaltic pump	1	Fig.4—Ref.E
Connector of handpiece	1	Fig.4—Ref.F
Plug of Footswitch	1	Fig.4—Ref.G

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Name	Quality	Ref
Footswitch	1	Fig.4—Ref.H
Tip Holder	Marked on the packing list	Fig.4—Ref.I
Tip	Marked on the packing list	Fig.4—Ref.J
Input of power-supply cable	1	Fig.4—Ref.K
Output of power-supply cable	1	Fig.4—Ref.L
Surgical tray	1	Fig.4—Ref.M
Rod for supporting the bag	1	Fig.4—Ref.N
Support for the handpiece	1	Fig.4—Ref.O
Pump tube	1	Fig.4—Ref.P





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Fig.4

Applied parts : Handpiece , tips .

6. Installation

6.1 Safety requirements during Installation

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⚠ **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**

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syringe.

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

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.

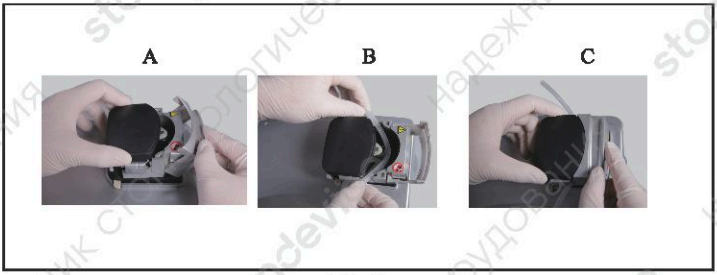


Fig.5

6.3 Connection the accessories

The accessories listed as follow should be connected with the DS-II (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) Close the door completely(Fig.5—Ref.C).

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Danger: personnel injury.

The footswitch of the DS-II (LED) must not be activated when the door of the peristaltic pump open. (Fig.5—Ref.B).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.D);

6.3.4 Plug the power cable into the connector on the casting of the device (Fig.6—Ref.E) and then into the power outlet;

6.3.5 Insert the handpiece support into the two holes provided for it (Fig.6—Ref. C);

6.3.6 Insert the tube of DS-II (LED) cord to the cord connector on the device (Fig.4—Ref.P);

6.3.7 Put the handpiece on the support (Fig.4—Ref.O);

6.3.8 Connect end of the tube of the peristaltic pump;

6.3.9 Connect the flow-control system to the bag containing the appropriate liquid for the treatment;

6.3.10 Use the torque wrench to screw the tip (Fig.8) till the clattering voice;

6.3.11 press the button "on/off" (Fig.6—Ref.B), then can use the device.



Fig.6

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Fig.7

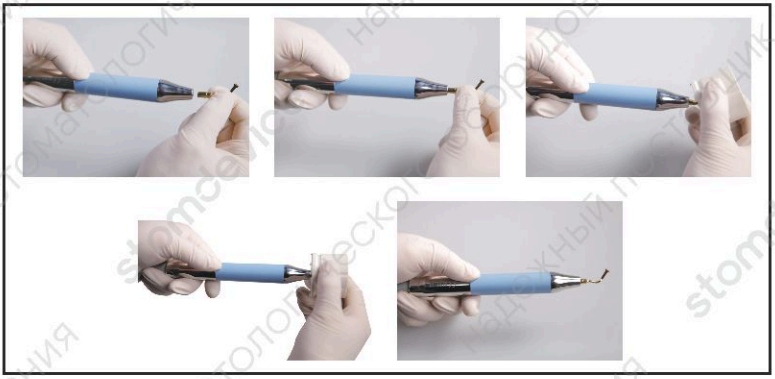


Fig.8

7. Controls

7.1 Description of the controls

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

7.1.1Description of bone function:

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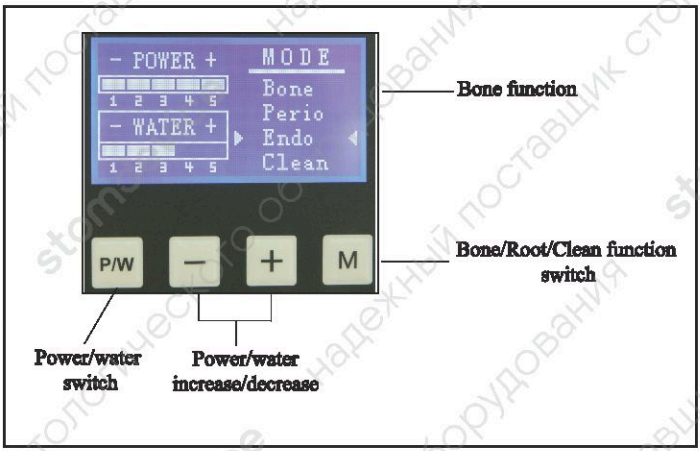


Fig.9

7.1.2 Description of root function:

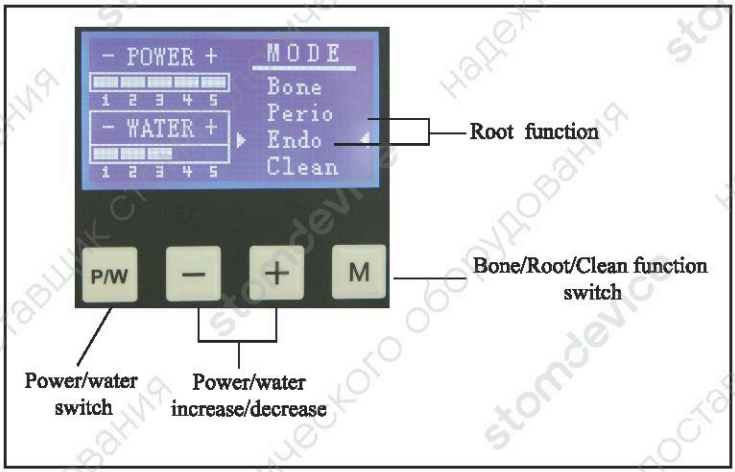


Fig.10

7.1.3 Description of clean function:

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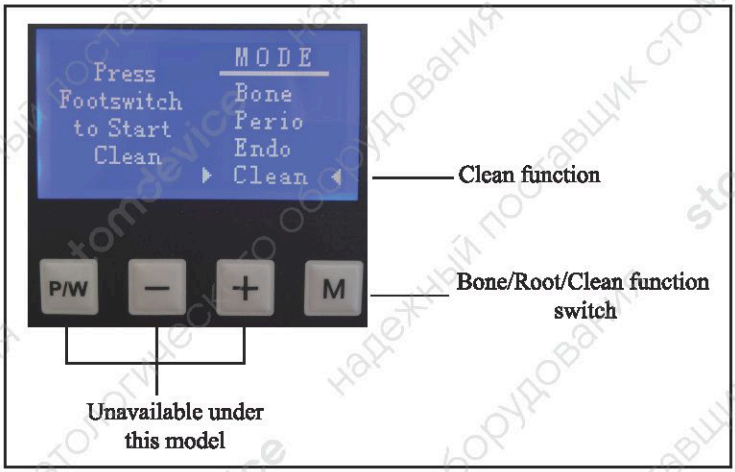


Fig.11

7.2 Description of the display and functions

There are three functions of bone root, clean for this DS-II (LED).

7.2.1 BONE function (Fig.9)

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

a)Power 5: Very high bone density

b)Power 4: High bone density

c)Power 3: Middle bone density

d)Power 2: Low bone density

e)Power 1: Very low bone density

7.2.2 Root function (Fig.10)

In this function, both the water and power model are available, two models as follow:

a) Perio.

b) Endo.

7.2.3 Clean function (Fig.11)

In this function, press the footswitch and hold it on for 3 seconds, the device can

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clean the tube automatically in 25 seconds.

7.3 Safety requirements during use.

⚠ **Danger: Contraindications.**

Do not use the DS-II (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.

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⚠ 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	Possible Cause
Warn 01	There is signal transmission problem or handpiece failure.
	Switch the device off and then on again, If the problem persists contact Woodpecker service centre.
Warn 02	Tuning circuit not working properly.
	Handpiece failure.

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Warning code	Possible Cause
Warn 03	Fan failure.
Warn 04	Pump failure.
Warn 05	Beyond the electricity.
Warn 06	Tip is not correctly secured to the handpiece or tip is worn or broken or deformed.
	Handpiece failure.
Warn 07	Tuning circuit not working properly.
	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 DS-II (LED) handpiece until it is flush against it;

7.5.3 To use the torque wrench correctly (Fig.8) 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.8) 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 DS-II (LED) handpiece is correctly connected to the handpiece connector (Fig.6-Ref.C, Fig.7);

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" (see 7.1) to switch;

7.5.6 Check the display to see the power level that has been set, if the type of

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power required differs from the level that has been set, use the key "+"/"−"(Fig.10) 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 "+"/"−"(see7.1)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-Power5
UL1-UL2-UL3-UL4-UL5	BONE	Power1-Power5
UC1	BONE	Power1-Power5
UI1-UI2-UI7-UI8-UI9	BONE	Power1-Power5
UP1-UP2-UP3-UP4-UP5-UP6-UP7	Perio	Power1-Power5
UE1-UE2-UE3-UE4	Endo	Power1-Power5

8. Cleaning, Disinfection and Sterilization

8.1CLEAN function—Cleaning of the liquid circuit

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⚠ **Warning: Failure to carry out cleaning of the tubes will lead to crystallization of salts that can seriously damage the equipment.**

⚠ **Warning: Handpiece and cord can't be detached.**

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.

8.2 Cleaning and disinfecting the casing of the apparatus

⚠ **Danger: The casing of the apparatus is not protected against the penetration of liquids. Do not spray liquids directly onto the surface of the casing of the apparatus.**

⚠ **Danger: The apparatus cannot be sterilized.**

After each treatment carry out the following operations:
a) Remove the tip from the handpiece;
b) Clean and disinfect the surfaces of the casting, the cords and their connectors using a cloth moistened with a mild detergent or disinfectant solution with a

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neutral PH (ph 7). Follow carefully the instructions given by the manufacturer of the disinfectant solution. Allow the disinfectant solution to dry in the air before using the apparatus.

⚠ **NOTE: Water-based disinfecting solutions with a neutral Ph are highly recommended, some alcohol-based disinfecting solutions may be harmful and discolour or otherwise damage plastic materials.**

8.3 Sterilization procedure

⚠ **Warning: Carry out sterilization using only a steam autoclave.**

Do not use other type of sterilization procedure (such as dry, radiation, ethylene oxide, gas, low temperature plasma etc.).
In order to avoid bacterial or viral infection, always clean, disinfect and sterilize the following components after each treatment:
a) Handpiece (Fig.3)
b) Tips (Fig.4-Ref.J)
c) Torque wrench (Fig.4-Ref.C)
d) Pump tube (Fig.4-Ref.P)
e) Cord/peristaltic pump tube connection (Fig.4-Ref.E)
f) Handpiece support (Fig.4-Ref.O)
The above components are made of materials that can be sterilized for 4 minutes with 134°C and 2.0bar~2.3bar (0.20MPa~0.23MPa).

8.4 Autoclave sterilization of the handpiece

⚠ **Warning: Handpiece and cord can't be detached;**

⚠ **Warning: Do not dip the handpiece into disinfectant solutions or**

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liquids of any other kind since this could damage it;

⚠ **Warning: Do not sterilize the handpiece with the tip screwed into it;**

⚠ **Warning: The electric contacts of the connectors of the handpiece and of the cord must be dry;**

At the end of the sterilization cycle and before connecting the handpiece to the cord, make sure that the electric contacts of both connectors are completely dry, if necessary, dry the contacts by blowing air on to them with the syringe.

⚠ **Warning: After completing the sterilization cycle, allow the handpiece to dry completely before using it.**

⚠ **Note: Water-based disinfecting solutions with a neutral pH 7 are highly recommended. Some alcohol-based disinfecting solutions may be harmful and discolour to otherwise damage plastic materials.**

a) Clean the handpiece carefully paying special attention to the threaded pin onto which the tips are screwed and to the adjacent ring-shaped cavity;
b) Disinfect the handpiece using a cloth moistened with a mild disinfectant solution having a neutral PH7;
c) Dry the electric contacts by blowing air onto them with the syringes;
d) Seal the handpiece in an individual disposable bag (without any tips);
e) Sterilize the handpiece in the autoclave.
Before connecting the handpiece to the cord, make sure that the electric contacts of both connectors are complete dry, if necessary; dry the contacts by blowing air on to them with the syringe.

8.5 Autoclave sterilization of the tips

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8.5.1 Clean the tip (preferably in an ultrasonic tank) and rinse it in distilled water;
8.5.2 Dry the tip;
8.5.3 Disinfect the tip with a mild disinfectant solution having a neutral Ph 7 and dry it carefully;

⚠ **Warning: Before starting the sterilization cycle make sure that the tip is completely dry also inside, to do this, blow air through the internal hole with the syringe.**

8.5.4 Seal the tips inside individual disposable bags;
8.5.5 Autoclave sterilizes the tips.

8.6 Autoclave sterilization of the wrench for tightening the tips
8.6.1 Clean the wrench;
8.6.2 Disinfect the wrench with a mild disinfectant solution having a neutral Ph 7 and dry it thoroughly;
8.6.3 Seal the wrench inside an individual disposable bag;
8.6.4 Autoclave sterilizes the wrench.

8.7 Autoclave sterilization of the peristaltic pump tube
8.7.1 Clean the peristaltic pump tube;
8.7.2 Disinfect with a mild disinfectant solution having a neutral pH 7 and dry it thoroughly;
8.7.3 Seal the tube inside an individual disposable bag;
8.7.4 Autoclave sterilizes the tube.

8.8 Autoclave sterilization of the connection between cord and peristaltic pump tube connection
8.8.1 Clean the connection between cord and peristaltic pump tube connection;
8.8.2 Disinfect with a mild disinfectant solution having a neutral pH and dry it thoroughly;
8.8.3 Seal the connection inside an individual disposable bag;

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8.8.4 Autoclave sterilizes the connection.

8.9 Autoclave sterilization of the handpiece support

8.9.1 Clean the handpiece support;

8.9.2 Disinfect with a mild disinfectant solution having a neutral pH 7 and dry it thoroughly;

8.9.3 Seal the connection inside an individual disposable bag;

8.9.4 Autoclave sterilizes the connection.

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.**

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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).

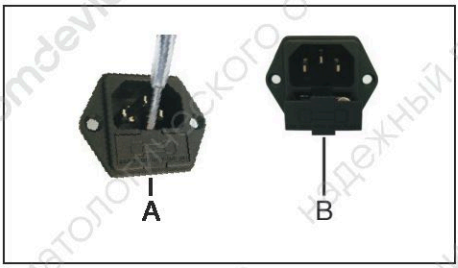


Fig.12

11. Disposal procedures and precautions

Danger: Hospital waste

Treat the following items as hospital waste

- Tips, when worn or broken.
- Irrigator, after each treatment.
- Tube of the peristaltic pump, after 8 sterilizing cycles.
- Torque wrench for tightening tips, when worn or broken.

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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

	Consult the accompanying documents		Use indoor only
	Alternating current		Socker for the foot switch
	Manufacturer		Date of manufacture
IPX1	Drip-proof		Caution mechanical injury
	Caution		Type B applied part
	Can be autoclaved	CE 0197	CE marked product

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Protective earthing

SN Serial number


Atmospheric pressure for storage


Temperature limitation for storage


Humidity limitation for storage


Appliance compliance WEEE directive

IPX8 Degree of protection against the impact of continuous diving

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 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 DS-II (LED) handpiece during operation.	The tip is not correctly tightened onto the handpiece.	Unscrew the tip and screw it back into place correctly.

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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.
No liquid comes out of the tip during operation.	The handpiece is clogged.	Contact the nearest dealer or authorized Woodpecker service centre.

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Problem	Possible cause	solution
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)

IPX8 (footswitch)

15.3 Device for intermittent operation: 60s ON, 10s OFF

15.4 Power-supply voltage: 100V-240V～ 50Hz/60Hz 120VA

15.5 Fuses: 2×1.6AT 250V

15.6 Working frequency: 24kHz～36kHz

15.7 Flow: 25～110ml/m

15.8 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

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15.9 Alarm: Front display show the e (see point 7.3 and 14)

15.10 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

15.11 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℃.

15.12 Pump tube: less than 8 sterilization cycles is highly recommended

15.13 Size of main unit: 330 mm×254 mm×167mm

15.14 Weight of main unit: 3.1kg

15.15 Type of protection against electric shock: Class Ⅰ equipment

15.16 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.

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.

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19.European authorized representative

EC REP MedNet GmbH
Borkstrasse 10 · 48163 Muenster · Germany

20. Declaration of conformity- EMC

Guidance and manufacturer's declaration - electromagnetic emissions		
The models DS-II LED, DS-II are intended for use in the electromagnetic environment specified below. The customer or the user of the models DS-II LED, DS-II 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 DS-II LED, DS-II 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 DS-II LED, DS-II 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 IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

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Guidance & Declaration — electromagnetic immunity			
The models DS-II LED, DS-II are intended for use in the electromagnetic environment specified below. The customer or the user of the models DS-II LED, DS-II should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±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 transient/burst 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 DS-II LED, DS-II require continued operation during power mains interruptions, it is recommended that the models DS-II LED, DS-II 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.			

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Guidance & Declaration - Electromagnetic Immunity

The models DS-II LED, DS-II are intended for use in the electromagnetic environment specified below. The customer or the user of the models DS-II LED, DS-II 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 IEC 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 DS-II LED, DS-II, 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 I 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 DS-II LED, DS-II are used exceeds the applicable RF compliance level above, the model DS-II LED, DS-II should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the models DS-II LED, DS-II.

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

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Recommended separation distances between portable and mobile RF communications equipment and the models DS-II LED, DS-II

The models DS-II LED, DS-II are intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the models DS-II LED, DS-II can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the models DS-II LED, DS-II 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 800MHz $d=1.2\times P^{1/2}$	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 I At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.

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

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.

21. Guarantee

21.1 Before being placed on the market, all WOODPECKER equipment undergoes a thorough final check to ensure that it is are in proper working order.

21.2 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.

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

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are faulty.
Complete replacement of WOODPECKER products is excluded.

21.4 Woodpecker cannot accept any liability for direct or incidental damage or personal injury in the following cases:
21.4.1 If the equipment is used for purposes other than that for which it is intended;
21.4.2 If the equipment is not used in accordance with all the instruction and requirement described in this manual;
21.4.3 If the wiring system in the room where the equipment is used does not comply with the applicable standards and appropriate requirements;
21.4.4 If any assemble operations, extensions, settings, alterations or repairs have been carried out by personnel not authorized by Woodpecker;
21.4.5 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.

21.5 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.

21.6 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.
21.7 The apparatus should be returned suitable packed (possibly in its original

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packing material).

21.8 Accompanied by all the accessories and by the following information:
21.8.1 Owner's details, including his telephone number;
21.8.2 Details of the dealer/importer;
21.8.3 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;
21.8.4 A description of the problem.

21.9 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.

22. 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.
All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD. The industrial design, inner structure, etc, have claimed for several patents by WOODPECKER, any copy or fake product must take legal responsibilities.

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