CE 0197

HANDPIECE of ULTRASONIC SCALER HD-7L INSTRUCTION MANUAL

1 Introduction of product

1.1 Foreword

Guilin Woodpecker Medical Instrument Co., Ltd. is a professional manufacturer in researching, developing and producing dental equipment which has a wholesome quality assurance system.

There are two brands of WOODPECKER company: WOODPECKER and DTE. Products include ultrasonic scaler, curing light, apex locator and ultrasurgery, etc.

1.2 Description of device

Handpiece of Ultrasonic Scaler HD-7L is the accessory of DTE series scalers, It is the latest handpiece that it has the LED function which can light the mouth and more conveniently to eliminate the dental calculus. It is matched the DTE brand Ultrasonic scaler of our company. It is the handheld energy transformation part of ultrasonic scaler, by using piezoceramics to transfer electric energy to mechanical energy for eliminate the dental calculus.

1.3 Model and dimensions

1.3.1 Model: HD-7L

1.3.2 Dimensions: 111 mm(length) 20.5mm(diameter) 57g(weight)

1.4 Product performance and structure

Handpiece of Ultrasonic Scaler HD-7L is composed of cover and ultrasonic transducer.

1.5 Scope of applicaton

Handpiece of Ultrasonic Scaler HD-7L is used for the dental calculus elimination when compatible with the scalers D3 LED, V2 LED; for the dental calculus elimination and root canal cleaning when compatible with the scalers D5 LED, D7 LED, V3 LED which belong to DTE.

1.6 Contraindication

1.6.1 The hemophilia disease patient is not allowed to use this equipment.

1.6.2 The patients with heart pacemaker are forbidden to use this equipment.

1.6.3 The doctors with heart pacemaker are forbidden to use this equipment.

1.6.4 The heart disease patient, pregnant woman and children should be cautious to use the equipment.

1.7 The classification of the device

1.7.1 Operating mode: Continuous operation

1.7.2 Protection degree against water(used on the pedal): IPX1

1.7.3 Degree of safety of application in the presence of a Flammable Anaesthetic Mixture with air or with Oxygen or Nitrous Oxide : Equipment not suitable for being used in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

1.8 The main technical specifications

1.8.1 Power source Input: ~190V-230V

1.8.2 Output primary tip Vibration excursion: 1μm~100μm

1.8.3 Output tip Vibration frequency: 28kHz±3kHz

1.8.4 Output power: 3W ~ 20W

1.8.5 Water pressure: 0.01MPa ~ 0.5MPa

1.9 Working condition

1.9.1 Environmental temperature +5°C~+40°C

1.9.2 Relative humidity:30% ~ 75%

1.9.3 Atmospheric pressure: 70kPa~106kPa

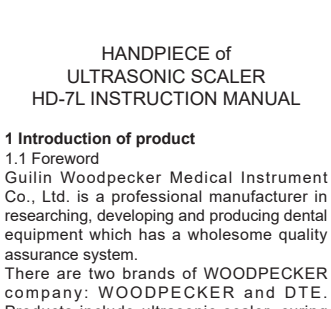
2 Installation of the product

2.1 Installation of handpiece

2.1.1 Open the packing box, make sure that all the parts and accessories are complete.

2.1.2 Keep dry when the detachable handpiece connects to the connector of the cable before installing the handpiece.

2.1.3 Make sure that the bottom jack point at the plug, make the handpiece fix to the cable correctly. (Picture 1)

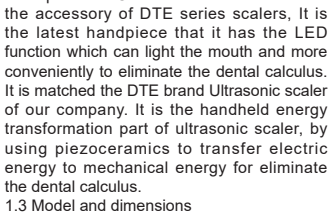


Picture 1

2.2 Installation of tips

2.2.1 Fix the tip to handpiece by torque wrench.

(Picture 2)



Picture 2

2.2.2 Please use "DTE" brand scaling tips.

Notes: The detachable handpiece is a high-tech device which should be used carefully. Don't use too much torque force to screw the tip, Screw the tips by torque wrench. In order to the vibration by touch the foot switch by accident, unscrew the scaling tips after each operation.

3 Product function and operation

3.1 Scaling function

3.1.1 Connect the handpiece and the connector of cable of the main unit of the scaler correctly, and adjust the water and vibration intensity to a suitable level.

3.1.2 The handpiece can be handled in the same gesture as a pen in hand.

3.1.3 Select a suitable scaling tip as you need, screw it on the handpiece tightly by the torque wrench.

3.1.4 During the clinical treatment, be sure not to make the end of tip touch the teeth vertically.

3.1.5 Not to make the tip overexert on the surface of the teeth in case of hurting the teeth and damaging the tip.

3.1.6 After finishing operation, keep the machine working for 30 seconds on the water supply condition in order to clean the handpiece and the scaling tip.

3.2 Endo funtion

3.2.1 Usage process

a) Fix endochuck to handpiece by endo chuck.

b) Unscrew the screw cap on the endochuck.

c) Put the ultrasonic file into the hole in the front of endochuck.

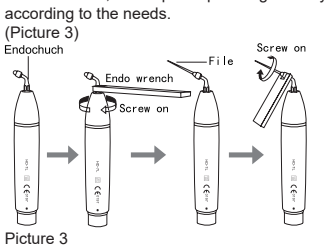
d) Screw down the screw cap with endo wrench to tight up the ultrasonic file.

e) Press option key, turn to endo root canal cleaning function.

f) Press option key, turn the water and vibration intensity to a suitable level.

g) Put the ultrasonic file into the patient's root canal slowly, step on the foot pedal, then make endo root canal cleaning. During the treatment, turn up the power gradually according to the needs.

(Picture 3)



Picture 3

3.2.2 Notes

a) When fixing endochuck, it must be screwed down.

b) The screw on the endochuck must be screwed down.

c) Don't press it too much when the ultrasonic file in root canal.

d) Don't start up the foot pedal until the ultrasonic file is in root canal.

e)The power range is supposed from 1st to 5th grades.

f) Please sterilize the endo chuch and handpiece after operation.

3.3 Instruction for main components of detachable handpiece

3.3.1 Nipple: The nipple can be removed, for easy cleaning.

3.3.2 Light pipe (if any): light guide, can be autoclaved under high temperature and pressure.

3.3.3 LED lamp (if any): illuminate the oral area, detachable and sterilized.

3.3.4 Handpiece: The main part of the whole handpiece, can be autoclaved underthe high temperature and pressure.

3.3.5 O ring: Please lubricate the waterproof O ring with dental lube frequently, as sterilication and repeated pulling and inserting will reduce their using life. Change a new one once it is damaged or worn excessively.

4 Notes

4.1 Don't knock or rub the handpiece.

4.2 Don't screw or unscrew the scaling tip and endochuck when step on the foot pedal.

4.3 The handpiece, scaling tip, torque wrench, endo wrench and endochuck must be sterilized before each treatment.

4.4 The internal screw threat of the scaling tips produced by some manufactures is coarse, rusty and collapsed. This will damage the external screw threat of the handpiece irretrievably. Please use "DTE" brand scaling tips.

4.5 We are only responsible for the safety on the following conditions: The maintenance, repair and modification are made by the manufacturer or the authorized dealer.

5 Troubleshooting

Fault	Possible causes	Solutions
Handpiece doesn't work	The tip is loosen	Tighten it
	Something wrong with the Handpiece	Take out the handpiece and send it back for repair
	Something wrong with the Cable	Contact our dealers or us
	The connect plug between the cable and circuit board is loosen	Contact our dealers or us
There is no spray when getting through the electricity	The water control switch is vibrates not on	Turn on the water control switch
	No pressure or low pressure	Check the presure
There is no water when getting through the electricity	The water control switch is vibrates not on	Turn on the water control switch
	There is impurity in the electric-magnetic valve	Contact our dealers or us
	Contact our dealers or us	Clean the water line by three-way syringe
Low vibration	The tip hasn't been screwed on the handpiece tightly	Screw the tips tightly by torque wrench
	The tip is shaken loose by vibration	Screw on the tip tightly
	The coupling between the handpiece and the cable isn't dry	Dry it, especially the water between handplece and connector
	The tip is worn out or deformation	Change another tip
The handpiece generates heat	The water control switch is in a low setting	Turn the water control switch to a higher grade
LED light don't work	poor contact	Contact tightly
	Something wrong with LED light	Change a new one
	Light pipe installed backwards	Please install the "+" of the Light pipe to the "+" of the handpiece
There is water seeping from the coupling between the handpiece and the cable	The waterproof "O ring is damaged	Change a new "O " ring

If the problem still can't be solved, please contact with local dealer or manufacturer.

6. Cleaning, Disinfection and Sterilization Warnings

The use of ultrasound cleaning device and strong cleaning and disinfection fluids (alkaline pH>9 or acid pH <5) can reduce the life span of products. The manufacturer takes no responsibility in such cases.

This device shall not be exposed to high temperature above 138℃ .

Processing limit

The products have been designed for a large number of sterilization cycles. The materials used in manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products. The allowed maximum times of sterilization for handpiece is 600 times.

6.1 Initial processing

6.1.1 Processing principles

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

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

6.1.2 Post-operative treatment

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

1. Let the Ultrasonic scaler works for 20-30 seconds at maximum water volume to flush the handpiece and tip;

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

3. Dry the handpiece with a clean, soft cloth and place it in a clean tray.

Notes

a)The water used here must be pure water, distilled water or deionized water.

6.2 Preparation before cleaning

Steps

Tools: torque wrench, tray, soft brush, clean and dry soft cloth

1. Use torque wrench provided by Guilin Woodpecker Medical Instrument Co., Ltd to remove the tip from handpiece and put it into the tray.

2. Unscrew the nipple of handpiece counterclockwise, remove the sealing ring, light pipe (if any), and LED lamp (if any), and put them in the tray.

3. Use a clean soft brush to carefully brush the joints between handpiece and the connector of cable, front thread, horn, nipple, seal ring, light pipe (if any)and LED lamp (if any) until the dirt on surface is not visible. Then use soft cloth to dry the handpiece and accessories and put them into a clean tray. The cleaning agent can be pure water, distilled water or deionized water.

Disassembling steps.

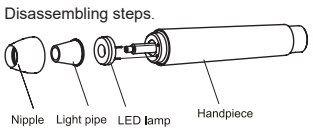


Fig. 4

6.3 Cleaning

The cleaning should be performed no later than 24 hours after the operation.

The cleaning can be divided into automated cleaning and manual cleaning. Automated cleaning is preferred if conditions permit.

6.3.1 Automated cleaning

•The cleaner is proved to be valid by CE certification in accordance with EN ISO 15883.

▪There should be a flushing connector connected to the inner cavity of the product.

▪The cleaning procedure is suitable for the handpiece, the flushing period is sufficient, and ultrasonic cleaning is prohibited.

It is recommended to use a washer-disinfector in accordance with EN ISO 15883. For the specific procedure, please refer to the automated disinfection section in the next section "Disinfection".

Notes

a) The cleaning agent does not have to be pure water. It can be distilled water, deionized water or multi-enzyme. But please ensure that the selected cleaning agent is compatible with the handpiece.

b) In washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it would be difficult to remove.

c) After cleaning, the presence concentration of the process chemicals is determined to be below the prescribed potential harmful concentration, i.e. the maximum acceptable level. The main chemical residue of detergent recommended here is 1,2-propanediol with residue value less than 10mg/L.

6.4 Disinfection

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

6.4.1 Automated disinfection – Washer-disinfector

• The washer-disinfector is proved to be valid by CE certification in accordance with EN ISO 15883.

• Use high temperature disinfection function. The temperature does not exceed 134 ° C, and the disinfection under the temperature cannot exceed 20 minutes.

• The disinfection cycle is in accordance with the disinfection cycle in EN ISO 15883.

Cleaning and disinfecting steps by using Washer-disinfector

1. Carefully place the handpieces in the disinfection basket. Fixture of the handpiece is permissible only when they are freely removable in the unit. The handpieces are not permitted to contact with each other.

2. Use a suitable rinsing adaptor, and connect the internal water lines to the rinsing connection of the washer-disinfector.

3. Start the program.

4. After the program is finished, remove the handpieces from the washer-disinfector, inspect (refer to section "Inspection and Maintenance") and packaging (refer to chapter "Packaging"). Dry the handpiece repeatedly if necessary (refer to section "Drying").

Notes

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

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

c) Cleaning: (c1) The cleaning procedure should be suitable for the product to be treated. The flushing period should be sufficient (5-10 minutes). Pre-wash for 3 minutes, wash for another 5 minutes, and rinse it for twice with each rinse lasting for 1 minute. (c2) In the washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it is difficult to remove. (c3) The solution used can be pure water, distilled water, deionized water or multi-enzyme solution, etc., and only freshly prepared solutions can be used. (c4) During the use of cleaner, the concentration and time provided by manufacturer shall be obeyed. The used cleaner is neodisher MediZym (Dr. Weigert).

d) Disinfection: (d1) Direct use after disinfection: temperature ≥ 90 ° C, time ≥ 5 min or A0 ≥ 3000;

Sterilize it after disinfection and use: temperature ≥ 90 ° C, time ≥ 1 min or A0 ≥ 600. (d2) For the disinfection here, the temperature is 93 ° C, the time is 2.5 min, and A0>3000.

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

f) After cleaning, the presence concentration of the process chemicals is determined to be below the prescribed potential harmful concentration, i.e. the maximum acceptable level. The main chemical residue of detergent recommended here is 1,2-propanediol with residue value less than 10mg/L.

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

h) Regularly repair and inspect the disinfector.

6.5 Drying

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

Methods

1. Spread a clean white paper (white cloth) on the flat table, point the handpiece against the white paper (white cloth), and then dry the handpiece with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the handpiece drying is completed.

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

Notes

a)The drying of product must be performed in a clean place.

b)The drying temperature should not exceed 138 °C;

c)The equipment used should be inspected and maintained regularly.

6.6 Inspection and maintenance

In this chapter, we only check the appearance of the handle. After inspection, if there is no problem, the handpiece should be immediately reassembled, installing the sealing ring, Light pipe (if any), LED lamp (if any), and nipple in sequence to the handpiece, and then tighten the nipple clockwise.

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

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

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

6.6.4 If the service time (number of times) of the handpiece reaches the specified service life (number of times), please replace it in time.

6.7 Packaging

The disinfected and dried handpieces and their accessories are assembled and quickly packaged in a medical sterilization bag (or special holder, sterile box).

Notes

a)The package used conforms to ISO 11607;

b)It can withstand high temperature of 138 °C and has sufficient steam permeability;

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

d)Avoid contact with parts of different metals when packaging.

6.8 Sterilization

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

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

2.The highest sterilization temperature is 138 ° C;

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

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

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

Notes

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

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

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

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

6.9 Storage

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

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

Notes

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

b)Product storage must be batched and marked and recorded.

6.10 Transportation

1. Prevent excessive shock and vibration during transportation, and handle with care;

2. It should not be mixed with dangerous goods during transportation.

3. Avoid exposure to sun or rain or snow during transportation.

7 Storage, maintenance and transportation

7.1 Storage, maintenance

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

7.1.2 Don't store the machine together with the articles that are combustible, poisonous, caustic or explosive.

7.1.3 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°C ~ +55°C.

7.2Transportation

7.2.1 Excessive impact and shake should be prevented in transportation. Lay it carefully and lightly and don't invert it.

7.2.2 Don't put it together with dangerous goods during transportation.

7.2.3 Avoid solarization and getting wet in rain or snow during transportation.

8 Environmental Protection

There is not any harm factor in our product. You can deal with it based on the local law.

9 After Service

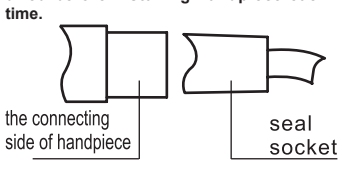
We offer one year's free repair to the equipment according to the warranty card. The repair of the equipment should be carried out by our professional technician. We are not responsible for any irretrievable damage caused by the non-professional person.

10 Symbol instruction

～	AC
IPX1	Drip-proof
	Date of manufacturer
	Manufacturer
	Follow Instructions for Use
	Used indoor only
134℃	Can be autoclaved
SN	Serial number
	Appliance compliance WEEE directiv
	Atmospheric pressure for storag
	Humidity limitation for storage
	Temperature limitation for storage
CE 0197	CE marked product
EC REP	Authorised Representative in EUROPEAN COMMUNITY

11. Statement

Be sure that the connecting side of handpiece and seal socket is completely dried before installing handpiece each time.



Guilin Woodpecker Medical Instrument Co., Ltd.
Information Industrial Park, Guilin National High-Tech Zone, Guilin, Guangxi, 541004 P. R. China
Sales Dept.: +86-773-5873196
Http://www.glwoodpecker.com
E-mail: woodpecker@glwoodpecker.com
EC REP MedNet EC-Rep GmbH
Borkstrasse 10 · 48163 Muenster · Germany

ZMN-SM-200 V1.9-20230819