i-Polish Instruction Manual

(Please carefully read Instrction Manual before first)

www.glwoodpecker.com

GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.

Contents

1 Product introduction

1.1 Preface

Guilin Woodpecker Medical Instrument Co., Ltd is a professional manufacturer researching, developing, and producing dental products. Woodpecker owns a sound quality control system. Guilin Woodpecker Medical Instrument Co., Ltd has two brands, Woodpecker and DTE. Its main products include Ultrasonic Scaler, Curing light, Apex locator, Ultrasurgery, Endo Motor, etc.

1.2 Product description

i-Polish is a cordless prophylaxis handpiece equipped with control buttons and wireless foot control. With its disposable prophy angle, it can be used for teeth cleaning and polishing.

Features:

a) Wireless handpiece

b) It has accurate and stable speed control. Compared with

traditional pneumatic low-speed handpiece, it enables more stable polishing and better treatment.

c) One-button speed control

d) Wireless foot control (optional) enables convenient treatment.

1.3 Model and specification

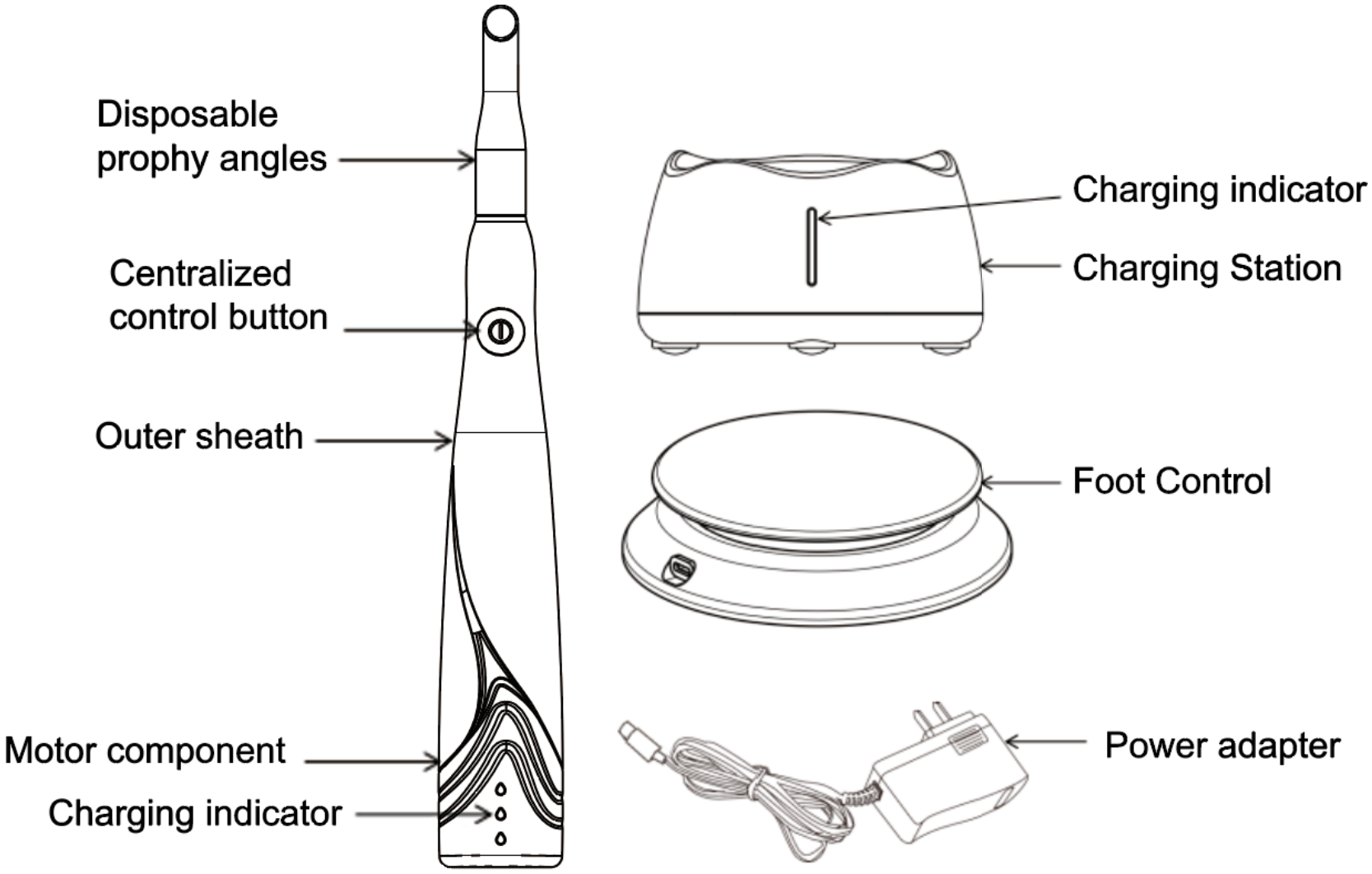
i-Polish

Please refer to the packing list for device configurations.

1.4 Performance and composition

The device is composed of motor component, outer Sheath, charging station, power adapter, foot control (optional), disposable silicon sleeve.

i-Polish



1.5 Scope of application

1.5.1 It is mainly used for teeth cleaning and polishing.

1.5.2 The device must be operated in hospital and clinic by the qualified dentists.

1.6 Contraindication

a) Doctors with a pacemaker are prohibited from using this device.

b) Patients with a pacemaker (or other electrical equipment) who are warned not to use small appliances (such as Electric razors, hair dryers, etc.) are prohibited from using this device.

c) Hemophilia patients are prohibited from using this device.

d) For patients with heart disease, pregnant women and young children, cautiously use this device.

1.7 Warnings

1.7.1 Please carefully read this Instruction Manual before first operation.

1.7.2 This device should be operated by professional and qualified dentists in qualified hospital or clinic.

1.7.3 Do not directly or indirectly place this device near heat source. Operate and store this device in reliable environment.

1.7.4 This device requires special precautions regarding electromagnetic compatibility (EMC) and must be in strict accordance with the EMC information for installation and use. Do not use this equipment near the fluorescent lamps, radio transmitting devices, remote control devices, handheld and mobile high-frequency communication devices.

1.7.5 Long term use of equipment may result in overheat of motor handpiece, thus it should be left to cool for next use. If the motor handpiece is overheated frequently, please contact local distributor.

1.7.6 Please use the original charging base. Otherwise it will cause malfunctions of device or cause adverse consequences.

1.7.7 Please do not make any changes to the device. Any changes may violate safety regulations, causing harm to the patients. The manufacturer will not accept any liability for the modified device.

1.7.8 Please use original power adapter. Other brand power adapter will result in damage to lithium battery and control circuit.

1.7.9 The component, charging base, power adapter, and foot control cannot be autoclaved. Use disinfectant of neutral pH value or ethyl alcohol to wipe its surface.

1.7.10 Before the motor component stop rotating, do not install or remove the outer sheath. Otherwise the motor component may be damaged.

1.7.11 Before the motor component stop rotating, do not remove the disposable prophy angle. Otherwise the disposable prophy angle and the handpiece will be damaged.

1.7.12 Before starting the handpiece, please ensure that the disposable prophy angle was correctly installed and locked.

1.7.13 Please use disposable prophy angle fitting the interface of this device. Otherwise the disposable prophy angle and the handpiece will be damaged.

1.7.14 Error in replacing detachable components can lead to unacceptable risks, so pleas replace the detachable components according to the correct steps in the instructions.

1.7.15 Wireless charging will generate heat, and the surface

temperature of the charging base and motor handpiece will rise. It is recommended that the time of contacting motor handpiece and charging base during wireless charging should not exceed 10 seconds.

1.7.16 The device not intended to be used in areas where liquids are likely to be present at floor level, such as emergency rooms or operating theatres.

1.7.17 Replacement of lithium batteries by inadequately trained personnel or incorrect replacement could result in a HAZARD,so please contact local distributors to replace the battery if necessary.

1.7.18 The adapter plug can be used to disconnect from the network power supply.Don't position the device to make it difficult to operate the disconnection device when charging.

1.8 Device safety classification

1.8.1 Type of operation mode: Continuous operating device

1.8.2 Type of protection against electric shock: Class II equipment with internal power supply

1.8.3 Degree of protection against electric shock: B type applied part

1.8.4 Degree of protection against harmful ingress of water:

Handpiece	IPX3
Foot control	IPX1
Charging base	IPX0
Power adapter	

1.8.5 Degree of safety application in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide: Equipment cannot be used in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

1.8.6 Applied part : Disposable prophy angles.

1.8.7 The contact duration of applied part: 1 to 10 minutes.

1.9 Primary technical specifications

1.9.1 Battery:

Lithium battery: 3.6V /750mAh

1.9.2 Power adapter (Model: DJ-0500100-A5)

Input: ~100V-240V 50Hz/60Hz 0.5-0.2A

Output:DC5V/1A

1.9.3 Speed range: 500rpm~4000rpm

1.9.4 Wireless charging

Frequency range: 112-205 KHz

Maximum RF output power of the product: 9.46dBuA/m@3m

1.10 Environment parameters

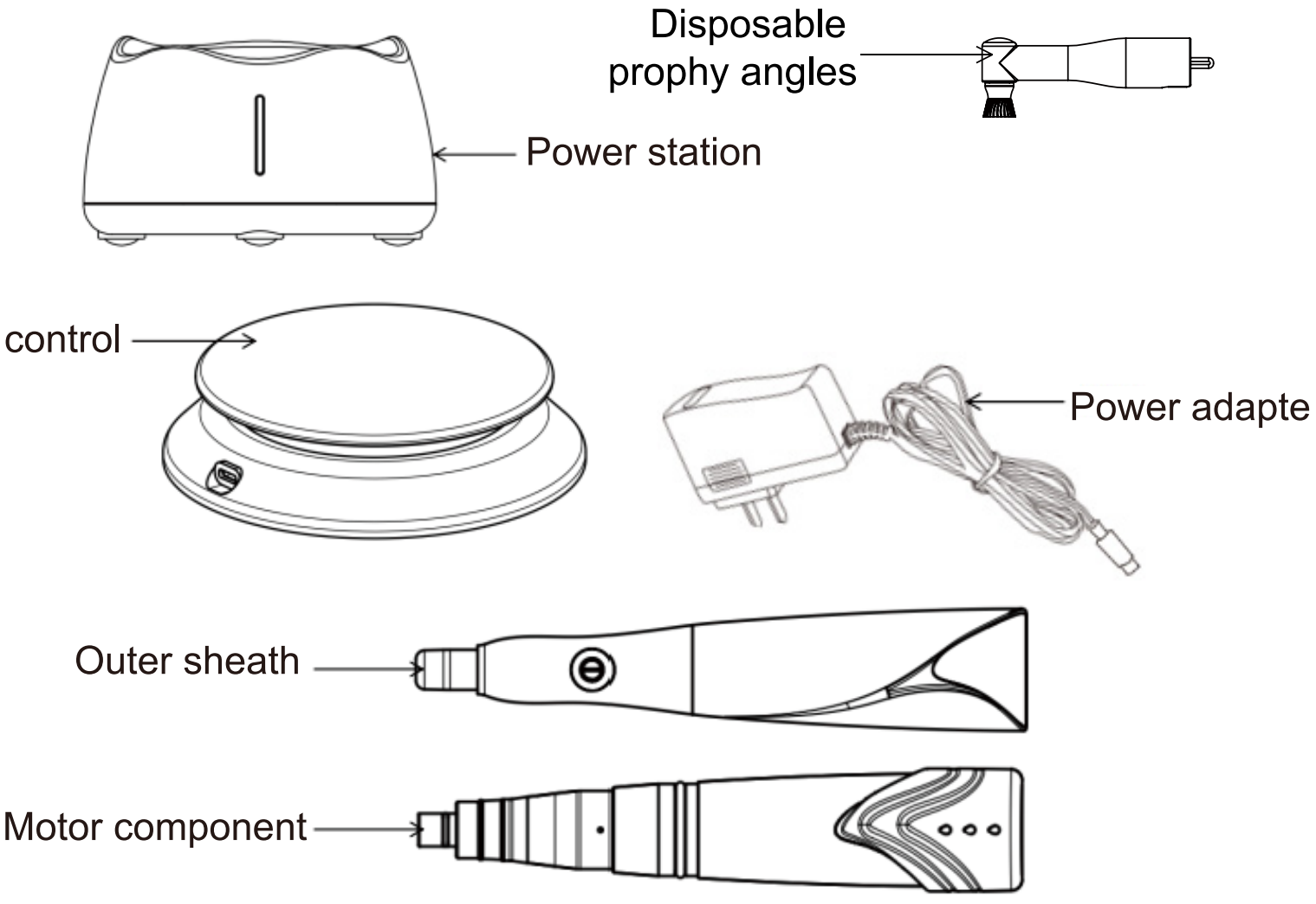
1.10.1 Environment temperature: +5℃ ~ +40℃

1.10.2 Relative humidity: 30% ~ 75%

1.10.3 Atmospheric pressure: 70kPa ~106kPa

2 Installation

2.1 Basic accessories of product



2.2 Instructions for Disposable Barrier

2.2.1 Before installing disposable barrier, please make sure that the motor handpiece is fully charged. If it is of low battery level, please first charging the device.

2.2.2 Insert the motor component into the disposable barrier.

⚠ Warnings:

Before installation, please check whether the disposable barrier is intact. If it is damaged, please do not use it.

2.3 Instructions for Outer Sheath

2.3.1 Ensure that the outer sheath has been autoclaved according to the Infection Prevention Procedure (Section 6.4).

2.3.2 Install the motor component covered with the disposable barrier into the outer sheath.

⚠ Warnings:

Before installing the outer sheath, please ensure the motor handpiece was stopped.

2.4 Instructions for Disposable Prophy Angle

2.4.1 Install the Disposable Prophy Angle into the cordless handpiece.

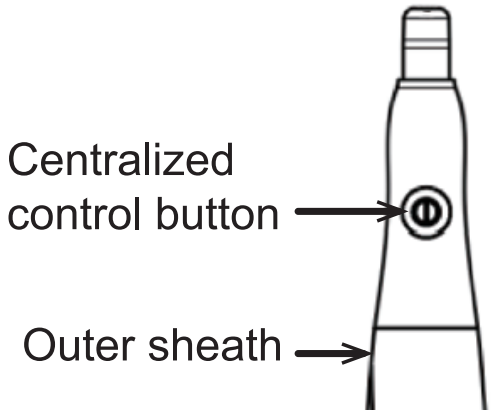
⚠ **Warnings:**

a) Please use the Disposable Prophy Angle fitting this device. Otherwise the Disposable Prophy Angle and the motor handpiece will be damaged.

b) Before installing the Disposable Prophy Angle, please ensure the motor handpiece was stopped.

3 Function and operation of product

3.1 Button definition and settings



3.1.1 Turn power on

Press Main Button to turn on the handpiece.

3.1.2 Turn power off

Hold down the Main button to turn off the handpiece.

3.1.3 Handpiece speed setting

With the handpiece turned on, press Main button to adjust the speed mode.

Foot control mode	When switching to this mode, it is controlled by wireless foot control by default
Low speed mode	500rpm
Medium speed mode	1500rpm
High speed mode	3000rpm
Super high speed mode	4000rpm

3.2 Function and operation of foot control

3.2.1 Activate the foot control

After the pedal is used for the first time or placed for a long time, you need to press the pedal for 3 seconds to activate the pedal. When the wireless connection indicator or power indicator of the pedal is on, it means that the pedal is activated successfully.

3.2.2 Foot control indicator

As shown in the figure below, the foot control has two indicator lights, the wireless connection indicator and the power indicator.

When the pedal is stepped on, if the wireless connection indicator flashes, it indicates that the pedal is not connected to the handpiece. When the pedal is stepped on, if the wireless connection indicator light is always on, it indicates that the pedal and the handpiece are connected. When the power indicator shows yellow, it means the pedal has a low battery and needs to be charged. When the power indicator flashes, it means that the battery power is extremely low. At this time, the pedal cannot work and needs to charge enough power to return to normal. When the pedal is charging, the battery indicator will always be green, and it will automatically turn off when it is fully charged.

3.2.3 Operation of foot control

After ensuring that the pedal has enough power and the handpiece is turned on, adjust the handpiece to the pedal mode. At this time, step on the pedal to control the speed of the handpiece.

4 Operation instruction

4.1 Power on

Quickly press the button on the installed handpiece to start the handpiece. When the power indicator of the handpiece is on, it means the handpiece is turned on.

4.2 Load polishing paste

Adjust the handpiece to pedal mode or low speed mode, and then load the polishing paste to the Disposable Prophy Angle.

4.3 Treatment

Use the handpiece buttons or the foot control to adjust to a proper speed, and then start the treatment.

4.4 Post-op

After the treatment, stop the handpiece first, and then remove the Disposable Prophy Angle, disposable barrier and handpiece outer sheath. Carry out high temperature and high pressure sterilization on the outer sheath, disinfect the internal components and base of the motor (see section 5 for

instructions), and discard the disposable barrier and Disposable Prophy Angle as medical waste.

4.5 Charging instruction

4.5.1 Charging of handpiece

Connect the original power adapter to the base, plug it into a suitable socket, and place the handpiece into the base for charging. When charging, the charging indicator of the base will flash regularly, and the indicator light will turn on when it is fully charged.

4.5.2 Charging of wireless foot control

Charge the wireless foot control directly with the original power adapter.

⚠ **Warnings:**

a) For safety reasons, the motor cannot be started when charging.

b) Please use the original power adapter for charging. Otherwise the device may be damaged.

5 Troubleshooting

Failure	Solutions
Disposable Prophy Angle is not rotating	1. Ensure that the outer sheath and the Disposable Prophy Angle are snapped together securely. 2. Ensure that the Motor Component and the outer sheath are snapped together securely. 3. Ensure the Disposable Prophy Angle is not damaged. 4. Ensure the outer sheath is not damaged.

Excessive noise or vibration during operation	1. Ensure that the outer sheath and the Disposable Prophy Angle are snapped together securely. 2. Ensure that the Motor Component and the outer sheath are snapped together securely. 3. Ensure the Disposable Prophy Angle is not damaged. 4. Ensure the outer sheath is not damaged.
Difficult to removing or installing the outer sheath.	1. Ensure the outer sheath is not damaged. 2. Check and clean the outer sheath.
Motor Component cannot be charged	1. Check for foreign matter between charging base and Motor Component. 2. Check whether the original power adapter is used.

6 Cleaning, Disinfection and Sterilization

6.1 Foreword

For hygiene and sanitary safety purposes, the outer sheath must be cleaned, disinfected and sterilized before each usage to prevent any contamination. This concerns the first use, as well as all subsequent uses.

6.2 General recommendations

6.2.1 Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, FDA and Health Canada approval) and in accordance with the DFU of the disinfecting solution manufacturer.

6.2.3 Do not place the outer sheath in a disinfectant solution or in an ultrasonic bath.

Do not use chloride detergent materials.

6.2.4 Do not use bleach or chloride disinfectant materials.

6.2.5 For your own safety, please wear personal protective equipment (gloves, glasses, mask).

6.2.6 The user is responsible for the sterility of the product for the first cycle and each further usage as well as for the usage of damaged or dirty instruments where applicable after sterility.

6.2.7 The water quality has to be convenient to the local regulations especially for the last rinsing step or with a washer-disinfector.

6.3 Cleaning and disinfection steps for the motor component, power adapter and charging base

Before and After each use, all the objects that were in contact with infectious agents should be cleaned using towels impregnated with a disinfecting and detergent solution (a bactericidal, fungicidal and aldehyde free solution) approved by VAH/DGHM-listing, CE marking, FDA and Health Canada.

⚠ **Warnings:** Do not sterilize the motor component, power adapter and charging base.

6.3.1 Pre-Op processing

Before each use, the motor component, power adapter and charging base must be cleaned and disinfected. The specific

steps are as follows:

⚠ **Warnings:** the motor component, power adapter and charging base cannot be cleaned and disinfected with automatic equipment. Manual cleaning and disinfection is required.

6.3.1.1 Manual cleaning steps:

1. Take out the motor component, power adapter and charging base on the workbench.

2. Wet the soft cloth completely with distilled water or deionized water, and then wipe all the surfaces of the components such as the motor component, power adapter and charging base, etc. until the surface of the component is not stained.

3. Wipe the surface of the component with a dry soft nap-free cloth.

4. Repeat the above steps at least 3 times.

Note:

a) Use distilled water or deionized water for cleaning at room temperature.

6.3.1.2 Manual disinfection steps:

1. Soak the dry soft cloth with 75%alcohol.

2. Wipe all surfaces of the motor component, power adapter, charging base and other components with a wet soft cloth for at least 3minutes.

3. Wipe the surface of the component with a dry soft nap-free cloth.

Note:

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

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

c) In addition to 75% alcohol, you can use non-residue disinfectants such as Oxytech from Germany, but you must respect the concentration, temperature and time specified by the disinfectant manufacturer.

d) After cleaning and disinfecting the motor component, you must install a disposable barrier before use and repeat steps 1, 2 and 3 to clean the disposable barrier (For detailed installation

steps, see section 2.*).

6.3.2 Post-Op processing

After each use, clean and disinfect the motor component, power adapter and charging base within 30 minutes. The specific steps are as follows:

Tools: Nap-free soft cloth, tray

1. Remove the outer sheath from the motor component, place it in a clean tray, and then remove the disposable barrier from the motor component.

2. Soak the nap-free soft cloth with distilled water or deionized water, and then wipe all the surfaces of the components such as the motor component, power adapter, charging base, etc. until the surface of the component is not stained.

3. Wet the dry soft cloth with 75% alcohol, and then wipe all surfaces of the motor component, power adapter, charging base and other components for 3minutes.

4. Put the motor component, power adapter, charging base and other components back into the clean storage area.

Note:

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

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

c) In addition to 75% alcohol, you can use non-residue disinfectants such as Oxytech from Germany, but you must respect the concentration, temperature and time specified by the disinfectant manufacturer.

6.4 The cleaning, disinfection and sterilization of Outer Sheath Unless otherwise stated, they will be hereinafter referred to as “products”.

⚠ **Warnings:**

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

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

Processing limit

The products have been designed for a large number of sterilization cycles. The materials used in manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products. The maximum number of sterilizations for products is 250 times.

6.4.1 Initial processing

6.4.1.1 Processing principles

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

Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or

clinic, especially with regard to the additional requirements for the inactivation of prions.

6.4.1.2 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. Remove the products from the base, and rinse away the dirt on the surfaceofhandpiecewithpurewater(ordistilledwater/deionizedwater);

2. Dry the products 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.

6.4.2 Preparation before cleaning Steps:

Tools: tray, soft brush, clean and dry soft cloth.

1. Remove the disposable prophy angle.

Remove the outer sheath from the handpiece, and then put

them into a clean tray;

2. Use a clean soft brush to carefully brush outer sheath, head and back cover of the outer sheath until the dirt on surface is not visible. Then use soft cloth to dry the products and put them into a clean tray. The cleaning agent can be pure water, distilled water or deionized water.

3. Disassembling steps

a) Remove the disposable prophy angle.

b) Remove the outer sheath from the handpiece.

6.4.3 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.

6.4.3.1 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 product, and the irrigating period is sufficient.

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 product.

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

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

6.4.4 Disinfection

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

6.4.4.1 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℃ , and the disinfection under the temperature cannot exceed 20 minutes.

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

Cleaning and disinfecting steps by using Washer-disinfector

1. Carefully place the product into the disinfection basket. Fixation of product is needed only when the product is removable in the device. The products are not allowed to contact each other.

2. Use a suitable rinsing adaptor, and connect the internal

water lines to the rinsing connection of the washer-disinfector.

3. Start the program.

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

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℃ , 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℃ , time ≥ 5 min or A0 ≥3000; Sterilize it after disinfection and use: temperature ≥ 90℃ , time ≥1 min or A0 ≥ 600 (d2)For the disinfection here, the temperature is 93℃ , the time is 2.5 min, andA0>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 chemical residue should be less than 10mg /L.

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

h) Regularly repair and inspect the disinfector.

6.4.5 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 product against the white paper (white cloth), and then dry the product with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the product drying is completed.

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

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.

6.4.6 Inspection and maintenance

6.4.6.1 Inspection

In this chapter, we only check the appearance of the product.

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

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

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

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

6.4.7 Packaging

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

Notes:

a) The package used conforms to ISO11607;

b) It can withstand high temperature of 138℃ 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.

6.4.8 Sterilization

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

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

• The highest sterilization temperature is 138℃ .

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

• Allow a maximum sterilization time of 20 minutes at 134℃ .

Verificationofthefundamentalsuitabilityoftheproductsforeffective 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.

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

6.4.9 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℃ to +55℃ ;

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.

6.4.10 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

7.1.1 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℃ .

7.1.2 Avoid the storage in a too hot condition. High temperature will shorten the life of electronic components, damage battery, reshape or melt some plastic.

7.1.3 Avoid the storage in a too cold condition. Otherwise, when the temperature of the equipment increases to a normal level, there will be dew that will possibly damage PCB board.

7.2 Maintenance

7.2.1 This device do not include accessories for repair usage, the repair should be carried out by authorized person or

authorized after service center.

7.2.2 Keep the equipment in a dry storage condition.

7.2.3 Do not throw, beat or shock the equipment.

7.2.4 Do not smear the equipment with pigments.

7.2.5 Calibration is recommended when using a new/other contra angle or after an extend period of operation, as the running properties can change with usage, cleaning and sterilization.

7.2.6 Replace the battery if it seems to be running out of power sooner than it should.

7.3 Transportation

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

7.3.2 Don’t put it together with dangerous goods during transportation.

7.3.3 Avoid solarization and getting wet in rain and snow during transportation.

8 Environmental protection

Please dispose according to the local laws.

9 After-sales service

From the date this equipment has been sold, based on the warranty card, we will repair this equipment free of charge if there are quality problems. Please refer to the warranty card for the warranty period.

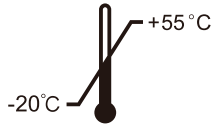
10 European authorized representative

EC REP MedNet EC-Rep GmbH
Borkstrasse 10 · 48163 Muenster · Germany

11 Symbol instruction

	Follow Instructions for Use	SN	Serial number

	Date of manufacture		Manufacturer
	Type B applied part		Class II equipment
	Used indoor only		Recovery
	Handle with care		Keep dry
CE 0197	CE marked product		Humidity limitation
	Appliance compliance WEEE directive		
IPX0	Protection Class IPX0 - IPX0 Classification of ingress of water for Charging Station – not protected		
IPX1	Protection Class IPX1 - IPX0 Classification of ingress of water for foot control.		

IPX3	Protection Class IPX3 - IPX3 Classification of ingress of water for Motor Component - Protected against falling spray.
	Temperature limitation
	Atmospheric pressure for storage
EC REP	Authorized Representative in the EUROPEAN COMMUNITY

12 Statement

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 undertake legal responsibilities.

13 EMC-Declaration of conformity

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

Technical Description Concerning Electromagnetic Emission

Table 1: Declaration - electromagnetic emissions

Guidance and manufacturer’s declaration - electromagnetic emissions		
The model i-Polish is intended for use in the electromagnetic environment specified below. The customer or the user of the model i-Polish should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance

RF emissions CISPR 11	Group 1	The model i-Polish uses RF energy Only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The model i-Polish is suitable for used in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Technical Description Concerning Electromagnetic Immunity

Table 2: Guidance & Declaration - electromagnetic immunity

Guidance & Declaration — electromagnetic immunity

The model i-Polish is intended for use in the electromagnetic environment specified below. The customer or the user of the model i-Polish should assure that It is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±2, ±4, ±8, ±15kVair	±8kV contact ±2, ±4, ±8, ±15kV 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 ±1kV for Input/ output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5, ±1kV line to line ±0.5, ±1, ±2kV line to earth	±0.5, ±1kV line to line ±0.5, ±1, ±2kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT.) for 1 cycle 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 250 cycles	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT.) for 1 cycle 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models i-Polish requires continued operation during power mains interruptions, it is recommended that the models i-Polish be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

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

Guidance & Declaration - Electromagnetic immunity			
The model i-Polish is intended for use in the electromagnetic environment specified below. The customer or the user of the models i-Polish should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

Conducted RF IEC61000-4-6 Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM frequency band 3 V/m 80 MHz to2.7 GHz	3V 6V 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the models i-Polish, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.2×P1/2 d=2×P1/2 d=1.2×P1/2 80 MHz to 800MHz d=2.3×P1/2 800 MHz to 2.7GHz where P is the maximum output power rating of the transmitter In watts (W) according to the transmitter manufacturer and d Is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur In the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz. the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
a Fieldstrengthsfromfixedtransmitters,suchasbasebasesforradio(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 model i-Polish is used exceeds the Applicable RF compliance level above, the model i-Polish should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model i-Polish. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 4: Recommended separation distances between portable and mobile RF communications equipment and the model i-Polish

Recommended separation distances between portable and mobile RF communications equipment and the model i-Polish			
The model i-Polish is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model i-Polish can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model i-Polish as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz d=1.2×P1/2	80MHz to 800MHz d=1.2×P1/2	800MHz to 2,7GHz d=2.3×P1/2
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3

10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.

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

14. FCC Statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause

undesired operation.

This device has been tested and found to comply with the limits for a WPC device, pursuant to Part 18 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment should be installed and operated with a minimum distance of 0mm between the radiator and your body.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules and has been tested and found to comply with the limits for a wireless power charger, pursuant to Part 18 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in

accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-- Reorient or relocate the receiving antenna.

-- Increase the separation between the equipment and receiver.

-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-- Consult the dealer or an experienced radio/TV technician for help.

Scan and Login website
for more information

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