

**Cordless Prophy System** 

# **Prophy-Mini Instruction Manual**

Federal law restricts this device to sale by or on the order of a dentist. Please carefully read Instruction Munual before operating ZMN-SM-936 V1.0-20240330



www.glwoodpecker.com

**GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.** 

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## **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

Device Name: Cordless Prophy System

Model: Prophy-Mini

Prophy-Mini is a cordless prophylaxis motor component equipped with control buttons. With Disposable Prophy Angle, it can be used for teeth cleaning and polishing.

Features:

a) Motor component

b) Connector

c) Base.

## 1.3. Intended use/Indication for use

Prophy-Mini is a cordless prophylaxis motor component equipped with control buttons for use with Disposable Prophy Angle in hygiene operatory to perform cleaning and polishing procedures on teeth surface and fillings.

#### 1.4. Contraindication

None.

#### 1.5. Precautions and Warnings

Before using this product, carefully read and follow all instructions and retain it for future reference. Observe all precautions and warnings.(DPA-Disposable Prophy Angle)

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

 $\cdot$  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.

· Hemophilia patients are prohibited from using this device.

 $\cdot$  For patients with heart disease, pregnant women and young children, cautiously use this device.

· Check items received and do not use if items are missing or damaged.

 $\cdot$  This device should be only operated by professional and qualified dentists in qualified hospital or clinic.

 $\cdot$  As with all dental procedures, use universal precautions (i.e., wear face mask, eyewear, or face shield, gloves and protective gown).

· Do not use if labels are illegible, smudged, damaged or lost.

 $\cdot$  Use only components and accessories in Section 1.8 of this manual. Failure to do so will void the warranty, may decrease motor component performance, may lead to unsafe operation, may negatively affect electromagnetic compatibility (EMC) performance and result in non-compliance.

· Charge the motor component using only the prophy-mini supplied power adapter. Failure to use the supplied power adapter might cause a malfunction and result in a void of your warranty.

• The connector must be steam autoclave sterilized before first use and between patients to prevent patient cross-contamination.

 $\cdot$  To prevent bodily injury and damage to the device, do not sterilize the motor component, AC adapter, or base. Using only the tested and approved disinfectants listed in Section 4.

· The motor component and power adapter are not waterproof. To prevent

damage to the equipment, contamination or bodily injury, do not immerse any of these components in water or a chemical solution.

 $\cdot$  Do not spray disinfectant or other fluids directly onto the motor component, or power adapter in order to avoid liquid from pooling on these components.

 Inspect the motor component before each use for worn, loose or damaged parts. Do not attempt to operate unless the DPA is properly installed. A loose DPA could separate from the motor component causing bodily injury. Reinstall the DPA or replace any damaged parts as necessary.

· Never insert a DPA into the connector while it is operating.

 $\cdot$  Before the motor component stop rotating, do not install or remove the connector. Otherwise, the motor component and the connector may be damaged.

 $\cdot$  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.

 $\cdot$  Do not place the motor component on or next to a radiator or any other heat source. Excessive heat may damage the motor component's electronics.

• According to IEC 60601-1/UL60601-1, this device must not be used in the presence of a flammable anesthetic gas mixed with air, oxygen, or nitrous oxide. (NOTE: Nitrous oxide by itself is not a flammable anesthetic gas.)

 $\cdot$  The lithium-ion battery is not user replaceable. When needed, the unit should be returned to local distributor.

• 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.

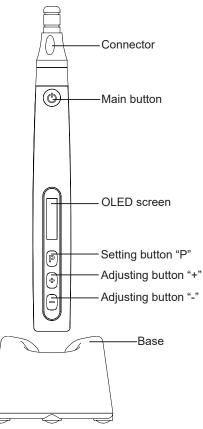
· Long term use of equipment may result in overheat of motor motor component; thus it should be left to cool for next use. If the motor component is overheated frequently, please contact local distributor.

 $\cdot$  Charging will generate heat, and the surface temperature of the motor component will rise.

· The motor component is prohibited for use while charging.

· Do not use Lubrication.

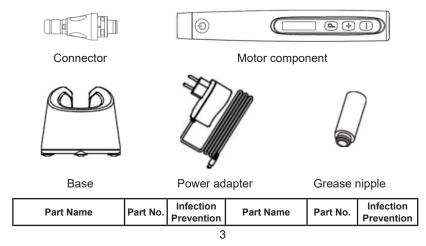
1.6. Product Composition



## 1.7. Packaging items

Confirm the prophy-mini on the packaging and verify the following components and accessories are included. If an item is mission, contact us.

- · 1 Connector
- · 1 Motor component
- · 1 Grease nipple
- · 1 Base
- · 1 Power adapter
- 1.8. Component description



Motor component The motor component house the motor, power supply (lithium-ion battery), OLED screen and four buttons. The motor component is not sterilizable and is to be	/	Disinfect	Power Adapter Converts AC current into DC current required for charging the motor compo-	Туре	Disinfect
used for provide speed and torque.			nent.		
Connector The connector is a sterilizable part that acts as an interface between DPA and the motor com- ponent. The connector features and on-board user centralized control buttons for power and rotation speed control.	AD141	Steam Autoclave	Grease nipple It is auxiliary for connector main- tenance.	N/A	N/A
Base The base is used to place the motor compo- nent.There is no elec- tronic component in this part.		Disinfect			

## 2. Direction for use

2.1. Charging for the motor component

Warnings

· Do not use if labels are illegible, smudged, damaged or lost.

· Check items received and do not use if items are missing.

The motor component must be charging prior to first use, fully charge the motor component using the power adapter provided. Failure to use the supplied power adapter might cause malfunctions and result in a serious hazard. 1) Be sure to plug in power adapter into appropriate electrical outlet.

2) Connect the motor component to the power adapter.

3) When charging the battery icon will flash regularly. After fully charged, the battery icon will be stationary.

Battery icon	Battery level	Battery icon state
	Battery full charged	
	Capacity of 2/3	
	Capacity of 1/3	
	Battery low	

2.2. Installation of the motor component

## Warnings

 $\cdot$  Before installing the connector and DPA, please ensure the motor component is stopped and fully charged.

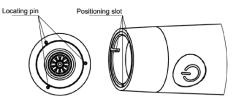
 $\cdot$  Before using the connector, please ensure it is intact. If it is damaged, please do not use it.

 $\cdot$  Please use the DPA fitting this device. Otherwise, the DPA and the connector will be damaged.

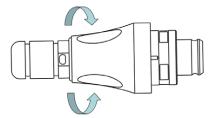
1) Ensure that the connector has been autoclaved prior to use according to the Infection Prevention Procedure.

2) Install the connector into the motor component.

Align any locating pin of the connector with the locating slot on the motor component, push the connector horizontally, and match the four locating pins on the connector with the four locating holes on the motor component, "click" indicates that it is installed in place.



The connector can rotate freely, adapt to the polishing of teeth in different positions, and it is convenient to watch the screen when operating.

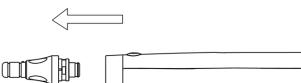


3) Disassembly

When the motor component is not started, directly pull out the connector horizontally.

a) Stop the motor component before unplugging and plugging the connector.b) After installing the connector, confirm that the connector has been assembled in place.

c) Connector cannot be repaired on site.

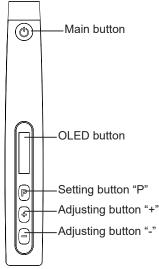


2.3. Function Introduction

Warnings

 $\cdot$  Before turning on the motor component, make sure it is fully charged and all components are in place.

2.3.1 Key definition and setting



2.3.2 Motor component key function

2.3.2.1 Main key function

(1) When the motor component is turned off, press the main button (b) of the motor component to turn the handle on.

(2)When the motor component is turned on, short press the main button (2) of the handle to start and stop the motor component.

2.3.2.2 Setting key "P" function

In the standby or running mode of the motor component, short press the setting key "P" to switch speed. There are two speed values that can be quickly switched.

2.3.2.3 Adjustment key function

In the standby or running mode of the motor component, short press the adjustment key "+" or "-" to adjust the handle speed.

2.3.2.4 Setting functions

(1) When the motor component is turned off, hold down the adjustment key "+" and short press the main button ((b) to calibrate the motor operation.

(2) When the motor component is turned off, hold down the setting key "P" and short press the main button (b) to enter the memory mode setting and the speed value corresponding to P1 mode flashes. Short press the adjustment key "+" or "-" to adjust the speed value memorized by P1. Short press the setting key "P" again to enter P2 mode to remember the speed value setting. The adjustment method is the same as above. After setting up, short press the main button to enter standby mode.

## 3. Operating your Prophy-Mini

## Warnings

 $\cdot$  Before turning on the motor component, make sure it is fully charged and all components are in place.

3.1 Power on and off

(1)Power on: when the motor component is turned off, briefly press the main button (2), the buzzer will sound a prompt tone, the blue indicator light will be on, the display screen will be on, and the motor component will enter the standby state.

(2) Power off:

(a) When the motor component is turned on, press and hold the "P" key first,

and then press the main key (b) and the display screen is off, and the motor component can be turned off.

(b) In the power-on state, if the motor component does not be operated within 10 minutes, it will be automatically shut down.

#### 3.2 Running Mode

(1)When the motor component is turned on, press the main key (b) briefly

to start and stop of the motor component. The rotation  $\mathbf{N}$  on the display indicates that the handle is working, and the non- rotation indicates that the handle stops working.

(2)In the standby or running mode of the motor component, short press the "+" and "-" buttons to adjust the speed of the handle.

The speed range is 500rpm,1000rpm,1500rpm,2000rpm,2500rpm,3000rpm in turn.

#### 3.3 Operation steps

3.3.1 After installing the motor component, briefly press the handle button to start the motor component. When the screen of the motor component is on, it means that the motor component hasbeen started.

3.3.2 Adjust the handle to the low speed gear (500rpm) and then immerse the head of DPA at the tooth protection corner into the polishing paste, so that the head of DPA is soaked with enough polishing paste.

3.3.3 Use the button of the motor component to adjust the rotation speed of the motor component to the appropriate speed, and then the patient can be treated.

3.3.4 After the treatment, stop the rotation of the motor component first, and then take out the DPA and connector.

3.3.5 Conduct high temperature and high pressure sterilization on the connector, and disinfect the motor component and base (see section 4 for instructions).

## 4. Cleaning, Disinfection and Sterilization

The objective of the information provided in this section is to reduce the potential for patient cross contamination when using the device. Please follow all cleaning, disinfection and sterilization procedures as recommended.

## Warnings

 $\cdot$  Do not place the connector in a disinfectant solution or in an ultrasonic bath.

· Do not use chloride detergent materials.

· Do not use bleach or chloride disinfectant materials.

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

 $\cdot$  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.

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

The Prophy-Mini consists of the following parts:

Part	Infection Prevention
Motor component	Manual cleaning and disinfection
Base	Manual cleaning and disinfection
Power adapter	Manual cleaning and disinfection
Connector	Auto Cleaning, steam Autoclave
Grease nipple	N/A

Note: Sterilize the connector prior to each use. Additional connectors are available for purchase to accommodate uninterrupted patient procedure.

4.1. Instruction for Cleaning and Sterilizing of the Connector

#### Warnings

· These instructions are for use ONLY on the connector;

 $\cdot$  The connector is not sterile upon receipt and must be steam autoclave sterilized prior to use in accordance with the following instructions.

 Cold liquid disinfection/sterilization, chemical vapor sterilization, and dry heat sterilization methods have not been tested or validated for efficacy and are not recommended for use.

· Do not immerse the connector in an ultrasonic bath.

 $\cdot$  The use of strong detergent and disinfectant (alkaline pH>9 or acid pH <5) will reduce the life span of products.

4.1.1. Limitation of re-processing

The connector has 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 connector is 250 times.

## 4.1.2. Initial processing

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 produce-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.

## 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 connector from the motor component, and rinse away the dirt on the surface of connector with pure water (or distilled water/ deionized water);

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.

#### Preparation before cleaning Steps

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

1) Remove the DPA.

2) Remove the connector from the motor component, and then put them into a clean tray;

3) Use a clean soft brush to carefully brush connector until the dirt on surface is not visible. Then use soft cloth to dry the products and put them into a clean tray.

#### 4.1.3. Cleaning

The cleaning should be performed no later than 24 hours after treatment. The connector could be cleaning by automated cleaning.

#### **Automated Cleaning**

Use only washer-disinfector which is meet the FDA requirement for cleaning process, and follow the manufacturer's instructions for correct use.

Wear appropriate PPE (e.g., mask, protective eyewear, and gown) when

splashing or spraying is anticipated during cleaning. Use only verified cleaning agent below to cleaning the connector: Cleaning agent name: RUHOF ENDOZIME®AW PLUS WITH APA Manufacturer: The RUHOF CORPORATION.

According to the following steps to cleaning the connector.

No.	Cleaning Process
Prepare	After removing the connector from the motor component, the con- nector is placed into the disinfection basket carefully. The mesh of the sterilization basket must not allow the connector to leak from it, do not allow products to touch each other to prevent scratching of the surface and cross contamination.
Pre-clean	Us tap water or purified water or distilled or deionized water at room temperature of 25°C to pre-rinse for 3 minutes to remove visible contaminants on the surface.
Cleaning	Cleaning with cleaning agent at the condition recommended by the cleaning agent manufacturer for 5 minutes: Detergent: RUHOF ENDOZIME®AW PLUS WITH APA Dilution Ration: 1:270 Temperature: <60°C Contact time: 5 minutes
Rinsing	Rinse away the dirt with purified water or distilled water or deion- ized water at room temperature of 25°C for 1 minute.
Wipe dry	Use a clean sterile cloth or dray paper to wipe the surface to re- move excess water.

#### Inspection and maintenance

1) In this process, we only check the appearance of the product. 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 connector. 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 service time (number of times) of the product reaches the specified service life (number of times), please replace it in time. Packaging

Install the cleaned/disinfected and dried connector and quickly package it to maintaining sterility. It is recommended use of a legally marketed warp, pouch, or other method of maintaining sterility for the following sterilization cycle.

Notes:

 $\cdot$  The packaging environment and related tools must be cleaned regularly to ensure cleanliness and prevent the introduction of contaminants;

· Avoid contact with parts of different metals when packaging.

4.1.4. Sterilization

Warnings

Use only the following steam sterilization procedures (fractional pre-vacuum procedure\*) for sterilization, and other sterilization procedures are prohibited. 1) Place bagged connector into a steam autoclave, per the autoclave manufacture's instruction.

2) It is recommended to use the validated sterilization parameters: The sterilization time is at 4 minutes at a temperature of 132°C/134°C and a pressure of 185kPa to 190kPa. And the drying time is 20 minutes.

3) The highest sterilization temperature is 138°C.

4) Allow a maximum sterilization time of 20 minutes at 132°C.

5) Connector should remain bagged until ready for use.

Verification of the fundamental suitability of the products for effective steam

sterilization was provided by a verified testing laboratory. Notes:

 $\cdot$  Only products that have been effectively cleaned and disinfected are allowed to be sterilized.

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

 $\cdot$  Do not use hot air sterilization and radiation sterilization as this may result in damage to the product.

 $\cdot$  Please use the recommended sterilization procedures for sterilization. It is not recommended to sterilize with other device.

• 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.

#### Storage

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;

After sterilization, the product should remain bagged until ready for use. The storage time cannot exceed 7 days. If it is exceeded, it should be reprocessed before use.

Notes:

· The storage environment should be clean and must be disinfected regularly;

· Product storage must be batched and marked and recorded.

### Transportation

Prevent excessive shock and vibration during transportation, and motor component with care.

It should not be mixed with dangerous goods during transportation.

Avoid exposure to sun or rain or snow during transportation.

4.2. Instruction for Cleaning and Disinfecting of the Motor component, base and power adapter

## Warnings

 $\cdot$  Do not sterilize the motor component, power adapter and base.

 $\cdot$  The motor component, power adapter and base can not be cleaned and disinfected with automatic equipment. Manual cleaning and disinfection are required.

4.2.1. Pre-Operation processing

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

4.2.2. Manual Cleaning Steps

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

2) Wet the soft cloth completely with distilled water or deionized water, thoroughly wipe all the surfaces of the components such as the motor component, power adapter and 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 until all visible soil is removed.5) Wipe surfaces dry with a clean cloth.

Note:

Use distilled water or deionized water for cleaning at room temperature. 4.2.3. Manual Disinfection Steps

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

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

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

4) Visually inspect to ensure that all contamination has been removed, and inspect power supply cord for damage.

Note:

 $\cdot$  The cleaning and disinfection must be performed within 10min before use.

4.2.4. Post-Operation processing

Storage

After cleaning and disinfection, store all components in a specified storage environment.

## 5. Specifications

5.1 Foreword

Items	Specification		
Power source	Rechargeable lithium battery 3.6V, 850mAh;		
Rated input	100V-240V~, 50Hz/60Hz, 0.4A Max		
Rated output	DC5V, 1A		
Type of protection against electric shock	Class II		
Degree of protection against electric shock	Type B applied part		
Degree of protection against harmful ingress of liquid	Motor component: IPX0; Base: IPX0 Power adapter: IPX0		
Operating environment	Ambient temperature: +5°C ~ +40°C Relative humidity: 30% ~ 75% Atmospheric pressure: 70kPa ~106kPa		
Transport and Storage Condition	Ambient temperature: -20°C ~ +55°C Relative humidity: 10% ~ 93% Atmospheric pressure: 70kPa ~106kPa		
Motor component speeds (+/-10%)	6 speed level: (500 rpm default) 500 rpm, 1000 rpm, 1500 rpm, 2000 rpm, 2500 rpm, 3000 rpm.		
Maximum Torque (+/-10%)	3.0Ncm		
Service life	5 years		
Auto-off time	The motor component will automatically shut down if the standby time exceeds 10 minutes		

## 6. Troubleshooting

Failure	Solution
Disposable Prophy Angle is not rotating	<ol> <li>Ensure that the connector and the DPA are snapped together securely.</li> <li>Ensure that the motor component and the connector are snapped together securely.</li> <li>Ensure the Disposable Prophy Angle is not damaged.</li> <li>Ensure the connector is not damaged.</li> </ol>
Excessive noise or vibration during operation	<ol> <li>Ensure that the connector and the DPA are snapped together securely.</li> <li>Ensure that the motor component and the connector are snapped together securely.</li> <li>Ensure the DPA is not damaged.</li> <li>Ensure the connector is not damaged.</li> </ol>
Difficult to removing or installing the connec- tor.	<ol> <li>Ensure the connector is not damaged.</li> <li>Check and clean the connector.</li> </ol>

Motor component cannot be charged	<ol> <li>Check for foreign matter between power adapter and motor component.</li> <li>Check whether the original power adapter is used.</li> </ol>
	3. Replace the battery.

## 7. Maintenance and Disposal

7.1. Maintenance

## Warnings

This device does not include accessories for repair usage, the repair should be carried out by authorized person or authorized after service center.

- $\cdot$  Keep the equipment in a dry storage condition.
- $\cdot$  Do not throw, beat or shock the equipment.
- $\cdot$  Do not smear the equipment with pigments.
- $\cdot$  Replace the battery if it seems to be running out.

#### 7.2. Replacing the O-ring

## Warnings

The O-ring should be regularly replaced every 6 months or if needed.

· Remove the DPA from the connector.

· Hold the O-ring between your thumb and index finger and apply firm pressure to disengage the ring from the metal channel.

· Pull the old O-ring off and replace with a new O-ring.

#### 7.3. Disposal of components

1) Dispose of the motor component components in accordance with state and local laws.

2) Dispose of the base and power adapter as industrial waste according to local laws and regulations.

3) Dispose of the connector as medical waste according to local laws and regulations.

4) The motor component include a battery pack (lithium-ion battery). Do not dispose of in a fire or source of heat. Doing so may cause rupture of the battery pack, scattering of the battery fluid, overheating, smoking, or explosion.

## 8. Symbol Instruction

	Follow Instructions for Use	SN	Serial number
	Date of manufacturing		Manufacturer
<b>†</b>	Type B applied part		Class II equipment
I	motor component with care	Ť	Keep dry
	For indoor use only	10%	Humidity limitation-indicates the acceptable upper and lower limits of relative humidity for transport and storage
-20°C	Temperature limitation-in- dicates the maximum and minimum temperature lim- its at which the item shall be stored, transported or used.	70kPa	Atmospheric pressure limitation- indicate the acceptable upper and lower limits of atmospheric pres- sure for transport and storage.

IPX0	Degree of protection against harmful ingress of liquid		Caution: Federal law restricts this device to sale by or on the order of a licensed dental professional
Ì	Appliance compliance WEEE directive		Warning
132°C ∫∫∫∫	Sterilize up to temperature specified	₩PY×××××× PA××××××Y	Serial number barcode

## 9. EMC Declaration of Conformity

The device has been tested and homologated in accordance with IEC 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.

Table 1: Declaration - Electromagnetic emissions

This equipment is intended for use in the electromagnetic environment specified below. The user should comply to specifications ensuring the device is only used in an appropriate environment.

Emissions test	Compliance	Electromagnetic Environment - Guidance		
RF emissions, CISPR 11	Group 1	The modelProphy-Mini 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, CISPR 11	Class B			
Harmonic emissions, IEC 61000-3-2	Class A	This equipment is suitable for domestic establish- ments and those directly connected to the public		
Voltage fluctuations/ flicker emissions, IEC 61000-3-3	Complies	low-voltage power supply network.		

#### Table 2: Guidance & Declaration - electromagnetic immunity

		-			
This equipment is intended for use in the electromagnetic environment specified below. The user should comply to specifications ensuring the device is only used in an appropriate envi- ronment.					
Immunity test	IEC 60601 test level	Electromagnetic environment - guidance			
Electrostatic dis- charge (ESD) IEC 61000-4-2		$\frac{128}{1}$ kV contact $\frac{128}{1}$ kV contact $\frac{128}{1}$ kV contact $\frac{128}{1}$ kV contact $\frac{128}{1}$ crete or ceramin should be at least $\frac{128}{1}$ kV contact $\frac{128}{1}$ crete or ceramin should be at least $\frac{128}{1}$ kV contact $\frac{128}{1}$ crete or ceramin should be at least $\frac{128}{1}$ kV contact $\frac{128}{1}$ crete or ceramin $\frac{128}{1}$ kV contact $\frac{128}{1}$ crete or ceramin $\frac{128}{1}$ contact $\frac{128}{1}$ kV contact $\frac{128}{1}$ crete or ceramin $\frac{128}{1}$ crete or ceramin $\frac{128}{$	Floors should be wood, con- crete or ceramic tile. Humidity should be at least 30% if it is synthetic materials.		
Electrical fast tran- sients/bursts (EFT) IEC 61000-4-4	±2kV for power supply lines ±1kV for Input/ output lines	±2kV for power	Main power quality should b		
Surge IEC 61000-4-5	±0.5kV, ±1kV line-to- line ±0.5kV, ±1kV, ±2kV line-to-ground	±0.5kV, ±1kV line-to-line ±0.5kV, ±1kV, ±2kV line-to- ground	that of a typical commercial or hospital environment.		

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	(>95% dip in U <sub>⊤</sub> .) for 1 cycle	(>95% dip in U <sub>T</sub> .) for 1 cycle 70% U <sub>T</sub>	Mains power quality should be typical commercial or hospital environment. UPS power is recommended if this device needs to be used continuously.			
RATED power frequency magnetic fields IEC 61000-4- 8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical lo- cation in a typical commercial or hospital environment.			
Note: $U_T$ is the A.C. mains voltage prior to application of the test level.						

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150 kHz to 80 MHz 6Vrms in ISM and amateur radio bands 10 V/m 80 MHz to 2.7 GHz	3Vrms 6Vrms in ISM and amateur radio bands 10 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any parts that the recommended separation distance that calculated from the equation applicable to the fre quency of the transmitter. Recommended separation dis tance: $d = 1.2\sqrt{p}$ 150 kHz to 80 MHz $d = 1.2\sqrt{p}$ 80 MHz to 800 MHz $d = 1.2\sqrt{p}$ 80 MHz to 800 MHz $d = 2.3\sqrt{p}$ 80 MHz to 2.7 GHz at RF wireless communications equipment bands (Portable RF communications equipmen (including peripherals such as antenna cables and external an tennas) should be used no close than 30 cm (12 inches) to any part of the device). Where "P" is the maximum output power rating of the transmitte in watts according to transmitte manufacturer and "d" is the reco ommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (b), should be less than the com pliance level in each frequency range (c). Interference may occur in the vicinity of equipment marked with the following symbol: $(((\cdot)))$

This equipment should be used in the electromagnetic environment specified below. The user

Note 1: at 80MHz-800MHz, the higher frequency range applies. Note 2: these guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and refection 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 product is used exceeds the applicable RF compliance level stated above, the product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the product.

b. Over the frequency range 150kHz to 30MHz, the field strength should be less than 3V/m

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

The model Prophy-Mini is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model Prophy-Mini can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model Prophy-Mini as recommended below, according to the maximum output power of the communications equipment.

Rated maximum	Separation distance according to frequency of transmitter (m)			
output power of transmitter (W)	150kHz -80MHz d= 1.2√P	80MHz -800MHz d=1. 2√P	800MHz -2.7GHz d=2. 3√P	
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 can be estimated using the equation applicable to the frequency of transmitter, where "p" is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer.

Note 1: at 80M-800MHz, 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 refection from structures, objects and people.

## 10. About Us

Scan and Login website for more information





## Guilin Woodpecker Medical Instrument Co., Ltd.

Information Industrial Park, Guilin National High-Tech Zone, Guilin, Guangxi, 541004 P. R. China Sales Dept.: +86-773-5873196/2350599 After-sales Service Dept.: +86-0773-5827898 E-mail: woodpecker4@glwoodpecker.com Website: http://www.glwoodpecker.com

#### Warranty Instruction

#### I Period validity:

The motor component, base, power adapter have two years warranty period from the date of purchase. The connector and battery are warranted for one year and other accessories are excluded from the warranty

II Range of warranty:

Within the warranty period of validity, we are responsible for any troubles caused by quality problems or products technique and structure.

III The following are beyond our warranty:1. The damage caused by disobeying the operation instruction or lack of the needed condition.

2. The damage caused by unsuitable operation or disassembly without authorization.

3. The damage caused by unadvisable

transportation or preservation.

4. There isn't the seal of distributor or the warranty card isn't filled in completed.

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3. The damage caused by unadvisable

transportation or preservation.4. There isn't the seal of distributor or the

warranty card isn't filled in completed.

#### Warranty Card Name of Customer Address Details T Ι Ι T Postal Code Ι (I) Tel Ι For Distributor Ι Model T Motor Handpiece No T 1 Purchase Date T Contact Persor 1 Date Maintenance Record Repairer 1 1 1 1 1 1 Guilin Woodpecker Medical Instrument Co.,Ltd. Information Industrial Park, Guilin National High-Tech Zone, Guilin, Guangxi, 541004 P. R. China Sales Dept.: +86-773-5873196/2350599 After-sales Service Dept.: +86-0773-5827898 E-mail: woodpecker4@glwoodpecker.com Website: http://www.glwoodpecker.com Distributor: Seal

# Name of Customer Address Details Postal Code (II)Tel Return to Manufactur Model Motor Handpiece No Purchase Date Contact Perso Date Maintenance Record Repairer Guilin Woodpecker Medical Instrument Co.,Ltd. Information Industrial Park, Guilin National High-Tech Zone, Guilin, Guangxi, 541004 P. R. China Sales Dept.: +86-773-5873196/2350599 After-sales Service Dept.: +86-0773-5827898 E-mail: woodpecker4@glwoodpecker.com Website: http://www.glwoodpecker.com Distributor: Seal

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Warranty Card