Directions for use

AeroPro™

Cordless Prophy System

Please read carefully and completely
before operating unit.

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1.1 Intro Page – Premier® AeroPro™ Cordless Prophy System

Thank you for purchasing Premier's AeroPro Cordless Prophy System.

Please read this manual to ensure proper operation and maintenance of the handpiece. Keep the manual available for future reference.

Take a few minutes to register your Premier AeroPro cordless handpiece as instructed in the warranty section of this manual (Section 9). By registering the unit it ensures prompt and accurate service and support should your unit need to be repaired or replaced during the warranty period. Register at www.premusa.com/aeroprowarrantyregistration

1.2 Overview

The Premier AeroPro cordless prophy system has been designed to provide the clinician with an ergonomic handpiece that provides independence from heavy cord-drag, complete control and operator comfort during prophylaxis procedures. This system was engineered with ChargeSMART™ technology to provide the clinician a full-day battery life. Premier's handpiece provides the flexibility of using Premier's 2pro® prophy angle or most other preferred disposable prophy angles (DPA) on the market.

In compliance with the CDC's sterilization and infection control guidelines, to protect the clinician and the patient, the sterilizable outer sheath has been designed to be steam autoclavable. Premier suggests the clinician acquires enough sheaths to cover the number of procedures during one shift between sterilization cycles. Per FDA guidelines, Premier has custom-designed a disposable polyethylene barrier to cover the motor component (handpiece) after properly disinfecting the system between patients.

1.3 User and Indications for Use

1.3.1 User

Licensed Dental Professional

1.3.2 Indications for Use

AeroPro Cordless Prophy System is a prescription only, high performance cordless prophylaxis handpiece with a centralized control button for use with disposable prophylaxis angles to perform cleaning and polishing procedures on teeth.

2.1 Contraindications

None known

2.2 Warnings

- Check items received and do not use if items are missing to prevent damage. **(See Section 3.1)**
- Do not use if labels are illegible, smudged, damaged or lost.
- Charge the cordless handpiece using only the AeroPro charging station and the supplied AC adapter. **Failure to use the supplied AeroPro AC adapter might cause a malfunction and result in a void of your warranty.**
- Sterilizing the motor component will cause damage to the cordless handpiece and the sterilizing equipment, and may cause personal bodily injury.
- The autoclavable outer sheath must be steam autoclave sterilized before first use and between patients to prevent patient cross-contamination. See **Section 4.8** for the Infection Control Procedures.
- The disposable prophy angles (DPAs) are designed for single-patient use only and should never be used more than once. DPAs are not autoclavable or designed to withstand disinfection solutions. The risks of reuse of a DPA are damage to equipment and patient cross-contamination. Install a new DPA between each patient.
- It is the responsibility of the Licensed Dental Professional to determine the appropriate uses of this product and to understand:
    - the general health status of each patient
    - the dental procedures being undertaken
    - applicable industry and governmental agency recommendations for infection control in dental healthcare settings
    - requirements and regulations for the safe practice of dentistry
    - the Directions for Use in their entirety
- Per FCC Part 15.21, changes or modifications not expressly approved by the party responsible for compliance (i.e., the manufacturer) could void the user's authority to operate this equipment.
- Failure to follow recommendations for environmental operating conditions **(see Section 5.1)** could result in injury to patients or users.
- Inspect the cordless handpiece system 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 cordless handpiece causing bodily injury. Reinstall the DPA or replace any damaged parts as necessary such as the O-rings. **(See Section 6.1)**

- To prevent bodily injury and damage to the device, do not sterilize the DPA, motor component, charging station or AC adapter. Disinfect the motor component, charging station or AC adapter using only the tested and approved disinfectants listed in **Section 4.8.2**, Infection Control Procedures.
- The motor component, charging station and AC 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.
- Do not spray disinfectant or other fluids directly onto the motor component, charging station, or AC adapter in order to avoid liquid from pooling on these system components. The user should spray solution onto a cloth or use a wipe to disinfect these items per the instructions in **Section 4.8.2**.
- Use only components and accessories listed in Section 3 of this manual. Failure to do so will void the warranty, may decrease system performance, may lead to unsafe operation, may negatively affect electromagnetic compatibility (EMC) performance and result in non-compliance.
- Never insert a DPA into the cordless handpiece while it is operating.
- Dispose of Premier's 2pro prophy angles after each patient according to CDC Guidelines for Infectious Waste and Federal, State and Local regulations.
- There are no user-serviceable items in the motor component, AC adapter, sterilizable outer sheath, or charging station. Opening the motor component or any unauthorized modification of any of these units may result in unsafe operation and will void the warranty.
- 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.)

2.3 Precautions for Handling and Operations

Before using this product, carefully read and follow all instructions and retain it for future reference.
Observe all precautions and warnings.

- As with all dental procedures, use universal precautions (i.e., wear face mask, eyewear, or face shield, gloves and protective gown.
- AeroPro's motor located inside the motor component is designed to be lube-free. Lubrication may cause damage to the cordless handpiece motor component.
- Oil and/or dirt may damage the motor, electronics and battery located inside the motor component. Take care to prevent external objects from entering the handpiece system.
- The lithium ion battery is <u>**not**</u> user replaceable. When needed, the unit should be returned to Premier for service.
- Do not place the system on or next to a radiator or any other heat source. Excessive heat may damage the system's electronics.
- This device complies with Part 15 of the FCC Rules and with Industry Canada license-exempt RSS standard(s). 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 undesirable operation.

- Changes or modifications not expressly approved by the party responsible for compliance (i.e. the manufacturer) could void the user's authority to operate the equipment.
- This Class A digital apparatus complies with Canadian ICES-003.
- FCC ID: 2AQ77-2018-AP
- IC: 24334 - AEROPRO
- Model # AP-18-PDPC
- Product Marketing Name: AeroPro System

2.4 Adverse Events

There are no known adverse reactions.

3.1 Your System Components

Confirm the AeroPro Cordless Prophy System by the REF# on the packaging and verify the following components and accessories are included. If an item is missing, call Premier Customer Experience at 888-670-6100 or 610-239-6000

Basic Kit - #5500500	Complete Package - #5500510
1 Motor Component	1 Motor Component
1 Autoclavable Outer Sheath	3 Autoclavable Outer Sheaths
1 Charging Station	1 Charging Station
1 AC Adapter	1 AC Adapter
1 Stand	1 Stand
1 Box Of 500 Disposable Barriers	1 Box Of 500 Disposable Barriers
1 Bag Of 48 Units 2Pro® Disposable Prophy Angles	2 Bags Of 144 Units 2Pro® Disposable Prophy Angles
1 Extra Set Of O-Rings And Tool For Maintenance	1 Extra Set Of O-Rings And Tool For Maintenance
(2 Small O-Rings For The Outer Sheath And 1 Large O-Ring For Motor Component)	(2 Small O-Rings For The Outer Sheath And 1 Large O-Ring For Motor Component)

3.2 Component Description

Part Name	Picture	Infection Control
Motor Component The motor component houses the motor, gear box, power supply (lithium-ion battery) and a battery light indicator. ***The motor component of AeroPro is not sterilizable*** and is to be used only with AeroPro disposable barriers.		Disinfect
Autoclavable Outer Sheath The outer sheath is a sterilizable protective cover that acts as a barrier to the internal handpiece component (motor component). It also houses the bearings and acts as an interface between a DPA and the motor component. The autoclavable outer sheath features an on-board user control button (ON/OFF/MODE) for power and rotation speed control.		Autoclave
Charging Station The charging station uses an induction charge mechanism, allowing the handpiece to be placed into the charger without regard to any particular alignment.		Disinfect
AC Adapter Converts AC current into DC current required for charging the AeroPro handpiece.		Disinfect
Stand Provides a passive support for the AeroPro handpiece on the tray when not in use. It is fully steam autoclavable. **NOTE:** *Do not confuse the autoclavable Stand for the non-autoclavable Charging Station.*		Autocalve
Disposable Barrier Placed over the motor component (under the outer sheath) for infection control.		N/A disposable
2pro® Disposable Prophy Angle (DPA)		N/A disposable
O-rings and Tool for Maintenance O-rings on the motor component and the outer sheath can be replaced as needed. A pack of O-rings and a replacement tool are included in the package.		Follow Instructions per component after replacement

3.3 Assembled Handpiece Features

4.1 Setting up the System

The system is packaged non-sterile. Refer to Section 4.8 for Infection Control Procedures.

- Do not use if labels are illegible, smudged, damaged or lost.
- Check items received and do not use if items are missing. (See Section 3.1)

4.1.1 Plug the power supply (AC Adapter) into the electrical outlet and insert the connector into the back of the charging station.

PRECAUTION: To prevent electrical failure/damage connect to single-phase AC power 100-240V power only.

4.1.2 The handpiece must be charged and unlocked prior to operation. Follow the initial charging instructions described below.

4.1.3 Charging for the first time - Prior to first use, fully charge the handpiece using the AeroPro AC adapter provided. **Failure to use the supplied AC adapter might cause malfunction and result in a void of your warranty.**

1) Be sure to plug in AC adapter into appropriate electrical outlet
2) Sit the motor component on the charging station connected to the AC adapter
3) (Optional: Assemble the autoclavable outer sheath on the motor component)
4) Charge for at least 2 hours
5) After fully charged, follow instructions for unlocking your AeroPro handpiece

4.2 Unlocking the Handpiece

4.2.1 Your AeroPro handpiece was factory shipped in a "Locked" position to prevent damage while in transit. The handpiece must be "Unlocked" prior to initial use.

4.2.2 To unlock the motor component follow the directions below. The unit will stay unlocked until it is relocked by the user.

4.2.3 Ensure that the motor component has been charged for at least 4 hours for initial use. Remove the motor component from the charging station. **The unit cannot be unlocked while in charging station.** Assemble the outer sheath onto the charged motor component; press and hold ON/OFF/MODE button for 3 seconds. The handpiece will beep 6 times and all the battery LED lights will flash simultaneously 6 times to indicate that the system is unlocked.

4.3 Pre-Operational Checks

PRECAUTION: The operator and the patient must wear safety glasses and the operator should wear the proper Personal Protective Equipment.

4.3.1 Ensure that the outer sheath has been steam autoclave sterilized according to the Infection Control Procedure **(Section 4.8).**

4.3.2 Insert the motor component into the AeroPro™ custom-fitted disposable barrier. Ensure that the nose of the motor component completely clears the opening of the disposable barrier.

PRECAUTION: Check the AeroPro™ disposable barrier for integrity before use; DO NOT use the barrier if it is damaged. Do not insert the covered motor component into the outer sheath without ensuring the AeroPro™ disposable barrier is clear of the motor component nose. Do NOT apply the AeroPro™ disposable barrier around the outer sheath. The protective outer sheath is designed to be sterilized before each use.

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

4.3.4 Attach a 2pro or equivalent DPA into the cordless handpiece. Due to the special friction grip tip design, no position pin is needed. So the handpiece can be operated by both right and left handed users.

NOTE: AeroPro is compatible with most DPAs.
PRECAUTION: Make sure motor is off before inserting the DPA.

4.3.5 Verify that all parts of the AeroPro system are securely attached before use.

4.3.6 Before use, operate the product outside the patients mouth and check that the DPA rotates properly. If abnormal vibration, noise or overheating is detected during testing or use, immediately stop use and contact Premier Dental customer support.

4.4 Adaptation Technique and Ergonomic Design

AeroPro's slim, lightweight, well-balanced ergonomic design allows for easy comfortable handling and operating while adapting to any size hand. With no position pin, the DPA can be positioned by rotation to gain access to any part of the mouth and all surfaces of each tooth, while being able to control the unit using the ON/OFF/MODE button. The tactile feel of the control button allows the operator to change speeds or shut down the unit easily with the finger of choice and comfort. AeroPro's high intensity motor is programmed to provide the same power and maintain a constant speed when pressure is applied to the tooth with the DPA's cup. This feature allows for tough stain removal without the worry of excessive heat or unit failure

4.5. Using your AeroPro™ Handpiece

4.5.1 Before turning on the AeroPro Cordless Handpiece, make sure it is fully charged and unlocked.

4.5.2 The AeroPro Cordless Handpiece can operate at three different speeds and has two (2) optional Speed Modes:

Speeds and Speed Modes

Operating Speeds	2-Speed Mode (factory setting)	3-Speed Mode
Low	500 rpm	500 rpm
Med	-	1500 rpm
High	2800 rpm	2800 rpm

The 2-Speed Mode allows the operator to go from low to high speed with one button touch (factory setting) or, if a greater range of speeds is preferred, the 3-Speed Mode can be selected by following the "Change Speed Mode" instructions in 4.5.7.

4.5.3 Using the Assembled Handpiece: Press the ON/OFF/MODE button once quickly using your thumb. The DPA tip will begin to rotate at low speed of 500 rpm. **Note:** The handpiece always goes to 500 rpm speed upon powering on from off state.

4.5.4 Use the low speed for dipping the DPA into the prophy paste. Press the cup of the DPA into the prophy paste, applying a downward force and light pressure. The low speed can also be used for very light stains and pedodontic patients.

4.5.5 Insert the handpiece into the patient's mouth and if desired change to high speed (2800 rpm) by pressing ON/OFF/MODE button again quickly and start polishing.

4.5.6 To turn handpiece off: To turn off the DPA rotation, press and hold ON/OFF/MODE button for 1 second.

4.5.7 Changing Speed Modes: Press and hold ON/OFF/MODE button for 3 seconds.
NOTE: Speed modes cannot be changed during operation. To change the speed mode, first turn off the hand piece, as per step 4.5.6.

4.5.7.1 ***From 2-speed to 3-speed mode:*** The factory setting is the 2-speed mode (low to high speed). To change the speed mode from 2-speed to 3-speed, press and hold ON/OFF/MODE button for 3 seconds. Three green LED lights flash and beep three times and the handpiece is switched to 3-speed mode.

4.5.7.2 ***From 3-speed to 2-speed mode:*** To change the speed mode from 3-speed to 2-speed, press and hold ON/OFF/MODE button for 3 seconds. Two top green LED lights flash and beep two times and the handpiece is switched to 2-speed mode.

4.5.7.3 Once the speed mode is selected, press and release ON/OFF/MODE button to go from one speed to another:

- ***2-speed mode:*** Press once to go from Low to High and again to go from High back to Low.
- ***3-speed mode:*** Press once to go from Low to Medium, press again to go from Medium to High, and again to go from High back to Low.

4.5.7.4 The selected speed mode will be saved until new speed mode selection is made.

4.5.8 After completion of treatment, turn off the handpiece and remove the DPA

4.5.8.1 To turn handpiece off: Press and hold ON/OFF/MODE button for 1 second.

4.5.8.2 To remove DPA: Pull straight on the DPA to remove.

4.5.9 Disassemble the hand piece for infection control procedure

4.5.9.1 Remove outer sheath for sterilization by steam autoclaving

4.5.9.2 Remove the AeroPro barrier from the motor component and discard it as medical waste

4.5.9.3 Disinfect the motor component

4.5.10 Place disinfected motor component back into the charging station.

4.6 Charging the Handpiece, ChargeSMART™ and Sleep Mode

4.6.1 Charge the battery prior to operation by placing the motor component into the charging station. The charging station uses an induction charge mechanism allowing the handpiece to be placed into the charger without regard to any particular alignment. **NOTE:** In order to provide the charge to the handpiece, the charging station must be plugged into the power source via the AC adaptor included with the system. **PRECAUTION:** Remove the barrier from the motor component before placing the handpiece into the charging station after use.

4.6.2 The handpiece is fully charged when all 5 LED lights are on. The disinfected handpiece can be put back into the charging station after each use.

NOTE: A smart charging management system, ChargeSMART™, allows for multiple charging throughout the day without the danger of premature battery decay. ChargeSMART™ senses when the unit is at 100% capacity and will stop the charging process to prolong battery life.

RECOMMENDATION: For maximum battery life avoid running battery to empty. The handpiece can perform up to 10 polishing cycles on a single charge.

4.6.3 Do not place the handpiece in charger while motor is running. Although the handpiece stops operating during charging, this is not recommended. NOTE: If ON/OFF/MODE button is pressed while the handpiece is in the charging station, it will not turn on. However, as soon as the handpiece is picked up from the charging station and ON/OFF/MODE button is pressed, it will start rotating at low speed.

4.6.4 During charging, the battery indicator lights blink in sequence from bottom to top: solid red, blinking yellow, 3 blinking green until charging is completed. If no lights are blinking, check position of motor component and reseat in the charging station.

4.6.5 The lights stop blinking in sequence when charging is completed. When the battery is fully charged, all five LED lights will display in a steady state (one red, one yellow and three green). NOTE: Allow 4 hours to fully charge the battery.

4.6.6 Battery indicator lights represent available power usage, as per table below:

Charge Status: Cordless Handpiece Charge Level

Battery Indicator Color (unit is outside charging base)	Light Functional Description	Charge Indicator Color (unit is in charging base)
Five Solid Lights: 1 red, 1 yellow, 3 green	Cordless Handpiece Charge is between 80% - 100%	Battery Fully Charged Five Solid Lights: 1 red, 1 yellow, 3 green
Four Solid Lights: 1 red, 1 yellow, 2 green	Cordless Handpiece Charge is between 60% - 79%	Battery charging in progress • Solid Red Stays on • 1 yellow, and 3 green lights are blinking in sequence from bottom segment to top segment
Three Solid Lights: 1 red, 1 yellow, 1 green	Cordless Handpiece Charge is between 40% - 59%	
Two Solid Lights: 1 red, 1 yellow	Cordless Handpiece Charge is between 20% - 39%	
Flashing Red Light	Warning indicator comes on - Cordless Handpiece Charge is less than 20%. Unit will soon shut off automatically, charge immediately.	
No Color	Cordless Handpiece is • turned off (locked mode) • in sleep mode • battery is fully discharged	Charge indicator light always stays on while the handpiece is in the charging station. If no lights are blinking, reseat motor component in charging station.

4.6.7 All the green lights disappear when the handpiece has less than 40% power remaining. Although the handpiece is able to perform normal operations, it is suggested to recharge the motor component immediately.

4.6.8 When the yellow light disappears and remaining red light begins flashing, the handpiece will shut off automatically to avoid damage to the motor, control system, and battery. At this point, the handpiece should not be operated and should be connected to the charging station immediately.

NOTE: When the battery power is very low (below 10%), the indicator lights will not display. The LED lights will turn back on when the battery returns to a safe power reserve level.

4.6.9 **Sleep Mode** (if cordless handpiece is not in a powered charging station)

4.6.9.1 Your AeroPro handpiece has been optimized with a sleep mode technology to improve the life of your battery. After 20 continuous seconds of non-use, the cordless handpiece will automatically enter the sleep mode phase and the battery light indicator will turn off. The Indicator light will illuminate again once you press the ON/OFF/MODE button.

4.6.9.2 If the handpiece is left in ON position (the motor is running) after 10 minutes of inactivity (ON/OFF/MODE button is not pressed) it will automatically turn off and the battery light indicator will turn off.

4.7 Locking the System

In the event the AeroPro cordless handpiece needs to be transported, it must first be set into the "Locked" position. The hand piece should only be locked when the battery LED lights show 4 lights or less

Important: To lock the handpiece must be placed into the charging station.

4.7.1 Place the assembled handpiece into the charging station, then press and hold the ON/OFF/MODE button for 3 seconds. **NOTE:** Make sure that the charging station is plugged into a power source.

4.7.2 The handpiece will beep 6 times and all battery LED lights will flash 6 times to indicate the system is going through the locking process.

4.7.3 Remove the handpiece from the charging station The handpiece is now "Locked" and all LED indicator lights are turned off. **NOTE:** If the handpiece is left in the charging station, the battery indicator lights will not go off, however, the handpiece will stay locked.

4.7.4 The system will remain in the selected speed mode setting that was used before locking the handpiece, and will restore to this mode upon unlocking.

4.8 Infection Control Procedures

The objective of the information provided in this section is to reduce the potential for patient cross contamination when using the AeroPro Cordless Prophy System during routine dental care. Please follow all Infection Control Procedures as recommended by your governing regulatory agency.

The AeroPro™ system consist of the following parts:

Part	Infection Control
Motor Component	Disinfect
Autoclavable Outer Sheath	Sterilize
Charging Station	Disinfect
Ac Adapter	Disinfect
Stand	Sterilize
Disposable Barriers	N/A - Disposable
2Pro® Prophy Angles (Soft Short)	N/A - Disposable
O-Rings And Tool For Maintenance	Disinfect

NOTE: Sterilize the outer sheath and the stand prior to each use. Additional outer sheaths and stands are available for purchase to accommodate uninterrupted patient procedures

4.8.1 Instructions for Steam Autoclave Sterilizing of the Outer Sheath & Stand

Instructions for Steam Autoclave Sterilizing of the Outer Sheath and Stand	
Warning	These instructions are for use ONLY on the outer sheath and the stand. All other components of the system should be disinfected according to the procedures in the "Disinfecting All Other Parts" **(Section 4.8.2)** The outer sheath and the stand in the AeroPro™ Cordless Prophy System are not sterile upon receipt and must be steam autoclave sterilized prior to use in accordance with the following instructions.
Limitations Of Reprocessing	Do not use an automatic washer/disinfector for the outer sheath and the stand. Discoloration of material will occur. Repeated cleaning and steam sterilization cycles have minimum effect on outer sheath and the stand. End of life is normally determined by wear and damage due to use. Do not use chemical disinfectants prior to sterilization or rapid deterioration of the material may occur. 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 outer sheath and the stand in an ultrasonic bath.**
Point Of Use	Remove excess soil with disposable cloth or paper wipe. It is recommended to reprocess the outer sheath and stand reasonably soon following use.
Containment And Transportation	Protect the outer sheath and the stand from contact with other dental instruments that may cause damage.

Instructions for Steam Sterilizing the Outer Sheath and the Stand

Preparation for decontamination & Pre-Sterilization Cleaning: manually	1. Disassemble by removing the disposable prophy angle (DPA) from the Outer Sheath, and the Outer Sheath from the Motor Component. 2. Prepare enzymatic solution per manufacturer's recommendation. 3. Using a lint-free cloth dampened with the prepared detergent, thoroughly wet the Outer Sheath/ Stand with the prepared detergent. 3.1 Using a soft bristled brush, brush the Outer Sheath/Stand until all visible soil is removed, paying attention to the disposable prophy angle area. 4. Rinse the Outer Sheath/Stand under potable running tap water for a minimum of 30 seconds to remove detergent residue. 5. Dry the Outer Sheath/Stand using clean lint-free cloth. 6. Visually inspect each Outer Sheath/Stand for visible soil. If soil is seen, repeat the cleaning procedure.
Disinfection	Do not use disinfectant solution on sterilizable outer sheaths.
Packaging	Place each Outer Sheath/Stand in a separate paper/plastic steam-sterilizing pouch. If using a sterilizing cassette, ensure that the sterilizer's maximum load is not exceeded.
Steam Autoclave sterilization	Place bagged Outer Sheath/Stand into a steam autoclave, per the autoclave manufacturer's instructions. Gravity Steam Sterilization - Outer Sheath/Stand Full Cycle: 135°C (275°F) for 10 minutes Pre-vacuum Steam Sterilization - Outer Sheath/Stand Full Cycle:132°C (270°F) for 4 minutes Alternate Method: Place non-bagged outer sheath into the steam autoclave and run at the above listed cycles. NOTE: Outer sheath steam sterilized should remain bagged until ready for use.
Drying	To dry, use the drying cycle of the steam autoclave. Set cycle for 20 to 30 minutes. Do not exceed 137°C (278°F).
Maintenance	Visually inspect to ensure that all contamination has been removed. Check for distortion, damage or wear. Discard damaged, worn or corroded Outer Sheath and the Stand.
Storage	To maintain sterility, Outer Sheath and the Stand should remain bagged until ready for use.
Manufacturer contact	In the United States, contact Premier Dental Customer Support at 1- 888-670-6100. For areas outside the United States call 1-610-239-6000, contact your local Premier Dental representative.

4.8.2 Instructions for Disinfecting the Motor Component, Charging Station, and AC Adapter

 Warnings	The charging station, motor component, and AC adapter are not sterilizable by autoclave, but can be disinfected following the procedures listed below. Only use water based non-immersion type disinfectant solutions. Per the Centers for Disease Control and Prevention (CDC), chemical germicide registered with the EPA as a "hospital disinfectant" and labeled for "tuberculocidal" (i.e., mycobactericidal) activity is recommended for disinfecting surfaces that have been soiled with patient material. Recommended Disinfectant: EPA hospital disinfectant with tuberculocidal claim or CDC intermediate level disinfectant. **Do not immerse in liquid.**
Limitations of Reprocessing	Repeated cleaning has minimum effect on these instruments. End of life is normally determined by wear and damage due to use. Do not use disinfectant solution on sterilizable outer sheaths. Refer to steam sterilization procedures for sterilizable outer sheaths.
Point Of Use	Remove excess soil with disposable cloth or paper wipe. Discard wipe after use.
Containment and Transportation	Handle with care.
Cleaning	Generously spray disinfectant solution on a clean cloth. Wipe charging station, motor component, the and the AC adapter. Discard used cloth. Wipe dry with a clean cloth.
Disinfection	Generously spray disinfectant solution on a clean cloth. Wipe charging station, motor component, and the AC adapter. Discard used cloth. Allow disinfectant to air dry.
Drying	When cleaning, wipe surfaces dry with a clean cloth. To achieve disinfection, allow surfaces to air dry.
Maintenance	Visually inspect to ensure that all contamination has been removed. Visually inspect power supply and cord for damage.
Storage	Temperature range: -10°C to 50°C/14o F to 122oF Relative humidity range: 45 - 95% (non-condensing)
Manufacturer Contact	In the United States, contact Premier Dental Customer Support at 888-670-6100. For areas outside the United States call 610-239-6000 or contact your local Premier Dental representative.

5.1 Specifications

Adaptor Power Supply manufacturer: Power Supply model number:	Shenzhen Ri Hua Da Electronic Co., Ltd RHD20W12010000U	
AC Input Voltage	Continuous (100-240V)	
AC Input Current	Less than 0.35A	
AC Input Phases	Single	
AC Input Frequency	50-60 Hz	
DC Output Power	12W	
DC Output Voltage and Current	12VDC at 1A	
Output Regulation	+/- 10%	
Induction Charging	Transmitting input voltage 12 VDC Receive module output voltage 5VDC Receive output 5V/400-500mA Coil inductance 10uH	
Weight	Handpiece with metal sheath = 125 g	
Dimensions	Handpiece with sheath L = 192 mm, W = 27 mm	
Operating Environment	Ambient temperature: Relative Humidity: Atmospheric Pressure: Altitude:	10°C-40°C/50o F to 104o F 45-95% (non-condensing) 80-106 kPa ≤ 2,000 meters
Transport and Storage Conditions	Temperature: Relative Humidity: Atmospheric Pressure: Altitude:	-10°C to 50°C/14o F to 122o F 45-95% (non-condensing) 50-106 kPa ≤ 5,000 meters
Handpiece Performance Speeds	Max Cup Speed Medium Speed Low Speed Max Torque	2800 rpm 1500 rpm 500 rpm 10 mNm
Handpiece Performance Modes	2-speed Mode (factory setting) 3 Speed Mode	500 rpm and 2800 rpm 500 rpm, 1500 rpm and 2800 rpm
IPX (Water Ingress Index)	Motor Component Charging Station AC Adapter	IPX3 IPX0 IPX0

5.2 Classifications

Type of protection against electric shock	Class II
Degree of Protection against electric shock	Type B applied part
According to medical device directive	IIA (Rule 9) (IEC 60601) UL 60601-1
Mode of operation for handpiece (Duty Cycle)	Non-continuous: 5 minutes ON, 30 minutes OFF
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Equipment **NOT** suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide
Method of sterilization or disinfection	Refer to Section 4.8: Infection control procedures
Degree of protection against ingress of water as detailed in the current edition of IEC 60529	Motor Component: IPX3 Charging Station: IPX0
Pollution Degree Classification	Pollution Degree 2
Overvoltage Category	Category II (connected to wall outlet)

5.3 Symbol Identification

	Class II Equipment
	Type B applied part
CLASSIFIED MET c us	MEDICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1CAN/ CSA-C22.2 No. 601.1, ANSI/AAMI ES60601-1 (2005, 3rd ed.), CAN/CSA-C22.2 No. 60601-1 (2008),13VA
	Consult instructions for use
135°	Sterilize up to temperature specified
	Do not reuse (for DPAs) and AeroPro disposable barriers
WEEE	Dispose of in accordance with the Waste Electrical and Electronic Equipment Directive 2002/96/EC for product and accessory disposal.
IPX0	Protection Class IPX0 - IPX0 Classification of ingress of water for Charging Station – not protected
IPX3	Protection Class IPX3 - IPX3 Classification of ingress of water for Motor Component - Protected against falling spray.
5 min 30 min	Duty Cycle for handpiece 5 minutes ON 30 minutes OFF
SN	Serial Number
LOT	Lot Number
12 V-1000mA	Direct Current (DC) supply. 12 Volts, 1000 milliamps
135°	Do Not Autoclave (Motor Component, Charging Station, or AC Adapter)
Year - Month	Date of Manufacturing
c US	This product meets UL safety standard requirements.
	Electromagnetic interference from the device is under limits approved by the Federal Communications Commission.
	For indoor use only
VI	Efficiency level

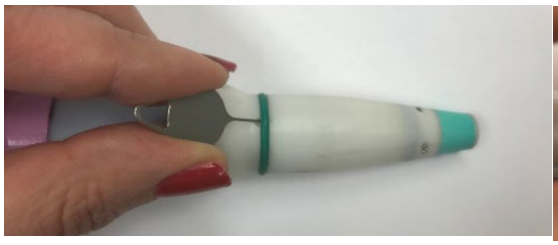
6.1 Periodic Maintenance, Replacing O-rings

6.1.1 There is one O-ring on the motor component, and two O-rings on the outer sheath. The O-rings are consumable parts. Inspect O-rings before each use for wear and damage. O-rings should be replaced as needed, but the actual wear rate is expected to be slow. Failure to check O-rings could result in patient harm. A pack of O-rings and a replacement tool are included in the package.

(O-ring replacement set)

6.1.2 **NOTE:** The cordless handpiece motor component motor is designed to be lube-free. **Do not lubricate the cordless handpiece motor component.** Doing so will result in damage to the unit.

6.1.3 To replace O-rings, insert the provided replacement tool into the notch below the O-ring, lift the old ring from its groove and roll it up off the motor component or the outer sheath. Then, roll the new O-ring down and place it into the appropriate groove.



Replacing O-ring on the Motor Component

Replacing O-rings on the Outer Sheath

6.2 Safety Features of AeroPro Cordless Handpiece

Auto turn off of the handpiece will occur for the following reasons:

6.2.1 Overcurrent Protection: Yellow light will flash and the handpiece will automatically turn off to provide over-current protection.

6.2.2 Overheating Protection: Red and Yellow light will flash and the handpiece will automatically turn off when internal circuit board temperature reaches 95ºC.

NOTE: For operator's safety the external temperature will never exceed a safe limit.

6.2.3 Battery Draining Prevention: If the handpiece is left turned on (motor is rotating) and idle it will automatically turn off in 10 minutes.

6.2.4 Protect Motor, Control System, and Battery from Damage and Overload: When the battery charge becomes very low (below 20%) yellow light on the battery indicator window disappears and the red light starts flashing. At this point the handpiece should not be operated and connected to the charging station immediately. Letting the battery drain completely down may shortened its life span.

6.3 Troubleshooting

Problem	Solution
DPA Cup is Not Rotating	Outside of the mouth: 1. Ensure the outer sheath and the DPA are snapped together securely. 2. Ensure that the cordless handpiece motor component and the outer sheath are snapped together securely. 3. Verify the cordless handpiece is powered up and properly charged. If the cordless handpiece lights do not illuminate, place the cordless handpiece in the charging station for a minimum of 5 seconds, and then remove it to use. 4. Ensure the DPA is not damaged by removing the DPA and spinning the cup between your fingers. The cup should spin freely. 5. Ensure that the outer sheath is not damaged by removing the cordless handpiece motor component from the outer sheath, leaving the DPA connected, and spinning the DPA cup between your fingers. The cup should spin freely. In the mouth: 1. Excessive force is being applied to the polishing surface, reducing the DPA rotation. Use a lighter force and follow standard prophylaxis procedures.
DPA Starts to Turn Around the Axis During a Procedure	1. Ensure the DPA is not damaged by removing the DPA and inspecting the base for cracks or other damage. 2. O-rings need replacement. Refer to O-ring replacement instructions **(Section 6.1.3)**. A set of replacement O-rings and the O-ring replacement tool are provided in the package.
Excessive Noise or Vibration During Operation	1. Ensure that the outer sheath is aligned correctly with the cordless handpiece motor component. 2. Try a new disposable prophy angle (DPA). 3. Check the components for gross debris or contamination and adhere to all infection control procedures. 4. Check motor component. 5. Check for damaged, worn or broken components. 6. Call Technical Support. 888-670-6100 or 610-239-6000
Difficulty Removing Outer Sheath from Cordless Handpeice Motor Component	1. Check the components for gross debris. 2. Hold the cordless handpiece outer sheath securely and give a slight twist to the cordless handpiece motor component. 3. Inspect parts for wear. 4. Call Technical Support. 888-670-6100 or 610-239-6000

Cordless Handpiece Does Not Charge	1. Insure there is no debris on the base of the cordless handpiece module and charging station seat. To remove any interfering debris, use one of the approved cleaning solutions described in **Section 4.8**. Do not spray cleaning solutions directly onto parts. 2. Verify that the power supply is properly connected to the charging station for the cordless handpiece and that the battery indicator lights are blinking in sequence: red-yellow-green-green-green 3. Verify that the cordless handpiece is able to properly sit inside the charging station for the cordless handpiece, and that there are no foreign obstructions. 4. If still not charging, call Technical Support. 888-670-6100 or 610-239-6000
Cordless Handpiece Does Not Hold Charge	1. Verify that the cordless handpiece properly charges (battery indicator LED lights are blinking in sequence when the handpiece is charging). 2. Ensure the cordless handpiece remains on charging station for a minimum of 4 hours 3. Call Technical Support. 888-670-6100 or 610-239-6000
Cordless Handpiece Does Not Turn On Even Through It Is Fully Charged	The Cordless handpiece is locked. Unlock the handpiece as per instructions in **Section 4.2**.
Yellow Light Flashed And Cordless Handpiece Automatically Turned Off	1. ***Overcurrent Protection:*** Too much current is going through the handpiece. 2. Do not use handpiece for several minutes and allow the current to return to the specified limits.
Red & Yellow Lights Flashed And Cordless Handpiece Automatically Turned Off	*Overheating Protection:* 1. Handpiece is heating up due to excess ON time or load. It will automatically turn off when internal temperature exceeds a safe limit. (For operator's safety the external temperature will never exceed a safe limit). 2. Do not use handpiece for 30-minutes and allow it to cool down.
Red Light Flashed And Cordless Handpiece Automatically Turned Off	*Low Battery Charge:* 1. When the battery charge becomes very low (below 20%) yellow light on the battery indicator window disappears and the red light starts flashing. At this point the handpiece should not be operated and should be connected to the charging station immediately. 2. Charge the battery for at least 20 minutes as per instructions in **Section 4.6.**
Cordless Handpiece Automatically Turned Off After Not Being Used For 10 Minutes	1. ***Battery Draining Prevention:*** To prevent battery draining, the handpiece will automatically turn off if left turned on (motor is rotating) and idle (ON/OFF/MODE button is not being pressed) for 10 minutes. 2. Press ON/OFF/MODE button to turn the handpiece back on.
Power Supply Overheating	Immediately unplug the unit. Call Technical Support. 888-670-6100 or 610-239-6000
Power Cord Is Frayed or Damaged In Any Way	Do not use. Call Technical Support. 888-670-6100 or 610-239-6000

6.4 Frequently Asked Questions

Question	Answer
How Long Will It Take To Fully Charge Aeropro Cordless Handpiece?	For full charge at least 2 hours
How Many Prophy Polishes Can Be Performed On A Single Full Charge Without Recharging?	Up to 10 polishes
How Long Will It Take To Charge A Completely Discharged Handpiece To Get One Prophy?	20 minutes
How Much Power Does Each Led Light On The Battery Indicator Display Represent?	There are five LED lights: one red, one yellow and three green. Each light represents approximately 20% of battery charge.
How Many Prophy Polishes Can Be Performed With The Red Light On?	When red light quick flashes, the voltage is very low. The handpiece cannot be used.
How Do I Lock Aeropro?	Handpiece MUST be sitting on the charging station. Hold ON/OFF/Mode button for 3 sec. The unit will beep 6 times and LED lights will flash 6 times. **See Section 4.7** for locking the handpiece.
How Do I Unlock Aeropro?	Handpiece MUST be removed from the charging station. Press & Hold ON/OFF/Mode button for 3 seconds. The unit will beep 6 times and LED lights will flash 6 times. **See Section 4.2**
How Do I Switch Speed Modes?	Turn off the rotation. Hold the power button down for 6 seconds. • When switching from 2-speed to 3-speed: 2-beeps and 2-times green LED lights flash • When switching from 3-speed to 2-speed: 3-beeps and 3-times green LED lights flash
Is It Safe To Place The Handpiece In The Charging Station After Each Use?	Yes. AeroPro uses ChargeSMART technology therefore; an excessive number of charging times will NOT cause premature battery decay.
Why Did The Handpiece Automatically Turn Off?	Auto turn off of the handpiece will occur for the following reasons: • Overcurrent Protection • Overheating Protection • Low Battery Charge • Handpiece not in use for 10 minutes

6.5 Disposal of AeroPro™ Cordless Handpiece

Dispose of the system components in accordance with state and local laws.

- Dispose of the stand, charging station and AC adapter as industrial waste according to local laws and regulations.
- Dispose of the outer sheath, motor component and barrier as medical waste according to local laws and regulations.
- The handpiece motor component includes 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.
- The battery pack (lithium-ion battery) included in the handpiece module is a recyclable resource. When disposing of it do not disassemble the battery pack. Dispose of the product according to local laws and regulations.

Guidance and manufacturer's declaration - electromagnetic emissions

The AeroPro™ is intended for use in the electromagnetic environment specified below. The Customer or the user of the AeroPro™ should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The AeroPro™ 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 A	The AeroPro™ is suitable for use 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	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not Applicable	

Electromagnetic Immunity

Guidance And Manufacturer's Declaration – Electromagnetic Immunity

The AeroPro™ is intended for use in the electromagnetic environment specified below. The customer or the end user of the AeroPro™ should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Result/ Environment
Electrostatic discharge (ESD) IEC 60601-1-2 (IEC 61000-4-2)	± 8 kV contact ± 15kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
RF Field Strength Susceptibility Test IEC 60601-1-2 (IEC 61000-4-3)	10 V/m	10 V/m	
Electrical fast transient/burst IEC 60601-1-2 (IEC 61000-4-4)	±2kV on power supply lines ±1 kV for input/output lines	±2kV on power supply lines No I/O lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 60601-1-2 (IEC 61000-4-5)	±1 kV line (s) to line (s)	±1 kV line (s) to line (s)	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 60601-1-2 (IEC 61000-4-11)	0 % U_T (100 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles 0% U_T (100 % dip in U_T) for 250 cycles	0 % U_T (100% dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles 0 % U_T (100% dip in U_T) for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AeroPro™ requires continued operation during power mains interruptions, it is recommended that the AeroPro™ be powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz) Magnetic Field Susceptibility IEC 60601-1-2 (IEC 61000-4-8)	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Electromagnetic Emissions

Power Line Conducted Emission Test, IEC 60601-1-2

Measuring Limits (Group 1, Class A)	Quasi-peak Level (dBµv)		Average Level (dBµv)	
Frequency (MHz)	IEC60601 test level limit	Compliance level (max measured)	IEC60601 test level limit	Compliance level (max measured)
0.15 ~ 0.50	79	46	66	43
0.50 ~ 5.00	73	59	60	32
5.00 ~ 30.00	73	62	60	26

NOTE 1: The lower limit shall apply at the transition frequencies
NOTE 2: The limit decreases linearly with the logarithm of the frequency in the range 0.15 MHz to 0.50 MHz.

Radiated Emission Test, IEC 60601-1-2

(Group 1, Class A) Frequency (MHz)	Distance (Meters)	IEC60601 test level Field Strengths Limit (dBµv/m)	Compliance level (max measured) (dBµv/m)
30 ~ 88	3	39.00	26.37
88 ~ 216	3	43.50	21.82
216 ~ 960	3	46.40	20.71

Note 1: The smaller limit shall apply at the combination point between two frequency bands
Note 2: Distance refers to the distance in meters between the measuring instrument antenna and the closest point of any of the EUT

Recommended separation distances between portable and mobile RF communications equipment and the product

The product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product 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 30MHz $d = 1.2\sqrt{P}$
0.01	0.12
0.1	0.37
1	1.17
10	3.69
100	11.67

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) according to the transmitter manufacturer.

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

Guidance and manufacturer's declaration - Electromagnetic Emission

The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that it is used in such an environment.

Electromagnetic environment - guidance
Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d= 1.2 $\sqrt{P}$ $\sqrt{P}$ 150kHz to 30MHz 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: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 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 10V/m.

Description	Premier Item Number
AeroPro™ Autoclavable Outer Sheath	5500520
AeroPro™ Disposable Barriers Box of 500	5500530
AeroPro™ Charging Station	5500540
AeroPro™ AC Adapter	5500541
AeroPro™ Motor Component	5500550
AeroPro™ Stand	5500560
AeroPro™ O-Ring Replacement Set	5500561

The Premier® AeroPro™ Cordless Prophy System is designed exclusively for use by licensed dental professionals. This warranty extends to AeroPro systems purchased from an authorized Premier dealer and is available only to the original purchaser of the unit who is able to provide proof of purchase from an authorized Premier dealer.

Premier warrants all components of the AeroPro Cordless Prophy System against defects arising from faulty materials and workmanship for three (3) years from the date of purchase, with the exception of (i) the AeroPro disposable barriers and the 2pro® Disposable Prophy Angles, which are single use only items and not subject to any warranty, and (ii) the lithium battery. If Premier determines that the lithium battery is defective and that the defects are not caused by misuse, abuse or accident by the user, Premier will provide a one-time replacement of the motor component within one (1) year from the date of purchase. **The use of an AC adapter other than the one provided with the AeroPro Cordless Prophy System, and the use of any other unauthorized parts or an unauthorized repair facility, will void the foregoing warranty.**

Parts will be repaired or replaced at the discretion of Premier provided that the system has been operated and maintained as prescribed in these instructions and has not been subjected to apparent misuse, abuse or accident. Claims covered by this warranty will be honored when presented to Premier within thirty (30) days from discovery of defect within the applicable warranty period.

There are no warranties, express or implied, which extend beyond the description on the terms described above. Premier neither assumes, nor authorizes any person to assume for it, any other liability in connection with the sale or use of the AeroPro Cordless Prophy System. Damages are limited strictly to repair or replacement of parts. Premier expressly disclaims liability for incidental, indirect and consequential damages resulting from the use of the AeroPro Cordless Prophy System.

WARRANTY REGISTRATION

Please register your AeroPro Cordless Prophy System and retain your dealer invoice. This will ensure prompt and accurate service should your AeroPro Cordless Prophy System require evaluation, repair or replacement during the applicable warranty period, and will enable Premier to send you important product information.

Register online at: www.premusa.com/aeroprowarrantyregistration

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