ULTRADENT

ultrapro™ Tx cordless

Instructions for Use

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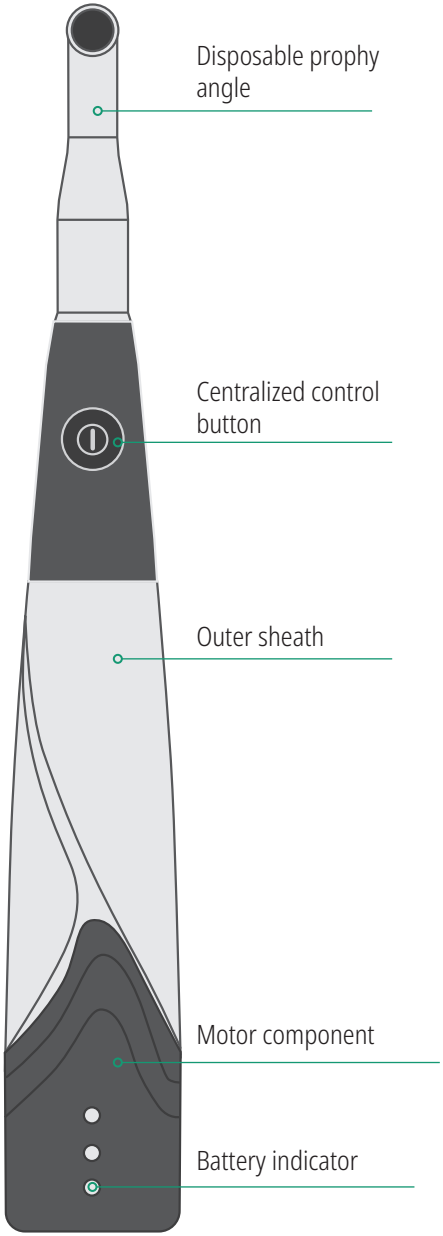
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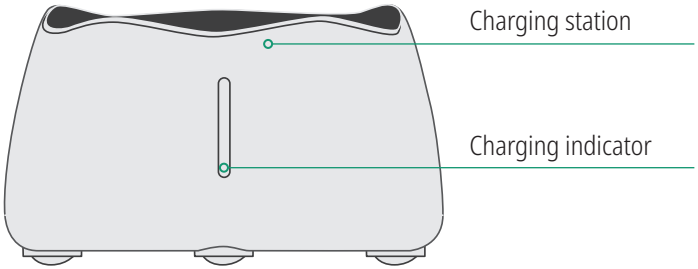
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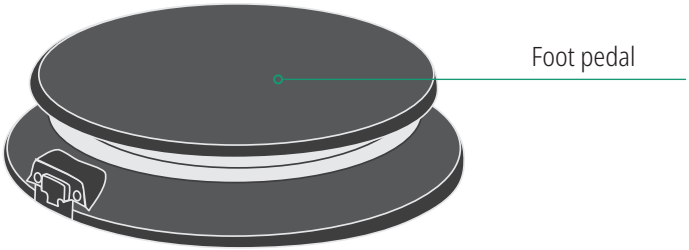
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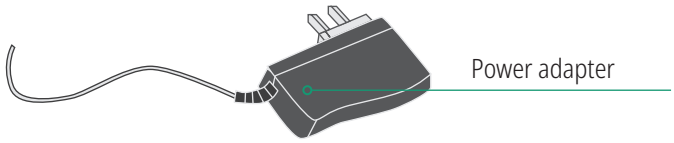
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1. PREFACE

Thanks for purchasing the Ultradent Ultrapro™ Tx Cordless hygiene handpiece. For the discerning dental professional who values an untethered alternative to cleaning and polishing, the Ultrapro Tx Cordless handpiece cuts the cord and allows the user to perform prophylaxis flexibly while providing the patient a comfortable and high-quality cleaning experience. It is recommended that you read the accompanying documentation to take full advantage of the features and benefits of the Ultrapro Tx Cordless handpiece.

2. PRODUCT DESCRIPTION

The Ultrapro Tx Cordless handpiece has an ergonomic and lightweight design for maximum clinician comfort and use. It is equipped with an on/off button and a wireless foot pedal used for dental prophylaxis procedures and is compatible with nearly all disposable prophy angles on the market.

Product Components:

1 – Motor component
3 – Autoclavable outer sheaths
1 – Charging station
2 – Power adapters
1 – Foot pedal
100 – Disposable sleeves
4 – Disposable prophy angles
6 – Black O-rings
2 – Green O-rings

Overview of Controls:

The manufacturer accepts no liability for any damage resulting from the improper use of this unit and/or any purpose other than those covered by these instructions.

For all products described, carefully read and understand all instructions in this manual and SDS information prior to use.

3. INDICATIONS FOR USE/INTENDED PURPOSE

The Ultrapro Tx Cordless handpiece is a cordless prophylaxis handpiece equipped with a control button and a wireless foot pedal. It is intended for use with disposable prophy angles in the hygiene operatory to perform cleaning and polishing procedures on tooth surfaces and fillings.

4. CONTRAINDICATIONS

- Doctors with a pacemaker are prohibited from using this device.
- 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.
- For patients with heart disease, pregnant women and young children, cautiously use this device.

For patients or users with allergy concerns, refer to product allergen document available at www.ultradent.com. If allergic reaction is observed, rinse exposed area thoroughly with water and have the patient consult their physician.

5. WARNINGS AND PRECAUTIONS

- Do not place device near a heat source.
- Operate and store device in a safe dry place.
- Do not use lubrication on the motor component.
- Use caution for patients with heart conditions, pregnant women, and children.
- 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 fluorescent lamps, radio transmitting devices, remote control devices, handheld or mobile high-frequency communication devices.
- Long term use of equipment may result in overheating of the motor handpiece and should be left to cool until next use. Please contact Ultradent if any issues arise.
- To avoid damage or malfunction of device, use the original charging base.
- Any changes to the device may violate safety regulations, causing harm to patients. The manufacturer will not accept any liability for a modified device.
- To avoid damage to lithium battery and control circuit, use original power adapter.
- If you think a battery replacement is necessary, please contact Ultradent. Do not attempt to replace the battery.
- To avoid damage, ensure that the device is in the off position before removing or installing the outer sheath or disposable prophy angle.
- To avoid damage to the handpiece and disposable prophy angle, only use disposable prophy angles compatible with this device and be sure that they are correctly installed before starting the handpiece.
- Wireless charging will generate heat. The surface temperature of the charging station and motor handpiece will rise.
- 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.)
- Do not use handpiece while charging.

6. STEPWISE INSTRUCTIONS

Wireless Connection of Foot Pedal

Ensure that the foot pedal is fully charged before first use. If the handpiece is turned on, the Bluetooth will be paired automatically. The Bluetooth indicator will flash while the handpiece and the foot pedal are connecting. If the connection has failed, the Bluetooth indicator will keep flashing. There may be a 3-second delay to the handpiece when the foot pedal is activated. If there is no response to the handpiece after depressing the foot pedal, check the battery and recharge if necessary. After ensuring full connection, step on the foot pedal to control the speed of the handpiece.

Charging the Handpiece and Foot Pedal

1. Plug the power adapter into an appropriate electrical outlet.
2. Place the motor component on the charging station connected to the power adapter.
3. When the device is charging, the indicator light on the charging station and foot pedal will flash green. Once fully charged, the battery indicator light will illuminate green.

Note:

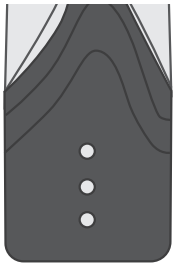
- Handpiece and foot pedal are provided partially charged (charge level 50%–70%).
- Do not depress the foot pedal while charging.

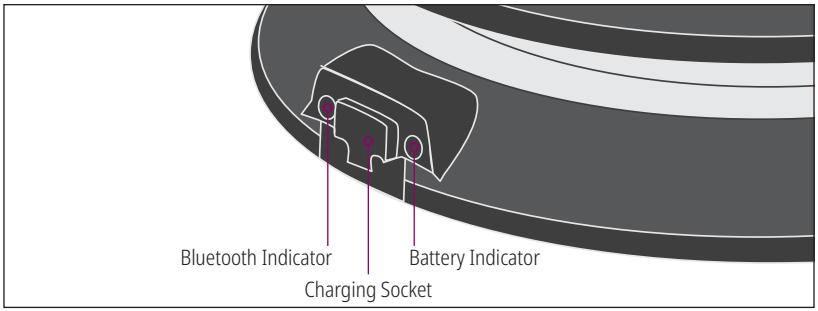
Preparation

1. Install disposable sleeve onto the motor component.
2. Install the sterilized outer sheath onto the motor component covered with the disposable sleeve.
   Note: Before installation, check whether the disposable sleeve is intact. Do not use if damaged.
3. Attach the disposable prophy angle onto the cordless handpiece.

Use

1. Press the button on the handpiece once to turn device on. Depress wireless foot pedal to control speed of motor handpiece.
   Note: There may be a 3-second delay during the Bluetooth connection of the foot pedal and handpiece.
2. Use according to clinical need.
3. After use, discard the disposable prophy angle and disposable sleeve. Disinfect and sterilize outer sheath between each use. Do not immerse sheath in disinfection solution or ultrasonic bath. Only disinfect the motor component, do not sterilize.

INDICATOR PICTURE	CHARGE LEVEL	LED COLOR
	Battery full charged	3 green
	Charged 2/3	2 bottom indicators green and 1 top indicator off
	Charged 1/3	1 bottom indicator green and 2 top indicators off
	Battery low	1 bottom indicator orange and 2 top indicators off. Unit will soon shut off automatically, charge immediately.



BATTERY INDICATOR'S COLOR	BATTERY OF FOOT PEDAL STATUS
Green light flashes	Charging
Green light illuminates	Fully charged or the battery is sufficient for operation
Orange	Low battery, unit will soon shut off automatically, charge immediately.

Power Off

The handpiece will automatically shut down once placed on the charging station or after 5 minutes of device not being in use.

7. MAINTENANCE

Repair

1. Do not use if product or accessories are damaged, smashed, detached, corroded, or bent.
2. This device does not include accessories for repair usage. Please contact Ultradent for repairs.
3. Repairs are only to be performed by authorized service personnel.

⚠ Warning:

- Keep the equipment in a dry storage area.
- Do not throw, beat, or shock the equipment.
- Contact Ultradent if the battery needs repair or replacement.

Replacing the O-ring

⚠ Warnings

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

- Remove the disposable prophy angle and outer sheath from the handpiece.
- 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.

Warranty

Ultradent hereby warrants that this instrument shall, for a period of 2 years*, conform in all material respects to the specifications therefore as set forth in Ultradent's documentation accompanying the product and be free from any defects in materials/or workmanship. This warranty applies solely to the original purchaser and is not transferable. All defective products are to be returned to Ultradent. There are no user service components of the Ultrapro Tx Cordless handpiece. Tampering with Ultrapro Tx Cordless handpiece will void its warranty. The Ultrapro Tx Cordless handpiece warranty does not cover customer damage. For example, if an Ultrapro Tx Cordless handpiece is misused or dropped and breaks, the customer would be responsible for paying for any necessary repairs.
*With sales receipt indicating the date of sale to the dentist.

8. PROCESSING

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.

- Sterilize the outer sheath prior to each use. Additional outer sheaths are available for purchase to accommodate uninterrupted patient procedures.
- Do not place the outer sheath in a disinfectant solution or in an ultrasonic bath.
- Do not use bleach or chloride disinfectant materials.
- For your own safety, please wear personal protective equipment (gloves, glasses, mask).
- 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.

PART NAME	INFECTION PREVENTION
Disposable Prophy Angle/DPA Prophy angle that helps clinician easily access hard-to-reach areas of the mouth quickly for optimal dental hygiene.	Single use Discard after use
Outer Sheath The outer sheath is a sterilizable protective cover that acts as a sleeve to the internal motor component. It also houses the bearings and acts as an interface between DPA and the motor component. The outer sheath features an on-board user centralized control button for power of the device.	Manual cleaning followed by steam autoclave
Disposable Sleeve The disposable sleeve is designed to protect the motor component from debris.	Single use Discard after use
Motor Component The motor component house, the motor, power supply (lithium-ion battery), and 3 indicator lights. The motor component is not sterilizable and is to be used to provide speed and torque.	Manual cleaning and disinfection

PART NAME	INFECTION PREVENTION
Power Adapter Converts AC current into DC current required for charging the handpiece.	Manual cleaning and disinfection
Foot Pedal Provides a wireless control for rotation speed control of handpiece. It has two indicator lights.	Manual cleaning and disinfection
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.	Manual cleaning and disinfection

Clean the outer sheath according to the following steps:

MANUAL CLEANING PROCESS	
Prepare	After removing the outer sheath from the motor component, carefully place the outer sheath onto the disinfection tray. To prevent scratching of the surface and cross contamination of sheath, do not allow products to touch each other, or place into a sterilization bag.
Pre-clean	Use tap water, purified, distilled, or deionized water at room temperature of 25°C to pre-rinse for 3 minutes to remove any visible surface contaminants.
Cleaning	Clean 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 any contaminants with purified water, distilled, or deionized water at room temperature of 25°C for 1 minute.
Wipe dry	Use a clean sterile cloth or dry paper to wipe the surface to remove excess water.

Instruction for Outer Sheath Cleaning and Sterilizing

- The cleaning should be performed no later than 24 hours after treatment. The outer sheath can be cleaned by automated cleaning.
- The outer sheath is not sterile upon receipt and must be steam autoclave sterilized prior to use in accordance with the following instructions.

1. After removing the outer sheath from the motor component, carefully place the outer sheath onto the disinfection tray. To prevent scratching of the surface and cross contamination of sheath, do not allow products to touch each other, or place into a sterilization bag.

2.A **For manual cleaning**

- Use tap water, purified, distilled, or deionized water at room temperature of 25°C to pre-rinse for 3 minutes to remove any visible surface contaminants.
- Clean 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.

2.B **For automated cleaning**

- Use only washer-disinfectant that meets the FDA requirements for cleaning processes 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 agents below to clean the outer sheath:
  - Cleaning agent name: RUHOF ENDOZIME® AW PLUS WITH APA
  - Manufacturer: The RUHOF CORPORATION

3. Rinse away any contaminants with purified water, distilled, or deionized water at room temperature of 25°C for 1 minute.
4. Use a clean sterile cloth or dry paper to wipe the surface to remove excess water.
5. Package the cleaned/disinfected and dried outer sheath in a sterilization pouch to maintain sterility. It is recommended to use a legally marketed pouch or other method of maintaining sterility for the following sterilization cycle.

Note:

- Avoid contact with different metals when packaging.
- 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 in an ultrasonic bath.
- The use of strong detergent and disinfectant (alkaline pH>9 or acid pH <5) will reduce the life span of products.

Note: It may be advised to bag sheath in a sterilization pouch prior to sterilizing to reduce discoloration and

breakdown of the outer sheath over time.

- The outer sheath 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 aging of the products. Discoloration and breakdown may occur around 500 uses. End of life is typically determined by wear and damage due to use.

Inspection and Maintenance

1. Check the product. If there are any remaining visible contaminants on the product after cleaning/disinfection, the entire cleaning/disinfection process must be repeated.
2. Check the outer sheath. If it is damaged, smashed, detached, corroded, or bent, it must be scrapped and not used.
3. If the service time of the outer sheath reaches the recommended service life (500 uses), perform routine inspections and replace if necessary.

Sterilization

Note: Use only the following steam sterilization procedures (fractional pre-vacuum procedure*) for sterilization. Other sterilization procedures are prohibited.

1. Place bagged outer sheath into a steam autoclave per the autoclave manufacturer's instruction.
2. It is recommended to use the validated sterilization parameters: The sterilization time of 4 minutes at a temperature of 132°C/134°C and a pressure of 185kPa to 190kPa with a drying time of 20 minutes.
3. The highest sterilization temperature is 138°C.
4. Allow a maximum sterilization time of 20 minutes at 134°C.
5. The outer sheath 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:

- Only products that have been effectively cleaned and disinfected are to be sterilized.
- Before use of the steam autoclave, read the Instruction Manual provided by the equipment manufacturer and follow the instructions.
- Do not use hot air sterilization and radiation sterilization as this may result in damage to the product.
- Please use the recommended sterilization procedures for sterilization. It is not recommended to sterilize with other device sterilization procedures such as ethylene oxide, formaldehyde, or low temperature plasma sterilization. The manufacturer assumes no responsibility for the procedures that have not been recommended. If you use 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.*

Instruction for Cleaning and Disinfecting of the Motor Component, Charging Station, Foot Pedal, and Power Adapter

⚠ Warnings

- Do not sterilize the motor component, foot pedal, power adapter, or charging station.
- The motor component, foot pedal, power adapter, and charging station cannot be cleaned and disinfected with automatic equipment. Manual cleaning and disinfection is required.

Pre-Operation Processing

Before each use, the motor component, foot pedal, power adapter, and charging station must be cleaned and disinfected.

Manual Cleaning Steps

1. Place the motor component, foot pedal, power adapter, and charging station onto a clean surface. Wet a soft cloth with distilled water or deionized water. Thoroughly wipe all the surfaces of the motor component, foot pedal, power adapter, and charging station, etc. until the surface is clean.
2. Wipe the surface of the component with a dry, soft nap-free cloth.
3. Repeat the above steps at least 3 times or until all visible soil is removed.
4. Wipe surfaces dry with a clean cloth.

Note: Use distilled water or deionized water for cleaning at room temperature.

Manual Disinfection Steps

1. Soak the dry soft cloth with 75% ethyl alcohol.
2. Wipe all surfaces of the motor component, foot pedal, power adapter, and charging station with a wet soft cloth for at least 3 minutes.
3. Wipe the surface of the component with a dry, soft nap-free cloth.
4. After cleaning and disinfecting the motor component, install a disposable sleeve before use.
5. Visually inspect to ensure that all contaminants have been removed and inspect power supply cord for damage.

Note:

- The cleaning and disinfection must be performed within 10 minutes before use.

Post-Operation Processing

Storage

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

9. STORAGE AND DISPOSAL

Store in a clean, dry, ventilated, non-corrosive atmosphere with a humidity of 10% to 93%, an atmospheric pressure of 70KPa to 106KPa, and a temperature of -20℃ to +55℃ .
After sterilization, the product should remain bagged until ready for use. If the storage time exceeds 7 days, it may be necessary to run through autoclave before use. Product storage must be batched, marked, and recorded.

Dispose of waste according to local rules, guidelines, and regulations.

Disposal of components

- Dispose of the charging station, foot pedal, and power adapter as industrial waste according to local laws and regulations.
- Dispose of the outer sheath, disposable sleeve, and disposable prophy angle as medical waste according to local laws and regulations.
- The motor component and foot pedal 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.

10. TECHNICAL CONSIDERATIONS

Technical Information/Data

ITEMS	SPECIFICATION
Power source	Handpiece: rechargeable lithium battery 3.6V, 750mAh; Foot pedal: rechargeable lithium battery 3.6V, 750mAh
Rated input	100V-240V~, 50Hz/60Hz, 0.4A Max
Rated output	DC5V, 1A
Weight	Handpiece:121.6 g Foot pedal:196.5 g
Dimension	Handpiece: 27.6 mm Dia×192 mm Foot pedal: 128 mm×128 mm×34 mm
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	Handpiece: IPX3; Foot pedal: IPX1; Charging station: 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
Handpiece speeds (+/-10%)	Speed range: 500 rpm–4000 rpm
Foot pedal speeds (+/-10%)	Speed is controlled and adjusted through varying pressure on the foot pedal. The adjustable range is 500 rpm to 4000 rpm
Maximum torque (+/-10%)	1.2Ncm
Service life	5 years
Charge time	Handpiece: Approximately 2.5 hours Foot pedal: Approximately 2 hours
Auto-off time	The foot pedal and handpiece will automatically shut down if the standby time exceeds 5 minutes

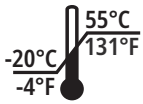
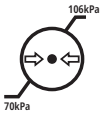
Troubleshooting

FAILURE	SOLUTION
Disposable prophy angle is not rotating	1. Ensure that the outer sheath and the disposable prophy angle are attached securely. 2. Ensure that the motor component and the outer sheath are attached 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 attached securely. 2. Ensure that the motor component and the outer sheath are attached securely. 3. Ensure the disposable prophy angle is not damaged. 4. Ensure the outer sheath is not damaged. 5. Ensure that the O-ring on the motor component or outer sheath is not damaged.
Difficulty 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 station and motor component. 2. Check whether the original power adapter is used.
The foot pedal is unable to connect to the handpiece	1. Place the handpiece into the wireless charging base until the indicator light of the charging base flashes. Long press the on/off button on the handpiece while in the charging state. At this time, you will hear a beep; continue pressing the handpiece button. 2. Using a thin paperclip-like wire, long press into the hole marked " ᯤ " at the bottom of foot pedal for about 3–5 seconds until the Bluetooth indicator turns from a flashing to steady light. Immediately release the pressed button in the " ᯤ " hole of the foot pedal and the pressed handpiece button to ensure a Bluetooth connection. In the case that this does not work on the first attempt, repeat the steps until there is a Bluetooth connection.

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.

	Appliance compliance WEEE directive
IPX0	Protection Class IPX0 - IPX0 Classification of ingress of water for charging station – not protected
IPX1	Protection Class IPX1 - IPX1 Classification of ingress of water for foot pedal.
IPX3	Protection Class IPX3 - IPX3 Classification of ingress of water for handpiece - Protected against falling spray.
	Temperature limitation
	Atmospheric pressure for storage

Technical Description Concerning Electromagnetic Emission

Table 1: Declaration - Electromagnetic Emissions

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS		
The Ultrapro Tx Cordless handpiece is intended for use in the electromagnetic environment specified below. The customer or the user of the Ultrapro Tx Cordless handpiece should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Ultrapro Tx Cordless handpiece 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 Ultrapro Tx Cordless handpiece 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	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 Ultrapro Tx Cordless handpiece is intended for use in the electromagnetic environment specified below. The customer or the user of the Ultrapro Tx Cordless handpiece should ensure 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, ±15kV air	±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 Ultrapro Tx Cordless handpiece requires continued operation during power mains interruptions, it is recommended that the Ultrapro Tx Cordless handpiece 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 and Radiated RF

GUIDANCE & DECLARATION - ELECTROMAGNETIC IMMUNITY			
The Ultrapro Tx Cordless handpiece is intended for use in the electromagnetic environment specified below. The customer or the user of the Ultrapro Tx Cordless handpiece should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF lEC61000-4- 6 Conducted RF lEC61000-4- 6 Radiated RF lEC61000-4- 3	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM frequency band 3 V/m 80 MHz to 2.7 GHz	3V 6V 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Ultrapro Tx Cordless handpiece, 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) 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 Ultrapro Tx Cordless handpiece is used exceeds the applicable RF compliance level above, the Ultrapro Tx Cordless handpiece should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Ultrapro Tx Cordless handpiece. 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 Ultrapro Tx Cordless handpiece.

Recommended separation distances between portable and mobile RF communications equipment and the Ultrapro Tx Cordless handpiece.			
The Ultrapro Tx Cordless handpiece is intended for use in electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Ultrapro Tx Cordless handpiece can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Ultrapro Tx Cordless handpiece 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.			

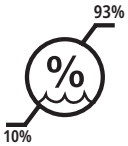
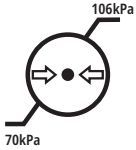
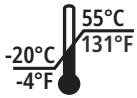
11. MISCELLANEOUS INFORMATION

Transportation

1. Prevent excessive shock and vibration during transportation and handle with care.
2. Device should not be mixed with dangerous goods during transportation.
3. Avoid exposure to direct sunlight or water during transportation to avoid damage.

Report any serious incident to the manufacturer and the competent authority.
www.ultradent.com / 1.800.552.5512 / 801.572.4200

12. SYMBOL INSTRUCTION

	Follow Instructions for Use		Serial number
	Date of manufacturing		Manufacturer
	Type B applied part		Class II equipment
	Handle with care		Keep dry
	Humidity limitation: indicates the acceptable upper and lower limits of relative humidity for transport and storage		Atmospheric pressure limitation: indicates the acceptable upper and lower limits of atmospheric pressure for transport and storage
	Temperature limitation: indicates the maximum and minimum temperature limits at which the item shall be stored and transported		Caution: Federal law restricts this device to sale by or on the order of a licensed dental professional
	Degree of protection against harmful ingress of liquid		Electromagnetic interference from the device is under limits approved by the Federal Communications Commission
	Dispose of in accordance with the Waste Electrical and Electronic Equipment Directive 2002/96/EC for product and accessory disposal		Sterilize up to temperature specified
	Warning		For indoor use only
	Do not reuse: for disposable prophy angles and disposable sleeves		Serial number barcode

ultrapro™ Tx
cordless

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Manufactured for Ultradent Products, Inc. Made in China.
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