

TurboSensor® +

ULTRASONIC SCALER

REF D660



MD Rx ONLY

This manual, in whole or in part, should not be considered a substitute for formal training in ultrasonic scaling. Appropriate dental professional education is strongly recommended prior to using this device clinically.



parkell®

Table of Contents

Device Description	3	Purging	5
Indications for Use	3	Priming the Handpiece	6
Contraindications to Use	3	Clinical Suggestions on Tooth Scaling	6
Warnings	3	Common Operator Errors that May Result in Poor Clinical Performance	6
Clinical Precautions	4	Cleaning and Infection Control	6
Inserts	4	How to Replace the Filter Disk	7
Installing Your Scaler	4	Troubleshooting	7
Water Connection	4	User Maintenance and Authorized Service	8
Controlling the Water Flow	4	Warranty and Terms of Use	8
Electrical Connection	4	Conformance to Standards	8
Use of 30KHz Detachable Handpiece	5	Explanation of Symbols Used	8
Turning on the Scaler and Controlling the Power Output	5		

What's Included

- (1) Magnetostrictive Scaler Control Unit with attached handpiece cable, foot controller and water line (with male quick-connect coupler); (REF D660)
- (1) Detachable, autoclavable 30K handpiece (REF D722)
- (1) Universal Power Adapter with attached cable (4 ft / 2.5 mm jack) (REF D723).
- (1) Power Adapter Line Cord (6 ft) (REF D7579-G).
- (1) Water line with standard chrome male quick-connect coupler.
- (2) Inline water filters (1) attached to water line. (10-pack Replacement REF D419).
- (1) Operator's Manual / Instructions for Use

Specifications

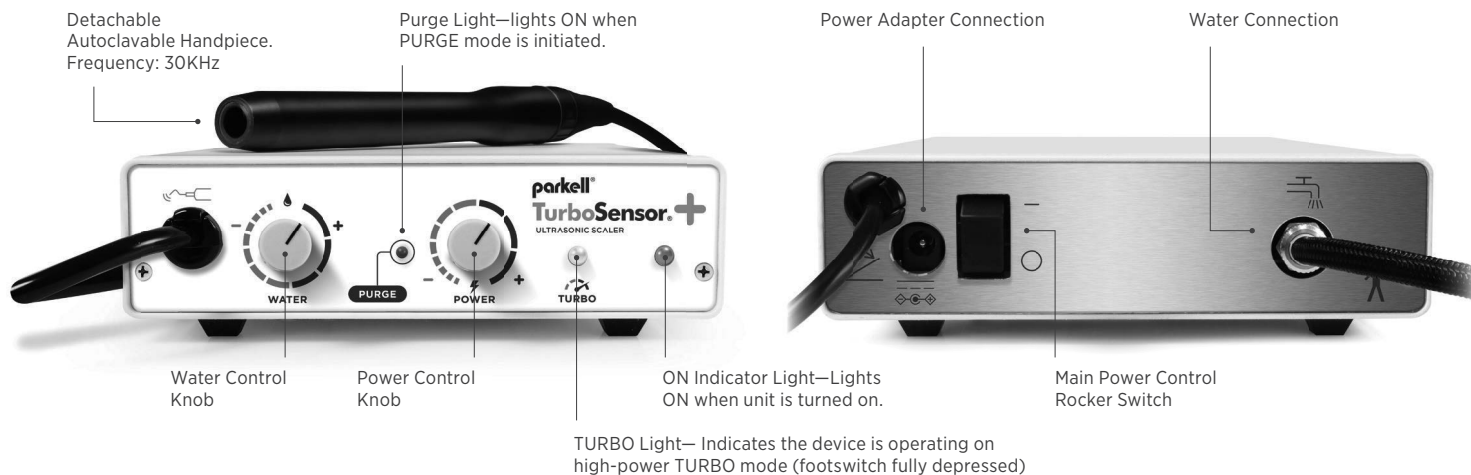
Power:	Input: 100-240 VAC, 1.0-2.0 A, 50/60 Hz; Output: 24 VDC, 3.0 A, 2.5mm, Center Positive
Weight:	0.73 Kg / 1.60 lbs.
Size:	1 ½" H x 5 ½" W x 7 ½" D
Weight of Transformer:	0.6 lbs. (270g)
Length of Handpiece Cable:	7' (215cm)
Length of Foot Pedal Cable:	7' (215cm)
Length of Water Hose:	7'6" (230cm)
Length of Power Cord:	110V: 12'6" (380cm); 220/230V: 7'6" (230cm)
Handpiece Operating Frequency:	30 KHz (REF D722)
Protection Against Electric Shock:	Class 1, Type B applied part
Protection Against Ingress of Liquids:	Foot Switch & Scaler: IPX1 (drip proof); Power Supply: IPX0 (Ordinary)
Mode of Operation of Equipment:	Intermittent - 10 minutes on, 5 minutes off
Operating Conditions:	15 - 30°C, 20 - 70% RH (non-condensing)
Transport and Storage Conditions:	-17°- 40°C, 20 - 70% RH (non-condensing)



This precision dental device was designed, manufactured and is serviced in the United States of America by:

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UKRP: Topdental (Products) Ltd.,
12 Ryefield Way, Silsden,
West Yorkshire BD20, OEF England UK



Device Description

The TurboSensor[®]+ is a magnetostrictive ultrasonic scaler (D660) that operates at a frequency of 30KHz, which translates to the insert tip vibrating 30,000 times per second during active scaling. The TurboSensor+ features a fully detachable and autoclavable handpiece for enhanced reprocessing and infection control between patients (D722). It also features an IntelliSense™ processor for ensuring top-level, consistent performance with all Parkell and market-leading 30k inserts. For more information about usage with non-Parkell inserts, please see Parkell's warranty information.

The TurboSensor+ also features: a tap-on “purge” mode for waterline cleansing; a “priming” mode for preparing the handpiece to begin scaling with the first compression of the foot pedal; a “press and hold” turbo feature for assistance in removing challenging deposits if required; and a more precise water flow system for heightened aerosol control.

Indications for Use

For removal of calculus, plaque, and oral debris from teeth during dental prophylaxis/scaling.

Contraindications to Use

Because of the potential for electromagnetic interference, this device should not be used on patients or by clinicians with cardiac pacemakers, internal defibrillators, intracorporeal fluid pumps or any other implantable electronic devices, or in close proximity to sensitive patient monitoring devices such as pulse oximeters.

If patient or operator is pregnant or has any medical condition which might be affected by this device during treatment, consult a physician prior to use.

In case of an adverse event, discontinue the scaling procedure.

Warnings

- Close manual shut-off valve on the dental office water supply every night before leaving the office.
- The water / fluid supply line to the scaler should always be turned off whenever the device is being connected, disconnected, or when not in use.

- Turn the scaler power off every night before leaving the office with the rocker switch on the back. When power is off, the green LED on the front panel will turn off.
- Locate the scaler and power adapter above and away from sources of fluid that may enter them. Always ensure that the electrical connections on the handpiece cable and the handpiece are clean and dry before assembling them for use.
- As with all electrical devices, the unit should not be immersed in fluids, and fluids should not be allowed to enter the unit through front or rear panel slots. Do not reach for the device if it has fallen into liquid until power is disconnected and do not use the device. Return it to Parkell for servicing. Modifying device violates safety codes, endangers patients and operators, and voids the warranty.
- Use of this equipment adjacent to or stacked with other equipment should be avoided.
- Only use the provided power supply by the manufacturer along with the unit.
- This equipment produces electromagnetic energy and may cause interference with other electronic devices. Should this occur, changing the position or location of the unit may be necessary.
- Use of accessories other than those specified / provided by the manufacturer of this equipment could result in increased electromagnetic emissions, decreased electromagnetic immunity or improper operation.
- The system is portable but must be handled with care when moving. Do not place the system on or next to a radiator or other heat source. Excessive heat may damage the system's electronics. Place the system where air is free to circulate on all sides and beneath it.
- Failure to follow properly validated sterilization processes and approved aseptic techniques for Parkell inserts or handpieces may result in cross contamination.
- Insufficient water flow could result in elevated water and the tip as well as insert stack temperature. When operated with sufficient water flow, the water and tip temperature should not exceed 50°C (122°F). Failure to follow recommendations could result in injury to patients or users. If temperature is elevated, increase water flow. If temperature remains elevated, discontinue use and contact Parkell.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the

manufacturer. Otherwise, degradation of the performance of this equipment could result.

- This equipment is not suitable for use in the presence of a flammable anesthetic gas mixture (when used along with air or oxygen).

Clinical Precautions

- Although the following precautions may be common sense to the experienced user of ultrasonic scalers, they bear repeating in the interest of safety, and the management of unnecessary risk.
- Ultrasonic scalers should only be used by trained, dental professionals.
- Use of appropriate personal protection equipment and high-volume intraoral suction is strongly recommended when operating this device, to avoid exposure to contaminated aerosols.
- **DO NOT OPERATE UNIT WITHOUT WATER FLOWING.** Water flow through tip during use must always be enough to cool handpiece and insert.
- Do not allow prolonged contact of insert tip with lips, cheek, tongue, or other soft tissues. Insert tips are sharp and should be used carefully.
- Handpiece and inserts supplied along with the unit are not sterile and needs to be cleaned and sterilized in autoclave by the user prior to the first use and before each use, as specified on the insert package instructions and in Infection Control procedure specified in this instruction manual.
- To keep heat generation to minimum, use the lowest scaling power that is effective.
- Before using the insert in the oral cavity, adjust water mist by varying the POWER & WATER settings.
- For patient comfort, use a generous flow of water as a coolant, lubricant, and debris flush.
- If patient is new to ultrasonic scaling, explain to them what to expect. When done properly, the patient should not experience any uncomfortable heat. If patient experiences excessive heat, adjust POWER and WATER controls accordingly, or examine inserts for wear or damage.
- Do not test a scaler tip on your fingers while operating, as this is not a valid test of how scaling feels to the patient. If you touch the tip, it will feel uncomfortably hot to your fingers.
- Hold the handpiece in a comfortable pen-grasp. Elevated heat may be felt if the lighted handpiece is gripped where the insert meets the handpiece.
- Keep the long axis of the insert tip parallel to the long axis of the tooth to wipe deposits from the tooth with a light, brushing stroke with the side of the insert. Do not gouge the tooth with the point of the tip.
- Excess pressure will not improve scaling efficiency and may cause overheating of the tooth and pain to the patient. Keep the scaler insert in motion always, using repeated gentle strokes to remove all tenacious deposits.
- Occasionally pause during scaling by removing foot from pedal to evaluate deposit removal. Exercise caution near ceramic or resin restorations, as they can fracture if stressed.

Inserts

Magnetostrictive Inserts for the TurboSensor+ scaler are available separately and are not included with the basic scaler unit. The unit

is designed to work with all Parkell and other market-leading 30KHz inserts. Brand new inserts may fit very tightly in the handpiece initially and may be inserted and removed more easily by using a slight twisting motion, and by lubricating the insert "O" ring with water. Old, worn, or blunt inserts will perform poorly, generate excess heat, and should be replaced when necessary.

Installing Your Scaler

- Parkell TurboSensor+ System is designed to rest on a level surface. Be sure the unit is stable. This will assure that an accidental pull on the handpiece or corded foot pedal does not cause the unit to fall onto the floor.
- The scaler requires access to a source of drinking-quality water and a grounded electrical outlet.
- Locate the control unit such that it can be easily disconnected from the mains power line in case it needs to be disconnected for any reasons. Disconnection from the mains power line can be accomplished by removing the power cord from the wall plug, removing the power cord from the in-line "power supply adapter" or by removing the 2.5 mm metal plug connector from the back of the scaler.
- Install the scaler where control panel and foot pedal will be easy to reach during scaling procedures.
- The rear of the unit requires access so the water filter may be changed periodically without difficulty.
- The device and its separate power adapter generate a minimal amount of heat. Avoid covering them to allow normal cooling.

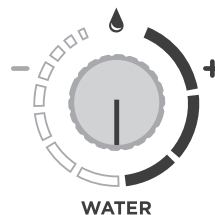
Water Connection

Before plugging in the device, connect the scaler's water line to a drinking-quality water supply (15-35 psi optimal), free of sediment. An external, office-wide water filter is recommended to minimize frequent changes of the device's in-line water filter.



The male quick-connect that comes on the end of the water hose is the standard fitting presently used in the dental industry. If you are replacing a scaler that uses an Adec-type or other type of connection, remove the old fitting from the unit hose and attach it to the new water line. Check for leaks at all hose and filter connections before use, and tighten if necessary.

Controlling the Water Flow

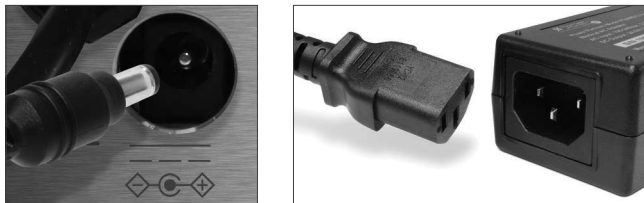


Observing the arrow printed on the control panel, turn the water control counter-clockwise to increase the flow, or clockwise to decrease water flow. If water does not flow through the insert when the foot pedal is depressed, the water passage in the scaling insert may be clogged.

Electrical Connection

The scaler must only be powered via the power supply assembly that is supplied with the device by Parkell. Power supply provided by Parkell is a Medical-Grade, IEC 60601 compliant, TUV approved

switching power supply adapter with Input being 100-240 VAC, 1.0-2.0 Amp, 50/60 Hz and Output being 24 VDC, 3.0 Amp.



- Insert the 2.5 mm metal plug from the Power Adapter into the back of the scaler.
- Insert the supplied AC cord female plug into the Power Adapter.
- Plug the male AC power cord into any grounded electrical outlet.

Use of 30KHz Detachable Handpiece

The TurboSensor® + is provided with a 30KHz detachable handpiece. The handpieces do not come sterilized and must be autoclaved prior to initial use.

To attach the cable to the handpiece, align the small groove in the plug with the mating groove in the jack and push the connector gently until it “clicks”. Removal is accomplished by rotating the hose collar and gently withdrawing the connector from the handpiece.

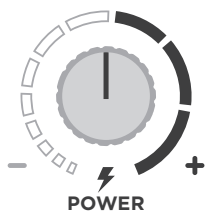


Turning on the Scaler and Controlling the Power Output

The unit provides a rocker switch on the rear panel for Main Power Control. UP position of the switch turns the device ON. Green LED on the front panel would illuminate indicating powered ON status of the device. DOWN position of the switch on the rear panel would turn the device and Green LED indicator OFF.

Scaling will be activated upon pressing the foot switch once the device is turned ON. The pedal should be placed where it will not accidentally be pressed when the device is not in use.

The TurboSensor+ gives you two ways to adjust the scaling power, by using the Power Control Knob for normal operation, or by depressing the Foot Pedal to enter the “Turbo Mode”.



Use the Power Control Knob to set the initial scaling power. Rotate the knob in a clockwise direction to increase the power, or counterclockwise to decrease the power.

When starting a procedure, use the Power Control Knob to set the power to “Medium”. When the foot pedal is slightly depressed to the first position, the insert will begin

vibrating at medium power. Then adjust the power up or down based the specific needs for the case being treated

Use the “Turbo Mode” for short-term increases in power during scaling. Using increased foot pressure, fully depress the foot pedal

to the floor to enter “Turbo” mode. A yellow indicator light will illuminate on the front panel to confirm the scaler is operating at “Turbo” power. Scaling power to a point midway between the current setting and the scaler’s maximum power.

Engaging the Turbo feature at a low power setting causes a significant boost in power.

Engaging the Turbo feature at high power will produce very little change.

Since water flow is not affected by “Turbo Mode”, extended procedures may require a water adjustment.

Partially lifting your foot off the pedal will return the scaler to normal, “non- Turbo” mode. Releasing your foot completely off the pedal will deactivate scaling. Green LED indicator will NOT turn OFF, as it indicates device ON status.

Purging

Per CDC recommendations, waterlines should be purged based on the following schedules:

- Two minutes at the start and end of each day.
- 20 seconds between patients.

The TurboSensor+ offers the following exclusive Purge features:

- Purging ONLY with the handpiece detached from the cable to prevent contamination of an autoclaved handpiece.
- Convenience of a foot controlled “Tap-On” Purge.

How to Purge

1. Confirm the unit is ON and that the green LED on the front panel is illuminated.
2. Disconnect the detachable-autoclavable handpiece from the cable.
3. Adjust the water control to Maximum flow.
4. Hold the cable end over a sink or drain.
5. Depress the foot pedal for more than 2 seconds to activate purge mode.
 - a. When initial pressure is applied to the foot pedal, a short burst of water will be expelled from the cable to confirm purge mode is being activated.
 - b. After two seconds, a steady stream of water will flow, and the Purge LED will begin to pulse.
 - c. Once water flow is continuous, and the Purge indicator LED pulses, foot pedal pressure can be released without interruption of the purge cycle.
6. The Purge light will pulse for the first 20 seconds of the purge cycle after which it will stay constantly on for an additional 1 minute 40 seconds. (2 minutes of total purge time).
7. When the Purge light changes from pulse to constant the 20 second purge cycle for between patient waterline purging is complete. Depress the foot pedal to stop purging.
8. The beginning and end of day purge cycle will automatically shut off after 2 minutes.

Safety Feature: Deactivation of the purge cycle can be manually accomplished at any time by tapping the foot pedal.

Priming the Handpiece

1. Confirm the unit is ON and that the green LED on the front panel is illuminated.
2. Attach an autoclaved handpiece to the handpiece cable that has already been purged. Make sure there is no insert connected into the handpiece. (Purging the waterlines can only be accomplished when the handpiece is not connected to the cable.)
3. Hold the handpiece in an upright position.
4. Depress the foot pedal.
5. Water will begin to flow and fill the handpiece. Priming of the handpiece should be done with a water setting between medium and maximum flow. (The lower the setting the longer it will take to prime and fill the handpiece with water.)
6. To stop water flow into the handpiece, remove foot from foot pedal.
7. An insert may now be placed into the handpiece for scaling.

Clinical Suggestions on Tooth Scaling

- To prevent any potential injury to the patient, ultrasonic scalers should be used by trained, dental professionals only.
- Protect patient's eyes, lips, cheek, tongue or other vulnerable soft tissues when using this device. Inadvertent contact with Insert tip may cause a slight burn.
- Inserts and detachable handpiece must be sterilized before each use.
- Use of a face mask by the clinician, and high-volume intraoral suction, is strongly recommended when operating this device to avoid inhalation of contaminated aerosols.
- To prevent a possible slight burn to the patient or clinician, NEVER OPERATE UNIT WITHOUT WATER FLOWING.
- Use the lowest effective scaling power for the case at hand. This keeps heat generation to a minimum.
- Before using the insert in the oral cavity, adjust the water spray following the graphics on the faceplate of the scaler over a sink or cuspidor until desired mist is obtained. Good water flow will act as a coolant and aid in flushing out debris to maximize patient comfort.
- If patient is new to ultrasonic scaling, explain to them what to expect. Usually, the patient should not experience discomfort. If patient experiences uncomfortable heat, adjust power and water controls accordingly.
- Do not test a scaler tip for vibration on your fingers while the unit is operating. This is not a valid test of how scaling feels to the patient.
- Hold the handpiece in a comfortable pen-grasp. To remove deposits from teeth, always use a light brushing stroke with the side of the insert tip, in contact with and parallel to the root surface. Excess pressure will not improve scaling action but may cause heating and pain to the patient. Keep the scaler insert in motion, using repeated gentle strokes to remove all tenacious deposits.
- If the patient experiences discomfort due to the sound and vibration from the Scaling procedure, provide ear protection.
- Do not use the point of the insert on the tooth surface. You may gouge the tooth.
- Pause occasionally during scaling by removing foot from pedal to evaluate deposit removal.

- Exercise caution near ceramic restorations, as they can discolor or fracture if stressed.

Common Operator Errors that May Result in Poor Clinical Performance

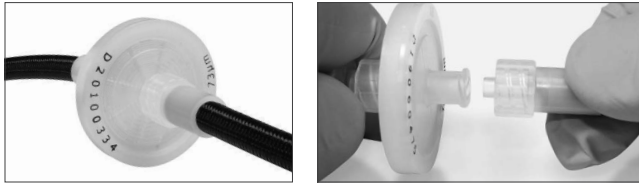
- Failure to keep insert tip parallel to the long axis of the tooth.
- Excessive use of hand pressure.
- Failure to use the lowest effective power setting for the case at hand.
- Insufficient water flow.
- Scaling with the point of the insert instead of the side.
- Inserts that are damaged, bent or worn out.

Cleaning and Infection Control

- Consult www.CDC.gov for the "Guidelines for Infection Control in Dental Health - Care Settings" and "Statement on Reprocessing Dental Handpieces".
- DO NOT AUTOCLAVE the TurboSensor+ control unit, as autoclave heat will destroy it. The control unit should be cleaned of debris with a water-damp paper towel, disinfected by wiping with a paper towel that has been saturated with an EPA-registered low-level (HIV/HBV claim) to intermediate-level (tuberculocidal claim) hospital disinfectant, wiped of chemical residue with a water- damp paper towel, and dried. Utilize the surface disinfecting protocol of the disinfectant manufacturer.
- Autoclaving does not remove debris that has accumulated on the handpiece or the insert. Failure to adequately remove debris will result in inadequate sterilization. Rinse the handpiece, and the insert under warm running water for 30 seconds to remove any external or internal soil or debris. Using a soft soapy cleaning brush to assist in the cleaning, if necessary. Use non-ammoniated detergent or dishwashing soap. Do not use ammoniated cleansers or disinfectants. Rinse the devices again under warm running water for 30 seconds to remove any residual soap and blot dry with a dry lint-free towel. Wipe Insert with a lint free towel that has been saturated in an EPA-approved, hospital-grade intermediate or high-level disinfectant (minimum 2.5% Glutaraldehyde solution), following the instructions for use provided by the disinfectant manufacturer. Dry the devices with a dry lint-free towel.
- The handpiece and inserts may be sterilized in any conventional steam autoclave following manufacturer's instructions. A typical steam sterilization cycle is 132 +/- 2°C for 4 mins. (Vacuum) or 132 +/- 2°C for 15 mins. (Gravity), followed by a 15-minute minimum cool-down period. Use a steam sterilization pouch that is compliant with ISO 1140-1 Type 4 and 11607 standards. Once items are sterilized, adhere to the shelf-life specified by the pouch manufacturer. After sterilization, inspect the device in the autoclave bag for integrity. If suspicion about the item exists, discard it and order a replacement from Parkell or your dealer.
- DO NOT USE DRY HEAT OR CHEMCLAVE on the handpiece or the insert.
- The handpieces are designed to withstand a minimum of 1,000 autoclaving cycles when reprocessed.
- The ultrasonic inserts from Parkell are designed to withstand a minimum of 500 autoclaving cycles when reprocessed.

How to Replace the Filter Disk

The water filter disk coming off the rear hose of the unit should be replaced when it becomes dark or clogged with debris so that water flow is not blocked (1-3 months).



Replacement Filters are available from Parkell (package of 10 filters—[REF D419](#)).

1. Close any water valves and bleed all water lines of residual water pressure.
2. Disconnect the scaler water supply hose from the water supply at the quick-connect.
3. Remove the old filter disk by holding it in one hand and loosening it by twisting it off the hose connectors on either side. They rotate in opposite directions.
4. Install the new filter disk in the same position as the old one and tighten the connectors in reverse.
5. Reconnect the scaler water supply hose to the water supply via the quick-connect and check for leaks.
6. Engage PURGE mode to allow water to flow out the end of the handpiece into a sink.

Note: If the filter becomes clogged and you do not have a replacement disk, the hose connectors may be locked together TEMPORARILY without the filter disk to allow emergency operation only. Water Filter is a single use part. Once replaced, the old water filter should be properly disposed in trash and must not be reused.

Troubleshooting

<p><i>Unit does not operate (“power on” indicator does not light)</i></p> <ul style="list-style-type: none"> • Main ON/OFF switch is not set to on; Check that switch on rear panel is in up position. • Power Adapter cable is disconnected from wall outlet or scaler. Reconnect properly. • Wall outlet is not powered. Use different wall outlet. • Unit fuse has failed. Contact Parkell.
<p><i>Insert does not vibrate properly</i></p> <ul style="list-style-type: none"> • Faulty, damaged, or worn insert. Replace. • Insert not correctly seated in handpiece. Reinsert properly. • Use a new Parkell® brand insert. • Power control not correctly adjusted. Readjust.
<p><i>Excess heat at handle or tip of insert</i></p> <ul style="list-style-type: none"> • Faulty, damaged, or worn insert. Replace. • Too little water flow. Insert may be blocked. Inspect & clear blockage or replace insert. • Power too high for water. Increase water flow. • Excessive hand pressure applied. Correct technique.

<p><i>No water spray when foot pedal is depressed</i></p> <ul style="list-style-type: none"> • Water line blocked or kinked. Correct. • Water passage in the scaling insert clogged. Inspect and clear blockage or replace insert. • Water filter clogged. Replace. • No water supply connected. Correct.
<p><i>Insert does not go into handpiece</i></p> <ul style="list-style-type: none"> • Insert stack is bent. Straighten plates carefully by hand and reinsert. • O-ring is too tight. Lubricate O-ring with water and use twisting motion to seat insert. • Detachable 30K Handpiece (REF D722) can only accept 30K insert. Make sure that it is not a 25KHz insert, as it will not fit inside the handpiece.
<p><i>Insert falls out of handpiece or water leaks from front of handpiece</i></p> <ul style="list-style-type: none"> • O-ring damaged or worn. Replace O-ring on the insert.
<p><i>Water leaks at base of handpiece</i></p> <ul style="list-style-type: none"> • Orange O-ring at end of handpiece missing or damaged.
<p><i>Insert comes out of handpiece when pedal is depressed</i></p> <ul style="list-style-type: none"> • Water pressure is too high. Adjust water pressure to 15-35 psi at dental unit connection or in floor junction box or replace insert O-ring.
<p><i>Purge Mode does not activate</i></p> <ul style="list-style-type: none"> • Make sure to disconnect detachable handpiece from the cable. • Activate the unit by pressing the foot pedal. Purge LED should start blinking. • Contact Parkell for support if problem is not resolved.
<p><i>Scaling Power has reduced to minimum automatically</i></p> <ul style="list-style-type: none"> • Foot switch remained pressed continuously for more than 3 minutes. To avoid any accidental damage, scaling power was reduced to minimum after 3 minutes of continuous foot switch press. Scaling and water flow will be disabled completely after 10 minutes of continuous usage. This is normal. • Release foot switch and press again. Contact Parkell for additional assistance. • Upon activation, TurboSensor+ detects if handpiece is detached from the cable / if there is no insert connected into the handpiece. TurboSensor+ then disables output oscillator reducing power consumption and heat generation. • To improve safety, Turbo+ disables water flow after 2 minutes of pre-determined purge duration. In the event of accidental – unattended continuous foot switch activation, this feature prevents water damage in the dental office and prevents handpiece overheating, if external valve is closed. • TurboSensor+ detects insert stall and instantly recovers upon release of the tip preventing damage to the teeth / gum line / other anatomical structure during a clinical procedure by momentarily shutting down the oscillator and reducing power output significantly. • Always Awake. Without a “Sleep” mode, TurboSensor+ always remains ready for activation while powered on. Position the foot pedal to avoid accidental activation.

User Maintenance and Authorized Service

The Parkell TurboSensor+ requires very little maintenance for years of trouble-free operation. There are no user-serviceable parts inside the control unit or the foot pedal. Opening the cases will void all warranties. Authorized Parkell personnel must make all internal repairs. Parkell urges all scaler users to monitor the condition of the water filter periodically and change the filter whenever noticeable darkening of the disk occurs, or when water flow decreases. The most common reason for service for ultrasonic scalers is failure by the user to periodically change the water filter. This will result in contamination and clogging of the internal water components.

The ultrasonic inserts, autoclavable handpiece, power supply, water filter and water hose are all detachable and may be replaced by the user. Contact Parkell for a list of authorized inserts and available replacement parts.

Within the US, all repairs must be made by Parkell. We maintain a complete service and parts facility in our factory at 300 Executive Drive, Edgewood, NY 11717. Equipment needing service in the US should be returned, freight pre-paid, via approved common carrier (e.g., USPS, UPS, FedEx), and adequately insured. Return all accessories with the unit and include an explanation of the problem. Pack in the original box, add plenty of cushioning material, and over box the unit during shipping. Transit should maintain a dry temperature of 0°F-110°F. You will be contacted for your approval of the repair, along with any associated costs, prior to any work. The unit will be repaired and returned to you.

Outside the US, repairs must be made by a Parkell-authorized facility.

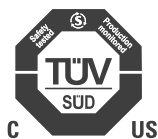
If you have any questions or problems with the installation or use of your TurboSensor+, call Technical Support Service at 800-243-7446, M-F from 8:30 AM to 5:00 PM EST.

Warranty and Terms of Use



















For full Warranty and Terms of Use information, please see www.parkell.com. Parkell's Quality System is certified to ISO 13485.

Conformance to Standards

The Parkell TurboSensor+ is TUV listed and conforms to IEC 60601-1, 60601-1-2 (Electromagnetic Compatibility of Medical Devices) and CAN/ CSA C22.2 No. 601.1. Parkell's quality system is certified to ISO13485.



Explanation of Symbols Used

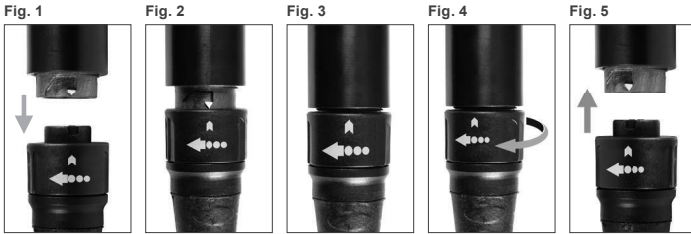
	Follow instructions for use
	Package contents
	Manufacturer
	Qualified User Symbol
	Medical Safety Classification Symbol
	Temperature limitations
	Do not use if package is damaged
	Keep dry
	Catalogue / stock number
	Unique Device Identifier
	Medical Device
	Protective Earth Connection
	Do not dispose this product into the ordinary municipal waste or garbage system
	Single use only
	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
	Footswitch Connection
	AC Power Connection
	Water Connection



Instructions for Use: Detachable Handpiece

REF D722

A01134revA0622



Use of Autoclavable Detachable Handpiece

IMPORTANT: Handpieces are not sterile upon receipt and must be sterilized prior to first use as per the instructions below.

To attach the handpiece to the TurboSensor®+ cable, line up the arrow mark on the cable connector to the arrow mark on the handpiece connector and push the two gently together until you hear a click (Figures 1-3). The click indicated the locking mechanism has engaged.

To disconnect the handpiece from the cable, hold the handpiece in an upright position and rotate the quick-lock connector ¼ turn to the left (Figure 4). This will disengage the locking mechanism, so the handpiece can be gently separated from the cable (Figure 5).

Cleaning and Infection Control

- Consult www.CDC.gov for the “Guidelines for Infection Control in Dental Health-Care Settings” and “Statement on Reprocessing Dental Handpieces”.
- **DO NOT AUTOCLAVE THE TURBOSENSOR®+ WITH DETACHABLE HANDPIECE CONTROL UNIT**, as autoclave heat will destroy it. The control unit should be cleaned of debris with a water-damp paper towel, disinfected by wiping with a paper towel that has been saturated with an EPA-registered low-level (HIV/HSV claim) to intermediate-level (tuberculocidal claim) hospital disinfectant, wiped of chemical residue with a water-damp paper towel, and dried. Utilize the surface disinfecting protocol of the disinfectant manufacturer.
- Autoclaving does not remove debris that has accumulated on the handpiece. Failure to adequately remove debris will result in inadequate sterilization. The handpiece must be washed in soap and water manually and rinse the device under warm running water for 30 seconds to remove any external or internal soil or debris. Using a soft soapy cleaning brush to assist in the cleaning, if necessary. Use non-ammoniated detergent or dishwashing soap. Do not use ammoniated cleansers or disinfectants. Rinse the item again under warm running water for 30 seconds to remove any residual soap and blot dry with a dry lint-free towel. Wipe device with a lint-free towel that has been saturated in an EPA-approved, hospital-grade intermediate or high-level disinfectant (minimum 2.5% Glutaraldehyde solution), following the instructions for use provided by the disinfectant manufacturer. Dry with a dry lint-free towel.

- Detachable, Autoclavable Handpiece and inserts shall be sterilized in any conventional steam autoclave following manufacturer's instructions. A typical steam sterilization cycle is 132 +/- 2°C for 4 mins. (Vacuum) or 132 +/- 2°C for 15 mins. (Gravity), followed by a 15 minute minimum cool-down period. Use a steam sterilization pouch that is compliant with ISO 11140-1 Type 4 and ISO 11607-1 standards. Once items are sterilized, adhere to the shelf-life specified by the pouch manufacturer. After sterilization, inspect the device in the autoclave bag for integrity. If suspicion about the item exists, discard it and order a replacement from Parkell or your dealer.








• DO NOT USE DRY HEAT OR CHEMCLAVE THE HANDPIECE.







- The handpiece from Parkell is designed to withstand a minimum of 1000 autoclaving cycles when reprocessed as per the recommended procedure.

Questions?

If you have any questions contact Technical Support Service at (800) 243-7446, M-F from 8:30 AM to 5:00 PM EST or e-mail techsupport@parkell.com.

Explanation of Symbols Used


	Medical Safety Classification Symbol
	Qualified User Symbol
	Temperature limitations
	Do not use if package is damaged
	Follow instructions for use
	Keep dry
	Sterilizable in a steam sterilizer (autoclave) at the temperature specified

	Package contents
	Manufacturer
	Catalogue / stock number
	Unique Device Identifier
	Medical Device
	Do not dispose this product into the ordinary municipal waste or garbage system

parkell®

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 **MADE IN USA**  **1639**

Important Instructions for Water Compliance & Waterline Maintenance (for use with all Parkell Ultrasonic Scalers)

Background: Effective dental unit waterline maintenance is a key component of an infection control program. This is due to the fact that water flowing through the long internal waterlines of dental equipment (including ultrasonic scalers) can harbor bacteria, and if untreated can harm your patients or staff.

Proper Water Compliance and Waterline Management:

The U.S. CDC (Centers for Disease Control and Prevention) recommends the use of water that meets the EPA regulatory standards for drinking water (i.e., 500 CFU/mL of heterotrophic water bacteria) for non-surgical, routine dental procedures. This includes, for example, the water used in ultrasonic dental scalers such as Parkell's scalers.

To help you stay in compliance with CDC recommendations, we provide procedural recommendations below. These recommendations should be incorporated into your offices' daily/weekly/monthly waterline maintenance routine and should become part of the standard operating procedure you employ when using and maintaining your Parkell ultrasonic scaler system.

With New Parkell Scalers:

- Before use on a patient clinically for the first time, an initial cleaning (shock treatment) should be performed, followed by water testing, in order to ensure that water bacteria levels are acceptable (i.e., 500 CFU/mL). If bacterial levels are higher than 500 CFU/mL, it may be necessary to repeat this process.
- Products designed for both shocking and testing are readily available and should be used as per the specific manufacturer's instructions.

Waterline Maintenance:

There are 3 critical steps to proper waterline maintenance: Test. Shock. Maintain.

1. "Test"

It is important to regularly monitor the water that passes through your scaler. Without testing, it is impossible to know if your water meets the CDC recommendations for quality and safety (i.e., 500 CFU/mL of heterotrophic water bacteria). Moreover, the frequency of your water testing depends on your ability to obtain consistent results that fall within CDC recommendations for water quality. Such testing should be performed in all your treatment rooms.

Once acceptable waterline test results are achieved, subsequent waterline testing may be performed monthly. After three successive months of successfully achieving your water quality goals, testing frequency may be able to be reduced to once every three months, though CDC and local recommendations should always be reviewed prior to doing so.

There are two types of dental waterline tests: in-office chairside test kits and mail-in external lab services. Because water quality can change quickly, Parkell recommends using a combination of both services to ensure compliance.

2. "Shock"

Shock treatment(s) of scaler waterlines should always be done prior to first usage.

After first use, monitoring your water quality through the above-described testing will help you determine if additional shock treatments are needed. Whenever applying any dental waterline treatment, always follow the manufacturer's instructions associated with the treatment product

3. "Maintain"

Once acceptable waterline test results are achieved, a maintenance solution for dental unit waterlines (or tablets or the like) should be used once a week as recommended by the CDC. Importantly, when using any of the various maintenance products on the market, please ensure that you are following the manufacturer's instructions associated with the product.

Important Warranty Information:

Parkell does not support or endorse the use of chemical formulations made in the office as it is very difficult to maintain consistent chemistry from mix to mix. Using such “homemade” products may damage the internal components of the scaler and, therefore, may void any warranty repair determined to be related to such use.

Additional Resources:

It is critically important to continuously monitor developments as they occur around local and federal water quality standards and recommendations. Two example sources for such information are:

- **OSAP (Organization for Safety and Asepsis and Prevention) www.osap.org**
- **CDC www.cdc.gov/oralhealth**

Always remember - Parkell is here to help!

If, at any time, you have questions or concerns about Parkell ultrasonic scalers or the proper maintenance of waterlines within your Parkell scaler, email us at compliance@parkell.com. We consider ourselves an extension of your team, and have experts on staff to assist.