Rx Only (product intended for use by a Licensed dental professional). This manual, in whole or in part, should not be considered a substitute for formal training in ultrasonic scaling. Appropriate professional education is STRONGLY RECOMMENDED prior to using this device clinically.

EN

Instructions for Use

parkell®

Turbo SENSOR®

Ultrasonic Scaler (REF D560-110, REF D560-230)

A00414_revQ0325

Device Description

The Parkell TurboSensor® is an autotune magnetostrictive ultrasonic tooth scaler that operates at either 25 KHz or 30 KHz. The TurboSensor automatically detects whether the handpiece contains a 25 KHz or 30 KHz insert, and switches to the correct operating frequency. The TurboSensor has an expanded low-power range to improve patient comfort during debridement, and a power-boosting, user-controlled Turbo feature to increase scaling power when needed for heavy deposits. The unit is designed to work with Parkell inserts. For information about usage with non-Parkell inserts, please see our warranty policy.

Indications/Intended for Uses

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

Contraindications

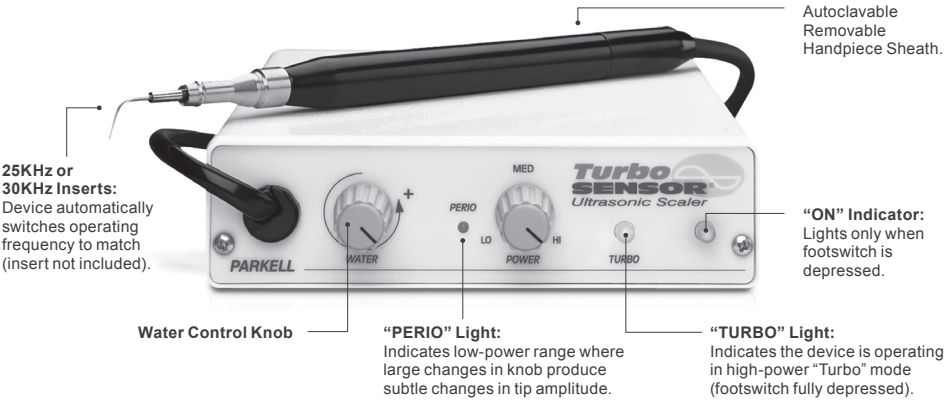
Because of the potential for electromagnetic interference, this device should not be used on patients or by clinicians with cardiac pacemakers, internal defibrillators, intracorporeal fluid pumps or any other implantable electronic devices, or in close proximity to sensitive patient monitoring devices 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 the event of any adverse reaction from the patient, discontinue the scaling procedure.

Warnings

- The water supply to the scaler should always be turned off whenever the device is being connected, disconnected, or when not in use.
- The power supply cord functions as the AC power disconnect device for the scaler.
- The transformer should be located above and away from any sources of water that may enter the unit. As with all electrical devices, the unit should not be immersed in water or other liquids. Do not reach for the device if it has fallen into liquid until power is disconnected, and do not use the device after it has fallen into liquid. Return the device to Parkell for servicing.
- 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.



- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.
- Modification of this device will void the warranty, and may violate safety codes, endangering the patient and/or the clinician.
- This equipment is not suitable for use in the presence of a flammable anesthetic gas mixture (when used along with air or oxygen).
- This equipment produces electromagnetic energy and may cause interference with other nearby electronic devices. Should this occur, changing the position or location of the device may be necessary.

Clinical Precautions

- Protect patient's eyes, lips, cheek, tongue or other vulnerable soft tissues when using this device.
- Protect the patient's clothing from water damage when using this device.
- Clinicians should wear eye protection and face mask when using this device.
- Water flow through tip during use must be sufficient to cool handpiece and insert.
- Keep the long axis of the insert tip parallel to the long axis of the tooth to wipe deposits from the tooth.
- Do not gouge the tooth with the point of the tip.

Conformance to Standards

The Parkell TurboSensor is TUV listed and conforms to IEC 60601-1, 60601-1-2 and CAN/CSA C22.2 No. 601.1. Parkell's quality system is certified to ISO13485.

Specifications

- **Size of Unit:** 1½"H x 5½"W x 7½"D
- **Weight of Unit:** 2.70 lbs (1.22 kg) (43.2 oz)
- **Weight of Transformer:** 3.85 lbs (1.75 kg) (61.6 oz)
- **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)
- **Total Length of Transformer Cable from Wall Outlet to Unit:** 12'6" (380cm)
- **Power:** 120VAC 50/60 Hz (REF D560-110), 230VAC 50/60 Hz (REF D560-230)
- **Protection Against Electric Shock:** Class 1, Type B applied part
- **Protection Against Ingress of Liquids:** Foot Pedal & 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)
- **Certifications:** All electrical devices have been certified to: IEC 60601-1, IEC 60601-1-2 and CAN/CSA C22.2 and are TUV listed

What's Included

- (1) Magnetostrictive Scaler Control Unit with attached handpiece, foot controller and water line (with male quick-connect coupler); (120VAC REF D560-110, 230VAC REF D560-230)
- (2) Autoclavable sheaths (one attached to handpiece) (REF D576)
- (2) Inline water filters (one attached to water line)
- (1) Transformer with cable
- (1) Operator's Manual / Instructions for Use

Inserts

Inserts and Handpieces are supplied non-sterile and must be autoclaved before first use, and before each subsequent use.

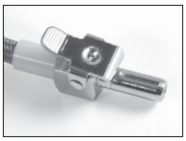
Magnetostrictive Inserts for the TurboSensor scaler are available separately, and are not included with the basic scaler unit. The unit is designed to work with Parkell inserts. For information about usage with non-Parkell inserts, please see our warranty policy. The scaler automatically adjusts the operating frequency to match that of the insert in the handpiece without operator intervention. 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

Locate the device where the control panel will be easy to reach during scaling procedures, and where the water filter at the rear of the unit may be periodically changed without difficulty. The scaler requires access to a grounded electrical outlet and a source of drinking-quality water. The device and its separate transformer 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 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 Transformer Assembly that is supplied with the device by Parkell.

1. Plug the round transformer power cord connector into the back of the scaler, with the arrow on the plug on top.
2. Plug the transformer into a grounded electrical outlet. Stepping on the pedal will activate the scaler.

Use of Autoclavable Sheaths and Ultrasonic Inserts

1. The TurboSensor handpiece is provided with the autoclavable handpiece sheath attached.

   NON STERILE

   Inserts and Handpieces are supplied non-sterile and must be autoclaved before first use, and before each subsequent use. To remove it, hold the handpiece at the base with one hand and turn the sheath counter-clockwise with the other, taking care not to twist the hose. The sheath will unscrew and slip off.

2. To replace the sheath, gently thread it onto the handpiece clockwise, until there is no gap between the two. Take care not to damage or dislodge the O-ring. Do not overtighten.

Turning On the Scaler and Controlling Power Output

The unit does not have a traditional on/off switch. The foot pedal turns the unit on when depressed, and off when released. **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 for the procedure at hand. Turn the knob in a clockwise direction to increase the power, or counterclockwise to decrease the power.

- Usually, the Power Control Knob is set at the "Medium" setting to start. When the foot pedal is slightly depressed to the first position, the insert will begin vibrating at Medium power.
- If the Power Control Knob is set for the "Perio" setting, the "Perio" light will illuminate, and the tip will vibrate at a much a lower power than a traditional scaler when the foot pedal is depressed. This permits very subtle adjustments in tip power, meaning that relatively large movements of the knob within the Perio mode of operation will produce small increases in power. This allows more comfortable debridement for sensitive patients.
- When the "Perio" light is not illuminated, tip amplitude reacts more dramatically to knob adjustment for high power calculus removal.

Use the "Turbo Mode" for short-term increases in power during scaling. Fully depress the foot pedal to the floor using increased foot pressure and the yellow "Turbo" light will illuminate. This will instantly boost 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 of the pedal will return the scaler to normal, "non-Turbo" mode.

Note that whenever you fully release the foot pedal, the green "on" light on the front panel will turn off along with the yellow "Turbo" light. This change may take several seconds.

Clinical Suggestions on Tooth Scaling

- To prevent any potential injury to the patient, ultrasonic scalers should be used by trained, licensed 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.
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Inserts and Handpieces are supplied non-sterile and must be autoclaved before first use, and before each subsequent 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.
- In order 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. For maximum patient comfort, use a good flow of water as a coolant, lubricant and to flush out debris.
- 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 at all times, using repeated gentle strokes to remove all tenacious deposits.
- In the event that 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 sheath or the insert. Failure to adequately remove debris will result in inadequate sterilization. Rinse the Sheath 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.
- Sheaths and inserts must be sterilized in conventional steam autoclave capable of the following sterilization cycles followed by a 15-minute minimum cool-down period;

Steam Sterilization Cycles:

VACUUM: 132 +/ 2°C for 4 mins.

GRAVITY: 132 +/ 2°C for 15 min.

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

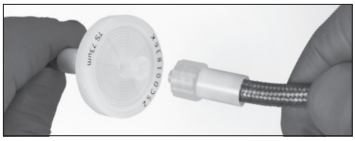
and ISO 11607-1 standards. Once items are sterilized, adhere to the shelf-life specified by the pouch manufacturer. After sterilization, inspect the device in the autoclave bag for integrity. If suspicion about the item exists, discard it and order a replacement from Parkell or your dealer.

- **THE SHEATH OR THE INSERT ARE NOT VALIDATED FOR USE WITH DRY HEAT OR CHEMCLAVE STERILIZATION. USE OF THESE METHODS MAY IRREVERSIBLY DAMAGE THE HANDPIECE OR INSERT AND VOID THE WARRANTY.**
- Detachable handpiece sheath and ultrasonic inserts from Parkell are designed to withstand a minimum of 250 autoclaving cycles when reprocessed as per the recommended autoclaving instructions by the manufacturer.

How to Replace the Filter Disk

The water filter disk coming off of 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 (REF D419 – 10 per package).

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. 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.

Troubleshooting

■ **Unit does not operate ("power on" indicator does not light):**
- Transformer cable disconnected from wall outlet or scaler. Reconnect properly.
- Wall outlet not live. Reconnect properly.
- Foot Pedal or cable is damaged. Contact Parkell.
- Unit fuse has failed. Contact Parkell.

■ **Insert does not vibrate properly:**
- 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.

■ **Excess heat at handle or tip of insert:**
- Faulty, damaged or worn insert. Replace.
- Too little water flow. Insert may be blocked. Inspect and clear blockage, or replace insert.
- Power too high for the amount of water. Increase water flow.
- Excessive hand pressure applied. Correct technique.

■ **No water spray when foot pedal is depressed:**
- 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.

■ **Insert does not go into handpiece:**
- 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.
- Autoclavable handpiece sheath is not attached to handpiece.

■ **Insert falls out of handpiece or water leaks from front of handpiece:**
- O-ring damaged or worn. Replace O-ring on insert and/or handpiece.

■ **Water leaks at base of handpiece:**
- Orange O-ring at end of handpiece is missing or damaged.

■ **Insert comes out of handpiece when pedal is depressed:**
- 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.

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, handpiece sheaths, 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 overbox 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 1-800-243-7446, 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.

Explanation of Symbols Used

	Medical Safety Classification Symbol
Rx	Qualified User Symbol
	Temperature limitations
	Do not use if package is damaged
	Follow instructions for use
	Keep dry
NON STERILE	Non-Sterile
UDI	Unique Device Identifier

MD	Medical Device
	Importer
132 +/- 2°C	Sterilizable in a steam sterilizer
	Package contents
	Manufacturer
REF	Catalogue / stock number
	Protective Earth Connection
	Do not dispose this product into the ordinary municipal waste or garbage system

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

parkell®

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