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

TurboVue®

parkell®

Illuminated Ultrasonic Scaler (REF D570-110)

A00764revE0321

Device Description

Parkell's TurboVue® is a 30 KHz magnetostrictive, ultrasonic tooth scaler that provides a bright, white light directly to the intraoral operating field when used in conjunction with Parkell's 30 KHz light-transmitting inserts. The unit is designed to work with Parkell 30k inserts. Users of the unit with non-Parkell inserts might experience heat proximate to the handpiece. Moreover, for other important information about usage with non-Parkell inserts, please see our warranty policy.

The TurboVue features auto-tuning technology, a dramatically expanded low-power range that improves comfort during debridement, and a power-boosting Turbo feature for an increase in scaling power when needed.

NOTE: The TurboVue will not operate with 25 KHz ultrasonic inserts.

Indications/Intended for Uses

For removal of calculus, plaque and oral debris during dental prophylaxis.

Contraindications

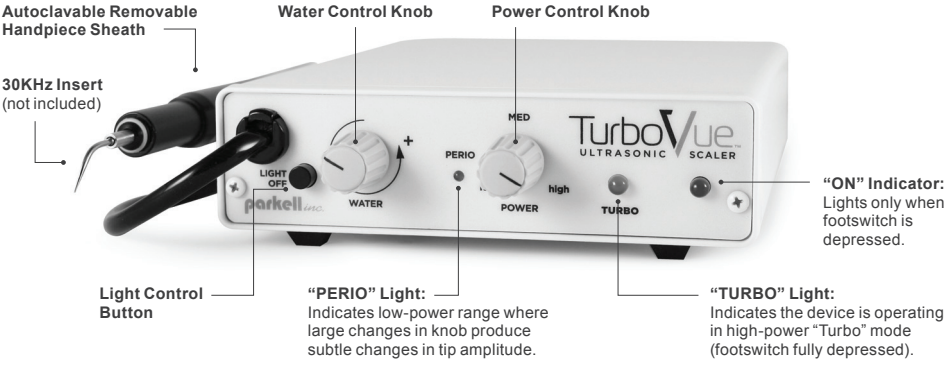
Because of the potential for electromagnetic interference, this device should not be used on patients or by clinicians with cardiac pacemakers, internal defibrillators, intracorporeal fluid pumps or any other implantable electronic devices, or in close proximity to sensitive patient monitoring devices 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.
- Parkell's light-transmitting inserts use a high-quality, high-strength glass sleeve to project a bright light onto the operative field. These tips may be ultrasonically cleaned, disinfected and autoclaved using standard techniques. However, take care to avoid dropping or impacting the insert, as this may result in glass breakage. Inspect the inserts prior to each use for integrity and safety.

Clinical Precautions

- Do not allow prolonged contact of tip with lips, cheek, tongue or other vulnerable soft tissues. Protect patient's eyes 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.
- When operating the unit with non-light-transmitting ultrasonic inserts, if you experience uncomfortable heat at the handpiece and desire to eliminate such heat, set the "Light Off" button to the OUT position to deactivate the light feature.

Conformance to Standards

The Parkell TurboVue 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

- **Power:** 120 VAC at 50/60 Hz or 230 VAC at 50/60 Hz or 100 VAC at 50/60 Hz (hD570-110)
- **Weight:** 35 oz.
- **Size:** 1 1⁄2" H x 5 1⁄2" W x 7" D
- **Handpiece Operating Frequency:** 30 KHz
- **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)

What's Included

- (1) Scaler control unit with attached handpiece, foot controller and water line (with male quick-connect coupler)
- (2) Autoclavable sheaths (one attached to handpiece - REF D572)
- (2) Inline water filters (one attached to water line - REF D419)
- (1) Transformer with cable (REF D408-120V, REF D403-230V)
- (1) Operator's Manual / Instructions for Use

TurboVue Light-Transmitting Inserts

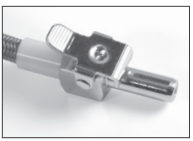
- Universal Tip V - Purple (REF DLH30U)
- Straight Perio Tip V - Blue (REF DLH30P)
- Burnett Power-Tip V - Yellow (REF DLH30T)
- Triple-Bend Precision Flow (REF DLH30Tri-PF)
- Triple-Bend (REF DLH30Tri)
- Replacement parts for certain components are available by contacting Parkell

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.

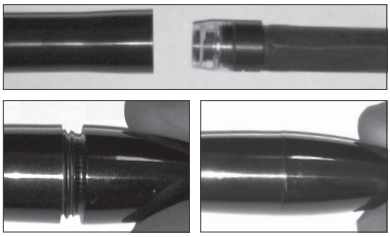
Electrical Connection

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. Gently thread an autoclaved handpiece sheath clockwise onto the handpiece, until there is no gap between the two at the base. Do not overtighten.



2. When removing the autoclavable handpiece sheath, 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.
3. Avoid dropping or impacting the insert's grip, which contains the glass sleeve. Such abuse may cause the glass to crack, and is not covered by the insert's warranty.
4. This scaler does not accept and will not function with 25K scaler inserts.
5. Brand new inserts fit very tightly in the handpiece. For ease of placement, lubricate the O-ring with water and use a slight twisting motion to seat or remove the insert from the handpiece.
6. Old, worn or blunt instruments will provide poor scaling action and should be replaced when needed.

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 TurboVue gives you two ways to adjust the scaling power, either by using the Power Control Knob for normal operation, or by using the Foot Pedal to enter the "Turbo Mode".

1. Use the Power Control Knob to set the initial power for the scaling procedure at hand. With the foot pedal depressed, turn the knob in a clockwise direction to increase the power, or counterclockwise to decrease the power. A tip powered by the TurboVue will begin oscillating at much lower amplitude (power) than a tip in a traditional scaler, allowing more comfortable debridement. When the "Perio" light is illuminated, the knob permits very subtle adjustments in tip amplitude (relatively large movements of the knob produce small increases in amplitude). When the "Perio" light is not illuminated, tip amplitude reacts more dramatically to knob adjustment for high power calculus removal.
2. For short-term increases in power during scaling, use the "Turbo Mode". Increase foot-pressure on the pedal 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 when the scaler is operating at a low setting causes a significant boost in power, while engaging the Turbo feature when the scaler is already operating 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 scaling.

Note: 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.

Controlling the Handpiece Light

The handpiece light is controlled by the "Light Off" button on the scaler front panel. To activate the light feature, make sure the

"Light Off" button is in the IN position. To deactivate the light feature, make sure the "Light Off" button is in the OUT position.

Note: The light will ONLY come on when the foot pedal is depressed.

To prevent leakage of light at the junction of the handpiece and the insert, be sure to fully press the insert into the handpiece before use, and make sure that the autoclavable sheath is fully threaded onto the handpiece.

There is a built-in, 4-second delay between release of the foot pedal and the shut off of the handpiece light. This time delay allows the clinician to inspect the operating site using the light after scaling has ceased.

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.
- Inserts and handpiece sheaths 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.
- 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 TurboVue 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. The sheath and ultrasonic insert must be washed in soap and water either manually or in an ultrasonic cleaner, and rinsed in running water prior to bagging them for processing in a steam autoclave. Rinse the Sheath 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 Sheath 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 Sheath and insert with a dry lint-free towel.

- Sheaths 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 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 on the sheath or the insert.**
- 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. Depress foot pedal while water flows freely out the end of the handpiece and drains into a sink.
7. Lubricate the scaler insert O-ring with water and use a slight twisting motion to seat the insert in the handpiece.

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.

■ **Light will not come on:**
- "Light Off" button is in the OUT position, which deactivates the light feature. Activate by pressing the button IN.
- The light will only come ON when the foot pedal is depressed and the "Light Off" button is pressed IN.

■ **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.
- A non-light-transmitting insert is being used with the light on. Deactivate the light by pressing the "Light Off" button.

■ **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 is a 25 KHz device, which is too long to fit in the TurboVue 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.

■ **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 TurboVue 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 TurboVue, 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

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
	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
	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®

300 Executive Drive, Edgewood, NY 11717
Toll-Free: (800) 243-7446 • **Phone:** (631) 249-1134 • www.parkell.com

MADE IN USA