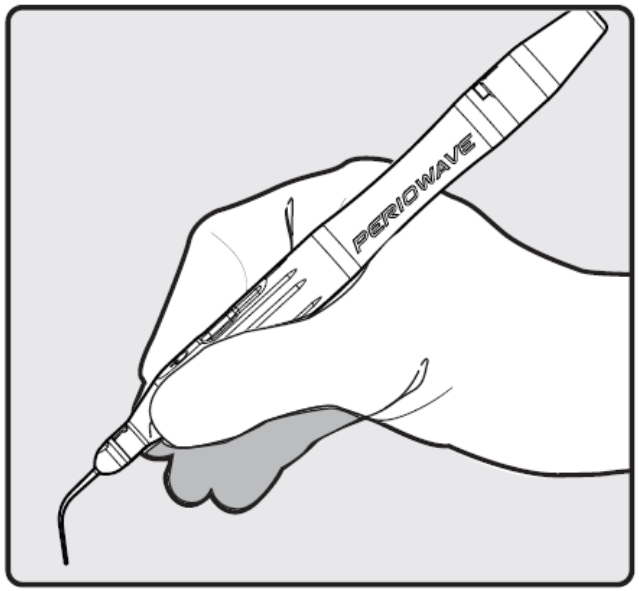
# Periowave™ HHL-1000

**Handheld Photodisinfection System**




**Important: read directions for use carefully before operating.**

**Manufactured by:**

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**Distributed by:**

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# 1 Warning and Safety Information

## 1.1 Laser safety

The Periowave™ HHL-1000 is a Class 1 laser device under IEC 60825-1:2007. A Class 1 laser is safe to use without protective eyewear under normal conditions.

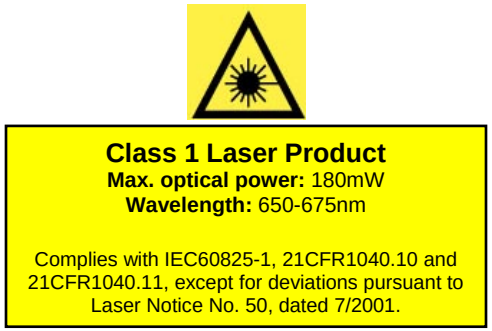


*Figure 1: Harmonized Laser Safety Label*

- The Periowave™ HHL-1000 is designed for **indoor use only.**
- Only approved Periowave™ Photodisinfection System accessories may be used in conjunction with the HHL-1000. Non-compliance with listed instructions in this manual may damage equipment, void warranty, and result in harm.
- Changes or modifications to this equipment may result in exposure to hazardous radiation.
- Optical cleaning swabs are provided with the HHL-1000. Do not use any other product to clean the HHL-1000 optics except those supplied by Periowave Dental Technologies, Inc. as these have


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been carefully evaluated as suitable for use with the HHL-1000. Additional cleaning materials can be purchased from your Periowave™ distributor.

## 1.2 General safety instructions

- Do not modify or alter in any way any component of the Periowave™ HHL-1000. Doing so may alter the performance of the laser, possibly resulting in hazard to the user or patient, and will void the product warranty.
- The light diffusing tip cannot be sterilized and is intended for single-patient use only.
- Use the supplied rechargeable batteries or equivalent AAA, NiMH, 1000 mAh batteries only. When necessary, dispose of these batteries in accordance with local recycling guidelines.
- Handle the device and treatment kits according to prescribed guidelines and dispose of waste in accordance with accepted medical practice and applicable local, state/provincial, and federal requirements.
- The Periowave™ HHL-1000 is not intended for operation in areas subject to explosion hazards or in the vicinity of flammable materials or substances.
- The equipment should be routinely inspected and maintained in accordance with the instructions given in the maintenance section of this manual.

## 1.3 Clinical precautions

The device should be used only by a licensed health-care practitioner who has received training from the manufacturer or a trainer authorized by the manufacturer.

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There have been no observed serious adverse events with the Periowave™ Photodisinfection system in clinical testing. However, there remains the potential for an adverse reaction in the following patients:

- **Patients currently taking photosensitizing medications.**
- **Patients with severe glucose-6-phosphate dehydrogenase (G6PD) deficiency.**
- **Patients with allergies / hypersensitivity to methylene blue or polymethyl methacrylate (PMMA).**
- **Patients with allergies / hypersensitivity to chlorhexidine.**

If any adverse reactions do occur, discontinue use.

The treatment procedure and instrumentation associated with the irrigation of the Periowave™ solution in periodontal pockets carries an inherent yet minimal risk of bleeding and/or pain, as do similar dental procedures. The usual precautions associated with such dental procedures should be taken. There may be minimal staining of the periodontal tissues which should rapidly resolve without further intervention.

Associated dental procedures (e.g., scaling and root planing) may cause bleeding in the periodontal pocket. This will diminish the efficacy of the Periowave™ treatment by displacing the photosensitizer from the pocket. Irrigation, suction, and application of gauze rolls under light direct pressure may be used to obtain as clean and dry a field as possible prior to Periowave™ treatment. Optimally, the Periowave™ treatment can be performed several days after scaling and root planing when all bleeding has resolved.

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The Periowave™ HHL-1000 is a class 1 laser device, and requires neither the user nor the patient to wear protective eyewear during treatment.

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# 2 Introduction

The user should be thoroughly familiar with this manual before operating the system.

The Periowave™ HHL-1000 handheld laser system complies with the following standards:

- IEC 60825-1: 2007 – Safety of laser products
- IEC\CSA 60601-1-1, Class 1, Type BF, Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC 60601-1-2:2007 – Electromagnetic emissions and immunity requirements for medical equipment – Group 1 Equipment Class B for non-life supporting equipment.
- ISO 7405:2008 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry

## 2.1 Intended use

The Periowave™ Photodisinfection System is a laser-based antimicrobial system intended for the treatment of chronic adult periodontitis. It is indicated for use in adults as part of a periodontal health maintenance program, which may also include scaling and root planing procedures.

The Periowave™ Photodisinfection System must be used only by trained personnel in compliance with applicable occupational safety regulations and accident prevention measures as well as these operating instructions.

## 2.2 Mode of action

The primary mode of action for the Periowave™ Photodisinfection System is disruption of the microbial cell

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wall both in biofilm and planktonic colony forms. The topically applied photosensitizer selectively stains bacteria by binding with microbial cell wall components. The laser light is absorbed by the photosensitizer molecules, causing electronic state transitions within the photosensitizer. The excited photosensitizer immediately transfers energy to surrounding molecular oxygen, thereby producing reactive oxygen species (ROS) which are responsible for lethally disrupting the microbial cell wall. These ROS products are very short-lived, and the ROS-production process ceases immediately upon deactivation of the laser. Low-intensity red light absorbed by oral tissue does not cause heating or other gross morphological alterations.

## 2.3 Operating conditions

The Periowave™ Photodisinfection System may be operated in the following environmental conditions:

- Temperature:15ºC (50ºF) - 35ºC (95ºF)
- Relative humidity: 30% - 75%

## 2.4 Transport and storage

The Periowave™ HHL-1000 laser is supplied in a reusable protective case. Store the HHL-1000 in the case to protect it during transport or extended periods of non-use. Between uses, the outer sheath and rear cap should be protected (i.e., autoclave bag, sterile instrument drawer, case). **The internal laser insert must not be autoclaved (see cleaning instructions)**. Cap the laser insert with the provided lens protection cap, and store in a secure location.

The Periowave™ HHL-1000 laser device withstands the following storage environmental conditions:

- Temperatures: 5ºC (41ºF) - 45ºC (113ºF)

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Before using the Periowave™ HHL-1000 laser device, allow the laser to acclimate to specified operating temperature and humidity conditions (see section 2.3) for a minimum of 30 minutes following transportation and/or storage.

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# 3 Description of Device and Components

## 3.1 Periowave™ HHL-1000 laser

The Periowave™ HHL-1000 laser is packaged complete with the parts and accessories listed here (see *Figure 2*). Check the system upon delivery to ensure all parts are included. Immediately notify your distributor or Periowave™ Customer Service at 1-866-669-0555 if any items are missing.

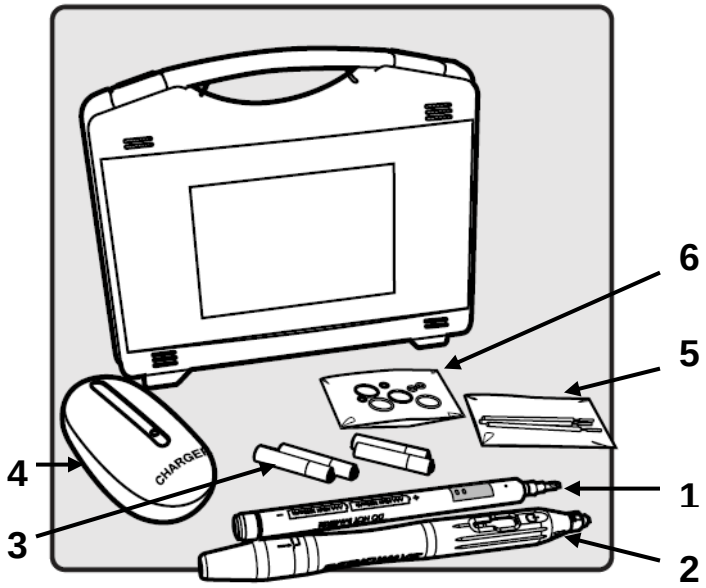


*Figure 2: HHL-1000 Components*

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1. One (1) Laser insert (*Figure 3*) with lens protection cap
2. One (1) outer sheath with rear cap
3. Four (4) Rechargeable AAA NiMH 1000mAh Batteries
4. One (1) battery charger
5. One (1) package of optic cleaning swabs
6. One (1) package of replacement O-rings
7. One (1) user manual

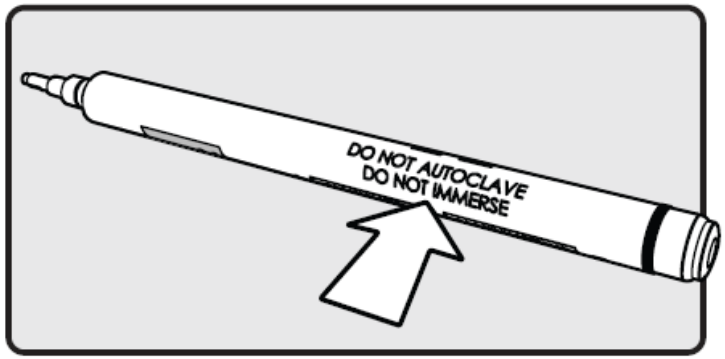


*Figure 3: HHL-1000 Laser Insert*

## 3.2 Initial unpacking

- Upon receipt, open package and verify that all components are present and intact. Problems or damaged products must be immediately reported to your distributor or Periowave Dental Technologies, Inc. at 1-866-669-0555. Use the Periowave™ HHL-1000 only if packaging and contents are complete and intact.
- Each laser insert and outer sheath in the Periowave™ HHL-1000 system is uniquely identified with a serial number. Please refer to this number whenever

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making contact with your distributor or Periowave Dental Technologies, Inc.

- Retain the plastic lens protection cap for re-installation on the laser insert during periods of transport or extended storage.
- Charge the two batteries supplied with the HHL-1000 for 12 hours in the battery charger or until the green light on the charger is lit, indicating a full charge.

### 3.3 Treatment kits

The treatment kits include the photosensitizer supplied in a capped pre-filled syringe, a blunt-ended subgingival needle irrigator (cannula) with a luer lock, and a snap-on light diffusing tip, as shown in *Figure 4*.

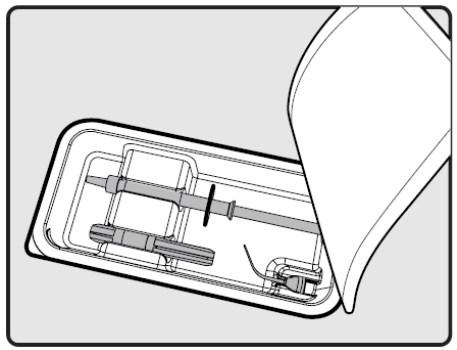

*Figure 4: Periowave™ Treatment Kits*

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# 4 Usage Information

### 4.1 User interface

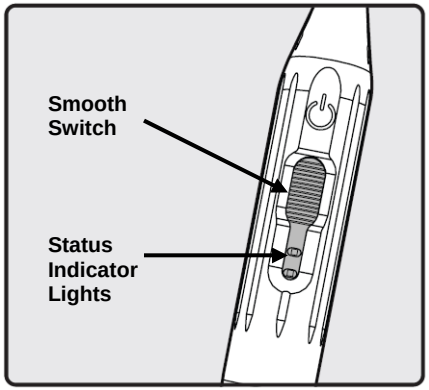


*Figure 5: User Interface*

**Smooth Switch**
Laser activation, termination and interruption of the treatment cycle are controlled by means of the unique Smooth Switch.

**Status indicator lights**
Two indicator lights (yellow and green LEDs) visible in the rear part of the Smooth Switch window indicate the operating status of the HHL. Interpretation of these indicators is discussed in Sections 5.3 – 5.4.

### 4.2 Device life expectancy

The laser insert and sheath are reusable, subject to useful life limitations and to appropriate cleaning, as identified in this manual. Single-use components, namely the disposable light-diffusing tip, syringe, residual photosensitizer solution and irrigation cannula must be discarded after each patient treatment.

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# 5 System Set-up and Operating Instructions

## 5.1 Pre-use inspection prior to each operation

**WARNING: Consult the sterilization and disinfection logs (Appendices D and E) prior to each use: do not use any part of the system if it is not possible to ascertain that it was correctly cleaned after previous use. REPEAT THE CLEANING PROCEDURES IN CASE OF DOUBT. This precaution is designed to minimize the possibility of cross-contamination between patients. The outer sheath must be cleaned and steam sterilized after each use.**

**NOTE: Prior to use of the Periowave™ HHL-1000 for the first time, the unit must undergo the cleaning procedures in *Sections 5.6 - 5.9*, and the batteries must be fully charged.**

- Inspect all Periowave™ HHL-1000 components for damage.
- Place 2 new AAA rechargeable batteries in the charger for twelve (12) hours or until the green LED on the battery charger is illuminated. For subsequent charging cycles, consult the charging instructions in section 5.7.
- If not already carried out, clean and disinfect the laser insert per *Sections 5.6 - 5.7.*

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## 5.2 Laser assembly

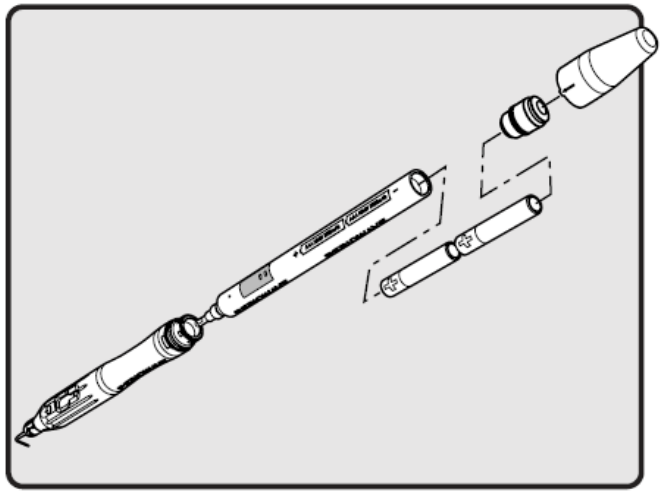

*Figure 6: HHL-1000 Exploded View*

- Unscrew the rear battery compartment cap of the clean laser insert. Place 2 fully charged batteries into the battery compartment (noting orientation of the batteries per the graphic on the outside of the laser insert). Replace the battery cap onto the battery compartment and tighten to finger tight **only**. See *Figure 6.*
- It is recommended that you install two, fully charged, AAA rechargeable batteries at the beginning of each day.
- After completing the cleaning, disinfection and sterilization procedures found in sections 5.6-5.9, you should place the following on your instrument tray: the sterilized outer sheath and rear cap, a dry, disinfected

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insert containing two fully charged AAA batteries, gauze and a new treatment kit.

- Remove the disposable light diffusing tip from a new treatment kit. Verify that the O-ring is installed correctly at the distal end of the outer sheath and that it is free of visible wear. Attach the light diffusing tip onto the front of the outer sheath in the proper orientation as shown in *Figure 7*. If the distal O-ring requires replacement at this point, it is recommended that the sheath be re-sterilized as described in *Section 5.9*.

**NOTE: The light diffusing tip must be attached to the outer sheath before the laser insert is installed.**

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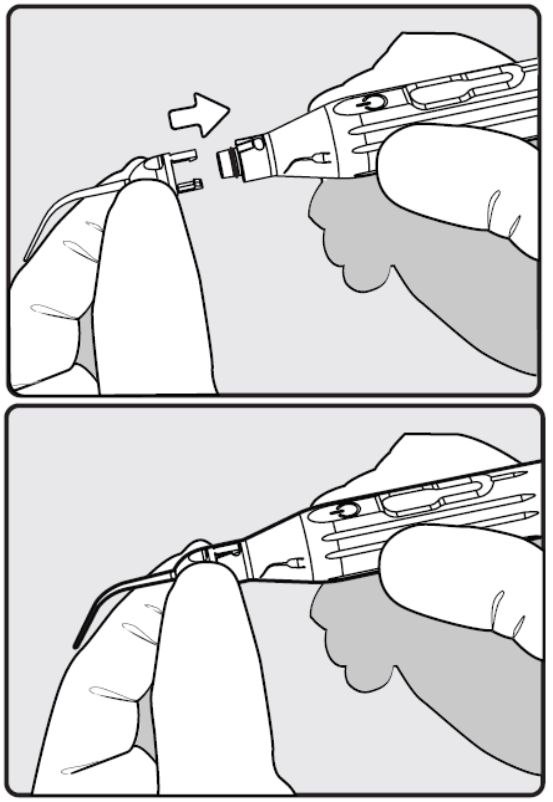

*Figure 7: Attaching the Light Diffusing Tip*

- Slide the laser insert into the outer sheath so that the Smooth Switch of the laser insert is aligned with the matching window located in the outer sheath as shown in *Figure 8*. The insert will only fit properly in a single orientation.

**NOTE: Do not tighten the battery cap after the laser insert has been placed into the outer sheath.**

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**NOTE: Without light diffusing tip attached, the laser will not activate.**

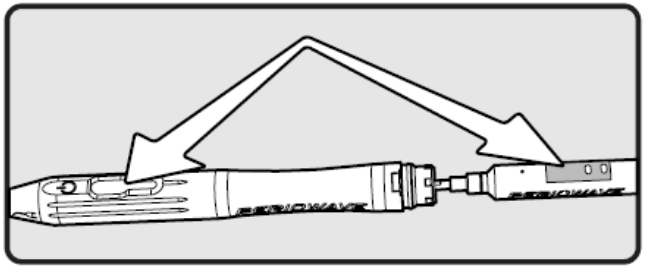

*Figure 8: Orienting the Laser Insert*

- Verify that the rear O-ring is still installed correctly and is free of visible wear, and replace if necessary. Fix the rear cap onto the outer sheath of the HHL-1000, turning it to lock it into position (marks on the rear part of the outer sheath and the rear cap indicate correct placement). This is shown in *Figure 9.*

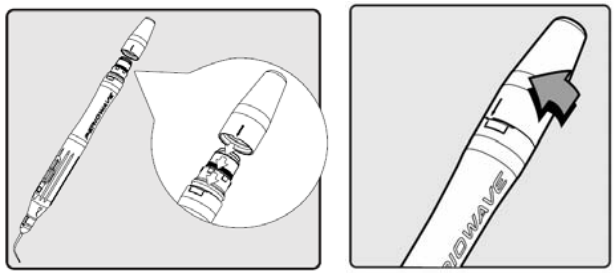

*Figure 9: Attaching the Rear Cap*

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## 5.3 Initiate treatment

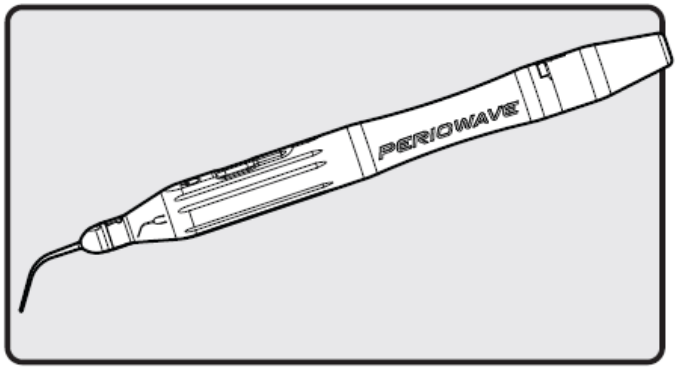


*Figure 10: Fully Assembled HHL-1000*

- When the disposable light diffusing tip is attached and the laser insert is correctly installed, (as shown in *Figure 10*) the yellow indicator will illuminate, indicating the laser is initialized and ready for use.
- Irrigate the first defect site with Periowave™ solution by inserting the irrigation cannula to the base of the defect and gently instilling sufficient solution to flood the pocket. Move the cannula gently in both mesio-distal and apico-coronal directions to ensure adequate filling of the pocket. Remove the cannula from the pocket once the blue coloured solution can be seen overflowing the free gingival margin.
- To start the laser activation cycle, insert the light diffusing tip into the irrigated defect site to the full depth of the sulcus. Slide your finger forward or backward on the Smooth Switch twice, thereby activating the laser. A green light indicates active laser illumination.

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**NOTE: In order to detect the double slide activation command, both slides on the Smooth Switch must occur within half a second of each other.**

- The treatment cycle lasts 60 seconds and is automatically timed. After 60 seconds, the laser illumination will end, the green 'laser on' indicator will extinguish and the yellow 'laser ready' indicator will illuminate.

**NOTE: After each 60 second treatment, remove the light diffusing tip from the defect site and use a damp gauze pad or roll to gently wipe off residual photosensitizer, fluid or debris from the tip. This cleaning step must be carried out between each 60 second treatment.**

- Irrigate the next defect site to be treated with photosensitizer and repeat the light activation cycle. Continue until all identified defect sites have been treated.

**NOTE: Do not irrigate more than one defect site at a time, as photosensitizer may be ejected from the defect site by gingival crevicular fluid flow or other fluids, thus diminishing efficacy of the treatment. Irrigate and illuminate each defect site sequentially.**

- To conserve battery life, the HHL-1000 automatically shuts down if there is no additional command for a treatment cycle within 15 minutes. The yellow indicator light will also extinguish. If a pause of this duration occurs and the laser enters automatic shut-down mode, the HHL-1000 may be re-initialized by removing and re-installing the rear cap. This will allow further 60-second treatment cycles to be provided. If treating a new patient, clean and disinfect the laser insert, and sterilize the outer sheath per instructions in sections 5.6-5.9, prior to beginning the new treatment.

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## 5.4 Interrupt treatment cycle

- The treatment cycle can be interrupted at any time by swiping the Smooth Switch with your finger twice during the treatment cycle: the green indicator light will extinguish and the yellow indicator will start blinking rapidly. To resume the treatment cycle, slide your finger on Smooth Switch two further times; the laser will activate and the green indicator will illuminate, indicating laser action. The treatment timer will count down the time remaining for the 60 second treatment.

**NOTE: If there is no action within 120 seconds after interruption, the treatment cycle will be aborted and HHL-1000 will return to readiness for a new treatment cycle**.

- To terminate the treatment cycle completely, irrespective of the elapsed time, swipe the Smooth Switch four times within one second while the laser is illuminating. The laser will extinguish and the yellow 'laser ready' light will illuminate.

## 5.5 After treatment procedure

- *Wear appropriate personal protective barriers when handling contaminated instruments and using disinfectant.*
- *Please follow these instructions carefully as the sequence of disassembly is important to maintain an effective cross-contamination barrier.*
- Remove the rear cap and the laser insert.

**NOTE: Remove the laser insert from the outer sheath before removing the light diffusing tip. This sequence is designed to minimize the possibility of**

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**cross-contamination between patients and to avoid damage to your laser.**

- To remove the light diffusing tip, firmly twist off the empty sheath, using forceps if required. The clips on the side of the light diffusing tip will snap off and the tip can then be disposed as medical waste.

## 5.6 Laser insert cleaning procedure

The insert is not expected to come in contact with patient body fluids when used as directed. The insert cleaning and disinfection procedures are designed to protect against accidental contamination during instrument handling.

Before beginning the procedures in *Sections 5.6 and 5.7*, assemble the following items:

- The laser insert
- CaviWipe® Towelettes (or equivalent)
- CaviCide® Ready-to-Use Liquid (or equivalent)
- 70% isopropyl alcohol
- Manufacturer's optical cleaning swabs

**NOTE: The outer sheath has a separate cleaning procedure that is detailed in *Sections 5.8 and 5.9*. Please follow the appropriate procedure for each item.**

- Remove a CaviWipe® towelette or equivalent disinfectant pad from the dispenser and, following instructions on the CaviWipe® dispenser, clean the exterior surfaces of the insert to remove debris, whether or not visibly present. See *Figure 11.* The surface of the insert should remain visibly wet for 3 minutes.



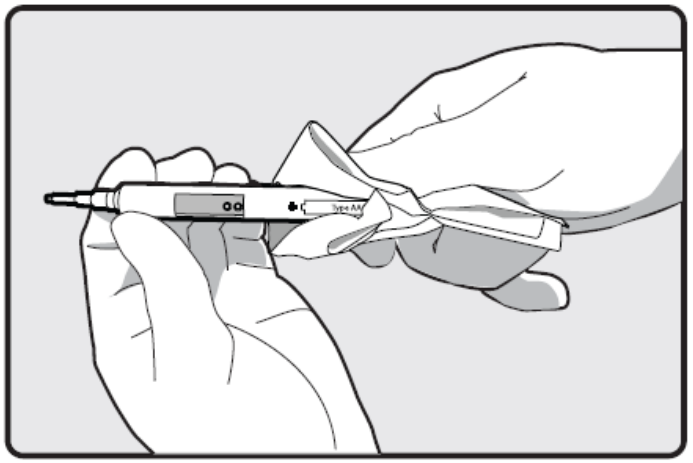

*Figure 11: Cleaning the Insert*

- Dispense a small quantity of CaviCide® Ready-to-Use Liquid, or equivalent, into an appropriate clean disposable container.
- Using only the manufacturers' approved optical cleaning swab, dip the swab into CaviCide® Ready-to-Use Liquid. The swab should be moist without dripping excessive liquid. Locate the hollow tube and lumen at the distal (patient) end of the laser insert; this tube contains a lens sealed into the assembly. Insert the cleaning swab directly into the lumen until it touches the lens, and rotate the swab to cover the entire surface area of the lens and lumen as shown in *Figure 12*. Allow surfaces to remain visibly wet for at least 3 minutes. Dispose of the swab.

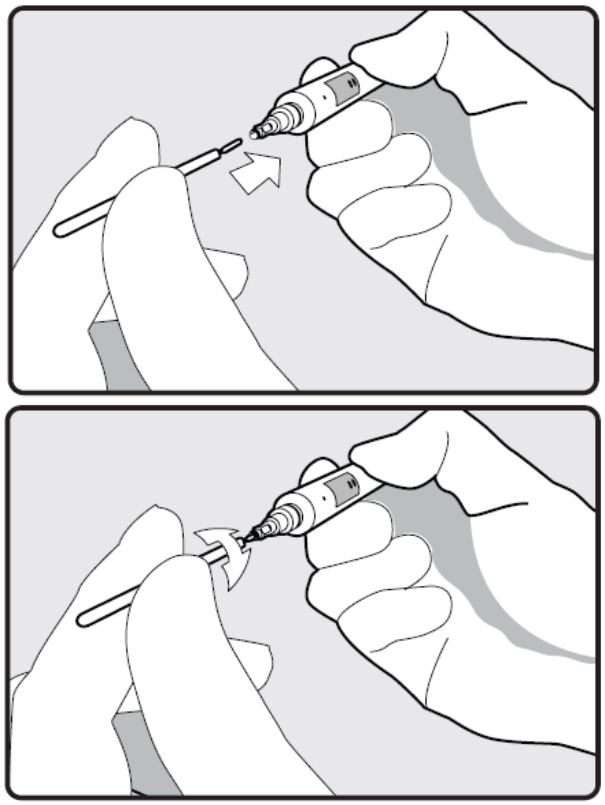

*Figure 12: Cleaning the Lumen*

**NOTE: To ensure that the surfaces remain wet for 3 minutes, it is permissible to wrap the insert with the towelette and leave the swab in the lumen after a thorough physical wiping has been completed. Remove towelette and swab after 3 minutes.**

- This concludes the cleaning process. Proceed with the insert disinfection procedure.

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## 5.7 Insert disinfection procedure

- DO NOT AUTOCLAVE THE LASER INSERT. This will cause permanent damage to the laser insert.
- If necessary, replace discharged batteries before commencing with disinfection of the insert. Ensure the batteries are fully charged by verifying the green light on the battery charger is illuminated.

**CAUTION: To prevent cross-contamination, do not use contaminated gloves when handling the batteries.**

- Using a second CaviWipe® towelette and optical cleaning swab, repeat the steps in *Section 5.6.*
- Dip a clean optical cleaning swab into 70% isopropyl alcohol. The swab should be moist without dripping excessive liquid. Insert the swab into the lumen and rotate to cover the entire surface area of the lens and lumen as shown in *Figure 12*.
- Use a clean, dry optical cleaning swab to dry the liquid covering the lens and lumen. Insert the swab into the lumen and rotate as shown in *Figure 12*.

**CAUTION: This lens-drying step must not be omitted, or treatment efficacy may be adversely affected.**

- Allow the insert to air dry completely. Ensure that laser insert is visibly dry before next use.
- Discard all medical waste in accordance with federal, state/provincial and local regulations.

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## 5.8 Outer sheath and rear cap cleaning procedure

**NOTE: The insert has a separate cleaning procedure that is detailed in *Sections 5.6 and 5.7*. Please follow the appropriate procedure for each item.**

Before beginning the procedures in *Sections 5.8 and 5.9*, you will need the following supplies:

- The outer sheath and rear cap
- A soft bristle brush
- Soap
- A steam autoclave bag large enough to hold the outer sheath and rear cap.

- Using a soft bristled brush, wash the empty sheath and rear cap with soap and water to remove debris.
- Thoroughly rinse with water prior to sterilization.

## 5.9 Outer sheath and rear cap steam sterilization

- DO NOT AUTOCLAVE THE LASER INSERT. This will cause permanent damage to the laser insert.
- Inspect the O-ring at the distal and rear end of the outer sheath. Replace any O-ring showing visible damage or wear prior to sterilization to prevent contamination.
- Ensure the outer sheath and rear cap are separate. Place clean sheath and rear cap into an appropriate autoclave bag as shown in *Figure 13*.

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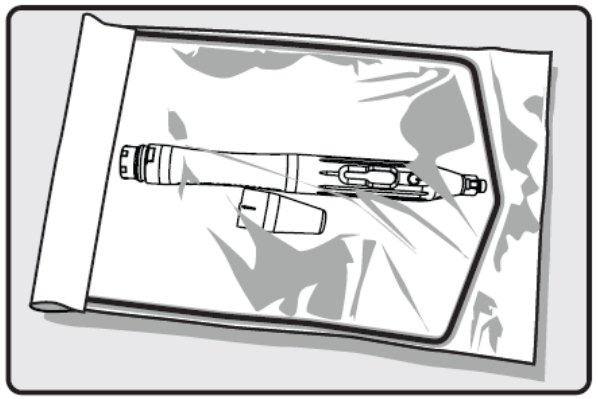

*Figure 13: Sterilization of the Outer Sheath*

- Load the sterilizer according to the manufacturer's instructions
- Ensure Outer Sheath and Rear Cap do not overlap at the distal or rear end.
- Place the bagged Outer Sheath and Rear Cap on perforated trays, cassettes or racks that have been validated for use with the selected sterilization cycle
- Do not overload the sterilizer chamber or individual trays, ensuring that the bag does not overlap with any other bags that are also in the sterilizer.
- Use a Type B sterilization cycle or the cycle recommended by the autoclave manufacturer for wrapped/bagged solid or hollow metal instruments. Typical cycles that are appropriate for this device will have the following attributes:
  - 132°C (270°F) +/ 2°C
  - A minimum 4 minutes exposure time

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### 5.10 After sterilization

- Check that the sterilizer automatic controller indicates that the cycle was satisfactory.
- Before using the sterilized Outer Sheath and End Cap, check that the outer wrapping and seals of the pouch are intact.
- Check that the bag/pouch is dry if intended for storage. If the pack is moist or damaged, do not use the contents.
- If the pack has a process indicator such as autoclave tape that has not changed colour correctly, do not use the contents. Open the pack and return to the start of the cleaning process.

**NOTE: Maintain the validation, periodic testing and maintenance of your steam sterilizer according to the manufacturer's instructions. The recommended sterilization procedures are valid only with sterilization equipment that is properly maintained and calibrated.**

- Ensure that the Outer Sheath and End Cap are dry prior to next use.



### 5.11 Changing the batteries during treatment

- The HHL-1000 will not allow a new illumination cycle to begin if the batteries will not allow the completion of one full treatment cycle. Low battery condition will be indicated by a slowly blinking yellow indicator light.
- Take the HHL-1000 to a clean surface and remove the rear cap.
- Invert the open sheath, allowing the laser insert to slide from the sheath onto the clean surface.
- After re-gloving, unscrew the battery cap on the laser insert. Remove the discharged batteries by inverting the open insert, allowing the batteries to drop onto the surface.
- Replace the discharged batteries with fully charged batteries and screw the battery cap back onto the insert to finger tight only.
- Replace the insert into the sheath in the proper orientation, as shown in *Figure 8*. Attach the rear cap onto the back of the sheath and resume treatment.

## *6 Maintenance and service*

### 6.1 General maintenance

- It is suggested that the O-ring at the patient (distal) end of the HHL-1000 be replaced after 100 sterilization cycles to prevent excessive wear. Use the log template in *Appendix E* to track your sterilization cycles. **Should you observe visible signs of wear to the O-ring at any time, replace it immediately.**

- The O-ring at the rear of the HHL-1000 should be replaced when it shows visible signs of wear.
- When removing either O-ring, do not use any tool that is sharp or abrasive, such as a Gracey curette or scalpel. The old O-ring should be removed using a blunt-ended periodontal probe or equivalent; gently slide the tool beneath the O-ring, and lift it off the outer sheath. Placing the new O-ring onto the sheath can easily be done by hand with no special tool required.

**NOTE: Use manufacturer-supplied O-rings only. Use of other O-rings could compromise the quality of the seal.**

- Periodically wipe the threads on the laser insert and battery cap with a gauze pad or similar and IPA to clean any residue that might accumulate on the threads.
- The HHL-1000 laser device does not require any further special maintenance or service. No user-serviceable parts are present within the unit, other than the rechargeable batteries and O-rings.

## 6.2 Technical support

Technical information regarding the Periowave HHL-1000 may be supplied by manufacturer only. For technical support contact your Periowave™ Representative.



## *APPENDIX A: Technical Data*

| Parameter | Units |
|---|---|
| Model | HHL-1000 |
| Laser Type | Diode (Laser Safety Class I) |
| Wavelength | 650 nm - 675 nm |
| Batteries | Rechargeable AAA, NiMH,1000 mAh |
| Output power | 160 mW nominal, from the light diffusing tip @ $25^0$ C |
| Treatment cycle duration | 60 seconds ± 3 s |
| Operating modes | Continuous Wave (CW) |
| Weight (including 2 batteries) | 95 g |
| Dimensions | Ø 18mm x 210 mm |
| Power requirement (battery charger) | 100 - 240 V~ , 50 – 60 Hz |
| Operation Temperature | 15 °C to 35 °C |
| Storage Temperature | 5 °C to 45 °C |

## *APPENDIX B: List of Figures*




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## *APPENDIX C: Symbols*

The following symbols are used on or apply to the equipment. Associated explanation is provided here:

| Symbol | Explanation |
|---|---|
|  | Laser Safety Label |
|  | Type BF Electrical Device |
|  | Attention, consult accompanying documents |
|  | Consult instruction for use |
| ~ | Alternating current |
| **SN** | Serial number |
| **PN** | Part number |
|  | Manufacturer |
|  | WEEE (Waste Electrical and Electronic Equipment)<br>RoHS Compliant |
|  | Do not reuse |


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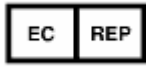
| Symbol | Explanation |
|---|---|
|   | Authorised Representative in the European Community |
|   | Sterilize Using Steam |
|  | Date of Manufacture |
|  | CE Mark – certifies that the product has met EU requirements |
|   | CCA-NRT with SEV mark of conformity |
|   | ENEC mark of conformity |

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***APPENDIX D: Laser insert log template***

Insert Serial Number SN#:……..

| | Date (yyyy/mm/dd) | Initials | Insert Cleaned | Insert Disinfected | Observation |
|---|---|---|---|---|---|
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | | | |
| 4 | | | | | |
| 5 | | | | | |
| 6 | | | | | |
| 7 | | | | | |
| 8 | | | | | |
| 9 | | | | | |
| 10 | | | | | |
| 11 | | | | | |
| 12 | | | | | |
| 13 | | | | | |
| 14 | | | | | |
| 15 | | | | | |
| 16 | | | | | |
| 17 | | | | | |
| 18 | | | | | |
| 19 | | | | | |
| 20 | | | | | |

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***APPENDIX E: Outer sheath log template***

Sheath Serial Number SN#:……..

| | Date (yyyy/mm/dd) | Initials | Sheath Cleaned | Sheath Autoclaved | Observation |
|---|---|---|---|---|---|
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | | | |
| 4 | | | | | |
| 5 | | | | | |
| 6 | | | | | |
| 7 | | | | | |
| 8 | | | | | |
| 9 | | | | | |
| 10 | | | | | |
| 11 | | | | | |
| 12 | | | | | |
| 13 | | | | | |
| 14 | | | | | |
| 15 | | | | | |
| 16 | | | | | |
| 17 | | | | | |
| 18 | | | | | |
| 19 | | | | | |
| 20 | | | | | |

**CHANGE O-RINGS AFTER 100 AUTOCLAVE CYCLES**

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