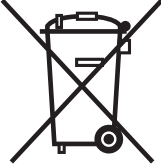










HYGEA™



OPERATOR'S MANUAL

SYMBOL	DESCRIPTION
	Do Not Throw Away Consult with local laws with respect to medical equipment disposal.
	Laser Danger
	Single Use Only
	Consult Instruction for Use
	Expiration Date
	Manufactured for CAO Group, Inc. 4628 West Skyhawk Drive West Jordan, UT 84084
	Fragile, Handle with Care
Rx Only	Only Applicable for USA



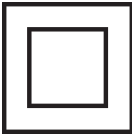

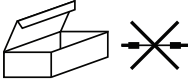


SYMBOL	DESCRIPTION
	Type B Applied Part
	Warning Label
	Class II Equipment
	Must Read Manual Prior to Use
	Non-Returnable if Seal is Broken
	Manufactured Date
	Protection Against Vertically Falling Drops of Water (e.g. Condensation)

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SECTION 1 - INTRODUCTION

Soft tissue diode lasers are transforming the practice of dental hygiene.

Taking the hygiene procedure beyond customary probing and scraping, lasers are used to proactively treat the inflammatory and the bacterial components of periodontal disease. Lasers further expand the capabilities of the dental hygienist with settings for in-office teeth whitening, therapeutic pain relief, treatment for aphthous ulcers, and more.

The hygiene department in many practices is driving business and revenue growth. Opportunities for, and capabilities of, the dental hygienist are increasing, driving a need for efficient, defined protocols and procedures.

In response to this need, CAO Group has developed Hygea™ Dental Hygiene Laser. The Hygea laser is streamlined and customized for the dental hygienist. It provides convenient presets for the various protocols that the hygienist requires, enhancing preventive and therapeutic procedures.

The name Hygea, taken from Hygieia, the goddess of hygiene in Greek mythology, encompasses the focus of prophylaxis, maintenance, and treatment. The logo reflects that focus as a laser handpiece and cable symbolically winds around a tooth, protecting and defending it. This logo for the Hygea laser was inspired by the Goddess Hygieia's symbol which is a chalice with a snake twined around its stem.



While other diode lasers can be used for hygiene, Hygea is a specialized tool with an interface and preset protocols developed for the hygienist and specifically for perio and gingival treatments. Therapeutic settings and optional teeth whitening settings expand the capabilities of the hygienist and dental office even further.



Laser safety is of paramount importance and each office should quickly develop and implement a laser safety program and identify a “Laser Safety Officer” to be responsible for the laser. The LSO’s duties include management of the laser and all accessories as well as training office personnel in all aspects of laser safety.

ALWAYS test fire the laser away from tissue before using it on a patient. The doctor, staff, patient and anyone present in the operatory should be wearing the appropriate safety eyewear whenever the laser is being operated. Strict adherence to protocols for safe laser use is essential.



US FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED DENTAL PROFESSIONAL.

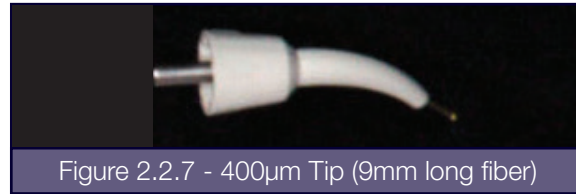
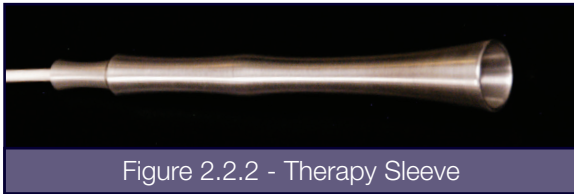
SECTION 2 – SPECIFICATIONS

2.1 Laser Specifications



Model	002-00424
Weight	2.5 lbs
Dimensions in inches (H x W x L)	In Cradle: 9.5" x 4" x 6" Out of Cradle: 7" x 4" x 3"
Laser Classification: (Per IEC 60825) Laser Diode	Class 4 Laser Device
Wavelength: Laser Aiming Beam	810nm ± 10nm 650nm ±10nm
Beam Divergence	9 degrees ± 1 degree
Power Range: Laser	0.1 to 1.5 Watts
Hertz Rate in Pulsed Mode - fixed	10.0 Hz
Pulse Duration - fixed	0.05 seconds
Duty Cycle Pulsed Mode Continuous Wave	50% 100%
Aiming Beam (3mW)	Yes
Audible Notification	Yes
Visual Notification	Yes
Power Requirements	110 – 120 VAC @ 60 Hertz 220 – 240 VAC @ 50 Hertz
Amperage	1.5 Amps @ 110 – 115 V AC 0.75 Amps @ 210 -230 V AC
Battery Pack	Rechargeable lithium polymer 45 minutes continuous lasing time 8 hours stand-by time (laser on but not firing)
Cordless Foot Pedal: Frequency Battery	2.4 GHz 9 volt Lithium
Electrical Safety Class	Class II
Operating Temperature	0° - 35° C (32° - 95° F)
Operating Humidity	5-95% RH
Equipment Classification	Type B
Moisture Ingress Rating Device Foot Pedal	IPX0 IPX2
Mode of Operation	Non-Continuous (5 minutes firing, 15 minutes resting basis)

2.2 Delivery System Specifications



See Sections 6.4 - 6.7 for all handpiece assembly instructions.

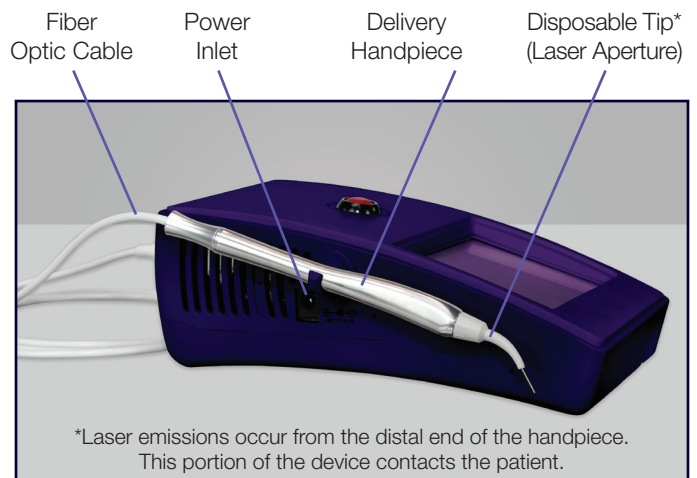
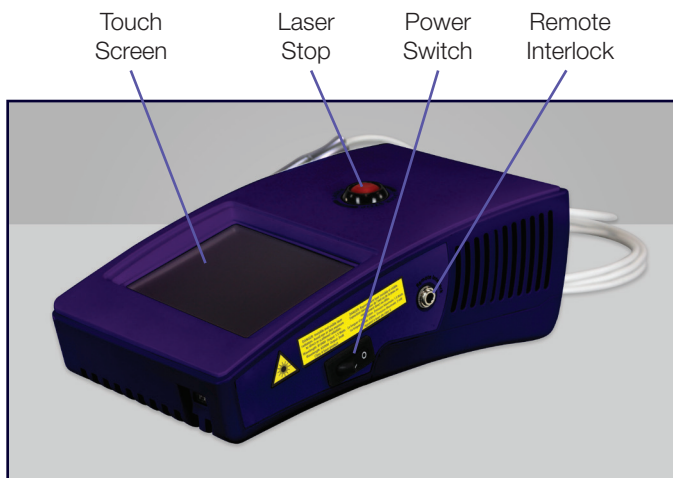
2.3 Warranty

Laser	2 year parts and labor
Rechargeable lithium battery	1 year
Fiber cable assembly	6 months

2.4 Kit Contents

1 Hygea 1.5 Watt Diode Laser	1 Laser Safety Sign
1 Wireless Foot Pedal with 9 Volt Lithium Battery	2 Protective Glasses
1 Power Supply	2 Standard Handpieces
1 Power Cord	1 Therapy Handpiece
30 400 micron Disposable Handpiece Tips	1 Owner's Manual
1 Lithium Polymer Battery (already installed in laser)	1 Quick Start Guide
1 Pack of 50 Surgical Handpiece Barrier Sleeves	

Please check all items sent with your laser to insure that all components are accounted for.



SECTION 3 – LASER ASSEMBLY INSTRUCTIONS

3.1 Removing the Laser from the Packaging

3.1.1 – Instructions on Unpacking & Dealer Assistance

Read the assembly instructions before removing the laser from its shipping container. If you are unsure about any aspect of the assembly, call your authorized dealer representative for assistance.

3.1.2 – Shipping Container Information

We recommend that you retain the original container in which the laser was shipped in case you need to return the laser for service or repair. The shipping container you received with your laser has been specially designed to safely transport the laser.

3.2 Assembling the Laser

3.2.1 Foot Pedal Battery Installation Procedure

NOTE: The foot pedal comes with the battery installed. Follow these procedures to install or replace the battery.

1. Make sure the laser is completely turned off before placing the battery in the foot pedal
2. Place the pedal face down on a hard, clean surface (Figure 3.2.1a)
3. Use a Phillips head screwdriver to remove the four screws securing the bottom plate of the pedal. Turn the driver counterclockwise until the screws come out completely. Remove the plate.
4. Detach the existing battery from the connector. Do not pull on the wires to detach the connector. Lift up on the black connector itself.
5. Remove the new battery from its packaging and attach the battery to the terminal (Figure 3.2.1b)
6. Place the battery in the well with the connector to the same side as the wire leads emerge from the housing (Figure 3.2.1b)
7. Replace the pedal base plate and replace the screws. Turn the screwdriver clockwise to tighten the screws. The screws are sufficiently secure once they no longer turn with gentle finger-applied force. Do not over-tighten.



Figure 3.2.1a

NOTE: It is recommended to use a 9 volt Lithium battery to power the cordless foot pedal. This type of battery has been tested to last for over 100 hours of foot pedal operation. When the battery voltage begins to drop, the foot pedal will begin to beep, signaling that you have approximately 2 hours of operating time left before the battery life is completed.

NOTE: A 9 volt alkaline battery may be used; however the life expectancy of an alkaline battery is less than 35 hours of operating time.



Figure 3.2.1b

3.2.2 Power Cord Installation

Remove the power cord from the Hygea package and plug the power cord into the appropriate receptacle on the back of the laser cradle (Fig 3.2.2). Plug the power cord into a 120 Volt AC outlet rated at 60Hz. Use only the power supply that comes with the device. Use of other power supplies may damage the device or cause electrical shock. Touching the power contacts may result in a shock.



Figure 3.2.2

3.2.3 Direct Power Supply Attachment

If immediate power is needed and the battery is not charged, unplug the power cord from the cradle and plug it directly into the laser (Fig 3.2.3).



Figure 3.2.3



- DO NOT leave the AC cord attached to the laser or cradle when the power supply is unplugged from the wall as this might inadvertently drain the battery.
- The battery will be charged if the cable is plugged directly into the laser.
- To prevent power surges due to electrical storms or spikes in line voltage, you should use a power strip with a circuit breaker or unplug the laser when you are not present.
- The battery can be charged while the unit is powered on or off.
- ONLY USE THE POWER SUPPLY PROVIDED WITH THE UNIT. IN THE U.S., ONLY PLUG UNIT INTO 120V OUTLET.

3.2.4 Connection of Handpiece Assembly to the Laser

1. The handpiece assembly is already installed when you receive your new Hygea diode laser. Always leave the handpiece assembly connected to the laser unit unless you have to switch handpiece assemblies or if you have to ship the laser for technical reasons.

Disconnecting the handpiece for even short periods can lead to contamination of the precision polished end of the fiber connector. This may result in reduced power output of your laser over time.

2. If you have to disconnect the cable, keep the fiber tip connector of the handpiece and the connector on the bottom of your Hygea unit clean. Use the protective metal dust cap to protect the end of the handpiece assembly at any time and be sure not to touch the precision polished end of the connector (Fig 3.2.4a). Install the protective metal cap to protect the connector on the bottom of your laser from dust and other contaminants. The protective metal cap serves also as protection from accidental firing of the laser (Fig 3.2.4b). The handpiece contains a locking nut design to ensure longer service life of the optical connection. Never use force to detach the handpiece if needed, a special tool has to be used to be able to release the set screw of the handpiece connector. This special tool is provided with each handpiece replacement. Please contact the CAO Group Service Center if you have questions.

Contaminants on the fiber end may lead to the malfunction of your handpiece. Please take special care in exchanging handpiece assemblies.

3. Installation of a handpiece assembly to the laser should be done in a clean environment. Attach the handpiece fiber assembly by screwing the knurled connector of the cable into the bottom of the laser unit. Lock the nut with the special tool provided with the handpiece replacement (Fig 3.2.4c). Avoid scratching the end of the fiber connector when inserting the cable (Fig 3.2.4c).

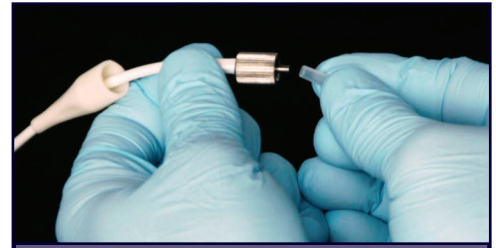


Figure 3.2.4a



Figure 3.2.4b



Figure 3.2.4c



CAUTION: Do not detach the fiber cable unless to replace it.

The custom engineered connector at the bottom of your Hygea unit does not allow operation if there is no handpiece assembly attached. This is a feature for your protection. A Safety Alert window will pop up on your screen if you switch on the laser without the handpiece installed or if the connector is loose. Make sure to moderately hand tighten the connection of your handpiece assembly after installation and tighten the locking nut (Fig 3.2.4d and Fig 3.2.4e).

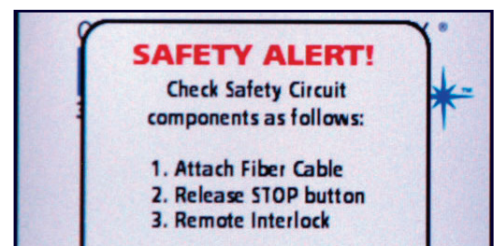


Figure 3.2.4d



Figure 3.2.4e

3.2.5 Attaching Unit-Dose Fiber Tip

Remove a unit-dose fiber tip from its package. Instructions for sterilizing the tip are provided in Section 6.1. Remove the plastic protective cap. If the tip was sterilized and liquid is present on the metal connector, use a blast of CLEAN DRY air for 5 seconds to remove the liquid. Insert the tip's metal connector into the handpiece (Figs 3.2.5a – c). Avoid placing your finger on either end of the handpiece tips as the tips must be clean for optimal performance and safety. Use gloves while handling the tips as natural oils deposited on the fiber or fiber connection can burn and diminish the effective transmission of radiant energy once the laser is installed.

Slide the disposable barrier sleeve over the handpiece assembly. If needed, puncture the barrier sleeve with the tip so the tip fiber protrudes out of the barrier sleeve.

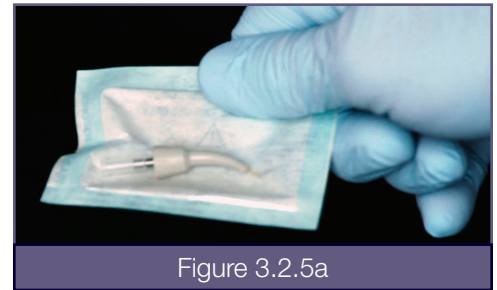


Figure 3.2.5a

3.2.6 Placing the Laser in the Charging Cradle

Place the laser unit in the cradle by tipping the laser unit slightly forward and inserting it into the cradle (Fig 3.2.6). Do not force the unit into the cradle and be sure to place the fiber cord through the cradle opening.

The Hygea diode laser is supplied with a rechargeable lithium polymer battery which provides up to 45 minutes continuous lasing or 8 hours stand-by time, (i.e. laser on, not being charged by cradle or AC power cord.)

THE LASER BATTERY MUST BE FULLY CHARGED BEFORE INITIAL USE.

THE LASER CAN BE SWITCHED ON OR OFF FOR THE BATTERY TO BE CHARGED.

Allow the battery to charge overnight before first use.
Recharging a completely discharged battery takes approximately 5 hours.



Figure 3.2.5b

3.2.7 Remote Interlock

The Hygea laser is equipped with a Remote Interlock Jack. The Remote Interlock Jack is provided so that a clinician may install the laser in a dedicated laser treatment room such that the laser will be interlocked with the entrance door of the room. In such an interlocked installation, the laser would shut off anytime the door is opened, hypothetically, to protect the person's eyes who is entering the room. It is recognized that such installment is not facilitated nor required in many operatories or clinics. To that end, the Remote Interlock is available to any practitioner that requires or requests it. The Remote Interlock Jack is located and clearly labeled on the side panel of the laser (Fig. 3.2.7).

The miniphono jack is wired in the normally closed position; meaning that no further action is required to operate the laser without the interlock loop. If the interlock loop is desired you may purchase the loop from a local electronics store. You need only inform the local electronics store that you require a mini (1/8") miniphono jack wired into a normally closed momentary switch and select the switch design that best suits your needs. To install the loop, install the switch on the door and simply plug the miniphono jack into the Remote Interlock Jack on the side panel of the laser.

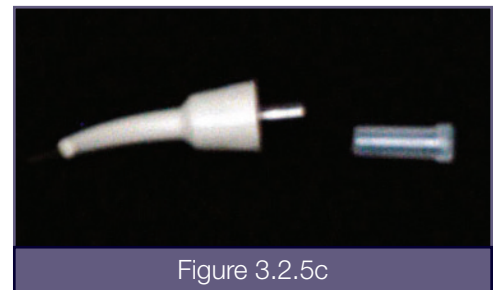


Figure 3.2.5c



Figure 3.2.7



Figure 3.2.6

3.2.8 Laser Stop Switch

Before you activate the laser, make sure the red Laser Stop button is in the depressed position. The laser will activate only with the button in the depressed position. If the laser needs to be stopped quickly, pushing and releasing the red Laser Stop button will immediately shut the laser off.

The Safety Alert Window will appear on the screen if the button is released.

1. To check the “Laser Stop” system, simply press and release the red “Laser Stop” button while the laser is activated. The shut down system will take the laser out of active mode (Fig. 3.2.8a).
2. To activate the laser, depress the “Laser Stop” button and the unit will resume normal functions (Fig 3.2.8b).

NOTE: When the Laser Stop button is restored, the screen will restore from a Firing Screen to a Quick Set Up Screen.

Remember: Always test fire the laser outside the mouth before using it on a patient. The doctor or hygienist, the patient and any staff member present in the operatory should be wearing the appropriate safety eyewear whenever the laser is being operated. Strict adherence to protocols for safe laser use is essential.

3.2.9 Turning on the Laser

Turn the laser on using the main power switch on the side of the laser (Fig. 3.2.9).

3.2.10 Digital Keycode

The Hygea laser has a keyless entry system for security purposes. After turning the power to the “On” position, the Hygea screen will appear. Touch the “Enter” key. The Login screen will appear, touch the screen and input the digital key code **1 2 3 4** and touch the “Enter” key (Fig 3.2.10).

3.2.11 Installation Test

1. After login, from the Main Menu, touch the “Quick Set Up” Button
2. The Hygea laser is pre-set to “Continuous Wave” (CW)
3. Power setting is pre-set to 1.0W
4. Hold the fiber approximately 2-4 mm away from a piece of articulating paper.
5. Touch “Ready” button – laser is in “Ready” mode. A green checkmark will be displayed (Fig. 3.2.11). You will be able to see the aiming beam on the articulating paper.
6. Depress the foot pedal to activate the laser.
7. The articulating paper will begin to develop smoke in 1-2 seconds.

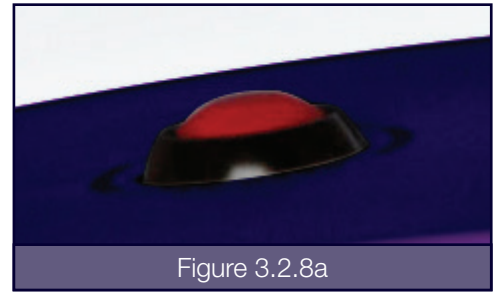


Figure 3.2.8a

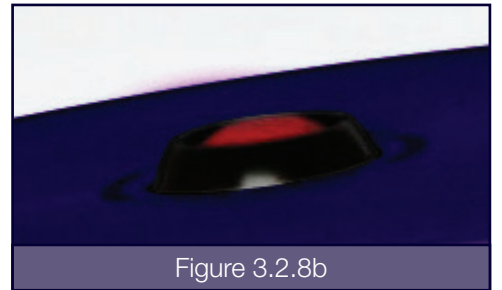


Figure 3.2.8b



Figure 3.2.9



Figure 3.2.10



Figure 3.2.11

3.2.12 Touch Screen Menu

The Main Menu screen introduces you to the eight pre-set procedures that are accessible with the touch of a button. Each procedure is portrayed with four adjustable settings that can be customized to your preference: Mode, Power, Time, and Aiming Beam.

Battery Symbols

There are two battery symbols in the top right corner of the touch screen (Fig. 3.2.12a). Green color indicates a fully charged battery. The first battery symbol on top indicates the status of the internal Hygea battery. The lower battery symbol indicates the status of the replaceable 9V lithium foot pedal battery.

Mode

Mode refers to “continuous wave” or “pulsed power” (Fig. 3.2.11). Use the MODE key to toggle between Continuous and Pulse as desired. The chosen mode is displayed in gray color.

Power

Pressing the Power setting allows the operator to adjust the power settings from 0 to 1.5 watts in 0.1W increments (Fig. 3.2.12b). This control is for the working beam only. Touching the right arrow increases the power, touching the left reduces the power. Hold down the desired key to rapidly change the value. Press “Done” to return to the Main Menu.

Time

You have the ability to use the “Time” settings pre-set by procedure or modify the timer by using the arrow keys (Fig. 3.2.12c). The laser will automatically shut off when the timer returns to 0. Touching the right arrow increases the time, touching the left reduces the time. Pressing “Done” returns to the main menu.

Releasing the foot pedal in the middle of a timed procedure will bring up a “Procedure Interrupted!” window. The timer will continue with the remaining time if you press “Continue” or go back to zero and start over if you press “Reset”.

Aiming Beam

The Hygea diode laser is actually two lasers in one. The infrared 810nm wavelength laser which performs the actual treatment of the soft tissue is called the “working beam”. The 650nm “laser pointer aiming beam” illuminates the focal point of the “working beam” allowing the operator to aim prior to and during laser activation. In addition, the aiming beam control allows for five levels of illumination ranging from off to maximum intensity. The open circle indicates no aiming beam and the solid blue circle indicates the brightest aiming beam.

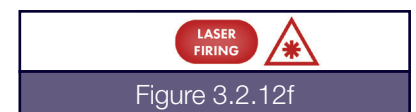
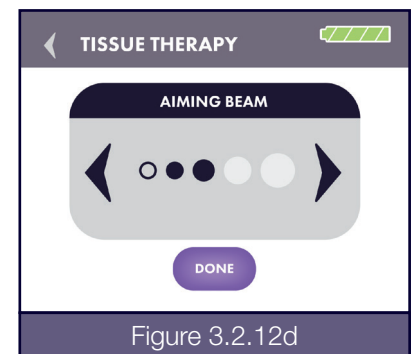
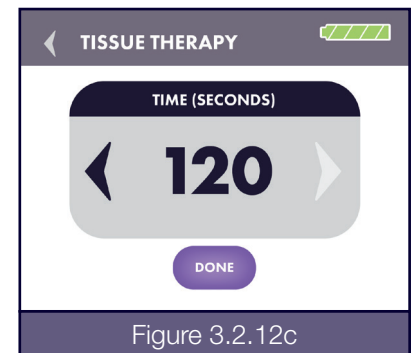
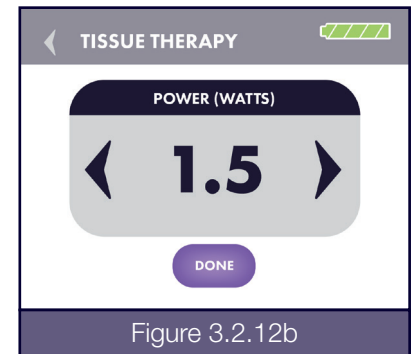
To adjust aiming beam intensity, the bar is pressed which activates the above screen (Fig 3.2.12d). The arrows are pressed upward or downward as desired. Each increment adjusts the aiming beam intensity by about 20%. When complete, press the “Done” key to return to the setting screen. Check if the new settings meet your desired aiming beam intensity. Adjusting the aiming beam does not affect the working beam.

Ready Indicator

The Ready indicator illuminates in green when the READY key is pressed. It will blink for 3 seconds, then remain steady. Once steady, the aiming beam will be activated and the laser is ready to be fired (Fig. 3.2.12e).

Laser On

The Laser On indicator illuminates in red when the foot pedal is depressed, indicating that the working beam (810nm) energy is being emitted (Fig. 3.2.12f).



3.2.13 Preset Programs

The Hygea laser comes with procedure-specific preset parameters. There are a total of eight unique procedures that can be accessed from the Main Menu (Fig. 3.2.19)

After selecting a procedure, the settings may be manually adjusted to suit your needs for the clinical procedure. The settings represent a good starting point and can be adjusted at any time.

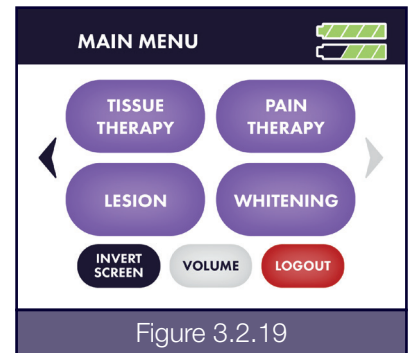
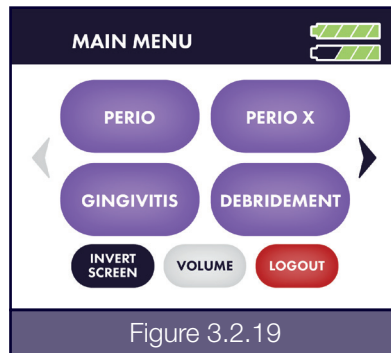


Figure 3.2.19

Figure 3.2.19

PRESET NAME	INDICATION	POWER	TIMER	MODE
Perio	Slight Perio, for which the clinical criteria is pocket depth of 4-5mm with possible signs of inflammation	0.5W	30 seconds	Continuous
Perio X	Moderate Periodontitis, for which the clinical criteria is pocket depth of 5-6mm with possible signs of inflammation	0.7W	45 seconds	Continuous
Gingivitis	Gingivitis, for which the clinical criteria is pocket depth of 0-4mm with localized or generalized inflammation	0.4W	20 seconds	Continuous
Debridement	Severe chronic periodontitis or aggressive periodontitis in patients with necrotic tissue needing treatment	1.4W	30 seconds	Pulse
Tissue Therapy	Photobiomodulation for joints, circulation, muscle. Use therapy handpiece	1.5W	500 seconds	Pulse
Pain Therapy	To alleviate intraoral pain. For example, post-operative analgesia following periodontic, oral surgery, orthodontics, or endodontic procedures. May use therapy handpiece	1.5W	300 seconds	Continuous
Lesion	Lesion management in cases of oral mucosal lesions or cold sores	1.0W	None	Continuous
Whitening	Teeth whitening with photoactivated gel. Use whitening handpiece	1.5W	1080 seconds (270 seconds/quadrant)	Continuous

3.3 Facility and Environmental Considerations

3.3.1 Power Requirements

120 V AC $\pm 10\%$ at 50 - 60 Hz
3 Amps
9 volt Lithium battery for the foot pedal

3.3.2 Heating and Ventilation

The laser should be operated in areas with the optimum temperature range of 20° - 30°C (68° - 86° F).

3.3.3 Transport and Storage

Avoid storing or transporting the laser in temperatures below 0°C (32° F).

3.3.4 Lighting

Overhead lighting and/or dental unit light should provide enough illumination to allow good operator vision when activating the laser intra-orally.

3.3.5 Combustible Chemicals and Gases

All gases that are combustible or support combustion and are used in the operatory area where the laser is in use must be turned off during the procedure. Cleaning supplies or other flammable chemical compounds should be stored in an area away from the surgical site in order to avoid possible combustion (e.g. alcohol gauze, liquid topical anesthetics).

3.3.6 Plume Evacuation

Plume evacuation is a priority when vaporizing tissues. The clinician or operator and their chair-side assistants should keep themselves and the patient safe by using a high volume vacuum system and filtration masks that are suitable for virus and bacterial control. Please use a high filtration mask with 0.1 micron or less to protect from airborne viruses or bacterial particles.

3.3.7 Access and Signage

Access to the treatment area should be restricted while the laser is in use. A "Laser In Use" safety sign should be adjacent to the entrance to the treatment area (Fig. 7.2.1a).

3.3.8 Wireless Technology

Hygea wireless technology is electronically coded. Each Hygea foot pedal and laser unit share a UNIQUE SERIAL NUMBER INTERLOCK protocol for reliable operation:

- A Hygea foot pedal communicates with only one Hygea diode laser; there is 2-way electronic code which must be verified for every transmission and acknowledgement. The pedal and laser unit are interlocked to only each other's electronic codes.
- If data from another Hygea pedal is ever received, embedded verification measures ensure that it will be ignored.
- If data were ever received from another wireless device with a compatible modulation scheme (2.4GHz frequency), it would immediately be ignored in the same way. In summary, the wireless receivers in the Hygea diode laser have less than 2% of the output power of typical Bluetooth or Wi-Fi devices, and therefore have no significant potential as an interference source. The Hygea wireless receiver modulation is incompatible with Wi-Fi or Bluetooth devices, and therefore cannot mistakenly receive data from such devices. Through a unique internal communication structure, and strict verification of all incoming data, nothing activates a Hygea diode laser except the wireless pedal which it is paired with via electronic code.

Interference from other radio frequency sources in the vicinity (WiFi routers, Bluetooth devices, RFID chips, antitheft devices) may cause interference and prevent the laser from receiving communication from the foot pedal. Some larger equipment like electrosurgery devices and CAD/CAM mills may also generate radio frequency disturbances. Additionally, metal tables or surfaces between the foot pedal and the laser may also interfere with transmissions. Avoid placing the laser adjacent to computers, heavy equipment, and routers or other wireless communication devices. Avoid placing the laser on a metal table or surface. If communication interruptions occur between the foot pedal and the laser, change the position or location of the foot pedal relative to the laser, or bring the foot pedal closer to the laser unit. You might also consider turning off wireless devices or heavy equipment that are nearby if transmission disruptions occur.

SECTION 4 – SAFETY CONSIDERATIONS

4.1 General

The safe use of Hygea laser is the responsibility of the entire dental team, the laser safety officer appointed, and the dental office team. Protocols for the safe use of lasers have been developed by a combination of medical and dental professionals working in concert with educators at the university level, scientists and laser manufacturers. Dental professionals have had to develop protocols and guidelines for using the laser on oral soft tissues. Sound judgment and the concern for patient safety should be the basis of all laser care.

Usually, states or provinces do not have a specific licensure requirement for use of a laser by a dentist. Certain states and provinces, like Texas and Alberta, however, require the dental office to be certified and inspected prior to using a laser. The user is advised to check with the local or state Dental Association website for specific and relevant requirements in your location. Some states require a hygienist to attend licensure training that includes both a lecture and hands-on training. Prior to using the laser, the hygiene applicants are required to pass a proficiency test for certification. These courses are usually taught by members of the Academy of Laser Dentistry who possess instructor credentials. Worker safety is the responsibility of the employer. ANSI standard Z136.1 (US) and CAN/CSA standard Z386-08 concerning Laser Safety in Health Care Facilities are sources for analyzing safety with respect to medical lasers. CAO Group recommends implementation of a Laser Safety Program for the safety of your patients and office staff in connection with the use of the Hygea diode laser.

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4.2 Laser Safety Program

We recommend implementation of a Laser Safety Program appropriate for your dental office. The plan may include the following:

- Delegation of authority and responsibility for supervision and control of the laser to a designated Laser Safety Officer;
- Minimum training requirements for users of the laser;
- Security to restrict unauthorized use of the laser;
- Standard operating procedures to regulate the work environment in order to protect the patient and office staff from laser hazards.

The safe use of a laser is the responsibility of the Laser Safety Officer (LSO) who can be a full or part-time employee, or the laser operator. It is their responsibility to train the staff, maintain records concerning training and the laser's performance, perform safety checks and prepare the laser for use on a daily basis. The LSO must keep records of any incidents that relate to the failure of the laser or any adverse effects related to laser therapy and report such incidents as prescribed by law. The LSO assures that a medical follow-up has been sought or has occurred following any adverse incident during treatment. The LSO is responsible for training of all office personnel who are involved with the laser preparation and use. Daily checks of the facility and equipment are also the LSO's responsibility. The LSO should test fire the laser each day prior to beginning each treatment procedure. For more information on the contents of a Laser Safety Plan, you can review ANSI Standard Z136.3 for Safe Use of Lasers in Health Care Facilities (US) or CAN/CSA-Z386-08 Laser Safety in Health Care Facilities(Canada).

4.3 Continuing Education

The Laser Safety Officer should ensure that the operator and staff attend laser courses taught by qualified laser educators. Ongoing reviews of laser safety procedures should be a part of normal office routine.

4.4 In-Office Safety

4.4.1 Lighting

Always use the Hygea laser in a well lighted and ventilated area.

4.4.2 Combustible Chemicals or Gases

Make certain that chemicals or gases capable of supporting or causing combustion are not present when using the laser (e.g. alcohol gauze, liquid topical anesthetics).

4.4.3 Safety Eyewear

While using the Hygea laser, doctors, hygienists, auxiliary staff, patients, and anyone attending them in the operatory must wear the appropriate safety eyewear that has been designed for use with the 810nm wavelength. Never point the laser tip directly at the face, eyes or skin of anyone while emitting energy. The aiming beam is also capable of causing eye damage.

4.4.4 Test-firing the Laser

Prior to using the Hygea laser intraorally, always test fire it using a power of 1 Watt continuous wave or less. Place the laser in the ready mode, then activate the laser for 1-2 seconds while aiming the fiber onto a 2x2 gauze sponge wetted with water. Do not use alcohol or any other combustible material to wet the 2x2 sponge as it may ignite. Please be aware the 810nm working beam is invisible to the human eye! You can only see the red 650nm aiming beam if it is turned on.

4.4.5 Danger Signage

Each operatory where the Hygea laser is used should have a "Laser in Use" sign placed at the operatory entrance when a procedure is in progress. This signage will help to eliminate eye damage caused by inadvertent exposure to laser energy. Additional signs can be ordered through the CAO Group care department.

4.4.6 Sharps Disposal and Sponge Removal

Used fiber tips should be disposed of in a sharps container. All sponges used for cleanup of lasers and fibers should be disposed of in a bag for contaminated soft products.

4.4.7 Plume Evacuation

Use high volume evacuation suction during procedures to remove laser smoke or 'plume' debris. Use masks suitable for viral filtration. Caution - laser plume may contain viable tissue particulates. Please use a high filtration mask with 0.1 micron or less to protect from airborne viruses or bacterial particles.

4.4.8 Laser Security

To prevent the unintentional use of the laser while not in use, the unit should be switched off. An electronic password is required to be entered before the unit may be used again. This code should be maintained by the Laser Safety Officer.

4.4.9 Emergency Shutdown

Any of these mechanisms can be used to shut down the emission of laser energy in a real or perceived emergency:

1. Depress and release the emergency shutdown button
2. Foot Pedal – remove your foot to stop lasing
3. Switch the Power/Fan to the off position (O)

4.4.10 Hard Tissue Procedures

Hygea is not an appropriate laser for hard tissue procedures. The 810nm wavelength is attracted to melanin, hemoglobin and, to some extent, water and oxygenated hemoglobin. Avoid prolonged exposure of the energy when working in and around the cervical areas of the tooth. Due to the thin layer of enamel in this area, the laser's energy may be absorbed by the hemoglobin in the pulp and pulpal hyperemia may occur. Extended exposure to laser energy could lead to pain and possible pulpal necrosis.

SECTION 5 – OPERATING THE LASER

5.1 Intended Uses

The Hygea diode laser is intended for use by a licensed and trained dental professional, for use in the dental office environment. The Hygea laser is suitable for use on patients without respect to age, gender or ethnicity who present dental and oral health conditions that require treatment where use of this device is appropriate, except for specific contraindications and precautions noted elsewhere in this manual.

The Hygea diode laser is indicated for dentistry and oral soft tissue procedures of:

- 1) Vaporization, hemostasis, and photocoagulation on soft tissue and removal of inflamed edematous tissue.
- 2) Temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local blood circulation, and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions;
- 3) Light activation of bleaching materials for teeth whitening and laser-assisted whitening/bleaching of teeth.

The pre-set programs in the Hygea laser provide suggestions for laser settings for certain procedures.

5.2 Standby and Ready Status

Standby mode is indicated by the laser having power and the digital key code entered to access programming options. However, laser energy will not be emitted even if the foot pedal is depressed. Ready mode is achieved by touching the Ready button found on the program screens. A green check mark on the screen will evidence Ready Mode (Fig. 3.2.12e). Once Ready is touched, the laser may be activated by depressing the foot pedal.

5.3 Continuous or Pulse Mode

Hygea diode laser will deliver energy in either a continuous wave (CW) mode or in a pulsed mode which are called temporal emission modes (time related modes). Selecting the appropriate mode is a factor of controlling target tissue temperatures and the efficiency of energy delivered. The pulse duration (0.05 seconds) and the number of pulses per second (10) have been fixed by the manufacturer using a 50% duty cycle. This setting can not be adjusted. The chosen mode is displayed in a gray color.



5.3.1 Continuous Wave Mode

Setting the laser to the CW mode allows you to deliver the specified amount of power in one second. Setting the laser to 1.5 Watts CW will allow you to deliver 1.5 Watts per second as long as you have the foot pedal depressed. The CW mode is generally the fastest way to ablate tissues but heat can build up and cause collateral damage to the target and adjacent tissues. Cool the tissues being lased by using periodic blast of air from a triplex syringe and high speed suction. You may use water to cool areas where there is prolonged exposure to the laser's beam.



Avoid using the air syringe when you have an opening in soft tissue adjacent to or within the surgery site. An air embolism may occur as a result of air captured within the tissue during the cooling process.

5.3.2 Pulse Mode

Pulsing the laser energy will allow some cooling of the tissue in between emissions of energy. The “duty cycle” is the percentage of the time in each second that the laser is emitting energy. The pulses per second, the duty cycle and the energy intensity per pulse will determine your average power. In the pulsed mode, the Hygea laser is programmed to deliver 10 pulses per second with each pulse lasting 0.05 seconds. The duty cycle is set for 50% so you will have 1 energy pulse with 1 period of rest with no energy between each pulse. The result will be an average power per second that will be 50% of what you have set the laser for. Therefore, when using pulsed energy, you will have to adjust your power upward in order to achieve the same rate of work as the same power set in CW - i.e. 1 Watt of pulsed energy will be the same average power output as 0.5 Watt CW.

5.4 Tissue Responses to Laser Energy

Maximum results will be achieved by regulating the laser power and the speed that the operator moves the fiber tip on the tissue. Tissue charring is an undesirable aftereffect of too much laser power or the tip moving too slowly. Always use the least amount of power necessary to complete your procedure. The ideal tissue response will show little or no discoloration after lasing and there will be less residual damage and faster healing. Avoid penetrating or damaging the periosteum, and do not use the laser on alveolar bone. Because the laser energy is attracted to melanin and hemoglobin, power must be reduced when treating patients with darker soft tissue. Always begin lasing with the lowest power you can use to modify the target tissues. Avoid damage to the gingival sulcus by moving the fiber tip quickly and using low power settings. Check so that no shard is present on the tip. A shard may act as a miniature scalpel and damage the small blood vessels, thus preventing hemostasis and coagulation.

5.5 System Procedures

5.5.1 Treatment Area Requirements

The laser should be placed in an area with good ventilation and lighting. The electrical service required is a 120 Volt AC outlet 50 - 60 Hz. The area where the laser is placed should be free of standing water. Combustible gases or those that support combustion should be turned off and all flammable materials or chemicals stored in the area should be removed.

5.5.2 Foot Pedal

It is recommended that a 9 volt Lithium battery is used to power the cordless foot pedal. This type of battery has been tested to last for over 100 hours of foot pedal operation. When the battery voltage begins to drop, the foot pedal will begin to beep, signaling that you have approximately 2 hours of operating time left before the battery life is completed.

NOTE: A 9 volt Alkaline battery may be used, however the life expectancy of an Alkaline battery is less than 35 hours of operating time.

5.5.3 Standard Handpiece and Single-use Fiber Tip

The standard handpiece sleeve as provided to the operator is not sterile. Make sure the sleeve is sterilized prior to use. Make sure the tip is “snapped” onto the handpiece. Please read section 6.4.4 for test instructions.

5.5.5 Laser Stop Button

Check the Laser Stop Button to see that it is depressed, if not, gently depress the button.

5.5.6 Digital Key

Activate the digital key by entering **1 2 3 4** on the touch pad. The Main Menu screen will appear.

5.5.7 Laser Settings in the Quick Setup Screen

Review your power and mode requirements and then press the mode button to select either continuous (CW) or pulsed mode.

5.5.8 Select Your Power

Press the arrows until you have reached the desired wattage. Beginning with a low of 0.1 Watts, the power increases in increments of 100 mW up to a maximum of 1.5 Watts (CW). By holding the arrow keys to increase or decrease the power, you can have an un-interrupted increase until you reach your desired power.

5.5.9 Selecting Presets

At the Main Menu Screen you will have choices to select a program by scrolling the “Procedures” list in alphabetical order.

5.5.10 Aiming Beam

The laser aiming beam can be turned on and off by pressing the aiming beam button on the laser control panel. Press the arrow buttons to progressively increase or decrease the aiming beam intensity from 0 (off) to full intensity. Each circle represents approximately 20% of the aiming beam output.

NOTE: Adjusting the intensity of the aiming beam has no effect on the output power of the primary working laser.

5.5.11 Tips

The Hygea laser uses unit-dose laser tips, for single use only. They are pre-cleaved and polished for immediate use. For infection control reasons, tips shall be used for one patient only. Tips are supplied to the user in a non-sterile condition. It is not possible to autoclave tips. Instructions for sterilizing the tip prior to use are in Section 6.1.

5.5.12 Procedure

1. Press the Ready button. The aiming beam should light after 3 seconds. Review your power and mode requirements and then press the mode button to select either CW or Pulsed mode.
2. Test fire the laser outside the mouth by activating the laser into a 2x2 gauze sponge that has been wetted with water to prevent combustion. Do not use flammable liquids to wet the sponge.
3. Depress the foot pedal and make short quick strokes at the lowest power that you can to remove the target tissues while lightly contacting it.
4. Remove your foot from the foot pedal and use a clean 2x2 gauze sponge wetted with water to remove debris from the fiber tip. Do not use flammable liquids to wet the sponge.
5. With your foot off the foot pedal, touch the Ready button to place the Laser in Standby Mode until you are ready to start another procedure.
6. Remove the unit-dose fiber tip and dispose in a suitable biohazard Sharps disposal.
7. Remove the handpiece sleeve only and follow the autoclave instructions in section 6.4.2.
8. If you are not going to be starting another procedure, return back to the Main Menu and press Logout. It is now safe to turn the power button to the OFF position.
9. Insert a new unit-dose fiber tip or the protective metal cap and snap it into the hand piece to prevent the fiber lens from becoming contaminated. Please read section 6.5 for proper care of the handpiece. If you insert a new unit-dose fiber tip into the handpiece, simply drape the tip package over the tip as an indication that this is a new, unused tip.
10. Record the Powers and total lasing times used for each procedure in the patient's chart.

Example:

Patient Name: Mary Jones

Procedure: Gingivectomy # 6 and # 7

#6 Lasing time 90 seconds @ 1.5 Watts CW air cooled, 810nm wavelength

#7 Lasing time 60 seconds @ 1.0 Watts CW air / water spray, 810nm wavelength

5.5.13 Therapeutic Procedures

The therapy sleeve as provided to the operator is not sterile. When using the Hygea laser for Therapeutic procedures, make sure the handpiece sleeve is sterilized and assembled prior to use according to Section 6.6, and the appropriate laser settings are established as indicated in the Procedures table in Section 3.2.14. If exterior surfaces of the skin are to be treated, use a gauze pad moistened with isopropyl alcohol to wipe the skin clean of excess oils, lotions, or other substances on the skin as these will collect on the handpiece window and absorb the laser energy. This will cause the handpiece to become warm, and may heat the top layers of the skin without achieving the desired tissue penetration. Advise the patient accordingly about this cleaning step. Position the handpiece over the target area and lightly contact the end of the handpiece onto the tissue. Press and hold down the foot pedal. Use consistent, circular motions to move the handpiece over the target area. Avoid holding the handpiece over the same area for more than a few seconds.

5.5.14 Tooth Whitening

Whitening is a preset option for the Hygea laser. The whitening handpiece, which includes the sleeve and cone, is available as an accessory and as provided to the operator is not sterile. When using the Hygea laser for a Tooth Whitening procedure, make sure the handpiece sleeve and cone are sterilized and assembled prior to use according to Section 6.7, and the appropriate laser settings are established as indicated in the Procedures table in Section 3.2.14. Apply the whitening gel as indicated in the instructions for the whitening gel that you are using. Once the gel is applied, position the whitening handpiece over the patient's arch. DO NOT touch the handpiece directly to the gel or to the teeth. Press and hold the foot pedal. Slowly move the handpiece from side to side along the arch and back and forth between upper and lower arches to expose the whitening gel to the laser energy. NOTE: If only one arch is being treated, then the exposure time will be 540 seconds. Once the exposure is completed, the laser energy can be stopped and the whitening gel allowed to remain in contact according to the gel instructions.

5.5.15 Self Diagnostic and Monitoring

When the Hygea laser's microprocessor detects an issue with performance it will immediately notify you by way of an audible beep. There are two different ways in which the Hygea unit will alert you to any issues:

1. Continuous audible beep when foot pedal is engaged. If you are operating the Hygea laser with the foot pedal engaged and the unit emits a constant audible beep and stops the beep when you release the foot pedal, the microprocessor has determined that the laser power output has fallen outside the set level. In this event the Hygea laser should be turned off and allowed to sit for 5 minutes then turned on again. If the Hygea laser then performs without beeping, the microprocessor has been able to make operational adjustments to the laser and the unit will perform its functions. If, however, upon restart the unit continues to beep when the foot pedal is engaged, the microprocessor was unable to adjust the unit enough and the unit will need to be sent in for adjustment.
2. Continuous audible beep when the unit is turned on. If you are operating the Hygea unit and it emits a constant audible beep whether or not the foot pedal is engaged, the microprocessor has determined that the laser has either low power or a general fault has occurred. In this event the Hygea laser should be turned off, allowed to sit for 5 minutes and turned on again. If the Hygea laser then performs without beeping the microprocessor has been able to make operational adjustments to the laser and the unit will perform its functions. If, however, upon restart the unit continues to beep, the microprocessor was unable to adjust the unit enough and the unit will need to be sent in for adjustment.

SECTION 6 – PREPARATION, CLEANING, AND CARE

All portions of the device should be cleaned of visible contaminants prior to disinfection and sterilization processing. Cleaning should be done with a soft cloth or gauze moistened with a mild soap solution or alcohol solution to remove visible contaminants. Avoid use of abrasive cleaning compounds that contain suspended insoluble particles. Disposable tips are provided in a non-sterile condition. Handpiece sleeves should be cleaned and sterilized prior to use. Once cleaned, proceed to the disinfection and/or sterilization processes indicated in the relevant sections below. No portion of the system requires maintenance while in use on the patient.

6.1 Single-use Fiber Tips

The fiber optic element of a laser is responsible for carrying the light from the diode array to the tissue being treated. The dental laser fibers are usually made of quartz, sapphire, silica or a combination of those elements. Quartz/silica is the most popular product used in diode lasers. Be advised about the potential hazards when inserting, steeply bending or improperly securing the fiber optics to the handpiece. Radiation exposure may occur in these instances which could be harmful to yourself, your staff and your patient. Special care should be taken not to break or snap the fiber when removing tips from packaging. As the aiming beam passes down the same delivery system as the Working Beam, it provides a good method of checking for integrity of the delivery system. If the aiming beam spot is not present at the distal end of the delivery system, its intensity is reduced, or it looks diffused, this is a possible indication of a damaged or not properly working delivery system.

The laser tips are Non-Sterile and are single-use only, and should be disposed of after each patient. Inspect the package to ensure there are no tears or punctures. DO NOT USE if such flaws are visible. The tip must be sterilized prior to use. When the pouch is opened, care should be taken to minimize the chance of accumulation of foreign debris or contaminants on the tips prior to use. DO NOT remove the clear cap and wipe the tip stem.

DO NOT attempt to autoclave the tips. They are not designed to withstand such a process and may melt or distort.

To sterilize the tips, remove the tip from its packaging. DO NOT remove the clear plastic cap on the back end of the tip. Immerse the tip in either Cidex Activated Aldehyde Solution or Sporox II Sterilization & Disinfectant Solution, following the exposure conditions indicated by each product to achieve sterilization: 10 hours @ 25°C for Cidex, and 6 hours @ 20°C for Sporox. The tips must not be stored in these sterilants for more than 72 hours. At this point the tip should be handled as a sterile article. Remove it from the solution, and rinse the tip with sterile water for 10 seconds. Remove the protective dust cap, and dry the tip with purged or sterile air only for another 5 seconds. Immediately attach the tip to the handpiece. The tip should be used for the procedure immediately following sterilization. DO NOT store the tip after it has been sterilized.

During use, the fiber on the end of the tip may become fouled with tissue or debris. When this occurs, laser energy is absorbed at the end of the tip rather than transmitted to the target tissue. This is often manifested by an intense white flash at the end of the fiber as organic matter is vaporized. If you find that the laser is losing cutting efficiency as you continue with the procedure, stop the laser emission and place the system into Standby Status. Use a clean lint-free cloth to remove foreign material adhered to the tip. DO NOT use a cloth premoistened in alcohol as this flammable liquid may still coat the fiber tip when the laser is reactivated. If wiping the tip does not improve laser performance, it may be necessary to discard the existing tip and attach a new tip.

DO NOT use the tip if the packaging is found to be torn, punctured, opened, or otherwise compromised.

DO NOT reuse the tip. The laser tip is for one-time use only.

6.2 Fiber Preparation

The unit-dose tips are pre-stripped and pre-cleaved for immediate use.

6.2.1 Quartz/Silica Fiber

The fiber is fairly flexible but can be broken if bent into a small circle or bent at an angle of 90 degrees. The cladding will burn as protein from the gingival accumulates on the fiber and will deteriorate the tip. It can fracture once the blackened area has reached 3-4 mm. To avoid accumulation of protein debris, stop lasing and wipe off the tip regularly as you work. Use water on a 2x2 gauze sponge to clean the tip. Do not use flammable materials like alcohol products when cleaning a hot tip.

6.2.2 Initiating the Fiber

Some procedures require that the fiber tip be initiated. The tip of the fiber can be prepared to retain heat by introducing it to a dark material. The easiest way to prepare the tip is to lightly move the end of the fiber across a piece of articulating paper at about 1 Watt CW. The tip will retain pigment which will make the tip glow. Do not exceed contact time of 1 second.

6.3 Laser Cleaning and Maintenance

6.3.1 Laser Body Disinfection

Prior to use, the exterior of the laser should be cleaned using a liquid disinfectant such as BIREX™, CaviCide®, or a 0.5% sodium hypochlorite solution. Do not spray the disinfectant directly on the chassis as liquids could damage the LCD display. Apply with a gauze sponge or wipe. Allow the surface to remain moist for 5 minutes (10 minutes for BIREX). Multiple applications may be needed to achieve the indicated contact time. Allow to air dry. Do not use abrasive materials to clean the system. Place an adhesive barrier material over the LCD screen prior to treating the next patient.

6.3.2 LCD Display

Over the lifespan of the device, the display may become opaque from repeated scratches, abrasions and/or organic debris. This could impair the proper display of information. Should your display show evidence of wear or scratches, the unit should be returned for service. In the event the LCD display becomes cracked or damaged, the liquid crystal chemical could leak. Use of the device should be immediately discontinued and the unit returned for servicing in this case.

6.3.3 Fiber Cable and Handpiece Stem

The exterior surface of the fiber cable and handpiece stem should be cleaned using a liquid disinfectant such as BIREX™, CaviCide®, or a 0.5% sodium hypochlorite solution. Do not spray the disinfectant directly on the cable or stem. Apply with a gauze sponge or wipe. DO NOT IMMERSERSE the handpiece stem as cleaning solution residuals could contaminate the optics in the stem and prevent laser transmission. Allow the surface to remain moist for 5 minutes (10 minutes for BIREX). Multiple applications may be needed to achieve the indicated contact time. Allow to air dry. Do not use abrasive materials to clean the system.

6.3.4 Calibration

The Hygea laser uses solid-state circuitry to continuously monitor the power output, and adjusts the power supplied to the laser module to keep the output consistent with the user defined setting. If output levels are more than $\pm 20\%$ of the set value, the unit is designed to shut down power to the laser, and an audible alarm will sound. If this happens, the unit should be turned off and allowed to sit for 5 minutes and turned on again. If the laser then performs without beeping, the microprocessor has been able to make operational adjustments and the unit will perform its functions. If, upon restart, the unit continues to beep, the unit will need to be sent to the CAO Group service department for adjustment.

We suggest that your practice establish an internal calibration program for your laser. Recalibration is recommended a minimum of once per year based on average usage. Recalibration may be performed by the manufacturer by returning the unit. Alternatively, you may purchase a calibrated hand held power meter approved for use with 810nm devices to check power output. The laser should be set at 0.5, 1.0, and 1.5 Watts with output checked at each level. The output display should be within 20% of the meter reading. If not, replace the unit-dose fiber tip and re-check. If the output display is still outside the 20% tolerance, return the unit to the CAO Group service department for recalibration. There are no methods available for the user to adjust the calibration of the unit and the unit chassis must not be removed by the user for any reason.

6.3.5 Battery Use

The Hygea laser is supplied with a rechargeable lithium polymer battery (Fig. 6.3.5) which optimally provides up to 45 minutes continuous lasing time or 8 hours standby time i.e. laser on, not being charged by cradle or AC power cord. If you find the battery runs the laser for 30 minutes or less after being charged for several hours, the battery may need replacing. A replacement battery can be ordered. To remove the battery, press on the center button while sliding the battery downward, then lift away from the unit. Install the new battery by placing it onto the back of the laser, the sliding upward until the lock clicks in place. The new battery must be charged overnight prior to using the laser.



Figure 6.3.5

6.4 Handpiece Sleeve Sterilization

6.4.1 Handpiece Components

For sterilization, the handpiece has two (2) components:

1. Handpiece stem and fiber assembly (Fig 6.4.1a).
See Section 6.3.3 for cleaning instructions.
2. Handpiece sleeve (Fig. 6.4.1b)

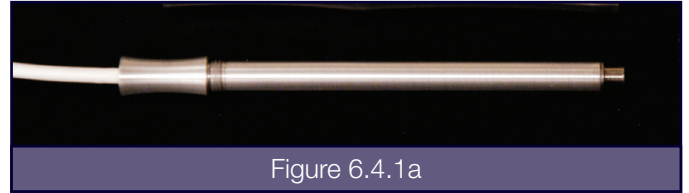


Figure 6.4.1a

6.4.2 Recommended Autoclave Procedure

1. **Autoclave the handpiece sleeve only.** First remove the unit-dose tip after the procedure and discard. Unscrew the metal handpiece sleeve counterclockwise and separate from the handpiece. Set the autoclave parameters for 250°F, at least 18 psi, and run for 30 minutes. Allow the handpiece sleeve to remain in the autoclave for at least an additional 30 minutes to complete the cycle (Fig 6.4.2a and b).
2. **Do not place the laser unit or the fiber cable in the autoclave!** The recommended cleaning procedure is to wipe the fiber cable with a liquid disinfectant according to the materials and procedures described in Section 6.3. After laser use, please wear gloves for disassembly and cleaning. Do not disconnect the fiber cable from the laser unit for cleaning procedures as this may contaminate the optical connections.

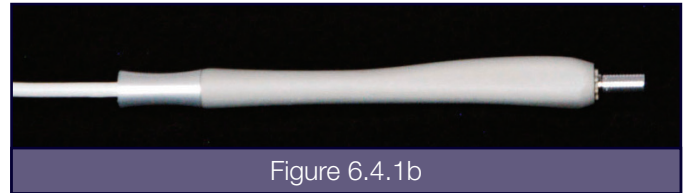


Figure 6.4.1b

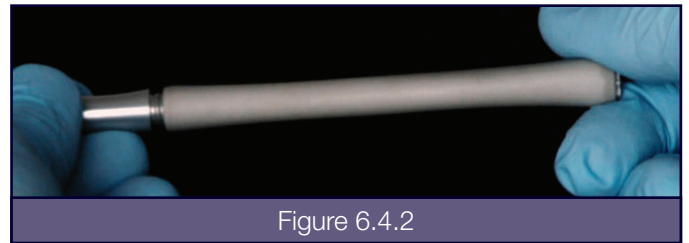


Figure 6.4.2

6.4.3 Prepare Fiber

If the packaging is visibly damaged or holes are visible, do not use the fiber tip. The unit-dose fiber tips are pre-stripped and pre-cleaved and once inserted on the handpiece are ready for use. The aiming beam should create a near perfect circle when directed onto a white surface from a distance of 1/4 - 3/8 inch. Ensure that the tip packaging is opened and the tip handled in such a way as to prevent contamination.

6.4.4 Attaching the Tip

Seat the disposable fiber tip securely on the handpiece body and snap the tip into place.

The fiber tip has to be completely inserted into the handpiece assembly. Make sure that the serrations at the end of the handpiece sleeve engage with the inner part of the plastic housing of the fiber tip. The gap between handpiece sleeve and plastic housing of the fiber tip should not be significantly greater than 1/32 inch or less than 1mm when fully inserted.

Proper fit can be tested by a simple shake test. Pick up the handpiece at the end of the sleeve and shake the handpiece in two or three abrupt downward movements.

If the tip slides out, re-insert it and try again or use a new fiber tip and follow the same procedure. Please call your CAO Group representative if the tip is not properly retained as intended. This is a safety measure to ensure proper seating of the tip during the intraoral procedure and to maintain the selected power output.

6.5 Proper Handpiece Care

6.5.1 Preventing Contamination

Your optical fiber handpiece will become contaminated and the energy output of your laser will decrease if the end of the handpiece is left exposed. Leaving the lens exposed for even a short time can lead to contamination of the lens. By leaving the end of the handpiece exposed, dust could settle on the lens. This dust will burn onto the lens when the laser is fired, causing the lens to become permanently contaminated (Fig. 6.5.1a and b). Once the lens is contaminated, the energy output of your laser will decrease and the cutting efficiency will degrade.

A unit-dose tip or metal protective cap must be on the end of the handpiece at all times to prevent dust from settling on the lens (Fig 6.5.2).

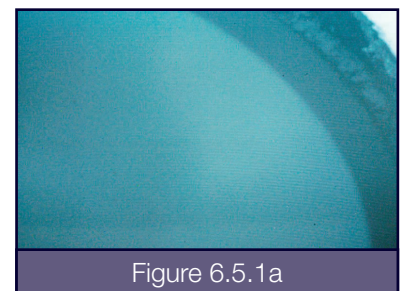


Figure 6.5.1a

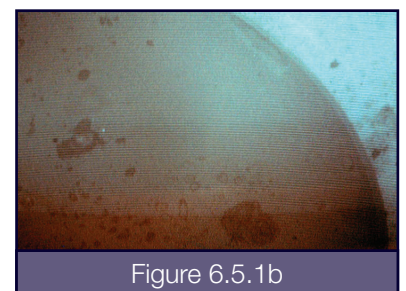


Figure 6.5.1b

6.5.2 Protecting the Glass Core

A glass core (at the center of the fiber cable) delivers the laser energy (Fig 6.4.2). This glass core can become cracked or broken if excessive weight or impact is applied to the cable. If the glass core becomes cracked or broken, the amount of laser energy delivered to the tip will be drastically reduced. Please ensure that everyone in your practice follows these simple instructions to prevent the glass core from cracking or breaking:

1. Keep the cable off the floor.
2. If the Hygea unit is stored in a drawer or cabinet, ensure that the cable does not become jammed or pinched.
3. If the cable is wound up for storage, slightly wind the cable so the circle is no smaller than the size of a CD.

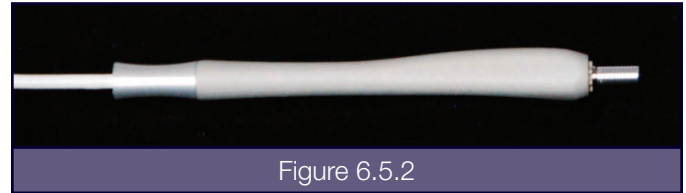


Figure 6.5.2

6.6 Therapy Handpiece (Sleeve)

The Therapy Handpiece consists of a single specialized handpiece sleeve that is designed for performing the therapeutic procedures indicated for this laser (pain relief to increase circulation, treat tissue, and treat muscle and joints). This sleeve is sterilized and prepared the same as the standard sleeve as described in Section 6.4.2. Once this sleeve is attached to the handpiece, the assembly is ready for use. No disposable tip is associated with the use of the therapy tip assembly.

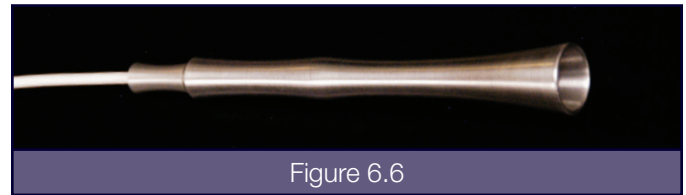


Figure 6.6

6.7 Whitening Handpiece (Sleeve)

The Whitening Handpiece consists of a specialized handpiece sleeve and reusable dispersion cone that together are designed for performing the tooth whitening procedure indicated for this laser. The sleeve and cone should be cleaned and sterilized the same as the standard sleeve as described in Section 6.4.2. Once this sleeve is attached to the handpiece, attach the reusable cone to the whitening sleeve. The cone will snap onto the sleeve, indicating it is fully attached.



Figure 6.7

Tooth whitening is an optional feature of the Hygea laser.

SECTION 7 – LABELING, WARNINGS, AND MANUFACTURER’S INFORMATION

7.1 Regulatory Compliance

The Hygea diode laser is designed to be compliant to the latest safety standards applicable to medical lasers in the US and Canada including IEC 60825, IEC 60601-2-22, IEC 60601-1, CSA/CAN C22.2 No. 601.1 and the Food and Drug Administration’s Laser Performance Standard (21 CFR 1040.10 and 1040.11) except for deviations pursuant to Laser Notice 50, date June 24, 2007. The laser has also been tested according to the telecommunications regulations for the US (FCC Part 15) and Canada (IC RSS 210). Various labels are included on the laser and the wireless foot switch as evidence of conformity to these requirements. The labels on the units are required under these standards for safety purposes and should not be removed. Please review all labels prior to using the laser.

7.2 Labels

7.2.1 Danger Laser in Use

Each treatment area should have a “Laser in Use” warning sign posted at the entrance to the treatment area. This signage serves to warn people to not enter the treatment area without proper safety eyewear and protective clothing when the laser is in use.

7.2.2 Class 4 Laser Product

810nm ± 10nm 1.5W

7.2.3 Aiming Beam Laser

650nm ± 10nm 2mW



Figure 7.2.1a

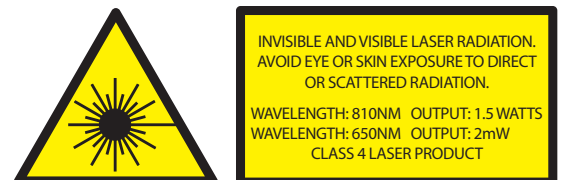


Figure 7.2.1b

7.2.4 Interference with Wireless Signals

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. (Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense).



7.3 Device Cautions

- **Changes or modifications not expressly approved by CAO Group, Inc. could void the user's authority to operate the equipment.**
- **Laser Radiation - Avoid exposure to the eyes or skin from direct or scattered radiation**
- **This product contains no user serviceable components within the chassis. Visible and invisible radiation may be present when the cover is removed. Do not open the laser chassis under any circumstances.**
- **US Federal law restricts this device to sale by or on the order of a licensed dentist.**
- **Eyewear that protects your eyes from wavelengths other than 810nm do not provide proper protection for use with this laser. Damage to the retina or cornea may be irreparable if exposed to direct, reflected or scattered radiation. Always wear protective eyewear when operating the laser.**
- **Use of controls or adjustments, or performance of procedures other than those specified herein may result in hazardous radiation exposure.**
- **The 810nm wavelength of the working beam is not visible to the human eye.**
- **Do not attempt to remove the cover from the laser chassis for the purpose of repairing the laser. Serious injury from an electrical shock or laser radiation could occur. Removing the cover on the laser chassis will void the warranty.**
- **Avoid prolonged exposure of the energy when working in and around the cervical areas of the tooth. Due to the thin layer of enamel in this area, the laser's energy may be absorbed by the hemoglobin in the pulp and pulpal hyperemia may occur. Extended exposure to laser energy could lead to pain and possible pulpal necrosis.**
- **Treatments performed with this device are subject to the same clinical assessment as with traditional techniques. Consider the patient's medical history and risks prior to treatment. Patient conditions may exist that may contraindicate use of this device. Consult the patient's general physician if doubts exist.**

7.4 Nominal Ocular Hazard Distance (NOHD)

The NOHD is the distance beyond which the exposure during normal operation is not to exceed the appropriate Maximum Permissible Exposure (MPE). The NOHD for persons wearing safety glasses is shown in Table 1 below. The Nominal Hazard Zone (NHZ) is the area where the laser source within which exposure levels exceeds the MPE (which is the highest level of laser radiation to which a person may be exposed without hazardous effects or adverse biological changes in the eyes or skin). The outer limit of the NHZ is the NOHD.

APPROPRIATE EYE PROTECTION MUST BE WORN BY ALL INDIVIDUALS WITHIN THE NOMINAL HAZARD ZONE.

Source of Radiation	MPE (mW/cm ²)	Divergence Angle (degrees)	NOHD (inches/cm)	
			No Eyewear	With Eyewear (OD=4)
Fiber Optic (Direct)	1.66	9	119.72/304.8	1.2/3.04
Reflected from Tissue	1.66	N/A	0.023/0.059	0.00023/0.00059

Assumptions: Maximum Laser Power = 3 Watts, Direct viewing angle =0, Reflectance viewing angle =20°, Reflectance coefficient of tissue = 0.001

Table 1 - Nominal Ocular Hazard Distance (NOHD) for various viewing conditions while wearing eye protection.

SECTION 8 – SERVICING

8.1 Limited Warranty

The Hygea diode laser is warranted against defective materials and workmanship for a period of:

- 2 years for the laser
- 1 year for battery
- 6 months for handpiece and fiber assembly

from the date of purchase, and will be repaired or replaced, at the discretion of CAO Group, Inc., if returned prepaid to the service center. This warranty does not cover damage to the Hygea diode laser unit or components caused by accident, misuse, or being tampered with. This warranty does not include postage, or delivery charges. This warranty does not apply to the external finish of the console, handpiece, fiber, power cord or foot pedal. CAO Group, Inc. reserves the right to make changes in design or to modify such previously manufactured products. Warranty coverage of your Hygea diode laser is facilitated by registering your laser online at www.caogroup.com.

8.2 Repairs & Returns

Should the laser fail to operate correctly, please call the CAO Group Customer Service at (877) 236-4402 to obtain a Return Material Authorization (RMA) number for shipping purposes. No lasers will be accepted without an RMA. Please ensure that the RMA number is clearly marked on the box used to return the laser. It is recommended that you return your laser in its original shipping box. Please clearly state the reasons for return.

8.3 Troubleshooting

Problem	Corrections
Unit has no signs of power or activity.	<ul style="list-style-type: none"> • Check that the power cord is securely plugged into back of the laser unit. • Check that the power switch on the side panel is turned to the on () position. • Check that the Laser Stop button is depressed. If not, depress the button. • Check the fiber/handpiece attachment and verify that it is properly engaged. • Confirm that the laser battery is charged. THE LASER BATTERY MUST BE FULLY CHARGED BEFORE INITIAL USE. Allow the battery to charge overnight before use.
Unit has power, but no laser output.	<ul style="list-style-type: none"> • Check the battery in the wireless foot pedal. • Depress the reset button on the wireless foot pedal. • Check that handpiece and fiber tip are properly initiated. • The aiming beam is set too low. Increase the intensity of the aiming beam. • Check that handpiece and fiber tip are properly initiated.
Measured power output is different from the displayed setting.	<ul style="list-style-type: none"> • Make sure the power meter is calibrated for use with 810 nm wavelength devices. • Take a new fiber tip and insert tip according to instructions.
Repeated audible beep when the laser is firing.	<ul style="list-style-type: none"> • Turn laser off for 5 minutes. Turn laser back on. If beep stops, the unit was able to make operational adjustments and the laser should perform its function. If the beep continues, the laser must be sent in for adjustment.
Repeated audible beep when the laser is not firing.	<ul style="list-style-type: none"> • Turn laser off for 5 minutes. Turn laser back on. If beep stops, the unit was able to make operational adjustments and the laser should perform its function. If the beep continues, the laser must be sent in for adjustment.
The laser beam doesn't fire when the pedal is pressed.	<ul style="list-style-type: none"> • The laser is not in "Ready" mode. • Depress the black reset button in the front part of the wireless foot pedal for three seconds. • Replace the 9 Volt battery (PP3, ANSI 1604A) in the foot pedal if the green light to the left of the actual foot pedal does not light up when the pedal is being depressed. A 9V lithium battery will last considerably longer than a regular alkaline battery. • This laser uses wireless transmission technology at a frequency of 2.4GHz. This is a popular frequency used by other devices such as cordless phones and computer equipment such as wireless peripherals and network connections. Place the laser system in an area away from these types of devices. Also, large metal surfaces may disrupt wireless communications as well. Make sure there are not large metal surfaces between the laser unit and the foot pedal when setting these items in place.

There is a “Safety Alert” pop-up on the screen.	<ul style="list-style-type: none"> • Tighten the nut that connects the handpiece assembly to the bottom of the unit so that it can make contact with the outer ring of the female adapter. • Depress the red “Laser Stop” button on the faceplate of the unit. • If you use a separate Remote Interlock assembly (3.1.7), make sure it works properly.
The laser doesn’t cut as expected (low output).	<ul style="list-style-type: none"> • Your handpiece assembly is a precision instrument and may be contaminated. Unit should be serviced. The handpiece assembly is a consumable item and should be replaced when laser output is consistently low. • Do not remove your handpiece assembly from the Hygea unit unless it requires replacement. Optical connectors can be polished during service intervals to make sure your fiber assembly performs as expected.

SECTION 9 – SELECTED REFERENCES

1. Pirnat S. “Versatility of an 810 nm Diode Laser in Dentistry: An Overview.” J Laser Health Academy, Vol. 2007 No. 4 (2007), pp. 1-9.
2. Lin J, L Bi, L Wang, Y Song, W Ma, S Jensen, and D Cao. “Gingival curettage study comparing a laser treatment to hand instruments.” Lasers Medical Science, Vol. 26 No. 1 (Jan 2011), pp. 7-11.
3. Gupta G. “Management of Gingival Hyperpigmentation by Semiconductor Diode Laser.” J Cutan Aesthet Surg, Vol. 4 No. 3 (Sep 2011), pp. 208-210.
4. Giannelli M, L Formigli, L Lorenzini, and D Bani. “Efficacy if combined photoablative -photodynamic diode laser therapy adjunctive to scaling and root planing in periodontitis: Randomized split-mouth trial with 4-year follow-up.” Photomed Laser Surg, Vol. 33 No. 9 (Sep 2015), pp. 473-480.
5. Giannelli M, D Bani, C Viti, A Tani, L Lorenzini, S Zecchi-Orlandini, and L Formigli. “ Comparative Evaluation of the Effects of Different Photoablative Laser Irradiation Protocols on the Gingiva of Periodontopathic Patients.” Photomed Laser Surg, Vol. 30 No. 4 (Apr 2012), pp. 222-230.
6. Bjordal JM, RJ Bensadoun, J Tuner, L Frigo, K Gjerde, and RA Lopes-Martins. “A systematic review with meta-analysis of the effect of low-level laser therapy (LLLT) in cancer therapy-induced oral mucositis.” Support Care Cancer, Vol. 19 No. 8 (Aug 2011), pp. 1069-1077.
7. Amarillas-Escobar ED, JM Toranzo-Fernández, R Martínez-Rider, MA Noyola-Frías, JA Hidalgo-Hurtado, VM Fierro Serna, A Gordillo-Moscoso, and AJ Pozos-Guillén. “ Use of Therapeutic Laser After Surgical Removal of Impacted Lower Third Molars”. J Oral Maxillofacial Surg, Vol. 68 No. 2 (Feb 2010), pp. 319-324.
8. Ahrari F, AS Madani, ZS Ghafouri, and J Tunér. “ The efficacy of low-level laser therapy for the treatment of myogenous temporomandibular joint disorder”. Lasers Medical Sci, Vol. 29 No. 2 (Mar 2014), pp. 551-557.

SECTION 10 – REORDERING

002-00433	Barrier Sleeves, pack of 250	002-00425	Disposable Fiber Tips, Standard length, Pack of 50
002-00267	Laser Protective Glasses	002-00426	Disposable Fiber Tips, Perio length, Pack of 50
002-00434	Fiber Cable - 4ft Length	002-00439	Treatment Handpiece Sleeve
002-00435	Fiber Cable - 6ft Length	002-00440	Therapy Handpiece Sleeve
002-00436	Battery Pack	002-00441	Whitening Handpiece Sleeve
002-00437	Power Supply w/cord	002-00442	Whitening Cone
002-00438	Charging Cradle	002-00108	Laser Safety Sign

SECTION 11 – ELECTROMAGNETIC COMPATIBILITY

The Hygea diode laser needs special precautions regarding the Electromagnetic Compatibility (EMC) of the system and needs to be installed and put into service according the EMC information provided in this manual.

Portable and mobile radio frequency (RF) communications equipment can affect the Hygea unit. The use of accessories and cables other than those specified by CAO Group, Inc. may result in increased emissions or decreased immunity of the Hygea laser. The Hygea unit should not be used adjacent to or stacked with other equipment adjacent to or stacked use is necessary, the Hygea laser should be observed to verify normal operation in the configuration in which it will be used.


Guidance and manufacturer's declaration – electromagnetic emissions		
The Hygea diode laser is intended for use in the electromagnetic environment specified below. The customer or the user of the Hygea laser should assure that it is used in such an environment.		
Emissions Test	Compliance	
RF emissions CISPR 11	Group 1	The Hygea laser uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not available	
Voltage Fluctuations/ Flicker emissions	Not available	
The Hygea laser is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes		

Guidance and manufacturer's declaration – electromagnetic emissions			
The Hygea diode laser is intended for use in the electromagnetic environment specified below. The customer or the user of the Hygea laser should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst	±2 kV common mode	±2 kV for power supply	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-4	±1 kV for input/output lines	Lines Not Applicable	
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 5 sec	
(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	

Guidance and manufacturer's declaration – electromagnetic immunity

The Hygea diode laser is intended for use in the electromagnetic environment specified below.
The customer or the user of the Hygea laser should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000 4-6	6 Vrms 150 kHz to 80 MHz	8 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Hygea unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [3.5/\sqrt{P}] \sqrt{P}$
Radiated RF IEC 61000-4-3	7 V/m 80 MHz to 2,5 GHz	3 V/m	$d = [3.5/E1] \sqrt{P}$ 80 MHz to 800MHz $d = [7/E1] \sqrt{P}$ 800 MHz to 2.5 GHz  <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^aField strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Hygea laser is used exceeds the applicable RF compliance level above, the Hygea laser should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Hygea unit.
Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Recommended separation distances between
portable and mobile RF communications equipment and the Hygea unit**

The Hygea diode laser is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Hygea laser can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Hygea unit as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = [3.5/\sqrt{P}] \sqrt{P}$	$d = [3.5/E1] \sqrt{P}$	$d = [7/E1] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.39
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



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