

3.2 Evaluating the Facility and Environmental Considerations (United States)

In order to insure the safe use of the laser in your facility, please check to make sure that the proposed location has the following:

3.2.1 Power Requirements:

110 -120 V AC $\pm 10\%$ at 60 Hz

3 Amps

Frequency range 45 - 63 Hz

9 volt Lithium battery

3.2.2 Heating and Ventilation:

The room where the laser is used should have good cooling and heating system so that the laser can be operated within the optimum range of 20° - 30°C (68° - 86° F). Avoid storing or transporting the laser in temperatures below 0° Celsius (32° F).

3.2.3 Lighting:

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

3.2.4 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.

3.2.5 High Speed Vacuum Systems:

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 high filtration masks that are suitable for virus and bacterial control.

3.2.6 Access and Visual:

Access to the treatment area should allow the dental team to restrict entry while the laser is in use. There should be a **Laser In Use Safety Sign** placed in a designated area adjacent to the entry into the treatment area. See Figure 7.1 on page 20.

3.2.7 Channel Programming Procedure:

There is no concern if 2 or more Odyssey 2.4G diode lasers in the same office are set to the same channel. Each laser and its corresponding pedal have additional programming that is unique to the pair. **The pedal from one laser will not activate any other laser.** However, if units on the same channel are near each other, the transmissions from one may interfere with the signal from another and thus prevent the second laser system from operating properly. It may become necessary to change the channels on one or more units to minimize interference.

Channel Programming Procedure

1. Make sure the unit is off before going forward with the programming procedure. Do not press the foot pedal for at least 30 seconds before proceeding.



2. Before turning the unit on, press and hold PROGRAM.



3. While holding the PROGRAM key down, turn on the unit. The display will briefly show "=P", then show "c1" for channel 1, "c2" for channel 2 up to channel 8 (depending on what programmed channel the unit is already on). Release the PROGRAM key.



4. Press the INCREASE key to scroll up through the channels, from 1 to 8. Press the DECREASE button to scroll from 8 back to 1 to select the desired channel.



5. Once the desired channel is selected, press PROGRAM again. The unit will beep the same number of times as the channel selected. After a few moments, the display will show "--".



6. With the main unit in this condition "--", press the pedal. While the pedal is pressed, the display will change to "-|I-".



The pedal is now set to the same channel and is matched with this laser.

When the pedal is released, the display will return to "--". This indicates that the channel change was successful and the new channel is saved in the memory.

7. If any problems occur during this process, the display will show "E r". If this occurs, turn the unit off, then on again. The original channel should be restored.
8. Once channel programming is complete, turn the unit back power fan switch off, then on again. The laser display should return to a laser power setting.

3.2.8 Odyssey 2.4G Diode Laser Frequency: The 2.4GHz frequency is very popular for networks and other wireless devices that share similar technology like bluetooth® cell phones, Wi-Fi® devices, wireless networks, cordless phones, CAD/CAM machines, wireless video senders, even microwave ovens. The nature of spread-spectrum modulation in the 2.4G frequency means that a multitude of devices can co-exist in the same 2.4GHz spectrum (as should be obvious, since many devices use 2.4GHz and operate well on a daily basis).

Bluetooth and Wi-Fi devices use multiple channels, recovering data reliably out of noise in the 2.4GHz spectrum. They will hop around strong interference, and quickly re-try for uninterrupted operation -- and can even avoid channels or areas of the band in use by other devices by adaptive hopping.

Since the Odyssey 2.4G wireless receivers have a much lower power output, it is highly unlikely that they would "interfere" with higher-power devices. Even if this were possible, the higher-power devices would quickly switch to another channel to achieve uninterrupted operation.

The 2.4G wireless receiver use an entirely different modulation scheme, and therefore can not de-modulate (receive) data from Wi-Fi or Bluetooth devices. The converse is also true; their modulation methods are incompatible.

Odyssey 2.4G diode laser wireless technology is electronically coded:

Each pedal and Odyssey 2.4G diode laser share a **UNIQUE SERIAL NUMBER INTERLOCK** protocol for reliable operation:

- An Odyssey 2.4G pedal communicates with only one Odyssey 2.4G diode laser; there is 2-way electronic code which must be verified for every transmission and

acknowledge. The pedal and laser unit are interlocked to only each-other's electronic codes.

- If data from another Odyssey 2.4G pedal is ever received, embedded verification measures ensure that it is always ignored and discarded.
- If data were ever received from another wireless device with a compatible modulation scheme (2.4GHz frequency), it would immediately be discarded in the same way.

In summary, the wireless receivers in the Odyssey 2.4G 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.

Odyssey 2.4G 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 an Odyssey 2.4G diode laser except the wireless pedal which it is paired with via electronic code.

4. Safety Considerations

The safe use of the Odyssey 2.4G is the responsibility of the entire dental team including the doctor, the laser safety officer appointed from 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. The following entities have influence over laser use.

4.0 Food and Drug Administration

Manufacturers of products subject to performance standards under the Federal Food, Drug, and Cosmetic Act, Chapter V, Subchapter C - Electronic Product Radiation Control are required to certify compliance with the regulations and furnish various reports to the Center for Devices and Radiological Health (CDRH). For medical laser manufacturers, additional review by the FDA of the safety and effectiveness of the device is required. Companies who intend to market a medical laser today must receive authorization from the FDA to permit the device into commercial distribution. There are two forms of premarket clearance procedures. The premarket notification (510(k) procedure is principally used for those devices that are documented to be substantially equivalent to legally marketed Class I and Class II devices. For new devices not equivalent to legally marketed devices, a more complex PMA is required.