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Improper use of the Medlite  $C^6$  Laser controls or performing procedures other than those specified in section **8.** Physician's Information in this manual may result in hazardous radiation exposure. Also, laser light presents a severe hazard for eye injury and a potential for burns or fire. Never view the laser beam directly or by reflection. Avoid exposure to the laser beam. Activate all of the necessary protective measures in areas where the laser beam is being used. Always use the appropriate laser protective eyewear when the laser is on.

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## **Manual Overview**

This manual contains the safety, operating requirements and instructions for the Hoya ConBio Medlite<sup>TM</sup> C<sup>6</sup> Medical Laser System. It also provides information about eye protection, laser maintenance, the laser delivery handpieces and other accessories available for use with the system.

## Wavelength and Frequency

Light can be represented as a stream of particles, called photons, that travel at a constant speed through time and space. Light can also be characterized by its wavelength or frequency. Wavelength is the distance between the wave peaks of the propagating light wave. Medical laser wavelengths are often expressed in nanometers  $(0.000,000,001 \text{ or } 1 \times 10^{-9} \text{ meters})$ .

Light frequency denotes the number of wave peaks that pass through a point in one second. For green light the wavelength is approximately 500 nm and the frequency is 60,000,000,000,000 Hz.

Wavelength



Figure 1 Wavelength of Light

Each photon, depending upon the wavelength of the light, has a specific energy. Photons with short wavelengths have more energy than photons with a longer wavelength.

Figure 2 is a graph that shows the relative wavelengths for various colors of light. Compared to visible light, ultraviolet wavelengths are shorter and infrared wavelengths are longer. Conversely, on a similar scale showing frequency rather than wavelength, ultraviolet frequencies are higher and infrared frequencies are lower when compared to visible light.



Figure 2 The Light Spectrum

The frequency of light multiplied by its wavelength always equals the speed of light, a constant number  $(3 \times 10^8 \text{ meters per} \text{ second})$ . Therefore, doubling the light frequency reduces the wavelength by half. The Hoya ConBio Medlite C<sup>6</sup> Medical Laser System is a Q-switched Nd:YAG laser that uses a frequency doubling device to reduce the 1064 nm light wavelength by half, to 532 nm. This alone enables the laser to produce two wavelengths of light. To the human eye, 1064 nm is invisible and 532 nm appears as green light.

# *Multilite Dye Laser Handpieces (Optional Accessory)*

The Multilite<sup>TM</sup> Dye Laser Handpieces are complete solid-state dye laser systems that are pumped by the 532 nm laser light from the Medlite to generate either 585 nm (yellow) or 650 nm (red) laser light. These additional wavelengths greatly expand the indications for use for the Medlite C<sup>6</sup> Medical Laser System. All other medical dye laser systems incorporate liquid dye solutions whose solvents create disposal problems due to their toxicity. The Hoya ConBio Multilite Dye Laser Handpieces are a convenient and ecologically-friendly alternative.

## **Continuous Wave vs. Pulsed Delivery**

In addition to wavelength, lasers are referred to as continuous wave (CW) or pulsed. A CW laser delivers a steady stream of light that is measured as average power in watts or kilowatts. A pulsed laser delivers a very short but intense light emission followed by a period of no light.

If the laser is repetitively pulsed, the pulse repeats itself on a regular basis. The time between pulses is referred to as the interpulse period and the length of each pulse is called the pulse duration. The number of Hertz (Hz) represents the number of pulses emitted per second.

The length of the pulse duration is an important pulsed laser characteristic. Pulses lasting a few milliseconds ( $10^{-3}$  seconds) are generally characterized as long. Nanosecond ( $10^{-9}$  seconds) pulses are considered short. Q-Switched Nd:YAG laser pulses are typically 3-7 nsec in length.

A laser operating at 10 kHz produces 10,000 pulses per second. If the laser is activated for 0.1 second, it will produce a train of 1,000 pulses. This is referred to as operating the laser in a gated mode. See Figure 3.



Figure 3 Gated Mode of Pulsed Laser Energy

The units of measurement for CW lasers are watts of output power. A watt is a measure of the "flow of energy" or power. The sum of this energy over one second is expressed in Joules. One Joule is one watt of energy for one second. To clarify, a watt is a measure of the number of photons multiplied by their energy striking a target in one second. A Joule is a measure of the total energy of photons striking a target over a period of time.

Figure 4 is an illustration of a laser pulse. The shaded area represents all of the energy (Joules) contained in the pulse. At any point in time, the height of the pulse represents the instantaneous power and is measured in watts. For a pulsed Nd:YAG laser, the total energy inside the shaded area is .01 to 1.0 Joules. The instantaneous power at the pulse peak may be in excess of 200 Megawatts (MW).



Figure 4 Laser Pulse

The Medlite  $C^6$  Laser measures the pulsed laser energy of a single pulse rather than average power. To compute average power, the repetition rate is multiplied by the pulse energy. For example, 10 pulses per second with a pulse energy of 1.0 Joules would yield an average laser power of 10 watts.

The pulsed Nd:YAG laser has a much lower repetition rate when compared to KTP and copper vapor lasers, 1-10 Hz vs. 8-25 kilohertz (kHz). Slower pulsing enables more energy to be compressed into a single pulse and longer interpulse time. The pulsed Nd:YAG laser produces up to 1.0 Joule in a single pulse, while KTP or copper vapor, have much lower pulse energies (approximately 0.002 Joules). Their repetition rates may be 25 kilohertz for an average power of 10 watts. Short pulses with high peak powers and longer interpulse times have unique tissue effects that are needed to perform the applications outlined in section **8.** Physician Information on page **79**.

### Fluence

Fluence (energy density) indicates how much laser energy is compressed into the laser spot size. For the Q-switched Nd:YAG laser, it is computed by dividing the amount of energy in a single pulse by the cross sectional area of the spot generated by the focusing lens at the treatment surface. The unit of measure for fluence is typically expressed as Joules/cm<sup>2</sup>.

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#### 2. Safety

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## **General Laser Hazards and Precautions**

Lasers produce concentrated light energy. The energy is intense enough to seriously burn tissue and ignite materials. All personnel working with lasers should be aware of the potential hazards associated with their use and take the necessary precautions to prevent them. This section describes specific hazards and appropriate precautionary measures.



Improper use of the Medlite  $C^6$  Laser controls or performing procedures other than those specified in section **8.** Physician's Information in this manual may result in hazardous radiation exposure. Also, laser light presents a severe hazard for eye injury and a potential for burns or fire. Never view the laser beam directly or by reflection. Avoid exposure to the laser beam. Activate all of the necessary protective measures in areas where the laser beam is being used. Always use the appropriate laser protective eyewear when the laser is on.

## Eye Injury

Visible and near-infrared laser energy passes through the transparent parts of the eye (cornea, lens, aqueous and vitreous humor) and then focuses onto the retina. This concentrated light can cause an accidental retinal burn. The degree of retinal injury depends on the power of the beam, how focused the beam is, and how long the eye is exposed to the beam. Precautions against eye injury must include appropriate protective eyewear for the procedure room staff, and also for the patient.



The Medlite  $C^6$  Laser is capable of producing up to four (4) different wavelengths of light. When used with the standard MultiSpot<sup>TM</sup> Handpiece it can deliver 1064 nm and 532 nm. When used with the optional Multilite Dye Laser Handpiece it can deliver 585 nm and 650 nm. Hoya ConBio supplies specially designed laser protective eyewear for each wavelength. Always read the label on the eyewear to be sure that it is intended for the laser wavelength that you are about to use.

## Burns

Accidental irradiation of tissue other than the target tissue can result in a burn. Surrounding the target tissue with moist drapes or saline-soaked gauze will keep it moist and greatly reduce this hazard. Care and precision in aiming and applying laser energy is very important.

## Reflection of the Beam from Instruments

Take care, when aiming the laser beam, to prevent reflection of the beam off of metallic instruments or material. Reflected laser light from metallic surfaces is potentially harmful.

## Ignition of Flammable Materials

The laser can ignite many materials used during a medical procedure. Use non-flammable materials whenever possible.

#### Vapor and Smoke Plume

There is widespread concern about the biological plume created by electrosurgery, bone saws, and lasers. Current medical literature recommends that a smoke evacuator be used to capture this plume. The plume should be regarded as a source of active biologic material and a possible carcinogen.

#### Electrical

Electrical hazards associated with the laser are the same as with any high power electrical device. Take care when plugging the device into the wall outlet. The surrounding area must be free of water and your hands must be dry. Always disconnect the laser by grasping the plug and not the power cord. Examine the electrical cord routinely; if signs of wear are noted, contact the Hoya ConBio Service Department or your local distributor to have it replaced. The Medlite  $C^6$  laser is classified as "Class I Equipment".

## **Procedure Room Environment**

This section describes the necessary safety measures for the procedure room to aid in the safe operation of the laser system.

### Laser Warning Signs

Place clearly labeled warning signs on all of the entrances to the room where the laser is in use. The warning signs should specify the wavelength of the laser being used. During laser operation, do not allow any non-essential personnel in the treatment room. Figures 5, 6 and 7 are examples of wavelength-specific warning signs that are supplied with the Hoya ConBio Medlite  $C^6$  Laser.



Figure 5 Laser Warning Sign for 1,064 nm and 532 nm Laser Light



Figure 6 Laser Warning Sign for 585 nm Laser Light



Figure 7 Laser Warning Sign for 650 nm Laser Light

## Remote Door Interlock

To protect personnel who enter the laser treatment room while the laser is in use, an optional remote door interlock can be installed that connects the laser system to the procedure room entrance door. Once connected, this interlock automatically turns off the power to the Medlite  $C^6$  Laser when the door is opened while the laser is on. (A small plug disables the interlock connection if this safety feature is not utilized.)

Call the Hoya ConBio Service Department if you require further information about use of the door interlock.

## Safety Recommendations

The following are general safety recommendations for the procedure room.

Insure that all personnel and patients wear the laser protective eyewear that Hoya ConBio supplies with the Medlite  $C^6$  Laser.

Never look directly into the laser beam or its reflection. Permanent eye damage can occur. Remove all shiny reflective objects such as rings, watch bands and metallic objects from the treatment area.

Do not depress the foot switch without first verifying the location of the articulated arm and the attached handpiece to prevent unintended exposure.

Do not leave the laser unattended while it is in the Ready or Emission mode.

When the laser is not in use, rotate the keyswitch to Off, turn the circuit breaker off, remove the laser key and store the key in a secure location.

Do not allow untrained personnel to operate the laser system.

• Do not attempt to remove the protective covers from the laser cabinet. Only factory authorized service technicians or representatives should remove the protective covers.

Avoid the use of flammable anesthetics or oxidizing gases, such as nitrous oxide and oxygen, which may ignite during normal use of the laser. Allow cleaning and disinfecting solvents to evaporate before using the laser.

## **Guidelines for Eye Protection**

#### Introduction

The subject of laser eye protection has been widely researched by a variety of institutions, including the American National Standards Institute (ANSI) and the United States Occupational Safety and Health Administration (OSHA). The medical institution where the laser procedure is being performed is responsible for establishing a written policy about eye protection during laser use. In the United States, most experts follow the strong OSHA position to adhere to ANSI Standards. Outside the United States, a different standard is established by the Medical Directives of the European Economic Community and it is commonly used. Refer to ANSI Z136.1 and/or IEC 825 to develop your facility's laser policy.

This guide will address some common questions raised on the issue of laser eye protection. This information is designed to assist you as you tailor a policy to fit the needs of your institution, particularly as it relates to the use of the Medlite  $C^6$  Laser system.

#### **Common Questions about Eye Protection**

#### Q. What does the "O.D." label on the laser eyewear mean?

A. O.D. stands for optical density. It represents the capability of the eyewear to block laser light. (Specifically, the transmission is:  $T=10^{-OD}$ . For example, an O.D. of 1 means a 10% transmission.) O.D. specifications are specific to each laser because they take into account laser wavelength, power and pulse characteristics. More light is blocked when the O.D. is high. The O.D. marked on the eyewear provided with the Medlite C<sup>6</sup> Laser is sufficient to provide protection for the uses described in this manual.

#### Q. Why is laser eyewear tinted different colors?

A. The filters in laser protective eyewear are designed to block specific wavelengths of light; hence they are different colors. Some filters block a single wavelength, while others filter a range. The Medlite C<sup>6</sup> Laser is capable of producing up to four (4) different wavelengths of light. When used with the standard MultiSpot Handpiece it can deliver 1064 nm (infrared) and 532 nm (green) light. When used with the optional Multilite Dye Laser Handpiece it can deliver 585 nm (yellow) and 650 nm (red) light. Green, yellow and red light are visible and infrared light is invisible to human eyes. Laser protective eyewear must be used during visible *and* invisible wavelength use. Always read the label on the eyewear to be sure that it is intended for the laser wavelength that you are about to use.

## Q. Does my eyewear protect me if I can still see green, yellow, or red light during lasing?

A. The eyewear that Hoya ConBio supplies for each wavelength is designed to block out most of the visible light. Any reflected light that you may see around the edges of the eyewear is of such low intensity that it is safe to view – as long as its color matches the wavelength you are using. While the laser is pulsing, the low intensity reflected light may appear brighter to some people; this is simply because the nerves in the eye are stimulated as the laser pulses on and off.

## Q. Why do laser protective goggles fog and what can be done to prevent this from happening?

A. Many laser users experience fogging in their goggles. Despite manufacturing design efforts to alleviate this problem, body temperature, stress induced by the procedure, and cool room temperature, all contribute to the ideal conditions for condensation formation. Anti-fogging agents, such as those available in skiing stores, can help reduce the fogging. Apply them to the inside of the eyewear lenses before each case.

## Q. What are some appropriate ways to protect the patient's eyes during laser surgery?

**A.** Always include information about the requirements for eye protection in your patient education prior to the start of laser procedure. Below are some protective measures that you should follow, particularly if the patient is to be awake during the procedure.

When the treatment area is away from the face, patients can wear the same protective eyewear as staff use. Instruct patients to wear the protective eyewear throughout the entire treatment and to make sure it fits snugly so that it does not fall off.

When the treatment area is on the face or close to the patient's eyes, use a standard eyeshield with moist gauze taped over the eyes.

- When treating around the eyes, use special eye shields. There are two commercially available types.
  - An external eyeshield is made of metal and has adhesive strips. It should be placed so that it covers the entire eye.
  - An internal eyeshield, also made of metal, inserts under the eyelid so that it covers the eyeball. Prior to insertion, apply ophthalmic anesthetic ointment to the eye. Obviously, good aseptic technique also applies.

- Q. Where can I find more information about eye safety and protection?
- **A.** Current literature about laser applications is available in medical libraries. Here are some other laser safety resources.

ANSI Z136.1 (American National Standards Institute)

ANSI Z136.4 (American National Standards Institute)

IEC 825 (the European Norm (EN) standard for personal protection)

Laser Institute of America 12424 Research Parkway Suite 130, Orlando FL. 32826

Rockwell Laser Industries P.O. Box 43010 Cincinnati, OH 45243

## **Safety Regulations**

The United States Code of Federal Regulations (CFR title 21, Chapter 1, Sections 1040, 1.0, 1040, 1.1) and applicable International Electrotechnical Commission (IEC) and EN standards require that lasers have certain safety features. They further require that labels be affixed to each laser device identifying the manufacturer, the class or classes of radiation produced, and the location of the laser aperture on the unit.

## **Safety Features**

These safety features are found on all Hoya ConBio Medlite C<sup>6</sup> Laser systems.

An automatic circuit breaker that shuts the system completely off in the event of an electrical overload.

An interlock connection to connect to an optional procedure room door interlock system.

A laser key that can only be removed when the laser is turned off.

An internal microprocessor that continuously monitors the system status and displays messages on the control panel screen along with appropriate operator prompts.

An audible tone that sounds when the laser beam is activated by the footswitch.

A three second delay before laser energy can be emitted after the system status has been changed from Standby to Ready mode.

An Emergency Stop button on the top panel to shut the system down in the case of emergency. The system cannot be restarted as long as this button is depressed.



Do not attempt to remove any panel from the laser console. Any attempt to remove the panel(s), unless instructed by authorized Hoya ConBio personnel, will void the manufacturer's warranty.

# Compliance Information with Safety Standards and Classifications

Hoya ConBio's user information is in compliance with 21 CFR Chapter 1, Subchapter J concerning Radiological Health published by the FDA, Department of Health & Human Resources, Center for Devices and Radiological Health, and the Medical Device Directives of the IEC.

## **Device Labeling**

This section contains information about the labels found on the Medlite  $C^{6}$  Laser.



Figure 8 Locations of the Rear Laser Labels

#### **Product Identification Label**

This label (Figure 8-#1) provides the date of manufacturing, the serial number of the unit, input voltage, CE mark, symbol (Triangle) for "Attention, consult accompanying documents" and the symbol (Man) for "Type B Equipment".



#### **Manufacturer's Certification Label**

This label (Figure 8-#2) indicates that the device manufacturer is in the United States.

HOYA ConBio
47733 Fremont Blvd. Fremont, CA 94538 MADE IN U.S.A.
This laser product complies With 21 CFR Chapter 1, Subchapter J.
310-9090 REV E

### **Dangerous Radiation Label**

This label (Figure 8-#3) warns of visible and invisible radiation when an interior cover is removed and interlocks are defeated.



### **Explosion Hazard Warning Label**

This label (Figure 8-#4) warns that the danger of explosion exists when the laser is used in the presence of flammable anesthetics.



## **Restricted Sale Medical Device Label**

This label (Figure 8-#5) indicates that the device can only be sold to a medical facility, a physician or a physician's representative.



#### **Class 4 Laser Warning Label**

This label (Figure 8-#6) indicates that the device is a class 4 laser product. It also provides information about the laser wavelength and output.



## High Voltage Warning Label

This label (Figure 8-#7) warns of high electrical voltage and gives instructions to switch off the power supply and disconnect all plugs before servicing the unit.

CAUTION: HIGH VOLTAGE Before working on this unit, switch off power supply, disconnect all plugs.

## Laser Output Warning Label

This label (not shown) is located at the end of the articulated arm. It warns that laser radiation can exit from this location.



### **Emergency Stop Switch Label**

This label (not shown) is located on top of the laser console. It informs the user that this is the "Emergency Stop" switch.



## 3. Controls, Displays and Handpieces

3. Controls, Displays and Handpieces

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## **Overview**

The Medlite  $C^6$  Laser system provides laser energy for use in a variety of dermatological procedures. The standard pulsed 532 nm and 1064 nm wavelengths and optional pulsed 650 nm and 585 nm wavelengths are absorbed by pigment and other chromophores within the skin to create the desired clinical effect.

The entire laser unit and controls are contained in a single console. Electrical power is supplied to the console by the facility's power source. Laser energy produced within the device is delivered to the tissue by means of an articulated arm and the specially designed MultiSpot Handpiece (532 nm and 1064 nm) or optional Multilite Dye Laser Handpieces (650 nm and 585 nm). The user activates laser emission by means of a footswitch.

## **Console Controls and Connections**



Figure 9 Medlite C<sup>6</sup> Laser System Console
#### **Emergency Stop Button**

Push this button (Figure 9-#1) in case of emergency. As soon as this button is pushed, the laser will cease to function and will not operate as long as the button is depressed. Dashes will also appear on the control panel display.

To restart the laser, release the Emergency Stop button by rotating it clockwise in the direction of the arrows. Next turn the keyswitch position to Off and then to On.

## Keyswitch

The keyswitch (Figure 9-#2) has as two positions:

 $\stackrel{\bullet}{\bigcirc}$  Off and  $\stackrel{\bullet}{\bullet}$  On.

• Off indicates that electricity is running through the system, but the control panel is inactive and the laser is not operational.

• On indicates that the laser is powered and operational.

#### **High Voltage Indicator**

This indicator (Figure 9-#3) illuminates when the laser system is electrically powered and charged.

#### **Articulated Arm**

The articulated arm (Figure 9-#5) is fully adjustable to allow the user to guide the laser.

#### Water Coolant Reservoir Window

The coolant level is visible through the reservoir window (Figure 10-#1) on the rear of the laser. It should be monitored on a monthly basis. See **How to Maintain the Water Cooling System** on page **62** for detailed procedure instructions.

## Water Coolant Reservoir Fill Port

The Fill Port (Figure 10-#2) is also located on the rear of the laser. The coolant reservoir is replenished with deionized or distilled water via this port. Hoya ConBio supplies a bottle, hose and connector that are designed especially for use with the Fill Port. See **How to Maintain the Water Cooling System** on page **62** for detailed procedure instructions.



Figure 10 MedLite C<sup>6</sup> Rear Panel

## **Control Panel Controls and Displays**

The control panel (Figure 9-#4) is used to select and display the treatment parameters and status of the system while in operation. In addition, it may display error codes to indicate that a fault has occurred somewhere in the system. Figure 11 is a close-up illustration of the control panel.

#### **Ready/Standby Mode Softkey**

Repeatedly pressing this softkey (Figure 11-#1) toggles the laser status between the Standby and Ready mode. Laser emission is possible only when the system is in the Ready mode.

#### **Ready Mode Indicator**

This indicator (Figure 11-#2) illuminates only when the laser is in the Ready mode. During Ready mode, laser light will emit when the footswitch is depressed.

The Ready Mode Indicator flashes when the system is responding to a requested change and is temporarily not ready.

When this indicator is not illuminated, the laser is in the Standby mode. During Standby mode, laser light will not exit the console; even if the footswitch is depressed.

#### **Emission Indicator**

This indicator (Figure 11-#3) flashes and the laser beeps when the footpedal is depressed.



Figure 11 Medlite C<sup>6</sup> Control Panel

### **Repetition Rate Display**

This two-digit display (Figure 11-#4) shows the selected repetition rate, measured in pulses per second (Hz).

#### **Increase Repetition Rate Softkey**

Repeatedly pressing or continually depressing this softkey (Figure 11-#5) increases the repetition rate. The available repetition rates are as follows:

SS (single shot), 1, 2, 5, and 10 Hz for 1,064 nm and 532 nm.

1 Hz for 650 nm.

2 Hz for 585 nm.

### **Decrease Repetition Rate Softkey**

Repeatedly pressing or continually depressing this softkey (Figure 11-#6) decreases the repetition rate. The available repetition rates are the same as those mentioned above for the Increase Repetition Rate Softkey.

## **Fluence Display**

This three-digit display (Figure 11-#7) shows the fluence (energy density), in Joules/cm<sup>2</sup>, that will be delivered using the parameters the user has selected. Fluence is a measure of the concentration of laser energy. The microprocessor in the laser calculates it by dividing the energy per pulse by the treatment spot area.

**Note:** The system monitors laser power during treatment. The laser continues normal operation as long as the power does not change by more than 20%.

If the power changes by more than 20% during treatment, an **ER 98** or **ER 99** error code will appear on the display panel and the laser will shut down. See **Error Codes** on page **66** for more information.

### **Increase Fluence Softkey**

Repeatedly pressing or continuously depressing this softkey (Figure 11-#8) increases the fluence (energy density).

## **Decrease Fluence Softkey**

Repeatedly pressing or continuously depressing this softkey (Figure 11-#9) decreases the fluence (energy density).

## Wavelength Softkey for 585 nm / 650 nm

Repeatedly pressing this softkey (Figure 11-#10) selects the Multilite Dye Laser Handpiece for either 585 nm or 650 nm wavelengths.

## 585 nm Indicator

This indicator (Figure 11-#11) illuminates when the Multilite Dye Laser Handpiece is selected for 585 nm.

## 650 nm Indicator

This indicator (Figure 11-#12) illuminates when the Multilite Dye Laser Handpiece is selected for 650 nm.

## Wavelength Indicator for 532 nm

When illuminated, this indicator (Figure 11-#13) signals that the active wavelength is 532 nm when using the standard MultiSpot Handpiece.

## Wavelength Softkey for 532 nm

Pressing this softkey (Figure 11-#14) activates the 532 nm wavelength when using the standard MultiSpot Handpiece.

## Wavelength Indicator for 1064 nm

When illuminated, this indicator (Figure 11-#15) signals that the active wavelength is 1064 nm when using the standard MultiSpot Handpiece.

## Wavelength Softkey for 1064 nm

Pressing this softkey (Figure 11-#16) activates the 1064 nm when using the standard MultiSpot Handpiece Spot Size Indicators.

## **Spot Size Indicators**

One of these four indicators (Figure 11-#17) will illuminate, depending on which spot size has been selected.

- If the 1064 nm wavelength is selected, the spot size corresponds to the values in column labeled 1064.
- If the 532 nm wavelength is selected, the spot size corresponds to the values in the column labeled 532.



Mismatching the parameters in the display and handpiece will result in incorrect fluence delivery to the patient. Always verify that the handpiece and wavelength selected in this display matches the handpiece and desired wavelength for the laser treatment.

### **Increase Spot Size Softkey**

Repeatedly pressing or continually depressing this softkey (Figure 11-#18) increases the spot size.

## **Decrease Spot Size Softkey**

Repeatedly pressing or continually depressing this softkey (Figure 11-#19) decreases the spot size.

Pressing the Spot Size Softkeys (Figure 11-#18 or 11-#19) activates the corresponding spot size for the active wavelength.

- Available spot sizes for the 1064 nm wavelength, via the MultiSpot Handpiece, are 3 mm, 4 mm, 6 mm, and 8 mm.
- Available spot sizes for the 532 nm wavelength, via the MultiSpot Handpiece, are 2 mm, 3 mm, 4 mm, and 6 mm.

## Standard MultiSpot Handpiece

The MultiSpot Handpiece connects to the articulated arm on the Medlite  $C^6$  Laser System. It is designed to provide a range of focused treatment spot sizes that are specific to the Medlite  $C^6$  Laser wavelengths. (See Table 1 below)

**Note:** The instructions in this manual detail the care and use of the MultiSpot Handpiece. They are not recommendations for the medical or surgical application of this accessory. Any physician using this accessory should be thoroughly familiar with the procedures prior to using the instrument. This accessory is sold by Hoya ConBio for exclusive use with the Medlite  $C^6$  Laser.

Wavelength	Selectable Spot Sizes			
1064 nm	3 mm	4 mm	6 mm	8 mm
532 nm	2 mm	3 mm	4 mm	6 mm

Table 1 MultiSpot Spot Sizes for 1064 nm and 532 nm Wavelengths

#### MultiSpot Handpiece Components

The MultiSpot Handpiece is packaged as a kit. The kit contents are listed below and illustrated in Figure 12.

MultiSpot Handpiece Barrel Optical Assembly (Figure 12-#1)

MultiSpot Handpiece Protective Window (Figure 12-#2)

Metal Extension Cone and Focal Guide Tip (Figure 12-#3)

Clear Plastic Containment Cones (Figure 12-#4 and #5)

Instructions for care.



Figure 12 MultiSpot Handpiece Components

#### **MultiSpot Handpiece Barrel**

The optics that change the laser beam to the appropriate spot size are contained in the MultiSpot Handpiece barrel. The barrel has a rotatable collar for spot size selection. One end threads onto the laser articulated arm. The other end attaches to a containment cone.

## CAUTION

Do not soak or steam sterilize the MultiSpot Handpiece Barrel. Doing so will damage the internal optics.

#### **Clear Plastic Containment Cones**

The MultiSpot Handpiece kit has two types of clear plastic containment cones, cylindrical and tapered. Containment cones slide onto the handpiece barrel and ensure the appropriate focusing distance from the laser optics to the tissue target. These cones may be soaked in disinfection solution or steam autoclaved using a 25 minute cycle at  $250^{\circ}-253^{\circ}$  F ( $121^{\circ}-123^{\circ}$  C) – not to exceed  $275^{\circ}$  F ( $135^{\circ}$  C). See **How to Clean**, **Disinfect, and Sterilize the Handpieces** on page **60** for detailed instructions.

#### Metal Extension Cone with Focal Guide Tip

The MultiSpot Handpiece kit contains one metal extension cone and two focal guide tips. The focal guide tip threads onto the metal extension cone and must be used to ensure proper focal distance of the laser beam. The metal extension cone and focal guide tip may be soaked or steam sterilized. See **How to Clean**, **Disinfect, and Sterilize the Handpieces** on page **60** for detailed instructions.

#### **Protective Window**

The protective window screws onto the output end of the handpiece barrel to protect the optics inside the handpiece barrel. The protective window should be installed onto the handpiece barrel during the Transmission Measurement Procedure and patient treatments. Two protective semidisposable windows are included with the MultiSpot Handpiece.

Inspect and clean the Protective Window after each use. The Protective Window will also require periodic replacement. See **How to Clean or Replace the Protective Window on the MultiSpot Handpieces** on page **59** for detailed instructions.

## 4. Set-up and Operation

4. Set-up and Operation

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## System Setup

Check the water coolant level. See **How to Maintain the Water Cooling System** on page **62** for instructions.

## Connect the Electrical Power

Plug one end of the power cord into the socket at the rear of the laser (Figure 10-#4 on page 32) and the other end into an appropriate voltage wall power outlet.

If using an optional door interlock system, verify that it is connected properly to the laser. Otherwise, ensure that the small plastic interlock plug is inserted into the interlock connector (Figure 10-#5 on page 32).

Ensure that the red Emergency Stop button located on top of the laser is not depressed. To release it, rotate the button clockwise.

## Connect the Footswitch

Connect the cable for the footswitch to the footswitch connector (Figure 10-#7 on page 32) located on the rear of the console.

## Connect the Handpiece to the Articulated Arm

- Free the articulated arm from its storage position. Release the clasp that secures the arm to the laser cabinet by pulling outward and rotating approximately one-quarter turn. Carefully remove the arm from the clasp.
- Next, release the arm from the fold down clamp located on the long tube of the articulated arm. Then, remove the red dust plug from the end of the articulated arm.

- Install either the standard MultiSpot Handpiece or one of the optional Multilite Dye Laser Handpieces.
  - Check to see that the Protective Window on the output end of the Handpiece Barrel is clean. If it is not clean, either clean or replace it. See How to Clean or Replace the Protective Window on the MultiSpot Handpieces on page 59 for instructions.
  - Thread the Handpiece Barrel onto the articulated arm until it is finger tight.
- Adjust the counter-weight at the rear of the articulated arm so that it counter-balances the articulated arm when you gently release it with a handpiece attached. It should not rise toward the ceiling or fall toward the floor.

## Start-up and Operation

Turn on the circuit breaker (Figure 10-#3 on page 32) located on the rear of the console from O (Off) to I (On).

The current system software revision number will display momentarily.

**Note:** Watch for all of the control panel illuminators to illuminate to insure that they are functioning properly.

Depending on how long the laser has been plugged in with the circuit breaker on, the display will count up from 0 to a maximum of 20:00 minutes while the laser warms. During countdown, elapsed minutes will appear in the Repetition Rate Display and elapsed seconds will appear in the Fluence Display.

• Once the laser is sufficiently warmed, the display will count down to 0:00 from 3 minutes. Remaining minutes will appear in the Repetition Rate Display and remaining seconds will appear in the Fluence Display.

**Note:** If the laser is sufficiently warm, you may not see the display count up. Only the 3-minute count down may appear.

**OFF** will appear on the display panel when the system warm-up is complete.

Rotate the keyswitch position to  $\bigcirc$  On.

An automatic self-test will automatically begin. (See the Automatic Self-Test information below.)

# If "CK KEY" Appears After System Warm-up

If the laser was left with the key in the • On position after a prior improper shutdown or power outage, the **CK KEY** message will appear on the Repetition Rate and Fluence Displays. The message means "Check Key" and it is instructing you to rotate the key counterclockwise to the Off position.

Rotate the key to the  $\bigcirc$  Off position. **OFF** will appear in the Fluence Display.

Now rotate the key to the • On position. The automatic self-test will begin. (See Automatic Self-Test below.)

## **Automatic Self-Test**

Table 2 shows the sequence of messages that will appear in the Repetition Rate and Fluence Displays during the automatic self-test.

Repetition Rate Display	Fluence Display	Meaning
SH	CNT	Current flashlamp shot count
##	###	Shot count in thousands. (Resets after 99,999)
TR	100	Transmission setting
СК	ING	Checking internal mechanisms, such as coolant pump, laser shutters, and various motor drives.
#	SEC	A five second countdown is displayed, and a High Voltage Indicator will illuminate.
SV	МЕМ	Save Memory. Diagnostic self-test is complete and satisfactory. Certain laser parameters will be stored in the microprocessor memory.
#	: ##	A two minute countdown is displayed for laser warm up.
ON	STB	On Standby. The laser is now in standby mode.

Table 2. Self-test Message Sequence

• Once the **ON STB** message appears in the display, you may press the Ready softkey to activate the Ready mode.

## Activate the Ready Mode

• Ensure that all of the laser safety precautions are satisfied. (See section 2. Safety on page 9 in this manual.)



Laser emission is possible when the laser is in the Ready mode. The patient and all personnel should have appropriate laser protective eyewear on when the laser is in the Ready mode.

Press the Ready/Standby Softkey to change the system from the Standby to Ready mode.

The laser can now be activated using the footswitch.

**Note:** If the laser is inactive (No FTSW) for 15 minutes, the laser will go into stand by mode and will continue to flash.

## Finish Assembling the Handpiece

- If using the MultiSpot Handpiece (532 nm or 1064 nm settings)
  - Select the desired cone (either the Plastic Containment Cone or the Metal Extension Cone) and attach it to the Handpiece Barrel by pushing it fully on with a slight twisting motion. The cone should fit snuggly.
    - If using a metal cone, be sure that the stainless steel tip is securely threaded onto the screw on the cone.
    - Set the spot size by pushing the outer sleeve of the barrel toward the output end of the MultiSpot Handpiece and rotate it until the notch aligns with the desired spot size indicator (see Figure 12 on page 40). This is the spot size that you will later select on the control panel (see Figure 11-#18 or Fig-#19 on page 34).

# Enter the Desired Treatment Parameters on the Control Panel

## Select Wavelength

- Press one of the Wavelength Softkeys that corresponds to the selected handpiece. Verify that the correct wavelength indicator is illuminated on the control panel.
  - If you have the MultiSpot Handpiece attached to the articulated arm, you can select either the 532 nm or the 1064 nm wavelength.

## **Select Spot Size**

• Check to see that the MultiSpot Handpiece is set to the desired spot size when either the 532 nm or 1064 nm wavelength is selected.

Press and hold the increase ( $\land$ ) or decrease ( $\lor$ ) soft key (Figures 11-#18 or 11-#19 on page 34) until the desired spot size is selected. Verify that the correct spot size indicator illuminates.

- If the MultiSpot Handpiece is attached to the articulated arm and you have selected the 532 nm wavelength on the control panel, you may select from the spot sizes listed in the 532 column (2 mm, 3 mm, 4 mm or 6 mm).
- If the MultiSpot Handpiece is attached to the articulated arm and you have selected the 1064 nm wavelength on the control panel, you may select from the spot sizes listed in the 1064 column (3 mm, 4 mm, 6 mm or 8 mm).

## Select Repetition Rate

 Press and hold the increase ( ^ ) or decrease ( ~ ) soft key (Figure 11-#5 or 11-#6 on page 34) until the desired repetition rate appears in the Repetition Rate Display. The repetition rate unit of measure is Hz.  For the standard MultiSpot Handpiece, available repetition rates are SS (Single Shot), 1, 2, 5, and 10 Hz (pulses per second) for the 1064 nm and 532 nm wavelengths.

### **Select Fluence**

Press and hold the increase ( $\land$ ) or decrease ( $\lor$ ) soft key (Figure 11-#8 or 11-#9 on page 34) until the desired fluence appears in the Fluence Display. The energy density (fluence) unit of measure is J/cm<sup>2</sup>.

**Note:** Wavelength and spot size may be adjusted when the laser is in the Standby mode or the Ready mode. Repetition Rate and Fluence may only be adjusted when the laser is in the Ready mode.

**Note:** Each time the laser is placed in Standby mode, the system will remember the last selected fluence for the selected wavelength. If a wavelength is selected that has not been used since the last Key On/Key Off sequence, the system will revert to the minimum fluence level for the selected wavelength. When the Ready mode is reactivated, the fluence level will be remembered if the wavelength selected had been used since the last Key On/Key Off sequence. The wavelength, repetition rate and spot size settings will remain unchanged.

## **Laser Emission**

• Position the handpiece over the treatment area and depress the foot switch to begin treatment.

**Note:** Position the handpiece perpendicular to the tissue target with the tissue target so that the tip of the plastic containment cone or Focal Guide tip just touches the tissue surface. This ensures proper spot size and uniform energy distribution. The Protective Window and internal handpiece optics must also remain undamaged and free of debris throughout the procedure.

- When the selected repetition rate is **SS** (single shot), fully depressing the footswitch will activate one laser pulse at the selected settings. Another pulse can be delivered when the footswitch is released and depressed again.
- When the selected repetition rate is **1**, **2**, **5**, **or 10 Hz** (pulses per second), fully depress and hold down the footswitch to deliver a continuous sequence of laser pulses at the selected repetition rate. Release the footswitch to stop the pulse delivery.

**Note:** Depressing the footswitch during the system self-test at the time of start-up or while pressing the softkey to change the Standby or Ready mode status will cause the laser to emit a 5-second tone. If the footswitch is not released during the tone, the laser will turn itself off and display the **ER 90** error code on the front panel.

To restart the laser, release the footswitch and rotate the keyswitch to Off. Rotate the keyswitch back to On. The error should have cleared itself. See the **Error Codes** on page **66** for additional information.

**Note:** The system monitors laser power delivered to the articulated arm during treatment and continually updates the Fluence Display. If the fluence delivered to the arm changes by more than 20% during treatment, the laser will display either the **ER 98** or **ER 99** error code on the front panel and turn itself off. See **Error Codes** on page **66** for more information.

To restart the laser, rotate the keyswitch to Off and then rotate the keyswitch back to On. The error should have cleared itself.

## Changing Treatment Parameters Mid-Treatment

You can use the appropriate softkeys to adjust the treatment parameters during the treatment session. The laser may remain in the Ready mode when the adjustment is made. The Ready Indicator LED will flash to indicate that the system is adjusting after changes are made to the wavelength, spot size, and fluence level. When the Ready Indicator LED stops flashing, the system will be ready for use. Changes to the repetition rate will impose no system delays.

## **Turning the System Off**

Press the Standby/Ready Softkey to place the laser in Standby mode. The laser will continue to flash in the stand-by mode.

The **SV MEM** message will briefly appear in the Fluence and Spot Size displays. This is an abbreviation for "save memory" and means that certain laser parameters are being stored in the microprocessor.

Next, the **ON STB** message will appear to indicate that the laser is now in the Standby mode.

**Note:** Prematurely turning the system off from the Ready mode by using the keyswitch, Emergency Off Button, or circuit breaker on the rear panel, may cause all treatment data stored in the microprocessor to be lost.

Now, turn the keyswitch to the  $\bigcirc$  Off position. **OFF** will appear in the display.

To turn the laser completely off, turn the circuit breaker off (located on the rear of the console).

## **Emergency Shut-off**

Figure 9-#1 on page 30 shows the location of the prominent red Emergency Off button on the console. Depress this button at anytime to immediately stop emission of the laser treatment beam. Pressing the Emergency Off Button disables the entire laser system.

To reestablish laser emission, rotate the keyswitch to the  $\bigcirc$  Off position and release the Emergency Off Button. Then rotate the keyswitch to the  $\bigcirc$  On position again.

## System Disassembly and Storage

## **Disassemble the Handpiece**

Unthread the handpiece from the laser articulated arm.

Remove the components from the handpiece barrel. Depending on the handpiece, pull off the extension cone or Focus Guide. Unscrew the Protective Window from the Handpiece Barrel.

Inspect, clean, and disinfect or sterilize the handpiece components. See **How to Clean, Disinfect, and Sterilize the Handpieces** on page **60** and **How to Clean or Replace the Protective Window on the MultiSpot Handpieces** on page **59** for detailed instructions.

## Fold and Store the Articulated Arm

Reverse the procedure that you used to release the arm from its storage position.

## 5. Routine Maintenance and Error Codes

5. Routine Maintenance and Error Codes

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## **Routine Maintenance Procedures**

This section contains a routine maintenance schedule for the Medlite  $C^6$  Medical Laser System and instructions for maintenance procedures. Following these recommendations will help to ensure that the Medlite  $C^6$  Laser performs reliably for 7 to 10 years.

## Service Assistance

For Hoya ConBio technical service assistance in the United States, call **800-524-5571**. Outside the U.S., please contact your local Hoya ConBio distributor.

## How to Clean the Laser Console

Wipe the cabinet clean using a general purpose cleaner and then dry it, on a weekly basis. Clean the display panel after each use. Do not allow cleaner to drip into the console.

## How to Protect the Articulated Arm

Place the red dust plug on the end of the articulated arm when no handpiece is attached.

## How to Disassemble and Clean the Handpiece

These instructions apply to the standard MultiSpot Handpiece. See **Figure 12** on page **40** for a diagram of the MultiSpot Handpiece components.

• Remove the handpiece barrel from the laser articulated arm by unthreading it. Place the red dust plug over the end of the articulated arm to prevent dust from entering the arm and damaging the optics.

- Remove all attachments from the Handpiece Barrel by pulling with a slight twisting motion.
  - If using the MultiSpot Handpiece, remove the plastic or metal containment cone. Unscrew the stainless steel tip from the metal cone.
- Wipe all of the disassembled components with damp cloth. Be sure to remove all debris and take care to not let water enter the optical assembly of the Handpiece Barrel.
- Dry the pieces thoroughly with a soft cloth. The cone portion of the handpiece can be disinfected or sterilized according to the instructions in **How to Clean**, **Disinfect**, **and Sterilize the Handpieces** on page **60**.
  - Note: Do not attempt to soak or autoclave the optical Handpiece Barrel or Protective Window. You may clean the Protective Window. The instructions are below.

## *How to Clean or Replace the Protective Window on the MultiSpot Handpieces*

The Protective Window is an optical device. By nature, it will become damaged while the laser is used and laser plume contaminates the optic – but it protects the more expensive laser optics inside the barrel of the handpiece. Once damaged, the Protective Window must be replaced. However, inspection and cleaning after every procedure will prolong its useful life.

- Remove the Containment Cone from the handpiece barrel.
- Unscrew the metal ring that contains the Protective Window from the handpiece.
- Use a lens tissue or clean cotton swab, moistened with methanol or isopropyl alcohol, to wipe the debris and dust from the Protective Window. Take care to not leave debris from the cotton swab behind on the window.

- Dispose of the cotton swab in an appropriate manner.
- Replace the Protective Window if there is any debris that cannot be removed or apparent damage.
- Dispose of the window in an appropriate manner.

## CAUTION

Not cleaning or improperly cleaning the protective window will damage its coating. This can cause a reflection of laser light back into the articulated arm and damage the arm mirrors. Do not use a damaged or dirty Protective Window.

## *How to Clean, Disinfect, and Sterilize the Handpieces*

The various materials that are manufactured into each of the handpiece components largely dictate how they must be cared for. The handpiece barrel contains optics with delicate optical coatings, so it can never be soaked or steam sterilized.

Table 3 summarizes the care limitations for each of the disassembled components.

Table 3. Care Summary for the MultiSpot Dye Laser Handpiece Components

Component	Wipe Clean	Disinfectant Soaking Permissible	Steam Sterilization Permissible
MultiSpot Handpiece Barrel and Protective Window	Yes	No	No
Clear Plastic Containment Cones	Yes	Yes	Yes
Metal Extension Cone and Focal Guide Tip	Yes	Yes	Yes

#### How to Perform High-level Disinfection

High-level disinfection is defined as selective destruction of disease-producing organisms.

Wash the item thoroughly in soap and water. Be sure to remove all visible debris.

Soak the item in an enzymatic detergent (such as Enzol) according to the manufacturer's instructions.

Soak the item in disinfectant solution of Glutaraldehyde (such as Cidex) according to the manufacturer's instructions.

Dry the item thoroughly with a clean dry cloth and store in a clean container until the next use.

#### How to Perform Sterilization

Sterilization is defined as destruction of all microorganisms and inactivation of all viruses.

- Wash the item thoroughly in soap and water. Be sure to remove all debris.
- Steam sterilize the item in an autoclave device for a 25 minute cycle at 250°-253° F (121°-123° C) not to exceed 275° F (135° C). This recommendation follows the AAMI guidelines.
- Dry the item thoroughly with a clean dry cloth and store in a clean container until the next use.

## How To Dispose of Handpiece Components

For infection control reasons, either disinfect handpiece components and then discard them normally or label the contaminated handpiece components as biohazardous material and dispose of according to your institutional policies and procedures.

## How to Maintain the Water Cooling System

## Check the Coolant Level Every Month

Figure 10-#1 on page 32 shows the location of the clear window to the coolant reservoir in the rear of the Medlite  $C^6$  Laser. The reservoir water level should remain between the bottom and the top notches. When the water reservoir level is below the lower notch, follow the procedure below to replenish.

## **Replenish the Water Reservoir As Needed**

Replenish the water coolant reservoir when the water level reaches below the lower notch.

Use the water bottle with hose and adapter that Hoya ConBio supplied with the laser for this procedure.

Only use deionized or distilled water to fill the system. Failure to use deionized or distilled water may result in equipment failure and invalidate the warranty. **Never** fill the cooling system with any concentration of ethylene glycol (also known as anti-freeze).

Insert the adapter on the end of the water bottle hose directly into the connection port at the location shown in Figure 10-#2 on page 32.

Fill the coolant reservoir until the level reaches approximately three-quarters full.

Release the quick-disconnect to remove the hose adapter from the refill port. The port seals automatically.

## CAUTION

Never subject the Medlite  $C^6$  Medical Laser System to temperatures below the freezing point of water, unless the water in the cooling system is completely drained. Doing otherwise, will cause extensive damage and will void the warranty.

## **Field-Service Maintenance Schedule**

Table 4 outlines the recommended actions that should be routinely performed by a factory authorized service representative. You can reach the Hoya ConBio Service Department at **800-524-5571**.

Maintenance Action	Suggested Interval
Mirror/Optic Cleaning and Inspection	Every 3 months for heavy usage*.
	Every 6 months for light usage.
Replacement of Water Filter	Once a year, unless there is contamination.
System Alignment	Every 3 months for heavy usage*.
	Every 6 months for light usage.
Inspect/clean air intake at heat exchanged	Every 12 months
Inspect/clean air intake on High Voltage Power supply	Every 12 months
Check flashlamp shot count	Every 12 months, recommend replacement of flashlamps at 50 million shots.

Table 4. Service-Performed Routine Maintenance Schedule

\*20 or more hours of laser operation per week is considered heavy usage.

## Troubleshooting Table

Problem	Meaning and Action		
An error code appears in the console display.	See <b>Error Codes</b> on page <b>66</b> and take the recommended corrective action.		
Laser suddenly stops and the display is blank.	Check the circuit breaker. If a power surge has caused it to trip, reset it by switching it to the On position.		
	Check the A/C connections to the laser and wall.		
Laser suddenly stops and dashes appear across the display.	The red Emergency Off Button was probably pressed. See <b>Emergency Shut-off</b> on page <b>54</b> for detailed information.		
No response when the keyswitch is rotated from Off to On.	Check the A/C connections to the laser and wall.		
	Check to see that the circuit breaker on the rear of the laser is switched On.		
	See <b>Start-up and Operation</b> on page <b>46</b> for detailed information.		
System warm-up seems abnormally long.	When power to the laser has been completely off, (i.e., circuit breaker switched Off or wall A/C disconnected) the laser will go through a complete 2-stage warm-up. See <b>Start-up and</b> <b>Operation</b> on page <b>46</b> for detailed information.		
System warm-up seems abnormally short.	If the keyswitch was Off with the laser plugged into the wall A/C and the circuit breaker On, the system remained warm. Warm- up would be shortened.		
	See Start-up and Operation on page 46 for detailed information.		

Problem	Meaning and Action		
<b>CK KEY</b> appears after system warm-up.	Rotate keyswitch from On to Off and back to On. This resets the laser status to ON STB which is the standby mode. See If "CK KEY" Appears After System Warm-up on page 47 for detailed information.		
No response when the footswitch is depressed.	Check footswitch connection.		
	Be sure laser is in Ready mode.		
Tissue response not consistent with fluence level.	1. Spot size selected on the control panel is different than the spot size selected on the handpiece. Verify that they are the same.		
	2. The protective output window on the handpiece may be contaminated, thereby reducing the energy delivered to the patient.		
	<ol> <li>The handpiece may be contaminated or damaged, thereby reducing the energy delivered to the patient.</li> </ol>		
	4. There may be damage to the mirrors in the articulated arm, which will reduce the energy delivered to the handpiece and therefore the patient. If conditions 1 or 2 appear to be okay, you may need to call Hoya ConBio Service for assistance (800-524-5571).		

## **Error Codes**

Error codes appear on the front panel display and indicate a specific system fault. They appear as the letters **ER** in the Energy Density Display followed by a number in the Repetition Rate Display. Table 5 lists the error codes with possible solutions for the problem.

**Note:** Call a factory authorized service representative to correct all error codes not shown in this table and when the possible remedies fail to correct the problem. (In the U.S., call **800-524-5571**.)

## *How To Reset the Laser After an Error Code Appears*

First correct the problem that caused the error code. Then, rotate the keyswitch to Off. Wait a few seconds, and then rotate the keyswitch to On again. The error code should be cleared.

Error Code	Problem	Possible Remedy
ER 11	Laser head temperature high	Leave the laser in Error Mode for a few minutes, allowing the coolant to circulate and cool down.
		Ensure that treatment room environment is within specifications.
		Check that the air intake vents are unobstructed.
		Check the coolant level. Replenish if level is less than half. See <b>How</b> <b>to Maintain the Water Cooling</b> <b>System</b> on page <b>62</b> for detailed instructions.
ER 13	External interlock	Check that the remote interlock plug is inserted and seated properly.
		Check interlocked room door.

Table 5	User Correct	table Medlite	$C^{6}$	Medical I	aser	System	Error
Codes							
Error	Problem	Possible Remedy					
-------	--	---					
Code							
		Adjust switch sensitivity as needed.					
		Check/replace defective switch.					
ER 22	Charge problem	Ensure that the laser is on a dedicated circuit with voltage and amperage within specification requirements.					
ER 32	Coolant flow interrupted	If water is leaking on the floor or surrounding area, STOP laser operation, turn OFF circuit breaker, and call service.					
		Check the coolant level. Replenish if level is less than half. See <b>How</b> <b>to Maintain the Water Cooling</b> <b>System</b> on page <b>62</b> .					
ER 61	Keypad problem	Release the pressed keypad.					
ER 74	Crystal warming failed	Ensure that the treatment room environment is within specifications.					
ER 82	Temperature too high	Leave laser in Error Mode for a few minutes to allow the high voltage power supply air circulation fans to cool the power supply.					
		Check that the air intake vents are not obstructed.					
		Ensure that treatment room environment is within specifications.					
ER 90	Footswitch depressed at inappropriate time	Release the footswitch					
ER 98	Energy low by 20% or more	If you get this error frequently (several times per power ON session or treatment), call service.					
ER 99	Energy high by 20% or more	If you get this error frequently (several times per power ON session or treatment), call service.					

6. System Specifications

# 6. System Specifications

### 6. System Specifications

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### Laser Parameters with Standard MultiSpot Handpiece

Nd:YAG
Q-Switched
532 nm: 400 mJ ±20% 1064 nm: 1.0 Joule ±20%
532 nm: 5 J/cm <sup>2</sup> @ 2 mm spot size
1064 nm: 12 J/cm <sup>2</sup> @ 3 mm spot size
<7ns at Max Energy - <20ns at Min Energy
1 Hz, 2 Hz, 5 Hz, 10 Hz and Single Shot
2 mm, 3 mm, 4 mm, and 6 mm
3 mm, 4 mm, 6 mm, and 8 mm
1064: 0.4 mrad, 532: 0.3 mrad
1064: 0.2 mrad, 532: 0.15 mrad

### Laser Parameters with Optional Multilite Dye Laser Handpiece

Laser Medium	Dye	
Operating Parameters	Q-Switched	
Nominal Delivered Energy	585 nm: 250 mJ ±20% 650 nm: 150 mJ ±20%	
Nominal Fluence	585 nm: 8 J/cm <sup>2</sup> @ 2 mm spot size 585 nm: 3.5 J/cm <sup>2</sup> @ 3 mm spot size	
	650 nm: $4.5 \text{ J/cm}^2$ @ 2 mm spot size 650 nm: 2 J/cm <sup>2</sup> 3 mm spot size	
Pulse Width	<7 ns	
585 nm Repetition Rate 650 nm Repetition Rate	SS (Single Shot) and 2 Hz SS (Single Shot) and 1 Hz	
Spot Sizes	2 mm and 3 mm for both 585 nm and 650 nm $$	
Maximum Divergence	585: 25 mrad, 650: 30 mrad	
Minimum Divergence	585: 13 mrad, 650: 15 mrad	
Dye Lifetime	Over 20,000 pulses @ 585 nm at full energy Over 10,000 pulses @ 650 nm at full energy	

Physical Parameters	
Classification (EMC)	Class 2 medical device
Electrical Shock	Type of Protection: Class I
	Degree of Protection: Type B
Mode of Operation	Continuous operation
Cooling	Closed cycle water-to-air heat exchanger
Electrical Power	115V, single phase 15 amp
	230V, single phase, 8 amp
System Weight	127 lb/57.6 kg
System Height without Articulated Arm	31.8 in/81 cm
System Height with Articulated Arm	44.5 in/113 cm
System Width	12 in/30.5 cm
System Depth	28.5 in/72.5 cm
Optical Delivery to Tissue	Articulated Arm with Handpiece

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# 7. Warranty Policy

7. Warranty Policy

### **Warranty Information**

Hoya ConBio warrants its products against defects in materials and workmanship for the periods specified. When installation is included in the purchase price, the warranty period begins on the date of installation. When installation is not included in the purchase price, the warranty period begins on the date of shipment. Every Hoya ConBio product is assigned a warranty code which defines the duration and extent of the warranty provided for the particular product. (See Table 6 later in this section.)

If Hoya ConBio receives notice of such defects during the warranty period, Hoya ConBio shall, at its option either repair or replace the equipment or components that prove to be defective. Hoya ConBio will opt to replace equipment or components, covered under the Warranty Policy, with refurbished or new equipment.

Hoya ConBio will decide whether to perform service on warranted equipment either on-site or at a Hoya ConBio facility. On-site warranty services will be performed at no charge. When warranty services are provided at Hoya ConBio, products must be returned to a service facility designated by Hoya ConBio. Products may only be returned with prior approval of Hoya ConBio. Such approval must be evidenced by a valid Return Material Authorization (RMA) number issued by Hoya ConBio headquarter personnel. The buyer shall pre-pay shipping charges (and shall pay all duties and taxes) for products returned to Hoya ConBio. Hoya ConBio shall pay for the return of products to the buyer. When warranty work is provided at the buyer's facility, such work shall be provided during normal business hours. If the buyer requests the work to be performed outside of normal business hours, then the buyer shall pay reasonable charges for the incremental cost of such work. The buyer agrees to make the equipment available to Hoya ConBio during normal business hours.

### **Limitation of Warranty**

The warranty shall be voided where, in Hoya ConBio's judgment, there has been:

- Improper or inadequate maintenance by the buyer.
- Unauthorized modification or misuse.
- Device operation outside of the product's environmental specification.
- Improper site preparation and maintenance, including, but not limited to improper electrical utilities.
- Use of delivery devices or accessories not manufactured by Hoya ConBio or approved for use with Hoya ConBio products.
- Mobile use of the product beyond that which occurs within the same building from room to room.

### Notice

The warranty set forth above is exclusive and no other warranty, whether written or oral, is expressed or implied. Hoya ConBio specifically disclaims the implied warranties or merchantability and fitness for a particular purpose.

The remedies provided herein are the buyer's sole and exclusive remedies. In no event shall Hoya ConBio be liable for direct, indirect, special, incidental, or consequential damages including loss of profits whether based on contract, tort, or any other legal theory.

### **Product Warranties**

Table 6 summarizes the product warranties and the Medlite  $C^6$  Medical Laser System products to which they apply.

Code A		Code B	Code C	
12 Months		90 Days	30 Days	
	Parts and Labor	Parts Only		
•	Medlite C <sup>6</sup> Medical Laser System	MultiSpot Handpiece (excluding Protective	Handpiece Protective     Windows	
•	Articulated Arm	<ul> <li>Multilite Dye Laser</li> <li>Handpiece (excluding Protective Window)</li> </ul>	<ul><li>Accessories</li><li>Eyewear</li></ul>	

### Table 6 Warranty Codes for Hoya ConBio Products

### **Product Returns**

In the United States, all returns are handled by the Hoya ConBio Customer Service Department. Someone is available to assist you at **800-524-5571** every Monday through Friday; 6 am to 5 pm Pacific Standard Time. Outside the United States, please contact your local Hoya ConBio distributor.

7. Warranty Policy

# 8. Physician Information

### 8. Physician Information

### Introduction

This section provides clinical application information for the use of the Hoya ConBio Medlite  $C^6$  Medical Laser System and standard MultiSpot Handpiece or optional Multilite Dye Laser Handpiece. Included are procedural recommendations and specific indications and contraindications. This information is not intended to be all-inclusive and does not replace physician training or experience.

Only physicians and staff who have been appropriately trained and who are thoroughly familiar with the instructions and safety precautions provided in this manual should use the Medlite  $C^6$  Medical Laser System. A review of the published literature is strongly recommended.

### Training

The Medlite  $C^6$  Medical Laser System is intended for use by physicians who are trained in the safe handling and use of the laser. Physicians should consider the training avenues listed below.

Accredited training courses within the physician's specialty.

"Hands-on" training under the preceptorship of a qualified user.

Specialty-specific courses presented during specialty academy or college meetings.

Nurses and other allied health professionals handling lasers may also complete a laser training program that may include topics such as, basic laser physics, potential hazards and laser safety precautions, laser-tissue interaction, laser set-up procedures, laser operating procedures, and hands-on experience.

On-site in-service training, pertaining to system operation, will be provided by Hoya ConBio or an authorized Hoya ConBio distributor at a mutually convenient time after installation. Hoya ConBio suggests that, in addition to providing laser safety training for all operating room or clinic personnel, the user/institution should adopt a training and safety program as outlined in the latest revision of the ANSI Z136.3 standard, the <u>American National Standard for the Safe Use of Lasers in</u> <u>Health Care Facilities</u>.

### **Clinical Application Information**

Clinical information described here is presented only as a reference and is based on clinical experience with the device and other laser devices reported in the public literature.

### Indications

The Medlite  $C^6$  Medical Laser System is a Q-Switched Nd:YAG laser with a frequency doubler. The fundamental wavelength is infrared at 1064 nm. The second harmonic is green at 532 nm. This laser system has been researched and used extensively. Table 7 summarizes appropriate indications, wavelengths, and fluence levels.

Indication	Wavelength	Fluence Level
Tattoo removal (dark ink: blue and black)	1064 nm	2-12 J/cm <sup>2</sup>
Tattoo removal (light ink: red)	532 nm	2-5 J/cm <sup>2</sup>
Tattoo removal (light ink: sky blue)	585 nm	2-5 J/cm <sup>2</sup>
Tattoo removal (light ink: green)	650 nm	2-5 J/cm <sup>2</sup>
Nevus of Ota removal	1064 nm	2-12 J/cm <sup>2</sup>
Hair removal	1064 nm	2-6 J/cm <sup>2</sup>
Vascular lesions	532/585 nm	1-5 J/cm <sup>2</sup>
port wine birthmarks		
telangiectasias		
spider angioma		
cherry angioma		
spider nevi		
Epidermal Pigmented lesions	532/650 nm	0.7-5.0 J/cm <sup>2</sup>
cafe-au-lait birthmarks		
solar lentiginos		
senile lentiginos		
Becker's nevi		
Freckles		
nevus spilus.		

Table 7. Medlite  $C^6$  Clinical Application, Fluence and Wavelength Recommendations

### Contraindications

The laser system should only be used in conditions where its use is appropriate and of proven efficacy. Clinical applications should be performed by a qualified physician. The use of the laser is contraindicated for patients who present with the following conditions.

**Prior treatment with parenteral gold therapy** (gold sodium thiomalate). If subsequently treated with the Medlite  $C^{\delta}$  Medical Laser System, these patients may develop localized chrysiasis. Chrysiasis is a rare blue-gray or blue-green skin discoloration that occurs in sun-exposed sites of some patients who are on gold therapy. The skin discoloration can persist long-term and be very traumatic to the patient. Gold salts are prescribed for some patients with rheumatoid or other arthritic conditions.

Laser therapy is not considered the treatment of choice for the indication.

General medical condition that contraindicates medical intervention.

### Warnings

All persons present during the operation of the Medlite  $C^6$ Medical Laser System must wear the laser safety eyewear provided with the system by Hoya ConBio. Patient eye protective measures must also be instituted, depending on where the laser treatment will be applied. See page 15 in section 2. Safety for further information.

### Precautions

Always begin treatment by using the lowest possible energy level. If more tissue effect is desired, increase the energy level in small increments until the desired tissue effect is observed.

### **Complications and Adverse Effects**

These complications and adverse effects can occur. They were observed inless than 5% of patients studied during the Medlite  $C^6$  Medical Laser System clinical trials.

Scarring, keloid formation and indentation of the tissue

Postoperative erythema, edema, and pain

Hypopigmentation or hyperpigmentation

Infection

The same complications and risks that exist for conventional or traditional surgery also exist for laser surgery. These include, but are not limited to the following.

Allergic reaction to medication

Arrhythmia

Pain

Ulceration

Fever

.

Delayed healing

# Addendum I: Printer User Manual (Optional)

Addendum I: Printer User Manual (Optional)

### MedLite C<sup>3</sup>/C<sup>6</sup> Printer User Manual

(NOTE: This is an optional section for customers that wish to use a printer. A separate printer package can be purchased from Hoya ConBio.)

### Unpacking Your Printer Package (if purchased from Hoya ConBio)

Printer Package includes an AC power adapter, rechargeable battery pack paper roll, coil cable, Velcro adhesive pack and user manual. Contact Hoya ConBio if any of the components are missing or damaged.

### Battery Initial Charge Up (if purchased from Hoya ConBio)

Install the battery pack provided into the battery compartment at the bottom of the printer. The battery pack can only be electrically connected in one orientation. The three contacts of the battery pack must be aligned with the three contacts in the battery compartment for proper operation. The battery pack provided must be charged for 24 hours prior to its first use.

### **Caution:**

The Medlite C Laser System and printer must be turned off while battery is recharging. Failure to shut down any of these devices may result in hazardous radiation exposure and shorten battery life.

### Printer Set up

- 1. Connect the cable for the printer to the Medlite C laser serial port (See Figure 10-#6 on page 32) located on the back of the laser.
- 2. Plug the AC power adapter directly into an AC power outlet while its mating DC plug, on a 6 ft extension, connects to the printer.

### Installing/ replacing printer paper

- 1. Remove the printer back cover.
- 2. Turn on the printer by pressing the <ON> switch.
- 3. Tear and discard any paper remaining in the printer paper tray.
- 4. Using the <FEED> switch to remove any paper remaining in the printer mechanism. Do not REVERSE pull paper out of the printer mechanism this will damage the printer mechanism.
- Feed the new roll of paper into the printer paper slot. The printer will automatically feed paper into the printer and stop after about 3" of paper is advanced. The last two feeds of the paper roll is marked with a red stripe to provide an indication that the paper roll should be replaced.

### **Start-up and Operation**

- 1. Verify the laser is in ready mode.
- 2. Turn on the printer by pressing the <ON> switch.
- 3. The following information will be printed:

Name:

Date:

Indication:

Tx Area:

Each time the user activates laser emissions by means of a footswitch or changing the parameters (wavelength, spot size, fluence...etc.), the following data will be printed once the system is switched to standby mode:

Fluence:		J/cm <sup>2</sup>	
Wavelength:		nm	
Freq:		Hz	
Spot Sizes:		 mm	
Number of Pu	lses:		Pulses

#### Indicators

*On-Line indicator* -The green LED, labeled<On-Line>, illuminates if printer is turned on.

*Low BAT indicator*-The yellow LED, labeled<LO BAT>, illuminates if the battery pack is depleted. Recharge battery pack if LED is on.

*Charge indicator*-The yellow LED, labeled<CHARGE>, illuminates if the battery pack is accepting a charge. It turns off automatically at the end of the charge cycle.

*Ready indicator*-The green LED, labeled<ready>, is used for the following: In Serial mode, the ready indicator illuminates if the command to enable Magnetic card reader is received.

*Fault indicator*-The red LED, labeled<Fault>, stays lit if the printer control card fails to turn on the printer mechanism due to low battery or paper jam, or if an error is detected while reading the magnetic card. It also stays lit if the printer is out of paper.

*Ready, Fault, and Low Bat indicators*-Indicates printer is paused; to continue printer current receipt, press<FEED> or to clear printer buffer press <OFF>.

#### **Initial Power Up and Self Test**

A self test feature is built into your MST compact printer series. To start the self test, press the <FEED> switch during initial power-up of the printer. If no problems are found, the following message is printed:

### TEST PRINT

### 32K Bufer Extech V. 77 © 1999

To stop the self test process, press the <Off> switch twice.

### **Trouble Shooting Guide**

Problem	Cause	Solution
Printer will not turn on.	Battery was discharged.	Recharge battery overnight.
Charge LED not lighting when AC adapter is plugged in.	No AC power	Check AC outlet and adapter.
Error LED on Steady	Printer mechanism jam Low battery	Check battery installation and AC adapter.
Printer will not print	Improper cabling	Verify proper cable connections. Incorrect dip switch setting. (see adjustment procedure below)

### Dip Switch Setting and Adjustment

If the printer does not print and your cable connections seem correct, then the dip switches may not be set properly. Check and set the dip switches as follows:

1. Turn printer off.

- 2. Remove the cover of the printer.
- 3. You will find the dip switches on the back left of the printer when the front of the printer is facing you. The dip switches are white and are numbered 1 to 8, from bottom to top.
- 4. All switches should be set to the left, except for switch #7 which should be set to the right. Once again, make sure the front of the printer is facing you.
- 5. If your dip switch settings are incorrect, use a pen tip or other small tool to make adjustments.
- 6. Replace the cover, turn the printer on, and retest. If the printer still does not print call Hoya ConBio Service (800-524-5571).

# Addendum II: Calibration

#### Calibration

- 1. Before beginning calibration all covers need to be on and secure.
- 2. Connect the PC or terminal to the RS232 communications port. Set the communications for 19200 baud, 8 data bits, no parity and 1 stop bit.
- 3. Connect the power meter to the end of the arm.
- 4. Turn on breaker. Do not bypass any warming steps.
- 5. Allow ~ 3 minute warm-up (countdown) and ~ 3 minute warm-up (count-up). Wait for display to read "**OFF**".
- 6. Turn key on and let laser go though 2 minute Q-Switching warm-up.
- 7. Wait for display to read "ON STB".
- 8. At the MedliteC6> prompt, enter **PWD LASER**, to enter the password.
- 9. At the MedliteC6> prompt, enter **OPD** Y, to turn Off open pyro detection.
- 10. At the MedliteC6> prompt, enter SRV N↓ to turn Off the Servo.
- 11. At the MedliteC6>prompt, enter MON N↓ to turn Off the Monitor.
- 12. Press orange button to begin lasing.
- 13. Set laser to 10Hz and 1064nm.
- 14. Adjust **QDLY** to find maximum and stable power for both wavelengths. Record energies and QDLY's for later use.
- 15. Set **QMAX** ###↓ for each wavelength.
- 16. Adjust **QDLY** to find minimum (200mJ for 1064nm and 50mJ for 532nm). Record energies and QDLY's for later use.
- 17. Set **QMIN** ###↓ for each wavelength.
- 18. At the MedliteC6> prompt, enter TRS 100.
- 19. At the MedliteC6> prompt, enter **OPD** Y↓ to turn Off open pyro detection.
- 20. At the MedliteC6> prompt, enter SRV N, to turn Off the Servo.
- 21. At the MedliteC6>prompt, enter MON N→ to turn Off the Monitor.

- 22. If the stage is not set to infrared, then press the 1064nm softkey on the display panel.
- 23. At the MedliteC6>prompt, enter **QDLY MAX**, to set QDLY to Maximum energy.
- 24. At the MedliteC6>prompt, enter SHT I Y, to begin Q-switching.
- 25. At the MedliteC6>prompt, enter **TEST 1**, ↓ to view calibration numbers
- 26. At the MedliteC6>prompt, enter **POT 1** → Calibrating (wait for Calibration to finish should be ~212AD).
- 27. Change wavelength to 532nm.
- 28. At the MedliteC6>prompt, enter **QDLY MAX**, to set QDLY to Maximum energy.
- 29. At the MedliteC6>prompt, enter SHT I Y, to begin Q-switching.
- 30. At the MedliteC6>prompt, enter **TEST 1**, ↓ (optional) to view calibration numbers
- 31. At the MedliteC6>prompt, enter **POT 1** → Calibrating (wait for Calibration to finish should be ~212AD).
- 32. At the MedliteC6>prompt, enter **TEST 0**→ (optional) to turn off calibration numbers
- 33. At the MedliteC6>prompt, enter **QDLY MAX**, ↓ to set QDLY to maximum energy.
- 34. Step on footswitch and measure energy.
- 35. At the MedliteC6>prompt, enter SHT I Y, to begin Q-switching.
- 36. At the MedliteC6>prompt, enter MAX ###↓ (maximum mJ found in step 34)
- 37. At the MedliteC6>prompt, **QDLY MIN**→ to set QDLY to minimum energy.
- 38. Step on footswitch and measure energy.
- 39. At the MedliteC6>prompt, enter SHT I Y→ to begin Q-switching.
- 40. At the MedliteC6>prompt, enter MIN ###↓ (minimum mJ found in step 38).
- 41. Change wavelength to 1064nm.

- 42. At the MedliteC6>prompt, enter **QDLY MAX**→ to set QDLY to maximum energy.
- 43. Step on footswitch and measure energy.
- 44. At the MedliteC6>prompt, enter SHT I Y, to begin Q-switching.
- 45. At the MedliteC6>prompt, enter MAX #### (maximum mJ found in step 43).
- 46. At the MedliteC6>prompt, QDLY MIN, to set QDLY to minimum energy
- 47. Step on footswitch and measure energy.
- 48. At the MedliteC6>prompt, enter SHT I Y→ to begin Q-switching
- 49. At the MedliteC6>prompt, enter MIN ###↓ (minimum mJ found in step 47).
- 50. At the MedliteC6>prompt, enter INT↓ to upload calibration data.
- 51. At the MedliteC6>prompt, enter **PWT 15**, → (Pockell Cell Warm-up Time period in minutes before another required 2 minute Q-switching warm-up).
- 52. At the MedliteC6>prompt, enter **PWT** Y→ to enable PWT.
- 53. Press orange button to go into Standby "ON STB".
- 54. Turn key to the "OFF" position.
- 55. Turn off breaker and wait 30 seconds.
- 56. Turn on breaker. Do not bypass any warming steps.
- 57. Allow ~3 minute warm-up (countdown) and ~3 minute warm-up (count-up) wait for display to read "**OFF**".
- 58. Turn key on and let laser go though 2 minute Q-Switching warm-up.
- 59. Wait for display to read "ON STB".
- 60. At the MedliteC6> prompt, enter **PWD LASER**, to enter the password.
- 61. At the MedliteC6> prompt, enter **EE DUMP**→ to check that the calibration data is stored correctly.

# Addendum III: Multilite Dye Laser Handpiece Operation (Optional)

# Caution!

Before operating the Multilite<sup>TM</sup> Dye Laser Handpiece for the first time, thoroughly read this manual and note the Repetition Rates and the 532nm Wavelength required for each handpiece.

# TECHNICAL REMINDER

We hope you've enjoyed using the Multilite Dye Handpiece with your Medlite Laser System and have benefited from the versatility it offers. Please read the following as a reminder of proper usage.

- 1. <u>Never use the Multilite Dye Handpiece in the 1064nm mode</u>. The dyes in the handpieces are activated with 532nm and should only be used in the Multilite mode. The goggles provided with the dye handpiece will not protect your eyes if 1064nm is selected.
- 2. The dye modules in both the red and gold handpieces <u>need to be replaced after approximately</u> <u>3 hours of accumulated use</u>, as the dye material is depleted over time and will no longer be effective.
- 3. If you ever see <u>green light</u> emitting from either dye handpiece during treatment, it is time to replace your dye cell <u>immediately</u>. Refer to Section 5.D. for information on replacing dye cells. A green visible light indicates that the dye in the cartridge is completely depleted and **may pose an ocular hazard**.
- 4. <u>Always verify that you are using the correct goggles</u> for each handpiece. The red dye handpiece must be used with the goggles labeled as 650nm. Similarly, the yellow dye handpiece must be used with the goggles labeled as 585nm. Using the incorrect goggles may pose an ocular hazard.

Please consult your Operation Manual if you have further questions or call 800-532-1064 or Service 800-524-5571 or visit our website at www.conbio.com for assistance.

# Important!

### Read this section before operating the Laser.

- Laser safety eyewear supplied with the Multilite<sup>TM</sup> Dye Laser Handpiece Accessory Kit must be worn by <u>all</u> persons present during the operation of the laser. Refer to Section 3.C. for the specific eyewear requirements.
- 2. <u>Do not</u> remove the protective eyewear until the laser is returned to the "Off" mode. This is accomplished by releasing the foot switch; pressing the "Ready/Standby" keypad button (the display will read "ON STB"); turning the key switch to the "Off" position; and securing the articulated arm in its clasp.
- 3. Never look directly into the laser beam or its reflection. Permanent damage to the eye can occur.
- 4. During laser operation, do not allow any non-essential personnel in the treatment room.
- 5. Remove all shiny reflective objects such as rings, watch bands and metallic pencils from the patient and the operating physician.
- 6. Never depress the foot switch without first verifying the safe orientation of the articulated arm and the attached hand pieces.
- 7. Never leave the laser in a READY or EMISSION mode unattended. Turn laser off and remove the KEY when not in use.
- 8. Never allow untrained personnel to operate the laser system unless directly supervised by a trained, experienced physician. Refer to Section 1.H. for information on training requirements.
- 9. Never attempt to remove the protective covers from the laser cabinet. Only allow a factory authorized service technician or representative to remove any of the protective covers.
- 10. Review the safety labels used on or in the Multilite<sup>TM</sup> Dye Laser Handpiece Accessory Kit. Refer to Section 3.D.

If you have any questions or concerns regarding the Multilite<sup>TM</sup> Dye Laser Handpiece, call Hoya ConBio at (510) 445-4500 or Service 800-524-5571. You can also visit our website at www.conbio.com
Hoya ConBio considers itself responsible for the effects on safety, reliability, and performance of the Multilite<sup>TM</sup> Dye Laser Handpiece only if:

- Assembly operations, readjustment, modifications or repairs are carried out by persons authorized by the company.
- The electrical installation of the relevant room complies with the appropriate requirements.
- The Multilite<sup>TM</sup> Dye Laser Handpiece Accessory Kit is used in accordance with the instructions for use outlined in this manual.

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# **<u>1. Physician Information Statement</u>**

# A. Description

The Multilite<sup>TM</sup> Dye Laser Handpiece is a dye laser producing laser emission at 585nm or 650nm, when used in conjunction with a Medlite C-6 Series Laser System. Refer to this Operation Manual for details on the Multilite<sup>TM</sup> Dye Laser Handpiece.

# **B.** Indications

The Medlite Laser Systems have been researched extensively for the treatment of tattoo removal, vascular lesions, benign epidermal pigmented lesions, and Nevus of Ota. Types of vascular lesions include port wine birthmarks, telangiectasias, spider angiomas, cherry angiomas, and spider nevi. Types of benign epidermal pigmented lesions include cafe au lait birthmarks, solar lentigines, senile lentigines, Becker's nevi, freckles, and nevus spilus. The Multilite<sup>TM</sup> Dye Laser can be used with Medlite C-6 Series Laser Systems to extend the wavelength capabilities. Refer to the table below.

# C. Intended Use

Medlite C-6 Series Laser Systems, when used with the Multilite<sup>TM</sup> Dye Laser Handpiece, have four wavelengths available to treat a variety of indications as noted in the table below. The fundamental wavelength is 1064nm (near infrared, invisible), which is frequency doubled to 532nm (green). The Multilite<sup>TM</sup> Dye Handpiece accessory can convert the 532nm wavelength to either 585nm (yellow) or 650nm (red).

Indication	Fluence Level	Wavelength
Tattoo removal (dark ink: blue, black)	$2 - 12 \text{ J/cm}^2$	1064nm
Nevus of Ota	$2-12 \text{ J/cm}^2$	1064nm
Tattoo removal (light ink: red)	$2-5 \text{ J/cm}^2$	532nm
Tattoo removal (light ink: sky blue)	$2-5 \text{ J/cm}^2$	585nm*
Tattoo removal (light ink: green)	$2-5 \text{ J/cm}^2$	650nm*
Vascular lesions	$1-5 \text{ J/cm}^2$	532nm/585nm*
Pigmented lesions	$2-5 \text{ J/cm}^2$	532nm/650nm*

The following treatment parameters are recommended:

\*Wavelengths available with the Multilite<sup>TM</sup> Dye Laser Handpiece accessory.

# **D.** Contraindications

There are no known contraindications to laser removal of tattoo, or treatment of vascular or pigmented lesions with the Medlite Laser and Multilite<sup>TM</sup> Dye Laser Handpiece. Patients who have had prior problems with laser therapy, however, should be carefully screened as potential candidates for treatment.

# E. Warnings

Laser safety eyewear provided by Hoya ConBio with the Multilite<sup>TM</sup> Dye Laser Handpiece Accessory Kit, must be worn by all persons present during the operation of the laser. Refer to Section 3.C. for specific eyewear requirements.

**Do not** remove the protective eyewear until the laser is returned to the "Standby" mode. This is accomplished by releasing the foot switch; pressing the "Ready/Standby" keypad button (the display will read "ON STB"); turning the key switch to the "Off" position; and securing the articulated arm in its clasp.

Observe all safety precautions described in the Section 2 - Safety.



If green light emerges from the Multilite Dye Laser Handpiece, stop firing the laser immediately! Your laser protective eyewear will not be effective in blocking the green light.

This situation can occur if the dye bleaches in the Dye Cell in the Multilite Dye Laser Handpiece barrel. To prevent this occurrence, the Dye Cell in the Multilite Dye Laser Handpiece barrel will need to be changed once clinically useful fluences are no longer obtained. See on Section 5.D. for further information.

# F. Complications/Adverse Effects

- Potential complications include: Scarring, keloid formation and indentation of the tissue may develop following laser therapy.
- Postoperative erythema, edema, and pain may be experienced after laser treatment.
- Hypopigmentation or hyperpigmentation may occur.

# G. Required Maintenance/Service

- The hand pieces must be cleaned and sterilized between patients. See Section 5 for details.
- Refer to the Medlite Operation Manual for maintenance of the laser system.

# H. Training Requirements

The Multilite<sup>TM</sup> Dye Laser Handpiece Accessory Kit is intended for use only by physicians trained in the safe handling and use of a Medlite Laser System. Hoya ConBio suggests that in addition to laser safety training of all operating room or clinic personnel, the user/institution adopt a training and safety program as outlined in the latest revision of the ANSI standard Z136.3, the American National Standard for the Safe Use of Lasers in Health Care Facilities.

It is further suggested that each physician desiring privilege for laser use be approved by the appropriate credentialing body within their respective institutions.

Physicians should consider the following training avenues:

- 1. An accredited training course within the physician's specialty.
- 2. "Hands-on" training under the preceptorship of a qualified user.
- 3. Attendance at specialty specific courses presented during academy or college meetings.

Nurses and other allied health professionals handling lasers may also complete a training program which may include subjects such as basic laser physics, laser safety, tissue interaction, laser operating procedures, laser set-up procedures, potential hazards, and hands-on experience.

In-Service training in the use of the Multilite<sup>TM</sup> Dye Laser Handpiece will be provided by Hoya ConBio sales representative after the Medlite Laser System's has been installed by a trained Hoya ConBio technician. Clinical techniques described here are presented only as a reference based on clinical experience with the device and other laser devices reported in the public literature.

Hoya ConBio maintains a current listing of recommended training courses, which are available to the user and allied health professionals. Contact Hoya ConBio for further information at (510) 445-4500 or 800-532-1064. You can also visit our website at www.conbio.com.

# 2. Safety

The Multilite<sup>TM</sup> Dye Laser Handpiece Accessory Kit is meant to be used with the Medlite C-6 Series Laser Systems by attaching it to the articulated arm. The safety precautions here are the same listed for the Medlite Laser and pertain equally when using the Multilite<sup>TM</sup> Dye Laser Handpiece Accessory Kit.

#### WARNING!

Improper use of the Multilite<sup>TM</sup> controls or performance of procedures other than those specified in the Physician's Information Statement (Section 1) may result in hazardous radiation exposure.

#### Laser Safety Precautions

Hoya ConBio's user information is in compliance with 21CFR 1040.10 Chapter 1, Subchapter J concerning Radiological Health published by the US Department of Health & Human Services, Center for Devices & Radiological Health, 1988. The following safety precautions should be read and observed by anyone using the laser.

1. Always wear the proper laser protective eyewear that is supplied by Hoya ConBio with the Multilite<sup>TM</sup> Dye Laser Handpiece Accessory Kit. Refer to Section 3.C. for the specifications. Eyewear must meet the ANSI Z136.3 standard.

2. Never look directly into the laser beam or its reflection. Permanent damage to the eye can occur.

3. During laser operation, do not allow any non-essential personnel in the treatment room.

4. Remove all shiny reflective objects such as rings, watch bands and metallic pencils from the patient and the operating physician.

5. Never depress the foot switch without first verifying the safe orientation of the articulated arm and the attached hand pieces.

6. Never leave the laser in a READY or EMISSION mode unattended. Turn laser off and remove the KEY when not in use.

7. Never allow untrained personnel to operate the laser system unless directly supervised by a trained, experienced physician.

8. Never attempt to remove the protective covers from the laser cabinet. Only allow a factory authorized service technician or representative to remove any of the protective covers.

9. Call Hoya ConBio at (510) 445-4500 or Service 800-524-5571 for further information on any safety features of the Multilite<sup>TM</sup> Dye Laser Handpiece Accessory Kit.

Review the safety labels used on or in the Multilite<sup>TM</sup> Dye Laser Handpiece Accessory Kit. Refer to Section 3.D. for their location,

# **<u>3. Multilite<sup>TM</sup> Dye Laser Handpiece Kit</u>**

# A. Multilite<sup>™</sup> Dye Laser Handpiece

The Multilite<sup>TM</sup> Dye Laser Handpiece is for use with the Medlite C-6 Series Laser Systems. It attaches to the articulated arm and converts the 532nm output of the Medlite to either 585nm or 650nm with the appropriate handpiece.

# B. Handpieces

Two handpieces are supplied with the Multilite<sup>TM</sup> Dye Laser Handpiece Accessory Kit. They are color-coded to differentiate between the wavelengths for which they can be used. The 585nm handpiece is gold, while the 650nm is red. The wavelength is also engraved on the side of the Dye Laser Barrel.

The handpieces have a removable protective window, which can be cleaned and/or changed as required. They also have removable end pieces, which determine the spot size used for treatment. Refer to Section 5 for the cleaning and maintenance of the handpieces.



# C. Laser Safety Eye Wear

The Multilite<sup>TM</sup> Dye Laser Handpiece Accessory Kit is supplied with laser safety eye wear manufactured by UVEX or TRINITY TECHNOLOGIES Hoya ConBio reserves the right to substitute eye wear with comparable laser safety eye wear, which meets the ANSI Z136.1 and Z136.3.3 standards.

#### UVEX:

**LOTG-Dye II -** The OD at 450-585nm is 4-5. This goggle meets the ANSI standards Z136.1 and Z136.3, and must be worn during the operation of the 585nm Dye Laser Handpiece.

#### **TRINITY TECHNOLOGIES:**

Dual wavelength goggles and spectacles. 1064nm OD>5 610-670nm OD>4

#### WARNING!

Use only laser safety eyewear provided by Hoya ConBio with the Multilite<sup>TM</sup> Dye Laser Handpiece Accessory Kit or eyewear with an OD of 4-5 at 585nm and 4-5 at 650nm. The eyewear must be worn by everyone present during the laser treatment.

# D. Warning/Safety Labels

- Label 1 This is the Laser Warning Label indicating the product is a class IV device. The label also lists the various laser parameters
- Label 2 This is the Manufacturer's Certification label. It indicates the manufacturer in the United States, the date of manufacturing and the serial number of the unit.
- Label 3This label indicates the MAXIMUM rep rate the handpiece can<br/>be operated at.





Label 1

<b>HOYA</b> ConBio					
PART NO.					
MODEL					
DATE	S/N				
This laser product complies with 21 CFR Chapter 1, Subchapter J, and EN-60825-1.					

Label 2



Label 3

# 4. Operation

#### WARNING!

Make sure all individuals in the vicinity of the laser system have the proper laser protective eye wear. See Section 3.C for description of this eye wear.

# A. Set Up

- 1. Turn breaker on at back of laser and allow laser to go through all warm steps until display reads "OFF".
- 2. Select desired wavelength handpiece from the storage case. Also remove the desired spot size end piece and attach to end of Dye Handpiece.
- 3. Attach the Multilite<sup>TM</sup> Dye Laser Handpiece (585nm or 650nm) to the articulated arm.
- 4. Turn key switch on and allow laser to go through 2 minute flashing warm-up until display reads "ON STB".
- 5. With laser in the "ON STB" mode select the Multilite keypad button on the display (if Multilite keypad button does not work see note below).
- Select the desired wavelength keypad button (585nm or 650nm). Display will read the shot count for the wavelength selected (585nm or 650nm). Next "ON STB" will display.
- When ready to begin treatment select the "Ready/Standby" button on the display, display will read "1 MAX" for 650nm and "2 MAX" for 585nm, wait for the green "Ready/Standby" LED to remain steady on. Step on footswitch to begin treatment.

Note: If the Multilite keypad button does not work. Turn key switch to the off position wait for display to read "OFF". Hold down the Multilite keypad button until it display reads "DH MDL". Go back to Step 4.

# Caution!

Improper repetition rate operation will result in damage to the product, which will not be covered under normal use warranty.

Improper wavelength selection operation will result in damage to the product, which will not be covered under normal use warranty.

For the best performance and stability from the Multilite<sup>TM</sup> Dye Laser Handpiece the Medlite laser should be warmed up and stabilized.

# 5. Cleaning and Maintenance

# A. Cleaning of the Handpieces

The handpiece should be cleaned after each patient treatment. This procedure is outlined below:

- While wearing unpowdered surgical gloves, remove the handpiece from the articulated arm by unthreading it.
- Remove the end piece from the adapter sleeve. See Section 3.B. Figure 3.
- Unscrew the adapter sleeve from the window housing. See Section 3.B. Figure 3.
- Soak the tip, removable end piece and adapter sleeve in a non-abrasive detergent, such as Enzol or Alconox for 5 minutes. Clean the residual debris from the removable end piece and adapter sleeve with a gauze pad or cotton swab. Rinse in warm water for 20 minutes.
- Remove the tip from the removable end piece (See Section 3.B. Figure 3.). Then soak the removable end piece and adapter sleeve in Cidex cleaner (Glutaraldehyde 2.4%) for 45 minutes. Rinse with water for a

minimum of 3 minutes. Dry with clean cloth.

• The tip requires steam sterilization for 25 minutes at 250°F.

These recommendations follow the AAMI Guidelines TIR No. 12, which provide a SAL of  $10^{-6}$ .

# **B.** Cleaning or changing the Protective Window

The protective window should be cleaned after each patient treatment. This procedure is outlined below:

- If the protective window is dirty remove end piece and unscrew adapter sleeve, clean with a cotton swab or lens tissue with methanol or alcohol. Remove all debris and streaks. If window is will not clean or is damaged follow direction below.
- Remove end piece and unscrew adapter sleeve from dye handpiece. Unscrew black piece with protective window. Replace with new one (part number 659-0327). Although the focusing lens is protected by the window, it should be inspected for dust or other debris. Clean by gently blowing with air or gently brushing with a cotton swab. A duster for a camera lens would work well here.

*Caution*: Lack of cleaning, excessive or abrasive cleaning of optics will result in coating damage. This can cause back reflections that may cause damage to the other optical elements in the dye laser handpiece and optics in the articulated arm. Never use with damaged optics. If you have any questions or concerns about the laser optics, contact Hoya ConBio Service at 800-524-5571

# C. Cleaning the handpiece body and storage case

- The external surface of the handpiece may be cleaned with alcohol to remove fingerprints or contamination.
- The storage case is meant to protect the handpiece when not in use. It may be wiped out with alcohol or a damp cloth from time to time to remove any loose debris or fingerprints.

### D. Dye Laser replacement

- The Dye laser housing piece needs to be replaced when sufficient treatment energy can no longer be obtained.
- Replacement Dye laser barrels can be purchased through the Hoya ConBio Sales Department.
  - Order part number 646-0400, Red Dye Laser Barrel.
  - Order part number 646-0500, Gold Dye Laser Barrel.
  - Order part number 659-0327, Protective Window.
- Remove the window housing and arm adapter from Dye laser housing. See Section 3.B. Figure 3.
- Reattach the window housing and arm adapter to new Dye laser housing. See Section 3.B. Figure 3.



If green light emerges from the Multilite Dye Laser Handpiece, stop firing the laser immediately! Your laser protective eyewear will not be effective in blocking the green light.

This situation can occur if the dye bleaches in the Dye Cell in the Multilite Dye Laser Handpiece barrel. To prevent this occurrence, the Dye Cell in the Multilite Dye Laser Handpiece barrel will need to be changed once clinically useful fluences are no longer obtained.

# **<u>6. Technical Description</u>**

### A. Specifications

The Multilite<sup>TM</sup> Dye Laser Handpiece has been designed to work with all Medlite C-6 Series Laser systems.

#### Medlite C-6

Listed below are the parameters for the Multilite<sup>TM</sup> Dye Laser Handpiece when operated with a Medlite C6:

Maximum Repetition Rates	2 Hz for 585nm
	1 Hz for 650nm

Energy densities listed here are based on nominal delivered energy of 250mJ for 585nm and 150mJ for 650nm.

Nominal Energy Density @ 2mm spot size	8 J/ $cm^2$ at 585nm
	4.5 J/cm <sup>2</sup> at 650nm
Nominal Energy Density @ 3mm spot size	3.5 J/cm <sup>2</sup> at 585nm
	2.0 J/cm <sup>2</sup> at 650nm
Minimum lifetime in pulses	20,000 for 585nm
	10,000 for 650nm

The lifetime for the handpiece may exceed the listed pulse lifetimes. Replace the dye laser housing when useful treatment energy is no longer obtained. See Dye Laser replacement for details.