

VersaPulse[®] PowerSuite[™]

*Holmium and Dual Wavelength
Surgical Lasers*

Operator Manual

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Authorized Representative:

Lumenis (Germany) GmbH
Heinrich-Hertz-Strasse 3
D-63303 Dreieich
Germany

Manufactured by Lumenis Ltd.

P.O.Box 240
Yokneam 20692
Israel

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Operation

Introduction

The Lumenis VersaPulse® PowerSuite™ Holmium and Dual Wavelength lasers are true multi-specialty lasers, providing utility in urology, orthopedics, ENT, gynecology, and general surgery applications. Fiber delivery of holmium and Nd:YAG laser energy is ideal for minimally invasive surgery.

The single-wavelength holmium laser can be upgraded to a dual-wavelength holmium/Nd:YAG laser to accommodate your expanding surgical needs. The holmium/Nd:YAG laser offers the broadest treatment options, combining the precise cutting and ablation of holmium with the deep tissue coagulation of Nd:YAG.

The VersaPulse PowerSuite features a swivel control screen for viewing treatment settings from any vantage point, as well as a handheld remote control for rapid adjustment of treatment settings from the sterile field.

Lumenis lasers and delivery systems are precision medical instruments. They have undergone extensive testing and with proper handling are useful and reliable clinical instruments. If you have questions regarding your laser or delivery system, contact your local Lumenis representative.

WARNING

Lasers generate a highly concentrated beam of light which may cause injury if improperly used. To protect the patient and operating personnel, the entire laser and the appropriate delivery system operator manuals, including all Safety and Regulatory sections, should be carefully read and comprehended before operation.

Characteristics of the Holmium and Nd:YAG laser wavelengths

The holmium and Nd:YAG laser wavelengths fall in the near-infrared region of the electromagnetic spectrum. These wavelengths are invisible to the human eye. Therefore, a low-power, visible aiming beam is used to target tissue.

The holmium laser wavelength is strongly absorbed by water in tissue. Since soft tissue is comprised primarily of water, holmium laser energy can be used effectively for excision, incision, ablation, and vaporization when in direct contact with soft tissue and for coagulation when in near contact with soft tissue.

The Nd:YAG laser wavelength is readily absorbed by pigmented tissue and penetrates nonpigmented tissue to greater depths. Nd:YAG laser energy can be used effectively for the excision, incision, ablation, vaporization, and coagulation of soft tissue.

Laser Preparation

The laser is shipped directly from the factory to your site. Your local Lumenis service representative initially uncrates, inspects, sets up, and installs the laser to ensure that it is working properly. In addition, Lumenis provides in-service training to ensure that your surgical staff is experienced with the performance and safety considerations of the laser.

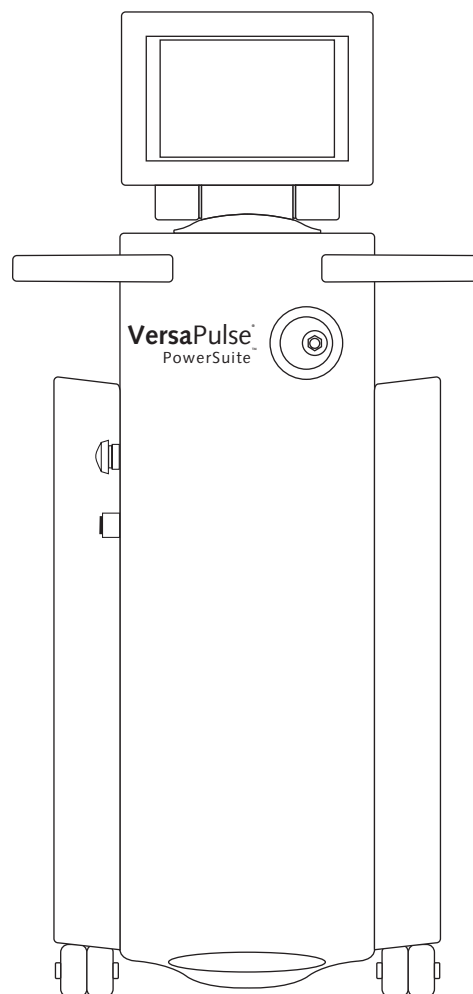
Thereafter, you or the nursing staff at your facility will perform the daily maintenance routines associated with the laser and any delivery systems used during surgery, including inspecting and cleaning the laser and delivery systems; connecting, disconnecting, and sterilizing the delivery systems; and verifying the aiming beam integrity. These procedures are detailed in this manual and in the delivery system instruction guide.

If your scheduled surgical procedure requires disposable delivery devices or accessories, it is helpful to have extra items ready and available in the treatment room should they be needed to complete a procedure.

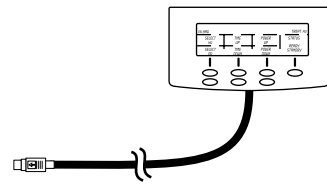
VersaPulse PowerSuite Components

The VersaPulse PowerSuite laser comprises:

- a laser console with control screen
- an external door interlock plug
- a single-pedal footswitch (Holmium laser) or a dual-pedal footswitch (Dual Wavelength laser)
- all electrical cables necessary for proper connection
- an optional remote control



VersaPulse PowerSuite laser console



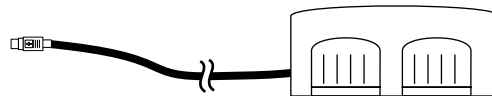
Optional remote control



External door interlock plug



Single-pedal footswitch




Dual-pedal footswitch

VersaPulse PowerSuite components

Laser console

The laser console houses the control screen, main power key switch, emergency off button, control electronics, laser source and associated optics, and power supply. Fiber optic delivery systems attach to the fiber receptacle on the front of the console, enabling laser energy to be delivered to the treatment site. The control screen allows you to select treatment settings outside of the sterile field.

External door interlock plug

The external door interlock plug must be inserted into the EXTERNAL INTERLOCK  receptacle on the rear of the laser console for the laser to operate. It may be wired to an external switch to disable the laser if the treatment room doors are opened during treatment.

Single-pedal footswitch

The single-pedal footswitch is standard on VersaPulse PowerSuite Holmium lasers. The footswitch activates the laser treatment beam when depressed.

Dual-pedal footswitch

The dual-pedal footswitch is standard on VersaPulse PowerSuite Dual Wavelength lasers. The individual pedals are wavelength-specific and are labeled “Holmium” and “Nd:YAG.” The pedals activate the corresponding laser treatment beam when depressed.

Remote control (optional)

The remote control enables you to rapidly adjust treatment settings from within the sterile field. The remote control must be used concurrently with the laser control screen, since all laser controls and displays are not located on the remote control.

Delivery systems

A variety of fiber optic delivery systems are available for use with VersaPulse PowerSuite lasers. Refer to the appropriate delivery system instruction guide for specific operating instructions.

Laser Component Inspection

Before connecting the VersaPulse PowerSuite components, inspect the individual components, cables, and electrical connections for dirt, debris, or damage. Ensure that the electrical cables are not frayed or split. Contact your local Lumenis service representative if any component appears damaged.

Delivery System Inspection


Inspect the delivery system as instructed in the appropriate delivery system instruction guide.

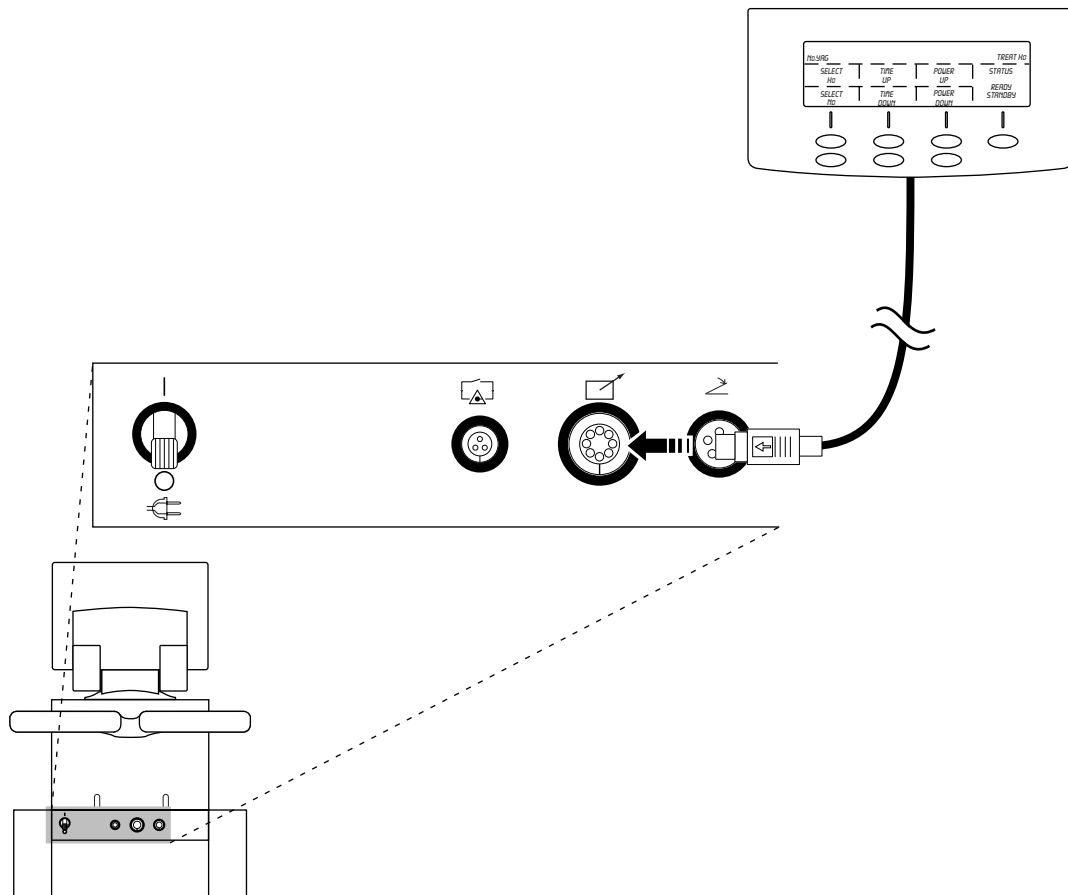
WARNING

Never inspect the delivery system while it is connected to the laser. Accidental laser exposure can cause severe eye damage.

Connection Instructions


Connecting the optional remote control

1. Line up the red dot on the remote control plug with the red dot on the REMOTE  receptacle on the rear of the laser.
2. Insert the remote control plug into the receptacle.



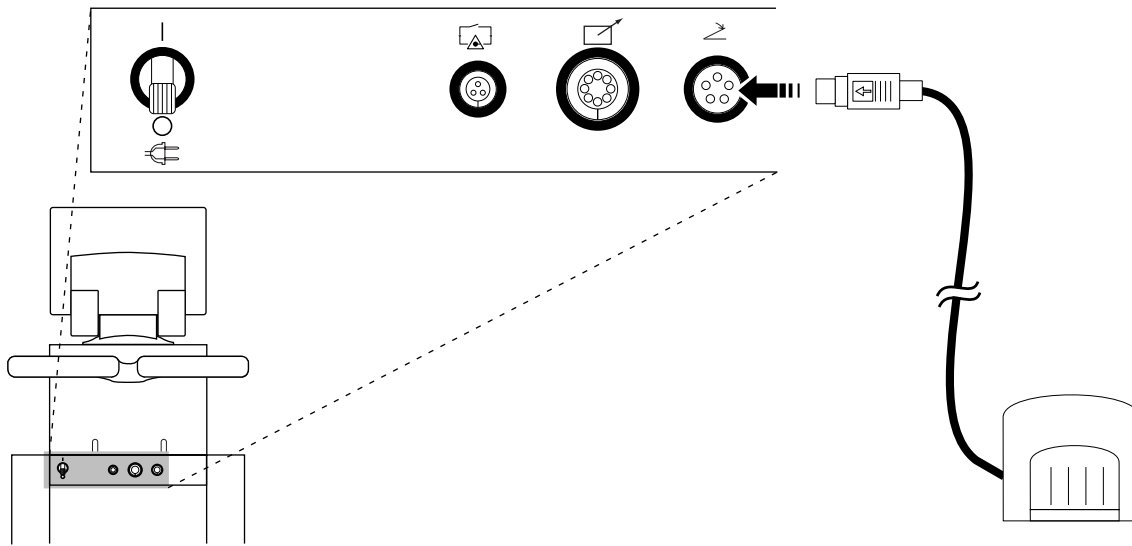
Connecting the optional remote control

Connecting the footswitch

Insert the footswitch plug into the FOOTSWITCH  receptacle on the rear of the laser. If the footswitch is not properly connected when the laser is turned on, “Attach footswitch” appears on the control screen until the footswitch is properly connected.

NOTE


Dual wavelength models may use either a single-pedal footswitch or a dual-pedal footswitch. When properly connected, “Single footswitch” or “Dual footswitch” appears on the control screen to indicate the type of footswitch in use.



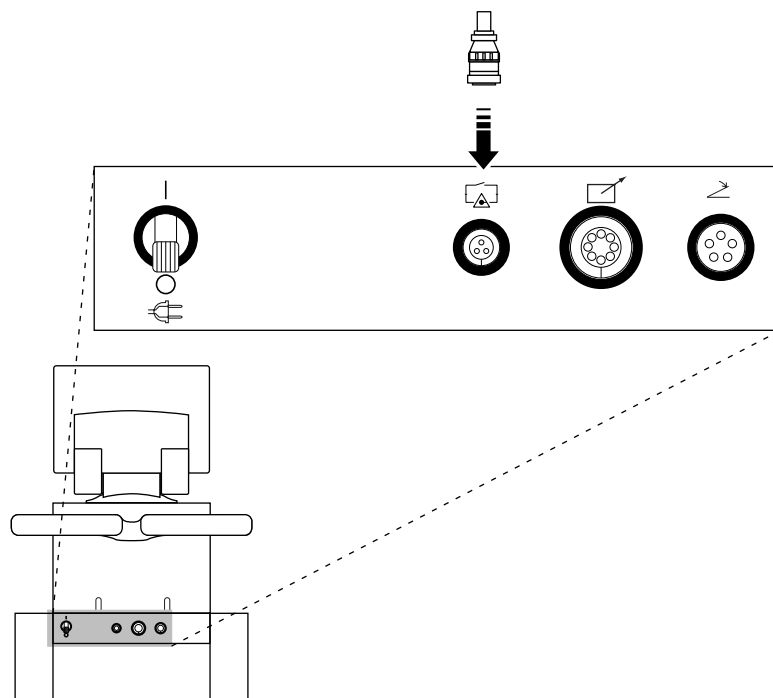
Connecting the footswitch (single-pedal footswitch shown)

Inserting the external door interlock plug

The external door interlock is a safety feature that disables the laser if the treatment room doors are opened or the interlock plug is removed while the laser is in ready mode.

Use of an external door interlock is optional; however, you must insert the interlock plug into the EXTERNAL INTERLOCK  receptacle whether or not you are using an external door interlock. The laser remains inoperative until the plug is inserted into the receptacle.

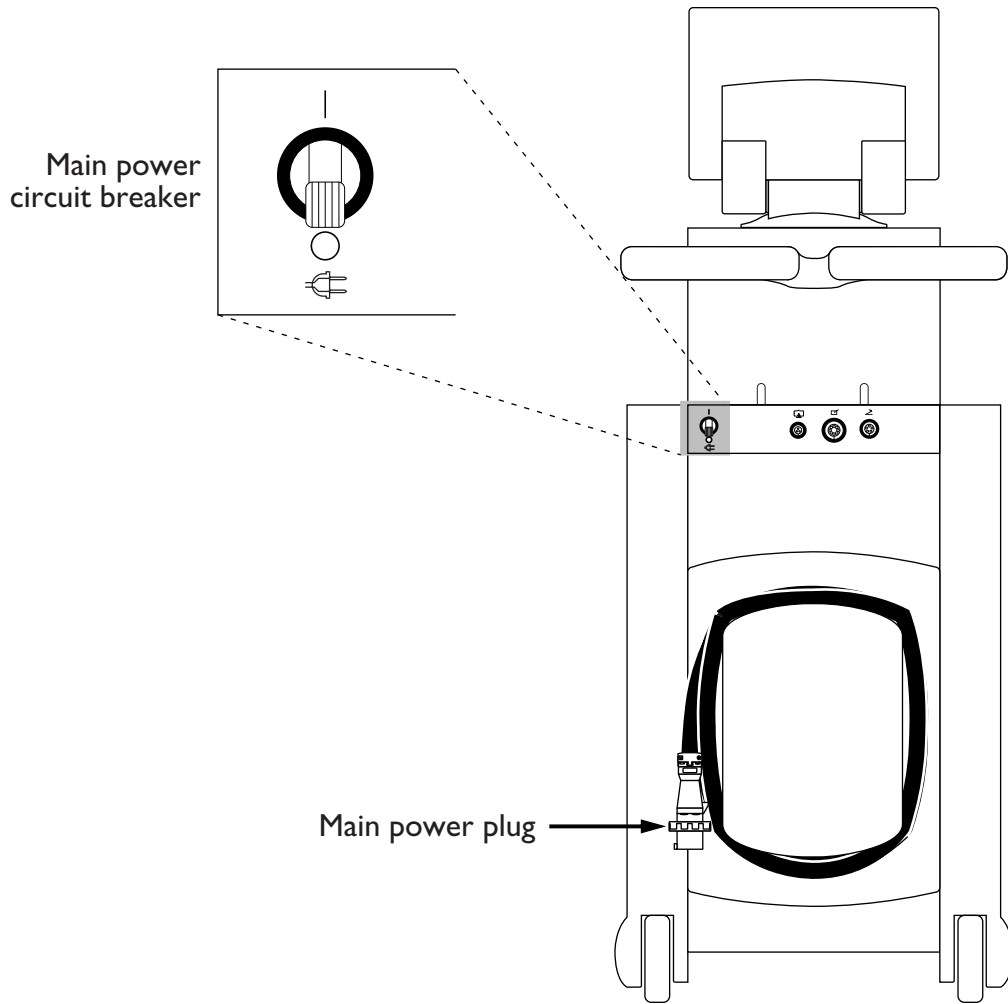
When using an external door interlock, the laser automatically disables and returns to standby mode if the treatment door is opened or the interlock plug is removed. “Remote interlock” appears on the control screen. To resume treatment, close the treatment room door or reinsert the interlock plug, and press the READY selector.



Inserting the external door interlock

Plugging in the main power cable (for removable wall plug configurations only)

1. Turn off the main electrical service (wall circuit breaker).
2. Ensure that the laser main power circuit breaker is in the off (down) position.
3. Insert the laser main power plug into the wall socket. If the laser has a locking plug and socket, connect the plug collar to the socket so that the plug is secure from loosening.
4. Turn on the main electrical service (wall circuit breaker).



Main power circuit breaker and main power plug

Connecting the delivery system

Before connecting the delivery system to the laser, refer to the appropriate delivery system instruction guide for specific instructions, such as delivery system inspection, sterilization, and assembly.

WARNING

To avoid possible damage to the optical system, use only qualified Lumenis delivery systems. Using other than Lumenis delivery systems may jeopardize safe operation or damage the laser and will void your Lumenis warranty or service contract.

WARNING

Carefully inspect the delivery system sterile packaging to ensure that it has not been torn or punctured. If there is any damage to the sterile packaging, do not use the delivery system.

WARNING

When using a fiber optic delivery device, always inspect the fiber optic cable to ensure that it has not been kinked, punctured, fractured, or otherwise damaged. The fiber optic cable may be damaged if stepped on, pulled, left lying in a vulnerable position, kinked, or tightly coiled. Do not clamp the cable with a hemostat or other instruments. If sterile tape is used, always remove the tape before lifting the cable. A damaged fiber optic cable may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.

CAUTION

To prevent accidental laser discharge, always turn off the laser before connecting the delivery system.

To ensure sterility of the delivery system, the following aseptic technique must be used when connecting the delivery system to the laser:

1. The scrub nurse hands off the laser connector to the circulating nurse.
2. The circulating nurse removes the protective cap from the laser connector.

WARNING

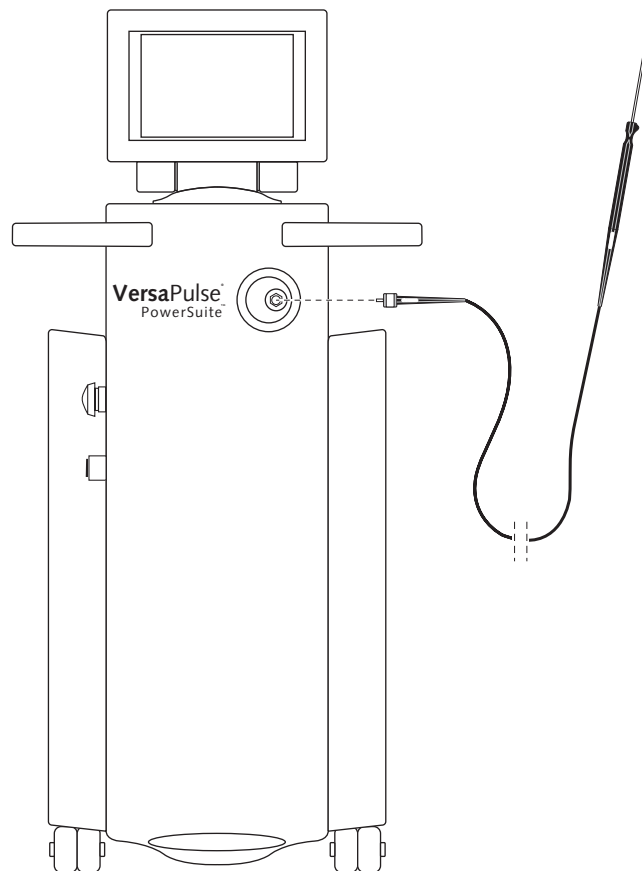
When removing the protective cap, hold the laser connector, not the strain relief or fiber optic cable. Pulling on the strain relief or fiber optic cable may damage the delivery system and result in unintended laser exposure.

CAUTION

Do not remove the protective cap from the laser connector in the sterile field. Removing the protective cap in the sterile field may compromise sterility.

3. The circulating nurse secures the laser connector to the laser by screwing the connector into the fiber receptacle on the front of the laser.

If the laser connector is not properly seated and securely screwed into the fiber receptacle, “Attach fiber” appears on the control screen.



Connecting the delivery system (InfraTome™ shown)

Laser Basics

Turning on the laser

1. Place the laser main power circuit breaker in the on (up) position.
2. Insert the key into the key switch, and rotate the key to the || (start) position; hold for one full second, and release the key. Upon release, the spring-loaded key rotates to the | (on) position.

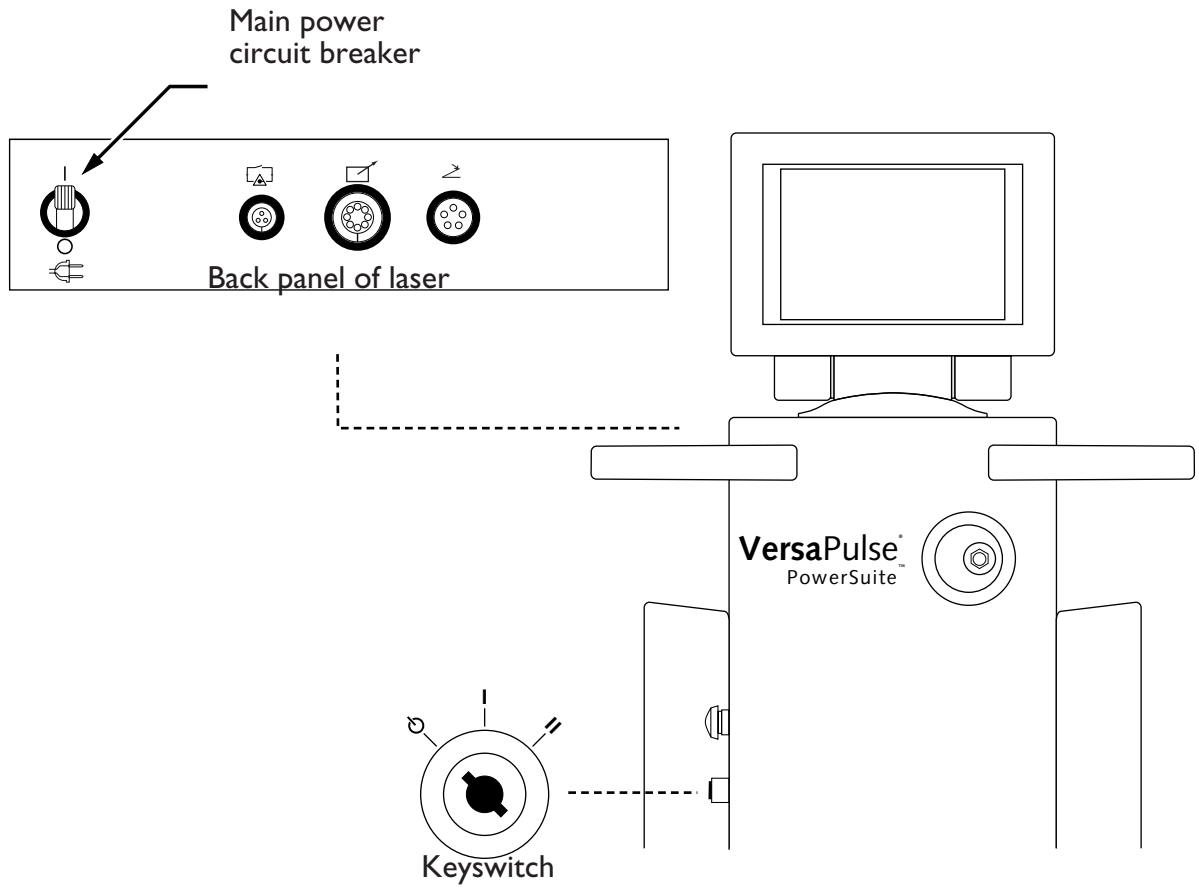
A laser self-test and warm-up begin. The self-test and warm-up take approximately one minute. As internal tests are performed, self-test pass/fail messages display on the control screen. When the self-test is successfully completed, the default treatment settings display on both the control screen and remote control, and “Laser emission” displays on the control screen to alert the user that laser energy is available.

NOTE

If any fault conditions are encountered during laser start-up and self-test, refer to the “Troubleshooting Guide” in the Maintenance section of this manual.


Restarting the laser

1. Turn the key switch to the ⏻ (off) position.
2. Wait 5 seconds, then rotate the key switch to the || (start) position; hold for one full second, and release the key.



Controls for turning on and restarting the laser

Turning off the laser

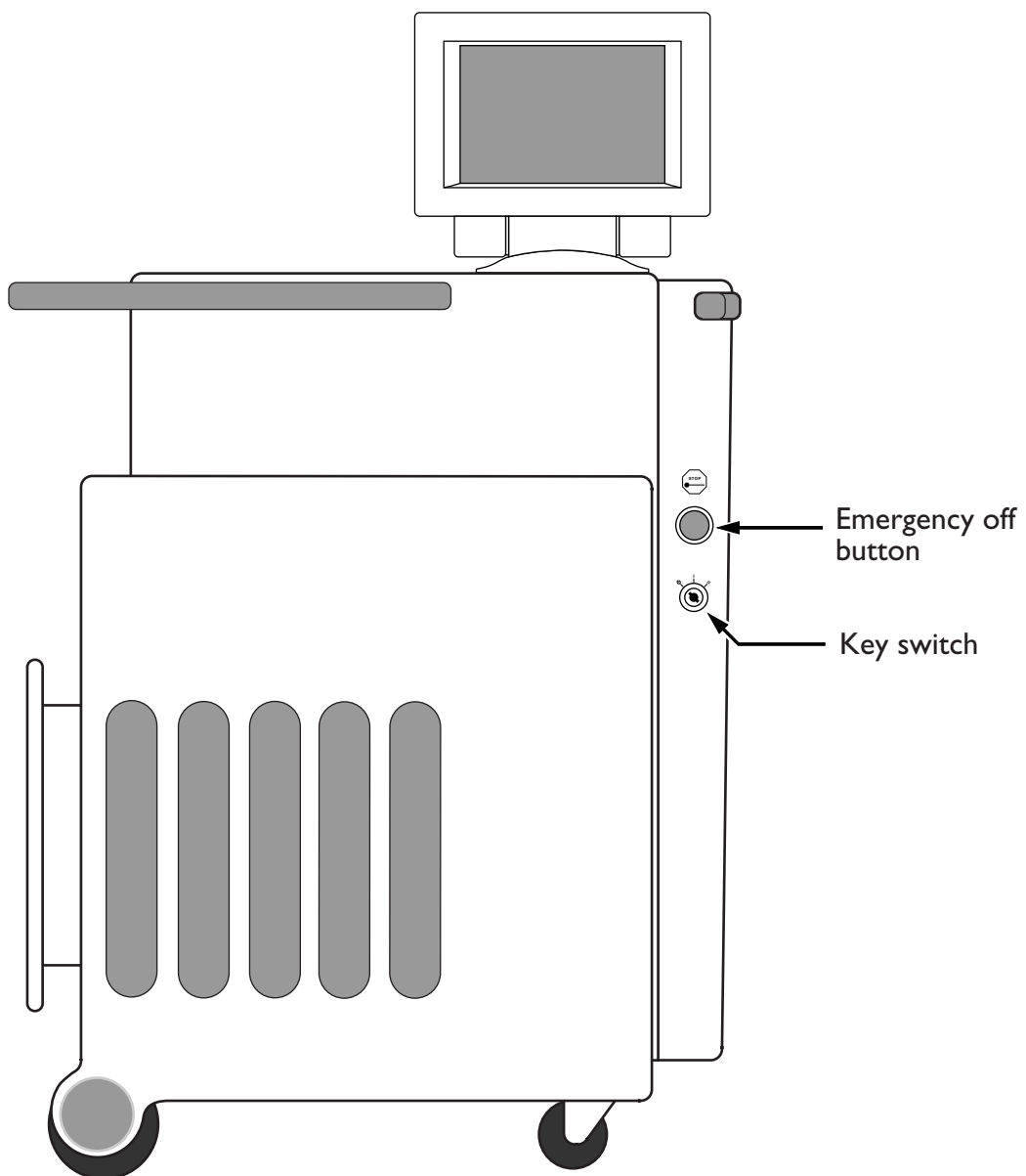
Under normal operating conditions, turn the key switch to the  (off) position to turn off the laser. Remove the key to prevent unauthorized use of the laser.

NOTE

When the main power cable is connected to the electrical source, some internal circuits remain energized. To de-energize all internal circuits, place the laser main power circuit breaker in the off (down) position, and turn off the main electrical service (wall circuit breaker).


Emergency off

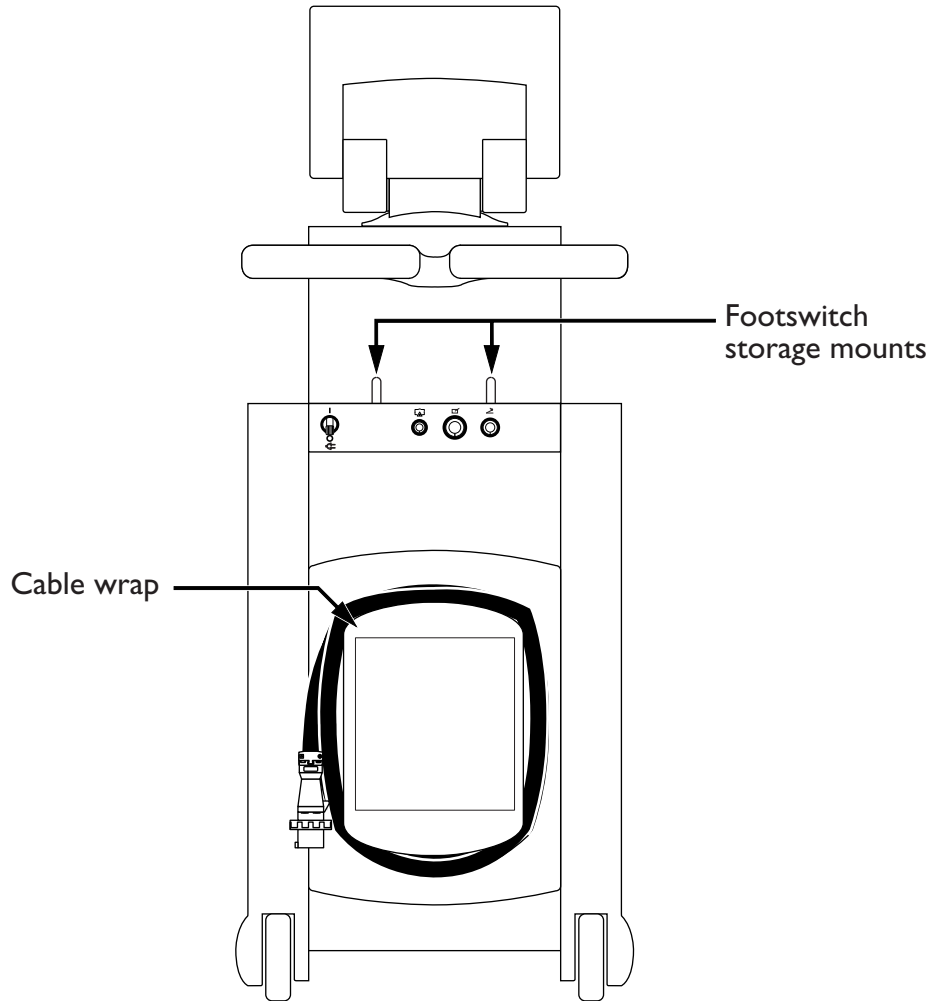
In an emergency, press the emergency off button on the front of the laser to immediately turn off the laser.



Controls for turning off the laser

Disconnecting the laser and delivery system

1. Turn the key switch to the  (off) position.
2. Place the laser main power circuit breaker in the off (down) position.
3. If the laser is configured with a removable wall plug, turn off the main electrical service (wall circuit breaker), and remove the main power plug from the wall receptacle. Wrap the power cable around the cable wrap.
4. Remove the footswitch plug from the laser. Insert the footswitch cable into the footswitch housing, and place the footswitch on the footswitch storage mounts.
5. If the remote control was used, remove the remote control plug from the laser. Place the remote control in the storage area on top of the laser, above the fiber receptacle.
6. Disconnect the external door interlock, if used.
7. Disconnect the delivery system from the laser. If the delivery system is single-use, discard it; if multiple-use, prepare the delivery system for reuse as instructed in the appropriate delivery system instruction guide.



Laser console cable wrap and footswitch storage mounts

Moving the laser console

1. Ensure that the laser is properly disconnected, as instructed above.
2. Unlock the laser console wheels.
3. Using the laser console handle, move the laser to the desired site.

CAUTION

As with any heavy equipment, use caution when tilting the laser console or moving it up or down an incline. For optimum safety, use a second person when moving up or down a steep incline.

NOTE

Do not move the laser console rapidly over uneven surfaces; doing so may damage the equipment.

4. Position the laser console a minimum of 50 centimeters (20 inches) from walls, furniture, or other equipment.

NOTE

Adequate space around the laser console ensures proper air circulation for system cooling.

5. Lock the laser console wheels.

Aiming Beam Verification

WARNING

Verifying the aiming beam integrity is extremely important for the safe operation of your laser equipment. Do not use the laser or delivery system if the aiming beam is not visible. Operating the laser without the aiming beam may result in laser exposure to nontarget tissue and possible injury.

WARNING

When using a fiber optic delivery device, always inspect the fiber optic cable to ensure that it has not been kinked, punctured, fractured, or otherwise damaged. The fiber optic cable may be damaged if stepped on, pulled, left lying in a vulnerable position, kinked, or tightly coiled. Do not clamp the cable with a hemostat or other instruments. If sterile tape is used, always remove the tape before lifting the cable. A damaged fiber optic cable may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.

To verify the aiming beam integrity:

1. Ensure that the delivery system is properly connected to the laser and that “Attach fiber” does not appear on the control screen. (See “Connecting the delivery system” in this section for detailed instructions.)
2. Turn on the aiming beam, and set it to high intensity. (See “Aiming beam intensity” in this section for detailed instructions.)
3. Hold a nonreflective surface, such as a tongue depressor, in front of the fiber tip or, for side-emission delivery systems, in front of the side opening at the fiber tip.

A red spot, the aiming beam, should appear on the surface. If the aiming beam is weak, check that it is set to high intensity. If the aiming beam is still weak, verify that the laser debris shield and delivery system laser connector are not damaged. (See “Inspect the debris shield optic” in the Maintenance section of this manual and “Inspect the laser connector” in the appropriate delivery system instruction guide for detailed instructions.)

WARNING

Do not use the delivery system if the aiming beam is set to high intensity and is still weak or not visible; the fiber optic cable may be damaged. A damaged cable may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.

NOTE

When using the delivery system with an endoscopic camera, lower the intensity of the camera light if the aiming beam is weak or not visible. Doing so will not affect visibility at the treatment site, since the camera compensates for the lower level of light.

General Laser Functions
-----***System beeps***

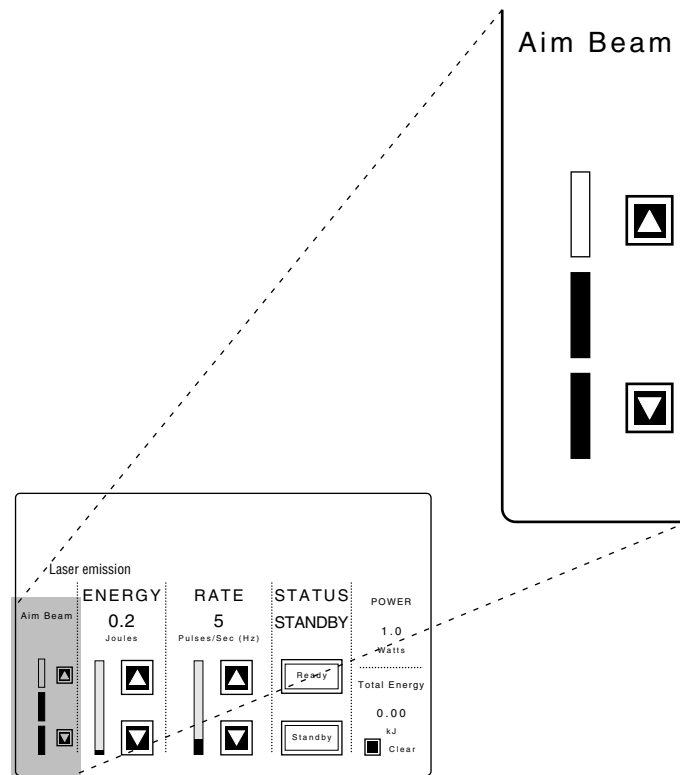
The laser emits a high-pitched beep with each control screen selection and a low-pitched beep when the minimum or maximum setting is reached. Immediately before treatment beam delivery, the laser emits a high-pitched double beep to indicate holmium laser emission or a low-pitched single beep to indicate Nd:YAG laser emission.

The laser typically emits no beeps during holmium treatment, and emits a very short repeating beep during Nd:YAG treatment on dual-wavelength systems. At the time of installation, however, you may request the Lumenis technician to either activate or deactivate beeps during holmium or Nd:YAG treatment.

The laser emits a repeating high pitched beep if the delivered laser energy is greater than the selected energy, or a repeating low-pitched beep if the delivered energy is lower than the selected energy. Under these circumstances, you may continue operating the laser. If the condition persists, however, contact your local Lumenis service representative.

Aiming beam

The AIM BEAM display shows the selected aiming beam intensity: low, medium, or high. At laser system turn on, the aiming beam setting retains the intensity setting from the last use of the laser. Press the AIM BEAM selectors to set the aiming beam intensity. To turn off the aiming beam, press the decrease selector until no bars are illuminated.



Aiming beam intensity

Laser status: Ready and Standby modes

The STATUS display shows the laser status, or mode: “Ready” or “Standby”. Press the READY or STANDBY selector to select the laser mode.

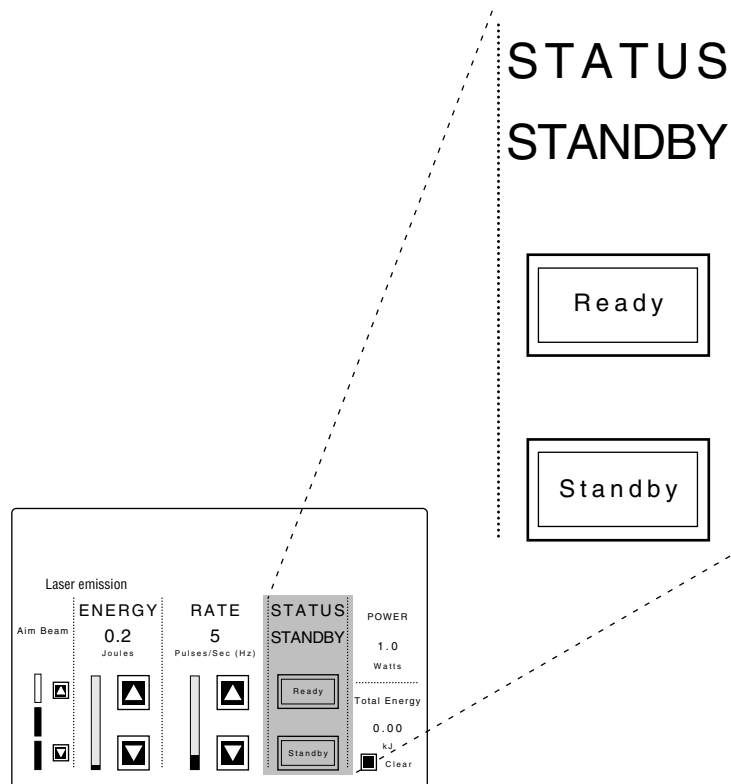
In standby mode, the footswitch is disabled and the safety shutter is closed; no treatment beam is available. In ready mode, the footswitch is enabled and the treatment beam is available.

WARNING

Except during actual treatment, the laser must always be in standby mode. Maintaining the laser in standby mode prevents accidental laser exposure if the footswitch is inadvertently depressed.

WARNING

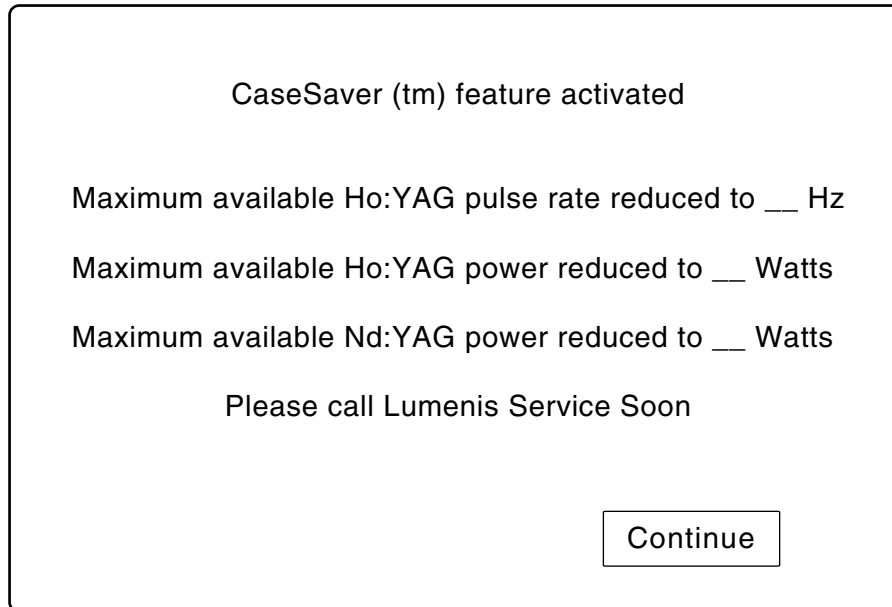
Verify that all persons in the treatment room are wearing the appropriate laser safety eyewear before placing the laser in ready mode.



Laser status

CaseSaver™ Mode

The VersaPulse PowerSuite may contain up to four internal lasers. Should one of these lasers fail during normal operation or at laser start up, CaseSaver mode automatically activates. Upon activation, CaseSaver mode provides you with the option of completing a surgical procedure with a lower maximum power rather than losing use of the laser altogether. Upon CaseSaver mode activation, the control screen displays the new maximum settings, as shown:



CaseSaver mode screen

NOTE

Nd:YAG power is only shown on Dual Wavelength systems. Should the Nd:YAG wavelength fail entirely, "Nd:YAG power no longer available" will display on the control screen, and only the holmium wavelength will be available.

Press CONTINUE to continue treatment with the reduced settings. When the procedure is completed, contact your local Lumenis service representative.

Setting Treatment Values

Treatment values are initially set from the laser control screen and can be adjusted from either the control screen or the remote control.

CAUTION

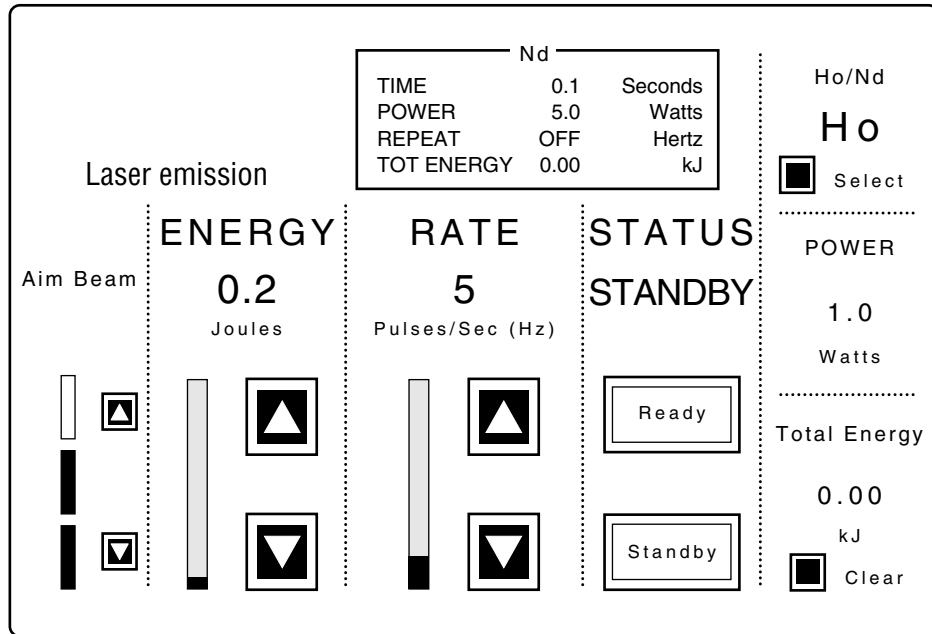
Always verify that the desired treatment values are displayed on the control screen before initiating treatment. If there is no change in display values when the control screen or remote control selectors are pressed, or if the control screen appears otherwise erratic, do not use the laser. Contact your local Lumenis service representative.

VersaPulse PowerSuite Dual Wavelength laser

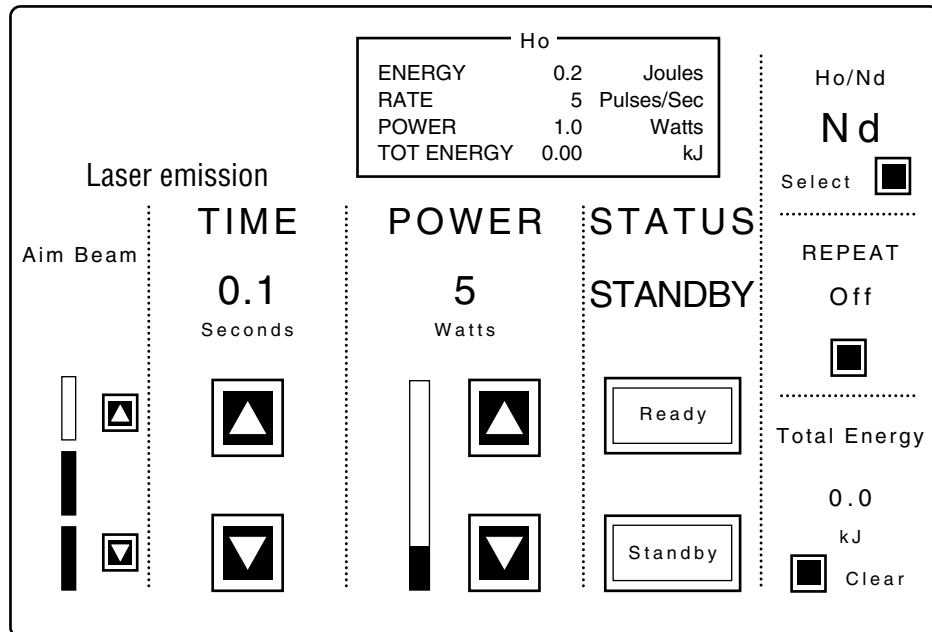
The VersaPulse PowerSuite Dual Wavelength control screen toggles between a holmium treatment screen with an Nd:YAG inset screen and an Nd:YAG treatment screen with a holmium inset screen. The treatment values for a particular wavelength can only be set from that wavelength's treatment screen. (See "Selecting the treatment screen" in this section for detailed instructions.)

NOTE

At laser start-up the control screen displays the holmium treatment screen with the Nd:YAG inset screen. To set the Nd:YAG treatment values, you must select the Nd:YAG treatment screen.



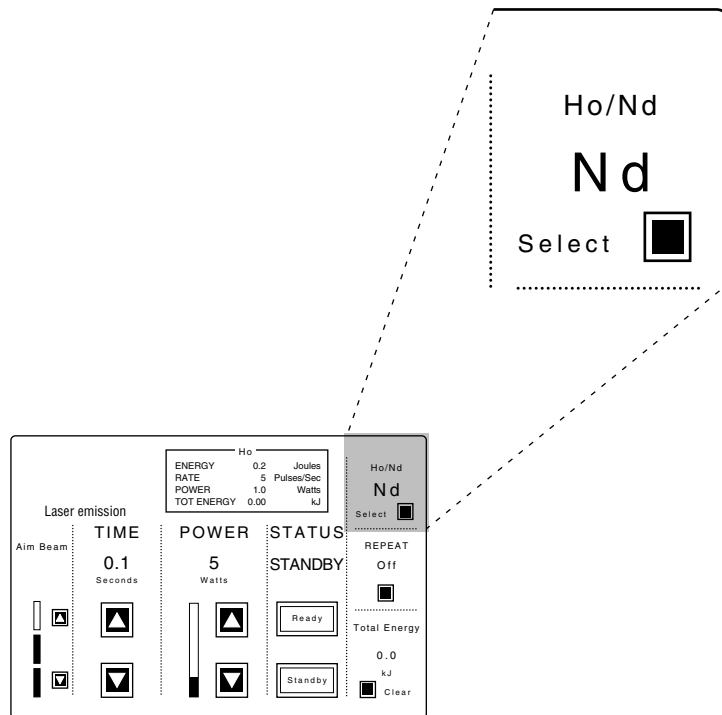
Holmium treatment screen (Nd:YAG inset screen)



Nd:YAG treatment screen (holmium inset screen)

Selecting the treatment screen

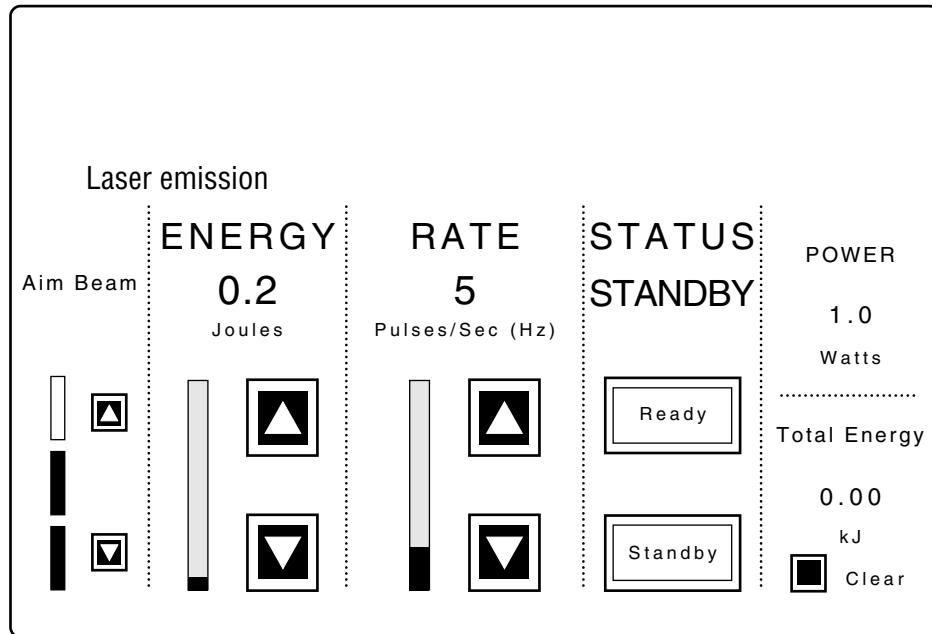
To toggle between the holmium and Nd:YAG treatment screens, press the SELECT control in the HO/ND display. The controls for the selected wavelength appear on the treatment screen, and the treatment values for the alternate wavelength appear on the inset screen.



Selecting the treatment screen

VersaPulse PowerSuite Holmium laser

The VersaPulse PowerSuite Holmium laser has only one treatment screen. Simply touch the control screen selectors to set the treatment values.



VersaPulse PowerSuite Holmium control screen

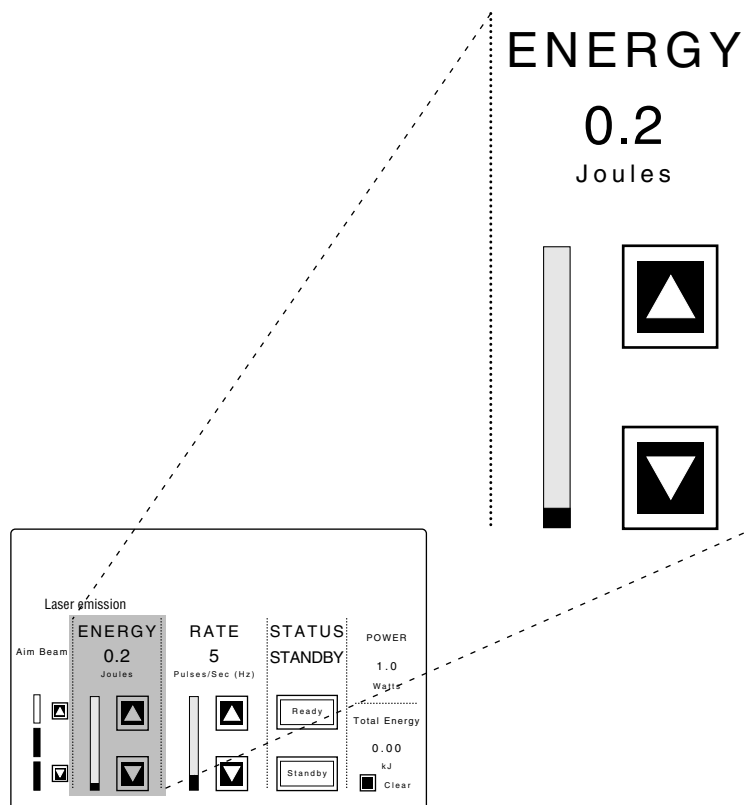
Setting holmium treatment values (for Dual Wavelength and Holmium lasers)

Energy

Set the desired energy per pulse with the ENERGY selectors on the control screen. The selected energy, in Joules, will appear in the ENERGY display.

NOTE

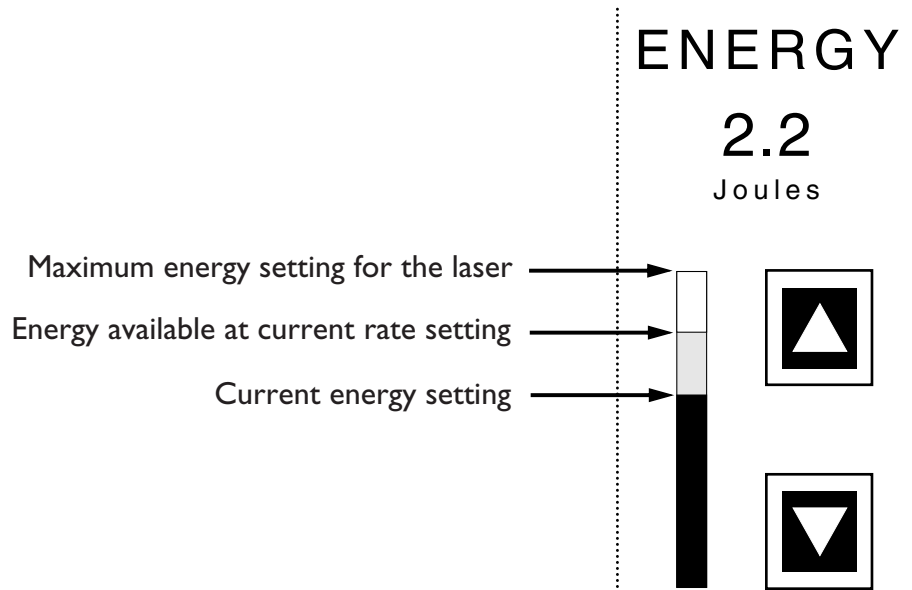
Some energy settings may not be available at higher pulse rate settings. If you attempt to select an energy setting that is unavailable at the existing rate setting, the system will emit a low beep, indicating that the selection is not available. Reducing the rate may increase the amount of available energy per pulse. Refer to the “Holmium Average Power Tables” at the end of this section, or in the Quick Reference Guide included with this manual, to determine the energy and pulse rate combinations available for your laser.



Holmium energy per pulse

Energy bar graph

The energy bar graph provides a visual indication of the energy setting. The bottom of the graph indicates zero joules, and the top of the graph indicates the maximum energy-per-pulse for your laser. The grey area represents the maximum energy available for the selected rate. The dark-colored bar represents the current energy setting.



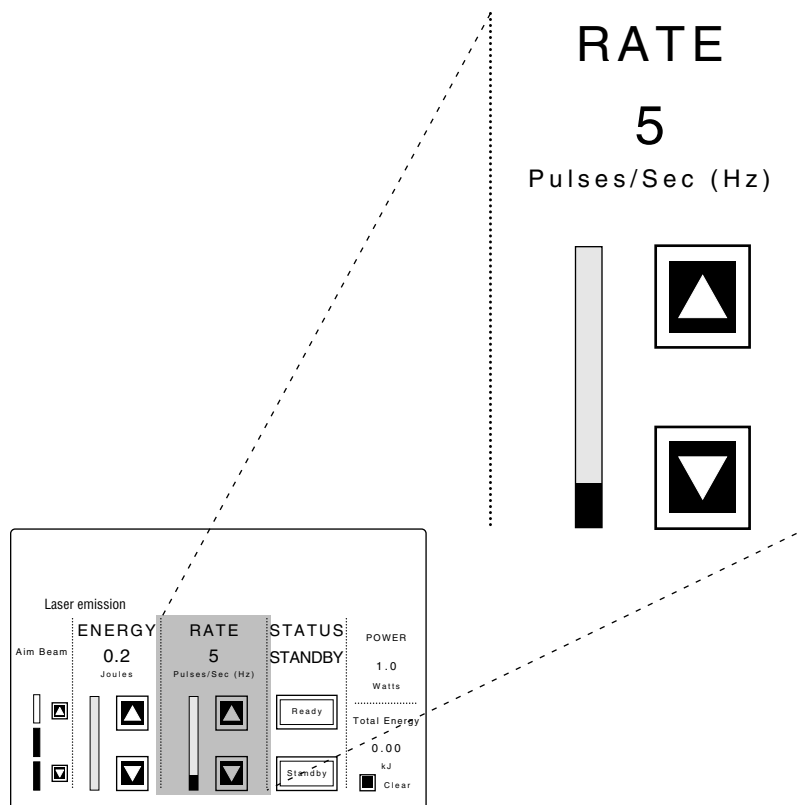
Energy bar graph

Pulse rate

The RATE selectors allow you to specify the speed at which you work. The pulse rate refers to the number of holmium laser pulses delivered per second, displayed in hertz. Press the RATE selectors to set the desired pulse rate.

NOTE

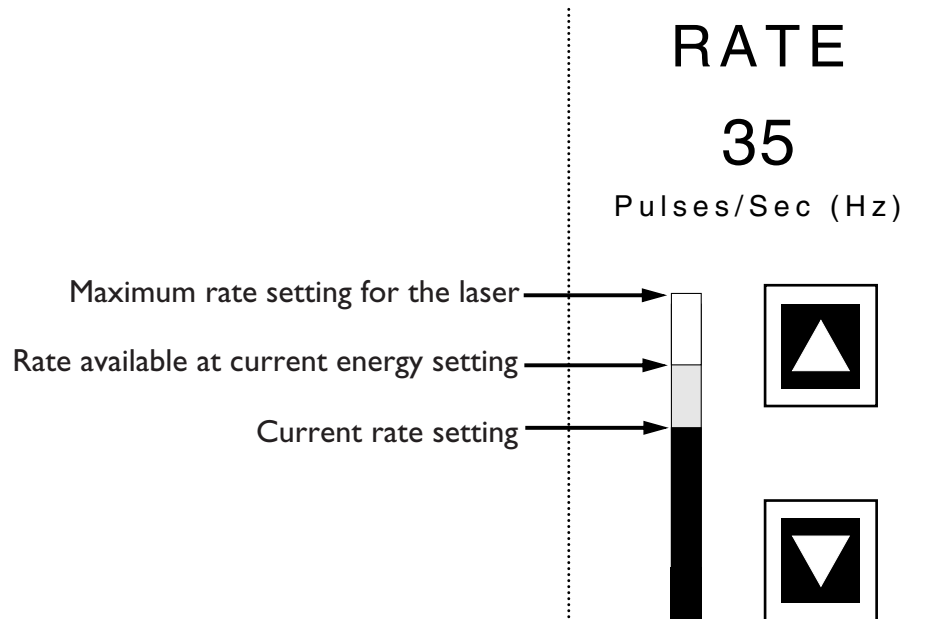
Some rate settings may not be available at higher energy settings. If you attempt to select a pulse rate that is unavailable at the existing energy setting, the system will emit a low beep, indicating that the selection is not available. Reducing the energy may allow a higher pulse rate. Refer to the “Holmium Average Power Tables” at the end of this section, or in the Quick Reference Guide included with this manual, to determine the energy and pulse rate combinations available for your laser.



Holmium pulse rate

Rate bar graph

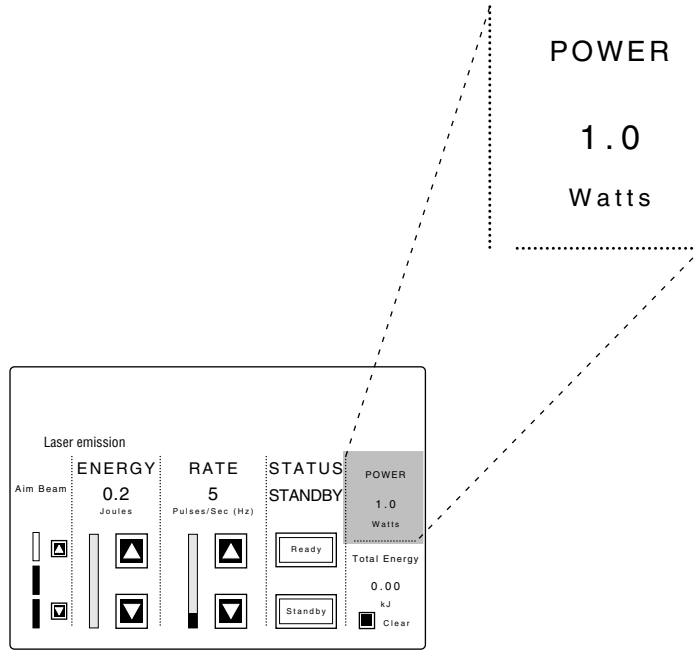
The rate bar graph provides a visual indication of the rate setting. The bottom of the graph indicates zero pulses per second (Hz) and the top of the graph indicates the maximum rate for your laser. The grey area represents the maximum rate available for the selected energy. The dark-colored bar represents the current rate setting.



Rate bar graph

Power

The POWER display shows the calculated average holmium power, in watts, for the selected energy and pulse rate.

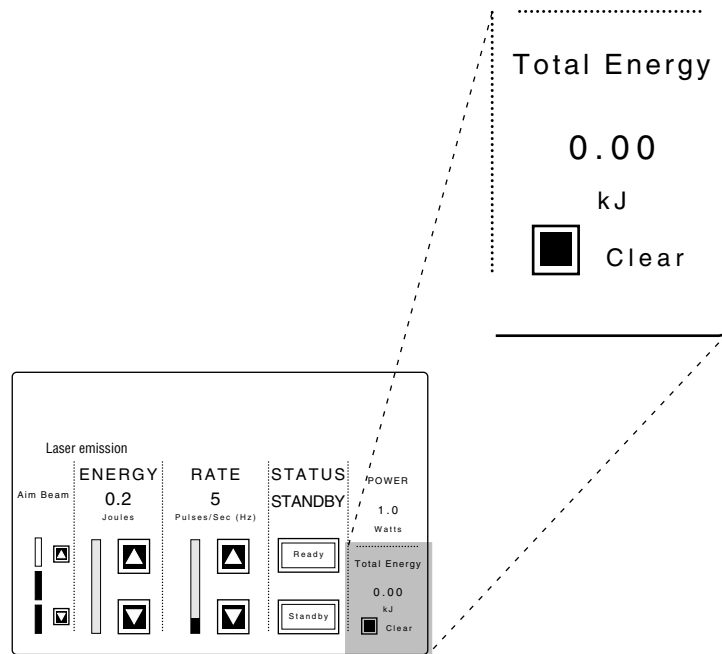


Holmium power

Total energy

The TOTAL ENERGY display shows the total holmium energy, in kilojoules, delivered since the last reset. The display automatically resets to zero the first time you press READY after turning on the laser.

To manually reset the display, press the CLEAR selector.



Holmium total energy

Setting Nd:YAG treatment values (for Dual Wavelength laser only)

Timed or continuous exposure

Exposure time is defined as the amount of time that the laser produces a single exposure of pulsed laser energy. You may control the Nd:YAG exposure time electronically (timed exposure mode) or manually (continuous exposure mode).

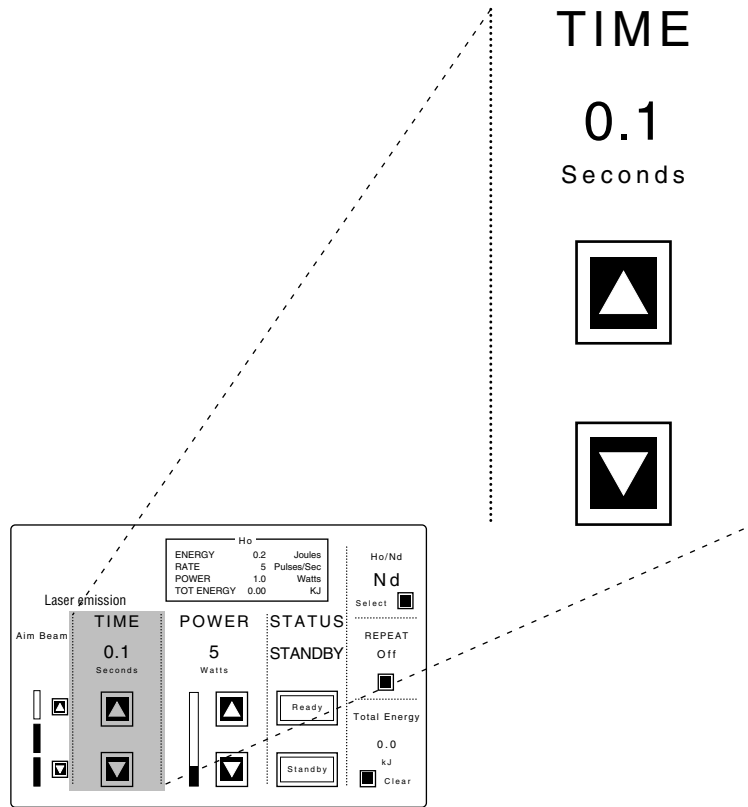
In timed exposure mode, the laser delivers a timed exposure of Nd:YAG laser energy each time you depress the footswitch. For example, if you select a timed exposure setting of 2 seconds, the laser delivers a single, two-second exposure of laser energy when you depress the footswitch. You must release the footswitch and depress it again for additional two-second exposures.

NOTE

Releasing the footswitch during a timed exposure stops laser exposure.

In continuous exposure mode, the laser delivers a continuous exposure of Nd:YAG laser energy for the duration of time you depress the footswitch. You must release the footswitch to stop laser exposure.

To select timed exposure, press the TIME selectors until the desired timed exposure setting displays. To select continuous exposure, press the TIME increase selector until "CONT" displays.



Nd:YAG timed or continuous exposure

Repeat exposure

NOTE

The repeat exposure function is available only when the laser is in timed exposure mode and the exposure time is set to 0.1, 0.2, or 0.5 seconds.

In repeat exposure mode, the laser delivers repeated, rather than single, timed exposures of Nd:YAG laser energy, with a delay between each exposure.

For example, if you select a timed exposure setting of 0.2 seconds and a repetition rate of 3 Hz, the laser repeatedly delivers 0.2-second exposures of Nd:YAG laser energy at a rate of 3 exposures per second while the footswitch is depressed. You must release the footswitch to stop laser exposure.

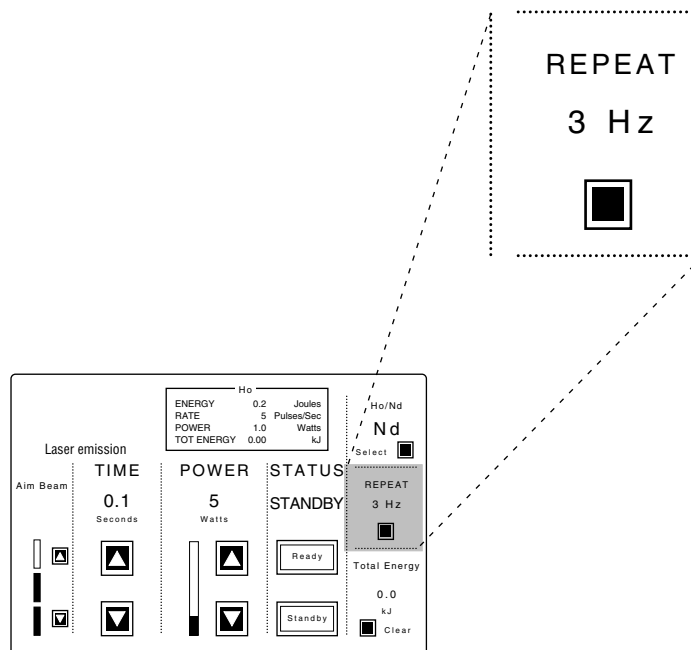
The following repetition rates are available at the indicated exposure times:

Exposure Time	Repetition Rate
0.1 sec	1, 2, 3, and 5 Hz
0.2 sec	1, 2, and 3 Hz
0.5 sec	1 Hz

To select repeat exposure, press the REPEAT selector until the desired repetition rate displays. To turn off repeat exposure, press the REPEAT selector until “Off” displays.

NOTE

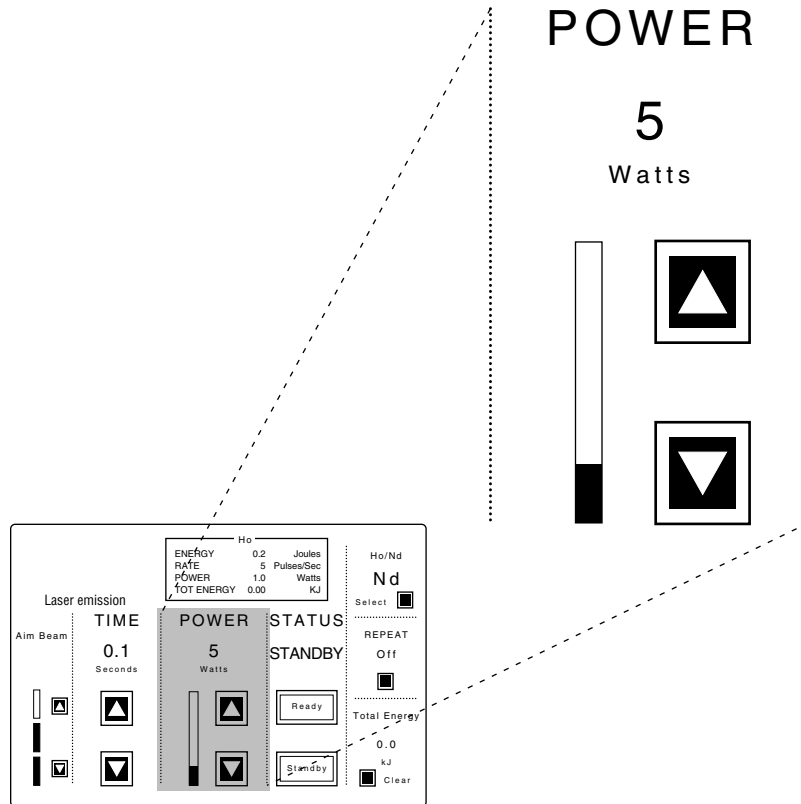
If no repetition rate is available at the selected exposure time, the REPEAT display automatically defaults to “Off.”



Nd:YAG repeat exposure

Power

The POWER display shows the selected Nd:YAG power, in watts. The power is adjustable in five-watt increments. Press the POWER selectors to set the power.

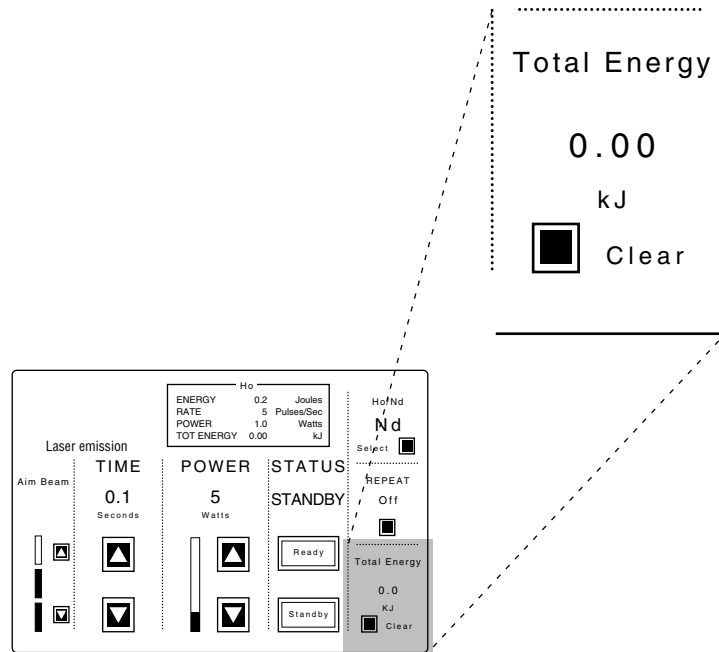


Nd:YAG power

Total energy

The TOTAL ENERGY display shows the total Nd:YAG energy, in kilojoules, delivered since the last reset. The display automatically resets to zero the first time you press READY after turning on the laser.

To manually reset the display, press the CLEAR selector.



Nd:YAG total energy

Treatment Beam Delivery

VersaPulse PowerSuite Holmium laser

A single-pedal footswitch is standard with the VersaPulse PowerSuite Holmium laser. To deliver the treatment beam, depress the footswitch. As the laser delivers the treatment beam, “Treatment” displays on the control screen.

NOTE

A dual-pedal footswitch may be used with the Holmium laser, but only the left pedal, labeled “Holmium”, is functional.

VersaPulse PowerSuite Dual Wavelength laser

Dual-pedal footswitch operation

A dual-pedal footswitch is standard with the VersaPulse PowerSuite Dual Wavelength laser. When using a dual-pedal footswitch, both the holmium and Nd:YAG treatment beams are available. It is not necessary to select the treatment screen for the desired wavelength; simply depress the left pedal for holmium and the right pedal for Nd:YAG to deliver the desired treatment beam at the selected treatment settings. As the laser delivers the treatment beam, “Treat Ho” or “Treat Nd” displays on the control screen.

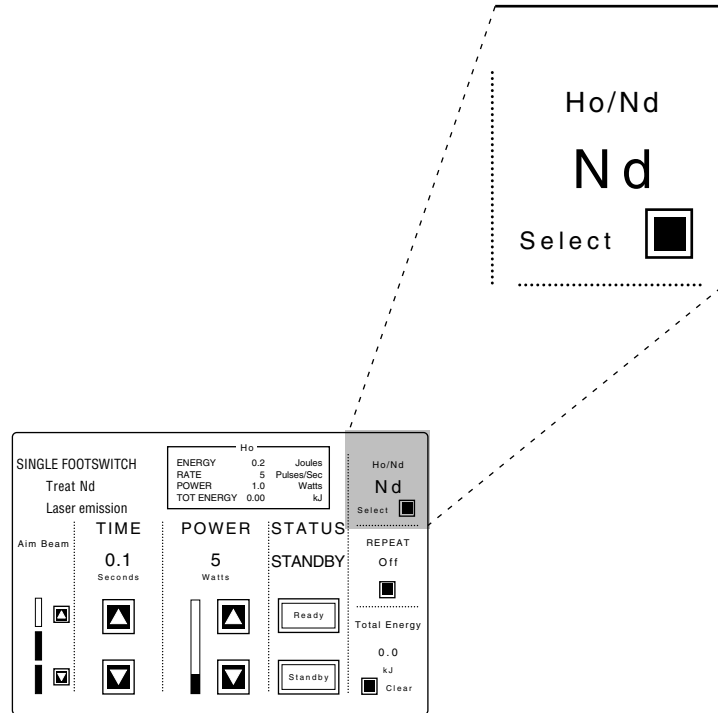
CAUTION

When using the dual-pedal footswitch for a procedure that requires only one treatment wavelength, it is recommended that you set the unused wavelength energy or power setting to the lowest possible value to avoid unintended delivery of that wavelength.

Single-pedal footswitch operation

You may use a single-pedal footswitch for treatment beam delivery. When using a single-pedal footswitch, you must first select the treatment screen for the desired wavelength to access the corresponding treatment beam. To deliver the treatment beam to the target tissue, depress the footswitch. As the laser delivers the treatment beam, “Treat Ho” or “Treat Nd” displays on the control screen.

For example, to deliver the Nd:YAG treatment beam, select the Nd:YAG treatment screen by pressing the SELECT control in the HO/ND display until “Nd” displays, as shown. Then, depress the footswitch to deliver the Nd:YAG treatment beam; “Treat Nd” displays on the control screen.



Select the Nd:YAG treatment screen

Control Screen Messages

Advisory messages

Advisory messages, such as “Attach fiber” or “Check coolant filter,” appear in the advisory message display to alert the user of a necessary action or a laser malfunction. (Refer to the “Troubleshooting Guide” in the Maintenance section of this manual for a list of advisory messages, their probable causes, and solutions.)

Laser emission message

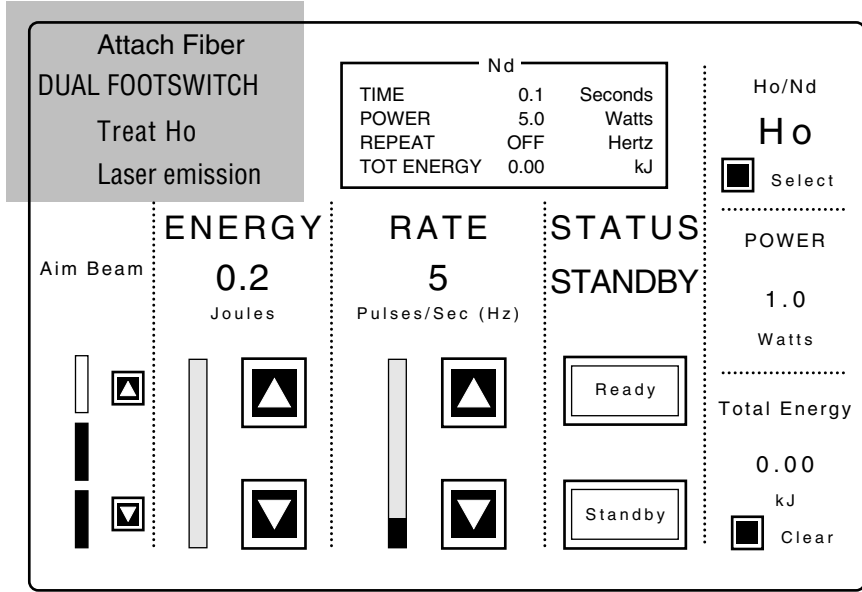
“Laser emission” appears on the control screen at all times during treatment to alert the user that laser energy is available.

Treatment message

During treatment beam delivery, “Treat Ho” or “Treat Nd” appears on the Dual Wavelength laser control screen, and “Treatment” appears on the Holmium laser control screen.

Footswitch message (Dual Wavelength laser only)

“Single footswitch” or “Dual footswitch” appears on the Dual Wavelength laser control screen to remind the user which type of footswitch is attached to the laser.



**Location of control screen messages
(Dual Wavelength control screen shown)**

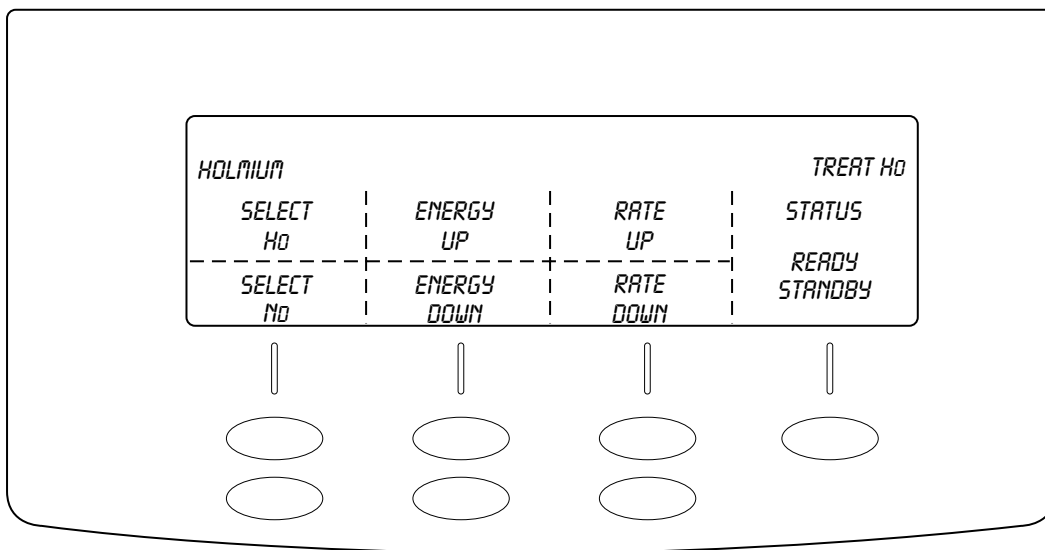
Optional Remote Control

The remote control enables you to rapidly adjust treatment settings from within the sterile field. The remote control must be used concurrently with the laser control screen, since all laser controls and displays are not located on the remote control.

VersaPulse PowerSuite Dual Wavelength remote control

The VersaPulse PowerSuite Dual Wavelength remote control features:

- holmium energy per pulse and pulse rate controls
- Nd:YAG timed exposure and power controls
- wavelength selection and laser status controls

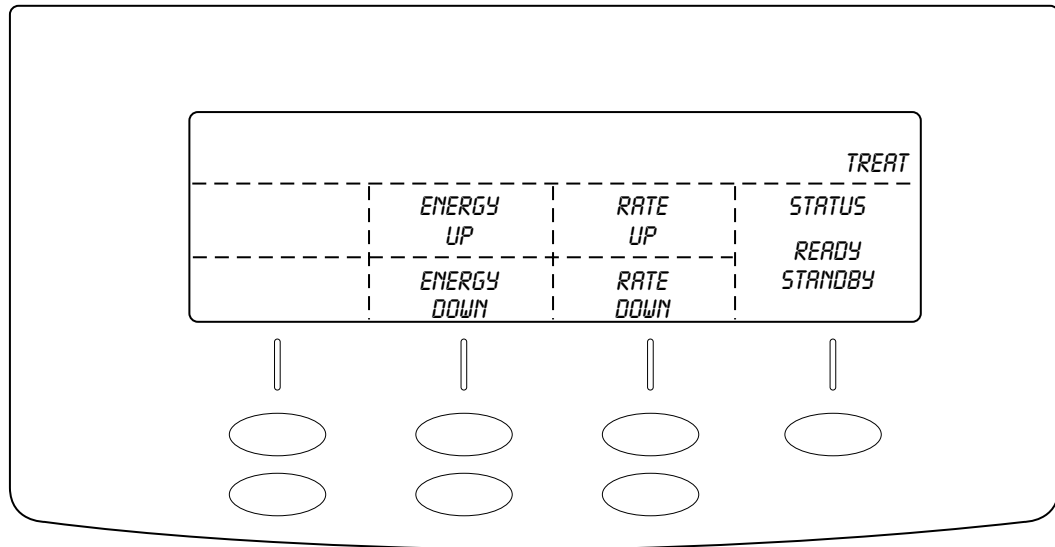


**VersaPulse PowerSuite Dual Wavelength remote control
(Ho:YAG screen shown)**

VersaPulse PowerSuite Holmium remote control

The VersaPulse PowerSuite Holmium remote control features:

- energy per pulse and pulse rate controls
- laser status control



VersaPulse PowerSuite Holmium remote control

Preoperative Instructions

1. Verify that the laser and its components are properly connected, as instructed in the “Connection Instructions” section of this manual.
2. Verify that the delivery system is properly connected, as instructed in this manual or in the appropriate delivery system instruction guide.
3. Post the “Laser in Use” warning sign outside the treatment room door.
4. Ensure that all persons in the treatment room are wearing the appropriate laser safety eyewear. (See “Laser Safety Eyewear” in the Safety and Regulatory section of this manual for detailed laser safety eyewear information.)
5. Turn on the main electrical service (wall circuit breaker).
6. Turn on the laser, as instructed in the “Laser Basics” section of this manual.
7. Verify the aiming beam integrity, as instructed in the “Aiming Beam Verification” section of this manual.

WARNING

Verifying the aiming beam integrity is extremely important for the safe operation of your laser equipment. Do not use the laser or delivery system if the aiming beam is not visible. Operating the laser without the aiming beam may result in laser exposure to nontarget tissue and possible injury.

Intraoperative Instructions

WARNING

Incorrect treatment settings can cause serious tissue damage. Therefore, it is recommended that you use the lowest acceptable treatment settings until you are familiar with the instrument's capabilities. Use extreme caution until you thoroughly understand the biological interaction between the laser energy and tissue.

NOTE

Do not attach any objects to the control screen during laser operation. Doing so may result in erratic operation.

1. Set the treatment values for the desired wavelength, as instructed in the "Setting Treatment Values" section of this manual. Do not exceed the maximum energy or power settings for your delivery system, as specified in the instruction guide which accompanied that device.
2. If using a single-pedal footswitch with the Dual Wavelength laser, verify that the desired wavelength appears in the HO/ND display. If using a dual-pedal footswitch with the Dual Wavelength laser, verify that your foot is on the appropriate pedal for the desired wavelength.
3. Position the aiming beam on the target tissue.
4. Place the laser in ready mode.
5. Depress the footswitch to deliver the treatment beam. "Treat Ho" or "Treat Nd" displays on the Dual Wavelength control screen; "Treatment" displays on the Holmium control screen.

If surgery is interrupted, place the laser in standby mode to disable the footswitch.

Postoperative Instructions

When patient treatment is complete:

1. Place the laser in standby mode.
2. Turn off the laser, as instructed in the “Laser Basics” section of this manual.
3. Disconnect the delivery system from the laser. If the delivery system is single-use, discard it; if multiple-use, prepare the delivery system for reuse, as instructed in the appropriate delivery system instruction guide.
4. Disconnect, clean, and store the laser components, as instructed in the “Laser Basics” and “User Maintenance” sections of this manual.
5. Clean the exterior surfaces of the laser, as instructed in the “User Maintenance” section of this manual.

Holmium Average Power Tables

When working with the holmium wavelength, the average power, measured in watts, is determined by multiplying the selected energy, in joules, by the selected rate, in pulses per second (Hz). The following tables show the relationship between energy, rate, and power, and identify the maximum pulse rates available at different energy settings, according to your laser model.

NOTE

Because the full range of laser power is always available with the Nd:YAG wavelength, no corresponding Nd:YAG power table is necessary.

		Pulse Rate (pulses/second)					
		5	6	8	10	15	20
Energy (Joules)	0.2	1.0	1.2	1.6	2.0	3.0	4.0
	0.3	1.5	1.8	2.4	3.0	4.5	6.0
	0.4	2.0	2.4	3.2	4.0	6.0	8.0
	0.5	2.5	3.0	4.0	5.0	7.5	10.0
	0.6	3.0	3.6	4.8	6.0	9.0	12.0
	0.8	4.0	4.8	6.4	8.0	12.0	16.0
	1.0	5.0	6.0	8.0	10.0	15.0	20.0
	1.2	6.0	7.2	9.6	12.0	18.0	
	1.4	7.0	8.4	11.2	14.0		
	1.5	7.5	9.0	12.0	15.0		
	1.6	8.0	9.6	12.8	16.0		
	1.8	9.0	10.8	14.4	18.0		
	2.0	10.0	12.0	16.0	20.0		

***Holmium average power table — 20 watt systems
(maximum rate, 20 pulses/second)***

		Pulse Rate (pulses/second)						
		5	6	8	10	15	20	25
Energy (Joules)	0.2	1.0	1.2	1.6	2.0	3.0	4.0	5.0
	0.3	1.5	1.8	2.4	3.0	4.5	6.0	7.5
	0.4	2.0	2.4	3.2	4.0	6.0	8.0	10.0
	0.5	2.5	3.0	4.0	5.0	7.5	10.0	12.5
	0.6	3.0	3.6	4.8	6.0	9.0	12.0	15.0
	0.8	4.0	4.8	6.4	8.0	12.0	16.0	20.0
	1.0	5.0	6.0	8.0	10.0	15.0	20.0	25.0
	1.2	6.0	7.2	9.6	12.0	18.0	24.0	30.0
	1.4	7.0	8.4	11.2	14.0	21.0	28.0	
	1.5	7.5	9.0	12.0	15.0	22.5	30.0	
	1.6	8.0	9.6	12.8	16.0	24.0		
	1.8	9.0	10.8	14.4	18.0	27.0		
	2.0	10.0	12.0	16.0	20.0	30.0		
	2.2	11.0	13.2	17.6	22.0			
	2.4	12.0	14.4	19.2	24.0			
	2.5	12.5	15.0	20.0	25.0			
	2.6	13.0	15.6	20.8	26.0			
	2.7	13.5	16.2	21.6	27.0			
	2.8	14.0	16.8	22.4	28.0			
	3.0	15.0	18.0	24.0	30.0			
3.2	16.0	19.2	25.6					
3.5	17.5	21.0	28.0					

**Holmium average power table — 30 watt systems
(maximum rate, 25 pulses/second)**

		Pulse Rate (pulses/second)									
		5	6	8	10	15	20	25	30	35	40
Energy (Joules)	0.2	1.0	1.2	1.6	2.0	3.0	4.0	5.0	6.0	7.0	8.0
	0.3	1.5	1.8	2.4	3.0	4.5	6.0	7.5	9.0	10.5	12.0
	0.4	2.0	2.4	3.2	4.0	6.0	8.0	10.0	12.0	14.0	16.0
	0.5	2.5	3.0	4.0	5.0	7.5	10.0	12.5	15.0	17.5	20.0
	0.6	3.0	3.6	4.8	6.0	9.0	12.0	15.0	18.0	21.0	24.0
	0.8	4.0	4.8	6.4	8.0	12.0	16.0	20.0	24.0	28.0	32.0
	1.0	5.0	6.0	8.0	10.0	15.0	20.0	25.0	30.0	35.0	40.0
	1.2	6.0	7.2	9.6	12.0	18.0	24.0	30.0	36.0	42.0	
	1.4	7.0	8.4	11.2	14.0	21.0	28.0	35.0	42.0		
	1.5	7.5	9.0	12.0	15.0	22.5	30.0	37.5	45.0		
	1.6	8.0	9.6	12.8	16.0	24.0	32.0	40.0			
	1.8	9.0	10.8	14.4	18.0	27.0	36.0	45.0			
	2.0	10.0	12.0	16.0	20.0	30.0	40.0				
	2.2	11.0	13.2	17.6	22.0	33.0	44.0				
	2.4	12.0	14.4	19.2	24.0	36.0					
	2.5	12.5	15.0	20.0	25.0	37.5					
	2.6	13.0	15.6	20.8	26.0	39.0					
	2.7	13.5	16.2	21.6	27.0	40.5					
	2.8	14.0	16.8	22.4	28.0	42.0					
	3.0	15.0	18.0	24.0	30.0	45.0					
3.2	16.0	19.2	25.6	32.0							
3.5	17.5	21.0	28.0	35.0							

**Holmium average power table — 45 watt systems
(maximum rate, 40 pulses/second)**

		Pulse Rate (pulses/second)									
		5	6	8	10	15	20	25	30	35	40
Energy (Joules)	0.2	1.0	1.2	1.6	2.0	3.0	4.0	5.0	6.0	7.0	8.0
	0.3	1.5	1.8	2.4	3.0	4.5	6.0	7.5	9.0	10.5	12.0
	0.4	2.0	2.4	3.2	4.0	6.0	8.0	10.0	12.0	14.0	16.0
	0.5	2.5	3.0	4.0	5.0	7.5	10.0	12.5	15.0	17.5	20.0
	0.6	3.0	3.6	4.8	6.0	9.0	12.0	15.0	18.0	21.0	24.0
	0.8	4.0	4.8	6.4	8.0	12.0	16.0	20.0	24.0	28.0	32.0
	1.0	5.0	6.0	8.0	10.0	15.0	20.0	25.0	30.0	35.0	40.0
	1.2	6.0	7.2	9.6	12.0	18.0	24.0	30.0	36.0	42.0	48.0
	1.4	7.0	8.4	11.2	14.0	21.0	28.0	35.0	42.0	49.0	56.0
	1.5	7.5	9.0	12.0	15.0	22.5	30.0	37.5	45.0	52.5	60.0
	1.6	8.0	9.6	12.8	16.0	24.0	32.0	40.0	48.0	56.0	
	1.8	9.0	10.8	14.4	18.0	27.0	36.0	45.0	54.0		
	2.0	10.0	12.0	16.0	20.0	30.0	40.0	50.0	60.0		
	2.2	11.0	13.2	17.6	22.0	33.0	44.0	55.0			
	2.4	12.0	14.4	19.2	24.0	36.0	48.0	60.0			
	2.5	12.5	15.0	20.0	25.0	37.5	50.0				
	2.6	13.0	15.6	20.8	26.0	39.0	52.0				
	2.7	13.5	16.2	21.6	27.0	40.5	54.0				
	2.8	14.0	16.8	22.4	28.0	42.0	56.0				
	3.0	15.0	18.0	24.0	30.0	45.0	60.0				
3.2	16.0	19.2	25.6	32.0	48.0						
3.5	17.5	21.0	28.0	35.0	52.5						

***Holmium average power table — 60 watt systems
(maximum rate, 40 pulses/second)***

		Pulse Rate (pulses/second)									
		5	6	8	10	15	20	25	30	35	40
Energy (Joules)	0.2	1.0	1.2	1.6	2.0	3.0	4.0	5.0	6.0	7.0	8.0
	0.3	1.5	1.8	2.4	3.0	4.5	6.0	7.5	9.0	10.5	12.0
	0.4	2.0	2.4	3.2	4.0	6.0	8.0	10.0	12.0	14.0	16.0
	0.5	2.5	3.0	4.0	5.0	7.5	10.0	12.5	15.0	17.5	20.0
	0.6	3.0	3.6	4.8	6.0	9.0	12.0	15.0	18.0	21.0	24.0
	0.8	4.0	4.8	6.4	8.0	12.0	16.0	20.0	24.0	28.0	32.0
	1.0	5.0	6.0	8.0	10.0	15.0	20.0	25.0	30.0	35.0	40.0
	1.2	6.0	7.2	9.6	12.0	18.0	24.0	30.0	36.0	42.0	48.0
	1.4	7.0	8.4	11.2	14.0	21.0	28.0	35.0	42.0	49.0	56.0
	1.5	7.5	9.0	12.0	15.0	22.5	30.0	37.5	45.0	52.5	60.0
	1.6	8.0	9.6	12.8	16.0	24.0	32.0	40.0	48.0	56.0	64.0
	1.8	9.0	10.8	14.4	18.0	27.0	36.0	45.0	54.0	63.0	72.0
	2.0	10.0	12.0	16.0	20.0	30.0	40.0	50.0	60.0	70.0	80.0
	2.2	11.0	13.2	17.6	22.0	33.0	44.0	55.0	66.0	77.0	
	2.4	12.0	14.4	19.2	24.0	36.0	48.0	60.0	72.0		
	2.5	12.5	15.0	20.0	25.0	37.5	50.0	62.5	75.0		
	2.6	13.0	15.6	20.8	26.0	39.0	52.0	65.0	78.0		
	2.7	13.5	16.2	21.6	27.0	40.5	54.0	67.5			
	2.8	14.0	16.8	22.4	28.0	42.0	56.0	70.0			
	3.0	15.0	18.0	24.0	30.0	45.0	60.0	75.0			
3.2	16.0	19.2	25.6	32.0	48.0	64.0	80.0				
3.5	17.5	21.0	28.0	35.0	52.5	70.0					

(80 Watt holmium is only available in Dual Wavelength configurations.)

***Holmium average power table — 80 watt systems
(maximum rate, 40 pulses/second)***

		Pulse Rate (pulses/second)											
		5	6	8	10	15	20	25	30	35	40	45	50
Energy (Joules)	0.2	1.0	1.2	1.6	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0
	0.3	1.5	1.8	2.4	3.0	4.5	6.0	7.5	9.0	10.5	12.0	13.5	15.0
	0.4	2.0	2.4	3.2	4.0	6.0	8.0	10.0	12.0	14.0	16.0	18.0	20.0
	0.5	2.5	3.0	4.0	5.0	7.5	10.0	12.5	15.0	17.5	20.0	22.5	25.0
	0.6	3.0	3.6	4.8	6.0	9.0	12.0	15.0	18.0	21.0	24.0	27.0	30.0
	0.8	4.0	4.8	6.4	8.0	12.0	16.0	20.0	24.0	28.0	32.0	36.0	40.0
	1.0	5.0	6.0	8.0	10.0	15.0	20.0	25.0	30.0	35.0	40.0	45.0	50.0
	1.2	6.0	7.2	9.6	12.0	18.0	24.0	30.0	36.0	42.0	48.0	54.0	60.0
	1.4	7.0	8.4	11.2	14.0	21.0	28.0	35.0	42.0	49.0	56.0	63.0	70.0
	1.5	7.5	9.0	12.0	15.0	22.5	30.0	37.5	45.0	52.5	60.0	67.5	75.0
	1.6	8.0	9.6	12.8	16.0	24.0	32.0	40.0	48.0	56.0	64.0	72.0	80.0
	1.8	9.0	10.8	14.4	18.0	27.0	36.0	45.0	54.0	63.0	72.0	81.0	90.0
	2.0	10.0	12.0	16.0	20.0	30.0	40.0	50.0	60.0	70.0	80.0	90.0	100.0
	2.2	11.0	13.2	17.6	22.0	33.0	44.0	55.0	66.0	77.0	88.0		
	2.4	12.0	14.4	19.2	24.0	36.0	48.0	60.0	72.0	84.0	96.0		
	2.5	12.5	15.0	20.0	25.0	37.5	50.0	62.5	75.0	87.5	100.0		
	2.6	13.0	15.6	20.8	26.0	39.0	52.0	65.0	78.0				
	2.7	13.5	16.2	21.6	27.0	40.5	54.0	67.5	81.0				
	2.8	14.0	16.8	22.4	28.0	42.0	56.0	70.0	84.0				
	3.0	15.0	18.0	24.0	30.0	45.0	60.0	75.0	90.0				
3.2	16.0	19.2	25.6	32.0	48.0	64.0	80.0	96.0					
3.5	17.5	21.0	28.0	35.0	52.5	70.0	87.5						

**Holmium average power table — 100 watt systems
(maximum rate, 50 pulses/second)**

NOTE

An updated average power table for VersaPulse PowerSuite Holmium 100 Watt systems operating in countries with an electric supply of 220 VAC / 50 Hz (excluding P.R. China) can be found in the Addendum at the end of this manual.

For 100 Watt Holmium systems in all other countries, refer to the table on this page.

Maintenance

Troubleshooting Guide

If the instrument fails to operate properly, this troubleshooting guide will help you to locate and correct the malfunction. First, please check for the following items:

1. Electrical power source...verify that the electrical disconnect switch, the circuit breaker, is turned on.
2. Laser console electrical...verify that the laser is on and properly connected to an electrical service outlet.
3. Delivery system connections...verify that the delivery system is properly connected.
4. External door interlock...if the external door interlock is used in conjunction with a remote switch, verify that the external door interlock plug is inserted in the external door interlock receptacle. Close the interlocked door.

Laser does not turn on. The control screen does not illuminate.

Probable cause:	The laser is not plugged in.
Suggestion:	Plug in the laser.
Probable cause:	The laser main power circuit breaker is in the off (down) position.
Suggestion:	Place the laser main power circuit breaker in the on (up) position.
Probable cause:	The building power (main electrical service) is turned off.
Suggestion:	Turn on the building power.
Probable cause:	The electrical outlet is defective.
Suggestion:	Use another outlet, or have the outlet professionally tested and repaired, if necessary.

Inadequate or no aiming beam.

Probable cause:	The aiming beam is off or set to low intensity.
Suggestion:	Adjust the aiming beam intensity.
Probable cause:	The delivery system optical fiber is defective.
Suggestion:	Replace the delivery system.
Probable cause:	The endoscopic camera light is too bright (when using an endoscopic camera with the delivery system).
Suggestion:	Lower the intensity of the camera light.
Probable cause:	The debris shield is damaged.
Suggestion:	Inspect and, if necessary, replace the debris shield as instructed in the “User Maintenance” section of this manual.
Probable cause:	The aiming beam is malfunctioning.
Suggestion:	Contact your local Lumenis service representative.

No laser power.

Probable cause: The delivery system optical fiber is defective.
 Suggestion: Replace the delivery system.

Probable cause: The debris shield is damaged.
 Suggestion: Inspect and, if necessary, replace the debris shield as instructed in the “User Maintenance” section of this manual.

Probable cause: The laser is malfunctioning.
 Suggestion: Contact your local Lumenis service representative.

“Attach fiber” advisory message appears on the control screen.

Probable cause: The delivery system laser connector is not properly connected to the laser.
 Suggestion: Connect the delivery system as instructed in the “Connection Instructions” section of this manual.

“Attach footswitch” advisory message appears on the control screen.

Probable cause: The footswitch is not properly connected to the laser.
 Suggestion: Connect the footswitch as instructed in the “Connection Instructions” section of this manual.

“Check interlock” advisory message appears on the control screen.

Probable cause: The interlock door is open, or the interlock plug is not properly inserted.
 Suggestion: Close the interlock door, or insert the interlock plug.

“Insert debris shield” advisory message appears on the control screen.

Probable cause: The debris shield is missing or is not properly inserted.
 Suggestion: Insert the debris shield as instructed in the “User Maintenance” section of this manual.

“No lasers” advisory message appears on the control screen.

Probable cause: No lasers are operative.
 Suggestion: Contact your local Lumenis service representative.

“Overheating” advisory message appears on the control screen.

Probable cause: The laser was used at a high power for an extended amount of time.
 Suggestion: Wait until the message clears. Press READY, and continue to use the laser. Pause occasionally during treatment to allow the laser to cool off.

NOTE

If the laser overheats, do not turn off the laser. Leaving the laser on allows the internal cooling system to quickly cool the laser. As the laser cools down, listen for the internal fan to slow down to the normal operating speed.

Probable cause: The air flow is restricted.
 Suggestion: Verify that the laser is at least 50 centimeters (20 inches) from walls, furniture, or other equipment.

Probable cause: The treatment room air temperature is too high.
 Suggestion: Verify that the treatment room temperature is between 10° C and 30° C (50° F and 86° F).

“Energy high” advisory message appears on the control screen.

Probable cause: The energy delivered is more than 50% higher than the selected level.
 Suggestion: Press the READY selector to clear the message. If the condition continues, turn off the laser for five seconds, then turn it back on. If the condition persists, contact your local Lumenis service representative.

“Energy low” advisory message appears on the control screen.

Probable cause: The energy delivered is less than 50% of the selected level.
 Suggestion: Press the READY selector to clear the message. If the condition continues, turn off the laser for five seconds, then turn it back on. If the condition persists, contact your local Lumenis service representative.

“Rate high” advisory message appears on the control screen.

Probable cause: The pulse rate delivered is more than 50% higher than the selected level.
 Suggestion: Press the READY selector to clear the message. If the condition continues, turn off the laser for five seconds, then turn it back on. If the condition persists, contact your local Lumenis service representative.

“Rate 20% high” advisory message appears on the control screen.

Probable cause: The pulse rate delivered is at least 20% more than the selected level.
 Suggestion: Press the READY selector to clear the message. If the condition continues, turn off the laser for five seconds, then turn it back on. If the condition persists, contact your local Lumenis service representative.

“Rate low” advisory message appears on the control screen.

Probable cause: The pulse rate delivered is less than 50% of the selected level.

Suggestion: Press the READY selector to clear the message. If the condition continues, turn off the laser for five seconds, then turn it back on. If the condition persists, contact your local Lumenis service representative.

“Rate 20% low” advisory message appears on the control screen.

Probable cause: The pulse rate delivered is less than 80% of the selected level.
 Suggestion: Press the READY selector to clear the message. If the condition continues, turn off the laser for five seconds, then turn it back on. If the condition persists, contact your local Lumenis service representative.

“Please call Lumenis Service soon” appears on the control screen

Probable Cause: The laser is in Service Soon mode. You can still use the laser. Approximately five or less treatments remain before service is required.
 Suggestion: Schedule a service call with your local Lumenis service representative.

An advisory code, such as “Fault 102,” appears on the control screen.

Probable Cause: The laser is malfunctioning.
 Suggestion: Press the READY selector to clear the message. If the condition continues, turn off the laser for five seconds, then turn it back on. If the message reappears, record the code and contact your local Lumenis service representative.

User Maintenance

Annual laser maintenance

Preventative maintenance, safety, power, and calibration checks should be performed annually by a Lumenis-certified service engineer to ensure proper laser performance.

Laser repair

All laser repairs should be performed by a Lumenis-certified service engineer. For training and information, contact your local Lumenis representative.

Clean the external surfaces of the laser console

Use a cloth dampened with a noncaustic cleaning solution, such as soap and water, isopropyl alcohol, or a “hospital-grade” disinfectant, to wipe the external surfaces of the laser console. Dry with a clean cloth, or allow to air dry.

Clean the laser control screen

Use a soft cloth to apply antistatic glass or plastic cleaner to the laser control screen.

CAUTION

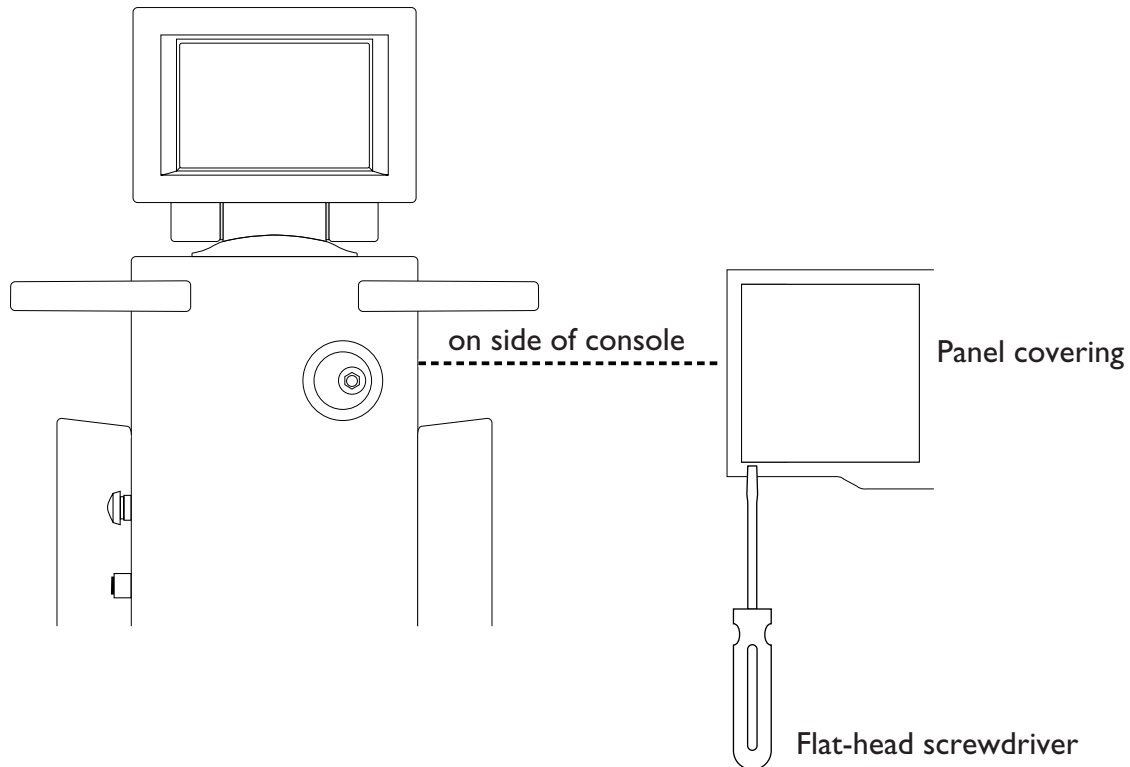
Do not spray or pour cleaning agents directly on the laser console or control screen. You may damage the console, screen, and laser system electronics.

Inspect the debris shield optic

The debris shield protects the internal optical components of the laser from damage by a faulty or misused delivery device.

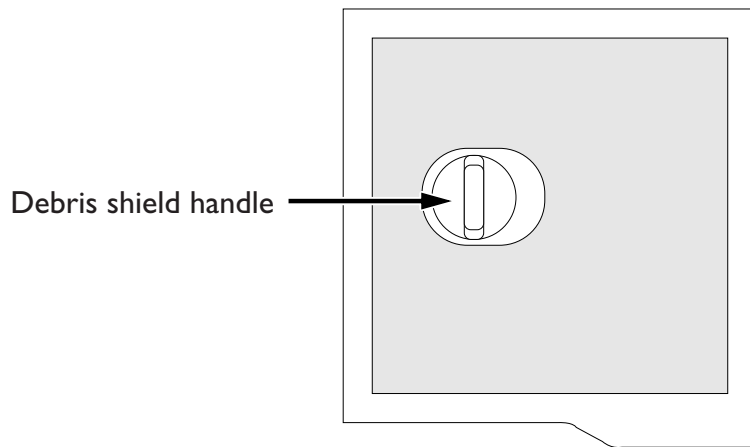
Remove the debris shield

1. Turn off the laser.
2. Locate the debris shield panel covering on the upper right-hand side of the laser console.
3. Remove the panel covering with a flat-head screwdriver.



Locate the debris shield

4. Grasp the debris shield handle, and pull the shield out of the receptacle.



Remove the debris shield

Inspect the optic

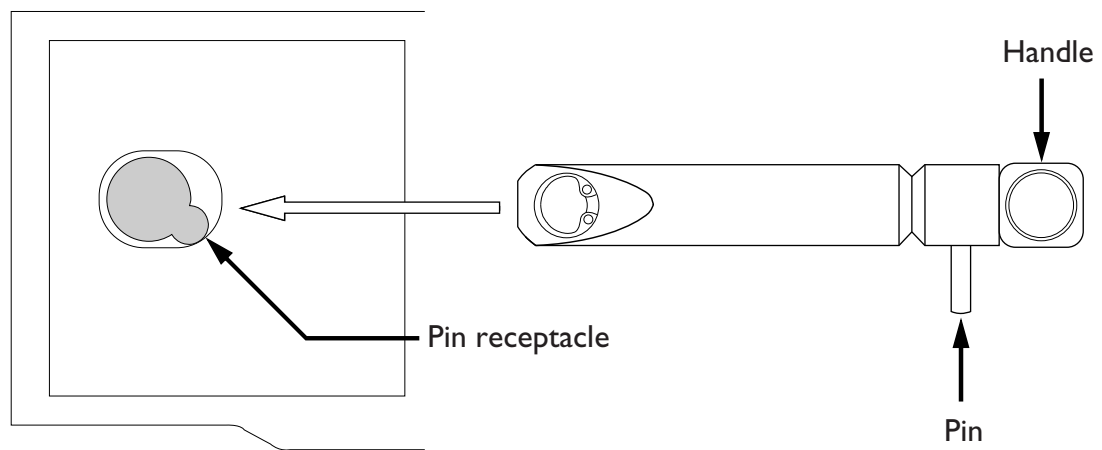
Inspect the debris shield optic to verify that it is free of any burn marks, scratches, dust, or fingerprints. If the optic is damaged or dirty, replace it as instructed in “Change the debris shield optic” in this section. If the optic is free of damage, reinsert the debris shield into the debris shield receptacle as instructed below.



Inspect the debris shield optic

Reinsert the debris shield

1. Holding the debris shield handle, position the shield so that the pin is aligned with the pin receptacle.
2. Insert the debris shield into the debris shield receptacle.
3. Replace the panel covering.
4. Restart the laser.



Reinsert the debris shield

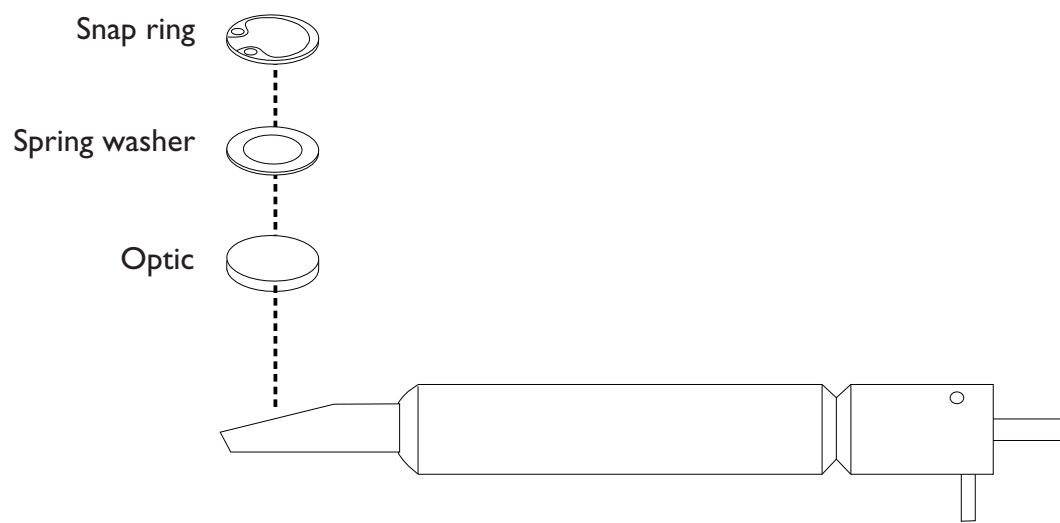
Change the debris shield optic

1. Use snap ring pliers to remove the snap ring that secures the debris shield optic to the debris shield.
2. Carefully turn over the debris shield holder, and allow the debris shield optic and spring washer to drop onto a lens cleaning tissue.
3. Open the vial containing the new debris shield optic.

CAUTION

To avoid contamination, do not touch the surface of the debris shield optic with your fingers.

4. Carefully turn over the vial, and allow the optic to drop onto a lens cleaning tissue.
5. Lay the debris shield over the new debris shield optic.
6. Hold the lens cleaning tissue over the debris shield optic opening, and slowly turn over the debris shield until the optic is facing up.
7. Place the spring washer over the debris shield optic.
8. Hold the debris shield optic and spring washer in place with the lens cleaning tissue, and use snap ring pliers to insert the snap ring over the spring washer. Ensure that the snap ring is in place and secure before releasing the snap ring pliers.



Change the debris shield optic

Electrical Utilities

VersaPulse PowerSuite Holmium and Dual Wavelength lasers are available in several electrical configurations. Electrical power should be set up according to the model ordered. The line wires in the power cable shall be connected to the building power, and the green/yellow wire must be connected to the building ground.

Systems designed for use outside of Europe

For the 200-230 VAC configuration, supply the electrical power from a dedicated 200, 208, or 230 VAC, single-phase, 50/60 Hz supply mains in accordance with local codes. The laser may be installed with a removable plug or wall socket and lockable plug, or hard-wired. When installed with a removable or lockable wall plug, the socket and wall plug connection must be rated for 30A @ 60 Hz, 32A @ 50 Hz, 230 \pm 10% VAC.

Systems designed for use in European communities under the MDD

To comply with the European Communities Medical Device Directive 93/42/EEC, and harmonized standards EN 60601-1 and EN 60601-2-22, the 230 \pm 10% VAC configured laser must be either permanently connected to a 32 A, 230 \pm 10% VAC, single-phase, 50 Hz supply mains in accordance with national wiring regulations, or connected by means of a dedicated single-phase, 32 A, 230 \pm 10% VAC wall socket and lockable plug combination designed to ensure the connection is “mechanically secured against accidental loosening.” Such a connection will ensure compliance with EN 60309 for this device. Wiring should be rated at 32 A. Leakage current for these lasers does not exceed 500 μ A.

This equipment has been tested and found to comply with the limits in Standard EN 60601-1-2 “Medical Electrical equipment, Part 1: General Requirements and tests.” These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in accordance with the instruction manual.

Hard-wired configurations

If the laser is to be hardwired to the electrical service, prior to installation, the customer's engineer or electrical contractor will be responsible for ensuring that the proper electrical requirements are available at the site. After the Lumenis Service representative arrives, the customer's engineer or electrical contractor will be responsible for connecting the power cable supplied with the system to the service box, in accordance with local codes.

Removable or lockable wall socket and plug configurations

If the laser is installed with a removable plug or wall socket and lockable plug combination, prior to installation, the customer's engineer or electrical contractor will be responsible for ensuring that the proper electrical requirements are available at the site.

Systems designed for use outside of Europe

When installed with a removable or lockable wall plug, the socket and wall plug connection must be rated for 30A @ 60 Hz, 32A @ 50 Hz, 250 VAC. In most instances, customers must purchase a suitable electrical connection kit locally.

Systems designed for use in European communities under MDD

To comply with the European Communities Medical Device Directive 93/42/EEC, the 32 A, 230 \pm 10% VAC wall socket and lockable plug combination must comply with EN 60309.

An installation kit can be ordered via your local Lumenis representative or, alternately, may be sourced locally. The wall socket and plug combination must meet the following specifications:

Plug:	32 A , 400 VAC, EN 60309, BS 43 43 IPX4
Wall Socket:	32 A , 400 VAC, EN 60309, BS 43 43 IPX4

Specifications

Specifications are subject to change without notice.

VersaPulse PowerSuite Dual Wavelength laser

Treatment beam wavelengths

Ho:YAG (2.1 μm)
Nd:YAG (1.06 μm)

20/60 W model

Wavelength	Power	Energy	Exposure Time	Pulse Rate	Pulse Width
Ho:YAG (2.1 μm)	0 - 20 W	0.2 - 2.0 J*	n/a	5 - 20 pulses/sec*	600 μs Max
Nd:YAG (1.06 μm)	0 - 60 W**	0.08 - 1.0 J	0.1 - 180 sec* or continuous	60 pulses/sec	2 ms Max

60/100 W model

Wavelength	Power	Energy	Exposure Time	Pulse Rate	Pulse Width
Ho:YAG (2.1 μm)	0 - 60 W	0.2 - 3.5 J*	n/a	5 - 40 pulses/sec*	600 μs Max
Nd:YAG (1.06 μm)	0 - 100 W**	0.08 - 1.67 J	0.1 - 180 sec* or continuous	60 pulses/sec	2 ms Max

80/100 W model

Wavelength	Power	Energy	Exposure Time	Pulse Rate	Pulse Width
Ho:YAG (2.1 μm)	0 - 80 W	0.2 - 3.5 J*	n/a	5 - 40 pulses/sec*	600 μs Max
Nd:YAG (1.06 μm)	0 - 100 W**	0.08 - 1.67 J	0.1 - 180 sec* or continuous	60 pulses/sec	2 ms Max

*adjustable in variable increments

**adjustable in 5-watt increments

VersaPulse PowerSuite Holmium laser

Treatment beam wavelength

Ho:YAG (2.1 μm)

Model	Power	Energy	Pulse Rate	Pulse Width
30 Watt Ho:YAG	30 W	0.2 - 3.5 J	5 - 25 pulses/sec	600 μs Max
45 Watt Ho:YAG	45 W	0.2 - 3.5 J	5 - 40 pulses/sec	600 μs Max
60 Watt Ho:YAG	60 W	0.2 - 3.5 J	5 - 40 pulses/sec	600 μs Max
100 Watt Ho:YAG	100 W	0.2 - 3.5 J	5 - 50 pulses/sec	600 μs Max

VersaPulse PowerSuite Dual Wavelength and Holmium lasers

Laser classifications

US FDA CDRH laser classification: Class IV
European EN 60825 laser classification: Class 4

Aiming beam

Type: Diode
Power: 5 mW maximum, continuous wave
US FDA CDRH laser classification: Class IIIa
European EN 60825 laser classification: Class 3A
Principal output: Red, 650 nm (± 10 nm)

Input power

Frequency: 50/60 Hz
Voltage: 200/208/230 VAC $\pm 10\%$
Phase: Single
Current: 30A @ 208/230 VAC @ 60 Hz
32A @ 200/208/230 VAC @ 50 Hz

Cooling

Internal water-to-air heat exchanger

Cooling air requirements

Minimum 46 cm (18 in) from walls

Physical characteristics

Width: 46 cm (18 in)
Length: 91 cm (36 in)
Height: 99 cm (39 in)
Weight: 200 kg (441 lb)

Power cord length

7.0 m (23 ft)

Footswitch cable length

5.2 m (17 ft)

Environmental requirements (operating)

Maximum altitude: 3,050 m (10,000 ft)
Temperature range: 10° C to 30° C (50° F to 86° F) - must be above
dew point
Maximum humidity: 90% at 27° C (81° F) non-condensing

Environmental requirements (nonoperating)

Temperature range: 0° C to 50° C (32° F to 122° F) — must be above
dew point
Maximum humidity: 90% at 55° C (131° F) non-condensing

Laser safety eyewear

Refer to “Laser Safety Eyewear” in the Safety and Regulatory section of this manual for detailed laser safety eyewear information.

Compatible delivery systems

The laser is intended for use only with Lumenis-qualified delivery systems. Contact your local Lumenis representative for a list of available products.

Laser safety eyewear

The following laser safety eyewear complies with ANSI and EN207 standards as noted in the laser safety section of this manual.

ANSI standard laser safety eyewear

<u>Part Number</u>	<u>Product Name</u>
MD1721800	Glasses, Safety, Holmium (2100 nm) and Nd:YAG (1064 nm)
MD1721900	Goggles, Safety, Holmium (2100 nm) and Nd:YAG (1064 nm)

CE standard (EN207) laser safety eyewear

<u>Part Number</u>	<u>Product Name</u>
MD1662600	Glasses, Safety, Holmium (2100 nm) and Nd:YAG (1064 nm)
MD1662500	Goggles, Safety, Holmium (2100 nm) and Nd:YAG (1064 nm)

Replacement parts

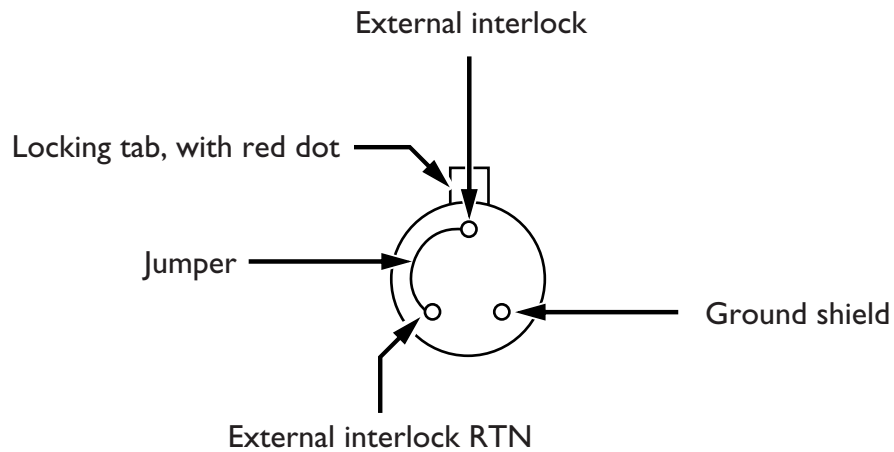
<u>Part Number</u>	<u>Product Name</u>
0624-015-01	VersaPulse Debris Shield (Glass and Holder)
0623-502-01	VersaPulse Debris Optic (Glass Only)
5107-0190	VersaPulse Laser Key

External Door Interlock Pin Assignments

The external door interlock is a safety feature that disables the laser if the treatment room doors are opened or the interlock plug is removed while the laser is in ready mode.

The interlock can be set up with a remote switch, or an external switch can be wired to the interlock plug. Plug wiring shall only be performed by a qualified electrical professional. Total length of cable shall not exceed five meters (16 feet).

Pin assignments are as follows:



***External door interlock pin assignments
(solder side of plug shown)***

Calibration Procedure

Regulatory agencies require that manufacturers of US FDA CDRH Class III and IV and European EN 60825 Class 3 and 4 medical lasers supply their customers with power calibration instructions.

DISCLAIMER WARNING

Calibration is a service procedure to be done only by Lumenis-certified service engineers or customers who have taken and passed a Lumenis Service Certification Training course. Adjustment by anyone other than a trained Lumenis service engineer or a certified customer voids any existing manufacturer's warranty on the instrument. A service manual for the laser may be purchased from Lumenis. It is company policy not to distribute service tools outside of the Lumenis service organization. Possession of service instructions or tools does not authorize repair or modification of a Lumenis instrument by uncertified personnel.

Calibration must be performed by an engineer or technician qualified to work on energized electronic laser equipment. Calibration questions should be referred to your local Lumenis representative.

Calibration instructions

The following equipment is required to perform calibration:

- Oscilloscope
- External power meter
- New Lumenis laser fiber
- Digital Voltmeter

To calibrate the laser:

1. Ensure all personnel are wearing the appropriate laser safety eyewear.
2. Turn on the laser.
3. Access SERVICE MODE by flipping the service switch (SW2) on the control board.
4. On service screen, press the INIT NVRAM button to clear and initialize the battery backup memory to its initial (default values).

5. Set VOLTAGE to 800 V, PULSE RATE to 10 Hz, LAMP ENERGY to 45 J; turn ON only the FIRST channel (all other channels should indicate OFF).
6. Place laser in READY mode.
7. Attach laser fiber and set up external power meter.
8. Depress footswitch and adjust LAMP ENERGY in increments of 5 J until a value of 6 ± 1 watts is measured out of the fiber on the external power meter.
9. Attach oscilloscope probe to TP15 (SFDIF) on control board; set the oscilloscope to 1V/div, auto trigger.
10. Depress footswitch and adjust SGAIN (R4) potentiometer on the optics bench board, such that 4.0 ± 0.1 V is measured on the oscilloscope.
11. Attach oscilloscope probe to TP24 (MNDIF) on control board.
12. Depress footswitch and adjust MGAIN (R3) potentiometer on the optics bench board, such that 4.0 ± 0.1 V is measured on the oscilloscope.
13. Depress footswitch and adjust LAMP ENERGY to obtain 10 W of delivered power out of the fiber (PULSE RATE still at 10 Hz, i.e., 1 J/pulse).
14. Attach Digital Voltmeter to GND and TP38 on the CPU PCB. Depress footswitch and adjust potentiometer "MAIN 2.1" (R32) on control board such that 1.00 ± 0.02 V is measured across GND and TP38 (i.e., 1 V = 1 J/pulse).
15. Attach Digital Voltmeter to TP36 and TP38 on the CPU PCB. Depress footswitch and adjust potentiometer "SAFE 2.1" (R15) on control board such that 0.00 ± 0.02 V is measured across TP36 and TP38.
16. Access USER MODE by flipping the service switch (SW2) on the control board. Set the ENERGY and RATE to 2 J and 40 Hz, respectively. Depress the footswitch and measure the power delivered out of the fiber on the external power meter. If the measured power is

not 80 ± 1 watts, finely adjust potentiometer “MAIN 2.1” on controller board such that 80 ± 1 watts is measured.

17. Attach Digital Voltmeter to TP36 and TP38 on the CPU PCB. Depress footswitch and adjust potentiometer “SAFE 2.1” (R15) on control board such that 0.00 ± 0.02 V is measured across TP36 and TP38.
18. If your system has a Nd:YAG laser then continue with the following instructions.
19. Access SERVICE MODE by flipping the service switch (SW2) on the control board.
20. Set VOLTAGE to 800 V, PULSE RATE to 50 Hz, LAMP CURRENT to 65 Amps; turn ON only the SECOND channel (all other channels should indicate OFF).
21. Depress footswitch and adjust LAMP CURRENT to obtain 10 W of delivered power out of the fiber (PULSE RATE still at 10 Hz, i.e., 1 J/pulse).
22. Attach Digital Voltmeter to GND and TP38. Depress footswitch and adjust potentiometer “MAIN 1064” (R34) on control board such that 1.00 ± 0.02 V is measured across GND and TP38 (i.e., 1 V = 1 J/pulse).
23. Attach Digital Voltmeter to TP36 and TP38. Depress footswitch and adjust potentiometer “SAFE 1064” on control board such that 0.00 ± 0.02 V is measured across TP36 and TP38.
24. Access USER MODE by flipping the service switch (SW2) on the control board. Set the TIME and POWER to CONT and 80 Watts, respectively. Depress the footswitch and measure the power delivered out of the fiber on the external power meter. If the measured power is not 80 ± 1 watts, finely adjust potentiometer “MAIN 1064” on controller board such that 80 ± 1 watts is measured.
25. Attach Digital Voltmeter to TP36 and TP38. Depress footswitch and adjust potentiometer “SAFE 1064” on control board such that 0.00 ± 0.02 V is measured across TP36 and TP38.

Warranty Information

For specific and detailed warranty information for this instrument, please refer to the first page of your purchase “Agreement” and the last page of the “Terms and Conditions of Sale.”

Decontamination of Returned Equipment

To comply with United States postal and transportation law, equipment shipped to Lumenis US offices for repair or return must be properly decontaminated with a chemical germicide that is commercially available and cleared for use as a “Hospital Disinfectant.” To ensure that all equipment has been properly decontaminated, a signed Decontamination Certificate (provided at the back of this manual) must be enclosed in the package, or Lumenis will assume that the product is contaminated and will assess the customer with cleaning costs.

Any decontamination inquiries should be directed to the Lumenis US service offices.

Safety and Regulatory

Introduction

Users must take precautions to prevent exposure of laser energy to the eyes and skin from either direct or diffusely reflected laser beams, except as a therapeutic application. Additional precautions must be taken to prevent fire, electrical injury, and explosion.

Lumenis does not make recommendations regarding the practice of medicine. Laser treatment parameters are provided as a guide. Individual treatment should be based on clinical training, clinical observation of laser-tissue interaction, and appropriate clinical endpoints.

Laser Safety Eyewear

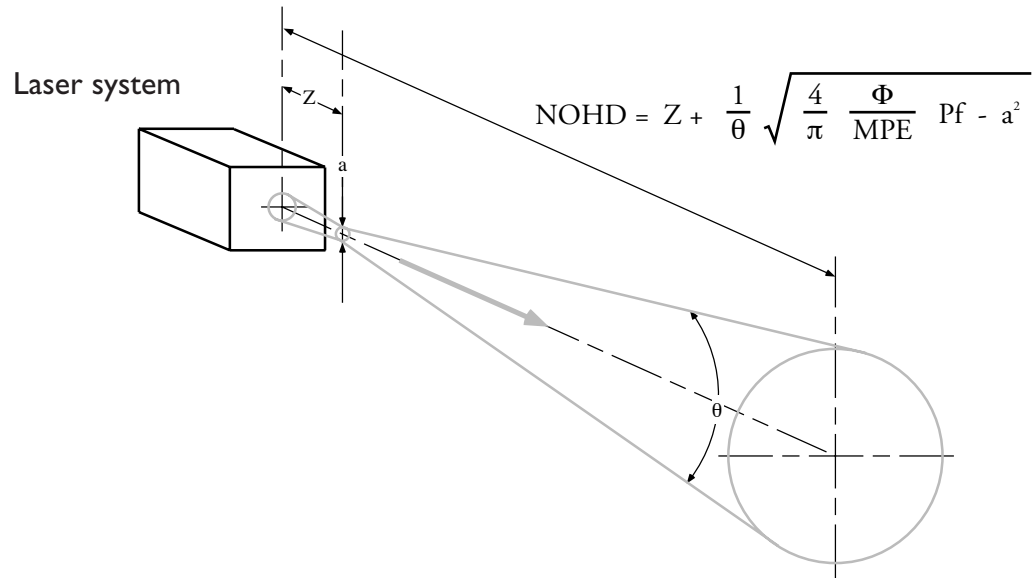
Laser safety eyewear is routinely required with most lasers. When using the laser system, the Laser Safety Officer should determine the need for safety eyewear based on the Maximum Permissible Exposure (MPE), Nominal Hazard Zone (NHZ), the Nominal Ocular Hazard Distance (NOHD), and the optical density (OD) for each of the available laser emissions and the configuration of the treatment room (usually within the controlled area). For additional information, refer to ANSI Z136.1-1993, ANSI Z136.3-1996, or European Standard EN 60825: 1992, Appendix A.

The following formula was used to calculate the worst case NOHD for Lumenis VersaPulse PowerSuite Holmium and Dual Wavelength lasers and compatible delivery systems:

$$\text{NOHD} = Z + \frac{1}{\theta} \sqrt{\frac{4}{\pi} \frac{\Phi}{\text{MPE}} \text{Pf} - a^2}$$

where,

- Z = the distance of the beam waist from the laser system;
- a = the beam waist diameter ($1/e^2$ of axial irradiance for gaussian beam);
- θ = minimum full angle beam divergence ($1/e^2$ of axial irradiance for gaussian beam);
- e = 2.7182818285, the base of natural logarithms;
- Φ = maximum energy of one laser pulse or maximum CW laser power;
- Pf = the profile correction factor (1 for uniform profile or 2 for gaussian irradiance profile);
- MPE = Maximum Permissible Exposure, in energy density units (energy per unit area), or power density units (power per unit area);
- NOHD = the Nominal Ocular Hazard Distance (measured from laser aperture);
 - = the distance required to reduce the energy density or power density to the MPE.



Using this approach we derive the following values:

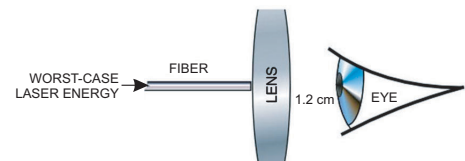
	θ	Φ	MPE	Pf	a	Z
Ho:YAG (2.1 μm)	320 mrad	2.0 J	2 mJ/cm ²	1	0.0365 cm	0 cm
Nd:YAG (1.06 μm)	360 mrad	1.67 J	17 $\mu\text{J}/\text{cm}^2$	1	0.0365 cm	0 cm

which results in a *worst case* NOHD of :

	NOHD
Ho:YAG (2.1 μm)	1.1 meters
Nd:YAG (1.06 μm)	9.8 meters

All personnel who are within the NOHD are considered to be within the controlled area and shall wear eye protection with a *minimum* optical density (OD) of:

	OD
Ho:YAG (2.1 μm)	4.0
Nd:YAG (1.06 μm)	5.0



Laser safety eyewear must also be resistant to physical damage or photobleaching resulting from laser exposure as per ANSI Z136.1-1993, section 4.6.2 and Appendix C. For users who must comply with EN 207, the safety eyewear must have a protection class of:

	Protection Class
Ho:YAG (2.1 μm)	L3
Nd:YAG (1.06 μm)	L5

In addition to providing the required laser safety eyewear, take the following steps to secure the treatment room, or the controlled area:

1. To alert personnel before they enter the controlled area, place a warning sign on the outside of the treatment room door when the laser is in use.
2. Close the treatment room door during operation of the laser.
3. External door interlocks that automatically disable the laser when the treatment room door is opened may be installed.

NOTE

A blocking barrier, screen, or curtain capable of blocking or filtering the laser beam could be placed to create a controlled area inside a large treatment room. The barrier should be made of material that can withstand the power of the treatment beam for the maximum exposure time, relative to the configuration of the controlled area and the treatment parameters for the specific medical application.

Depending on the procedure, the physician must protect the patient's eyes with either laser safety eyewear or one of the following items moistened with a nonflammable solution: thick cloth, eye pads, or gauze 4 x 4's. For periorbital treatment, the physician must protect the patient with dulled, metal eye shields.

Additional Ocular Protection

WARNING

Always verify that the delivery device is properly connected to the laser. An improper connection may result in an inadvertent secondary laser beam. Severe eye or tissue damage could occur.

WARNING

Never substitute prescription eyewear for the appropriate laser safety eyewear, as severe eye damage could occur. Prescription eyewear can concentrate the laser light to the eye and/or can be shattered by a high power density beam, possibly causing severe eye damage.

WARNING

Use caution when performing procedures around the eyes. Severe and irreversible eye damage and scarring may occur from direct or indirect exposure to the treatment beam. The predominant ocular structures at risk are dependent on the laser wavelength in use. In general, visible and near-infrared wavelengths are most damaging to the retina, while ultraviolet or infrared wavelengths are most damaging to the cornea and sclera. Severity of injury depends on how concentrated or diffused the treatment beam is and the length of exposure. A thorough understanding of the specific ocular risks and safety precautions for each laser wavelength is necessary to ensure the safety of the patient and operating personnel.

WARNING

Never look directly into any optical lens, optical fiber, handpiece, probe, laser articulated arm, or laser system aperture while the laser is energized. Severe eye damage could occur. Turn off the laser before inspecting any delivery system or laser components.

Additional Safety Considerations

CAUTION

US federal law restricts this device to sale by or on the order of a physician.

CAUTION

Lumenis medical lasers and laser delivery systems are intended solely for physicians trained in the use of these instruments.

CAUTION

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.

CAUTION

Smoke evacuation may be required if using the laser in open-air procedures.

NOTE

This package conforms to the conditions and limitations specified in 49 CFR 173.426 for radioactive material, excepted package-articles manufactured from natural thorium, UN 2910.

Protecting nontarget tissues

WARNING

When using a fiber optic delivery device, always inspect the fiber optic cable to ensure that it has not been kinked, punctured, fractured, or otherwise damaged. The fiber optic cable may be damaged if stepped on, pulled, left lying in a vulnerable position, kinked, or tightly coiled. Do not clamp the cable with a hemostat or other instruments. If sterile tape is used, always remove the tape before lifting the cable. A damaged fiber optic cable may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.

WARNING

Never deliver the treatment beam to the target tissue if the aiming beam is not visible; the fiber optic cable may be damaged. A damaged cable may cause accidental laser exposure to the treatment room personnel or patient, and/or fire in the treatment room.

WARNING

Except during actual treatment, the laser must always be in standby mode. Maintaining the laser in standby mode prevents accidental laser exposure if the footswitch is inadvertently depressed.

CAUTION

To prevent accidental laser discharge, always turn off the laser before connecting the delivery system.

CAUTION

Never place hands or other objects in the path of the laser beam. Severe burns could occur.

CAUTION

Only the person directing the aim of the laser beam should have access to the laser footswitch. Use caution depressing the laser footswitch when it is in proximity to footswitches for other equipment. Make sure the footswitch depressed is the correct one to avoid accidental laser exposure.

CAUTION

Never discharge the laser without a target to absorb it and without consideration given to what lies behind the target. Place energy-absorbing material behind the target tissue when aiming the laser at an oblique target.

Electrical hazards

WARNING

Never open the laser console protective covers. Opening the covers will expose the user to high voltage components, the laser resonator, and possible laser radiation. Only Lumenis-certified service technicians shall work inside the console.

WARNING

The area around the laser and footswitch should be kept dry. Do not operate the laser if any of the cords are faulty or frayed. The laser should undergo routine inspection and maintenance per Lumenis manufacturer's recommendations and institutional standards.

Fire hazards

WARNING

Do not use this device in the presence of flammables or explosives, such as volatile anesthetics, alcohol, certain surgical preparation solutions, and similar substances. An explosion and/or fire could occur.

WARNING

The treatment beam can ignite most nonmetallic materials. Use fire retardant drapes and gowns. The area around the treatment site can be protected with towels or gauze sponges moistened with sterile saline solution or sterile water. If allowed to dry, protective towels and sponges can increase the potential fire hazard. A UL-approved fire extinguisher and water should be readily available.

WARNING

When performing procedures in the perianal area, the flammability of methane gas must be considered. Moistened sponges should be inserted into the rectum.

Regulatory Compliance

Lumenis lasers and delivery systems comply with 21 CFR Chapter I, Subchapter J, as administered by the Center for Devices and Radiological Health of the US Food and Drug Administration (FDA).

CE-labeled devices comply with all appropriate performance standards as specified in Annex II of the European Medical Device Directive MDD 93/42/EEC.

Emergency off push button

The laser has an emergency off push button that, when pushed, immediately turns off the laser in emergency situations.

Key lock switch

The laser can only be turned on with the master key. The key can only be removed in the off position, and the laser only operates with the key in place. When the key switch is turned to the start position, power is available to the laser. When treatment is complete, always remove and secure the key to prevent unauthorized use of the laser.

Laser emission indicators

“Laser emission” appears on the control screen at all times to alert the user that laser energy is available. Before treatment beam delivery, the laser emits a high-pitched double beep to indicate holmium laser emission or a low-pitched single beep to indicate Nd:YAG laser emission. During treatment beam delivery, “Treat Ho” or “Treat Nd” appears on the Dual Wavelength laser control screen, and “Treatment Ho” or “Treatment Nd” appears on the remote control. “Treatment” appears on the Holmium laser control screen and remote control.

External door interlock

An external door interlock outlet and plug are provided to disable the laser if the treatment room doors are opened while the laser is in ready mode.

Protective housing

The laser has a protective housing that prevents unintended human access to laser radiation. No sections of the protective housing can be easily

opened without special tools. This housing is to be opened only by a Lumenis-certified technician.

Location of controls

The controls are located on the control screen and the remote control so the user need not be exposed to the treatment beam.

Safety shutter

The laser features a safety shutter that prevents the treatment beam from exiting the laser. The safety shutter opens only when the laser is in ready mode and the footswitch is depressed.

Manual reset

If laser emission is interrupted during treatment (e.g., main electrical power loss), the laser automatically turns off. To resume treatment, you must manually restart the laser with the key switch. (See “Restarting the laser” in the Operation section of this manual.)

Electronic fault detection circuitry

If any of the electronic system monitors detect a fault condition, laser exposure cannot occur. The high voltage power supply disables, the safety shutter closes, and the footswitch disables.

Safety interlocks

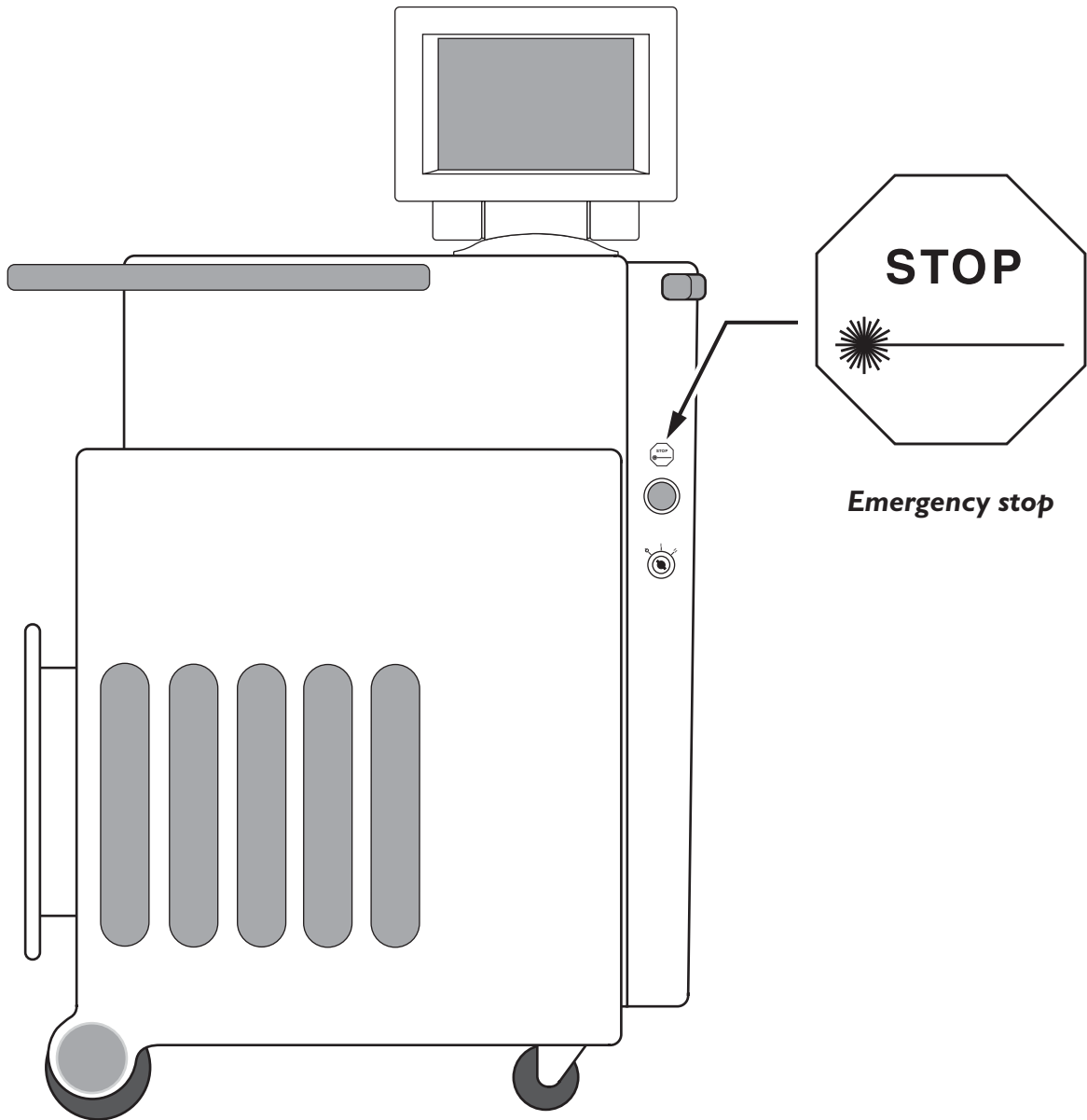
The laser has a safety interlock on the fiber optic laser connector in accordance with Section 1040 of 21 CFR.

Precision of displayed values

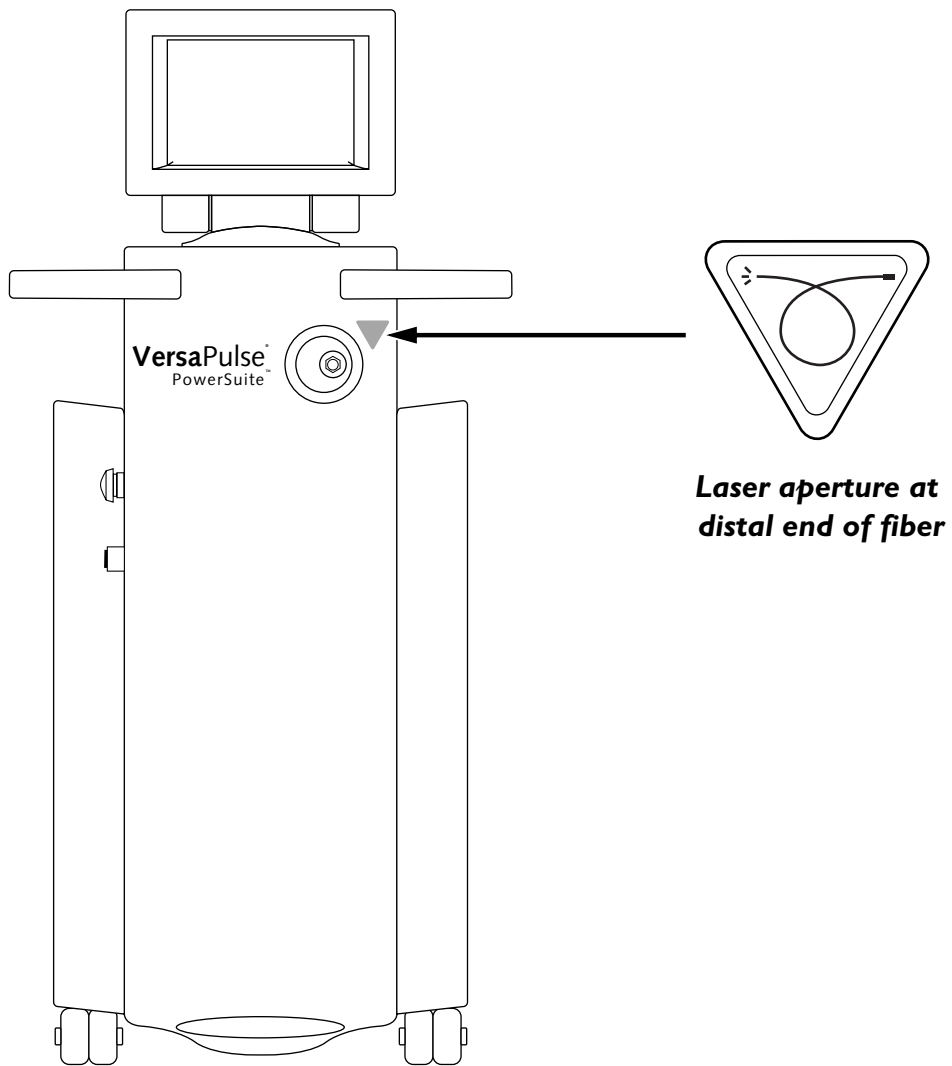
The precision of the energy and rate values displayed on the control screen are factory preset to within $\pm 5\%$ of a calibrated standard. The energy of every pulse is monitored by two internal detectors to ensure no safety hazard is caused by failure of a single component. If the delivered system energy deviates from the commanded parameters by more than 20%, the user is notified but allowed to continue. If the deviation is greater than 50%, the treatment is stopped, the user is notified of the fault, and allowed to continue.

Location of regulatory and other system labels

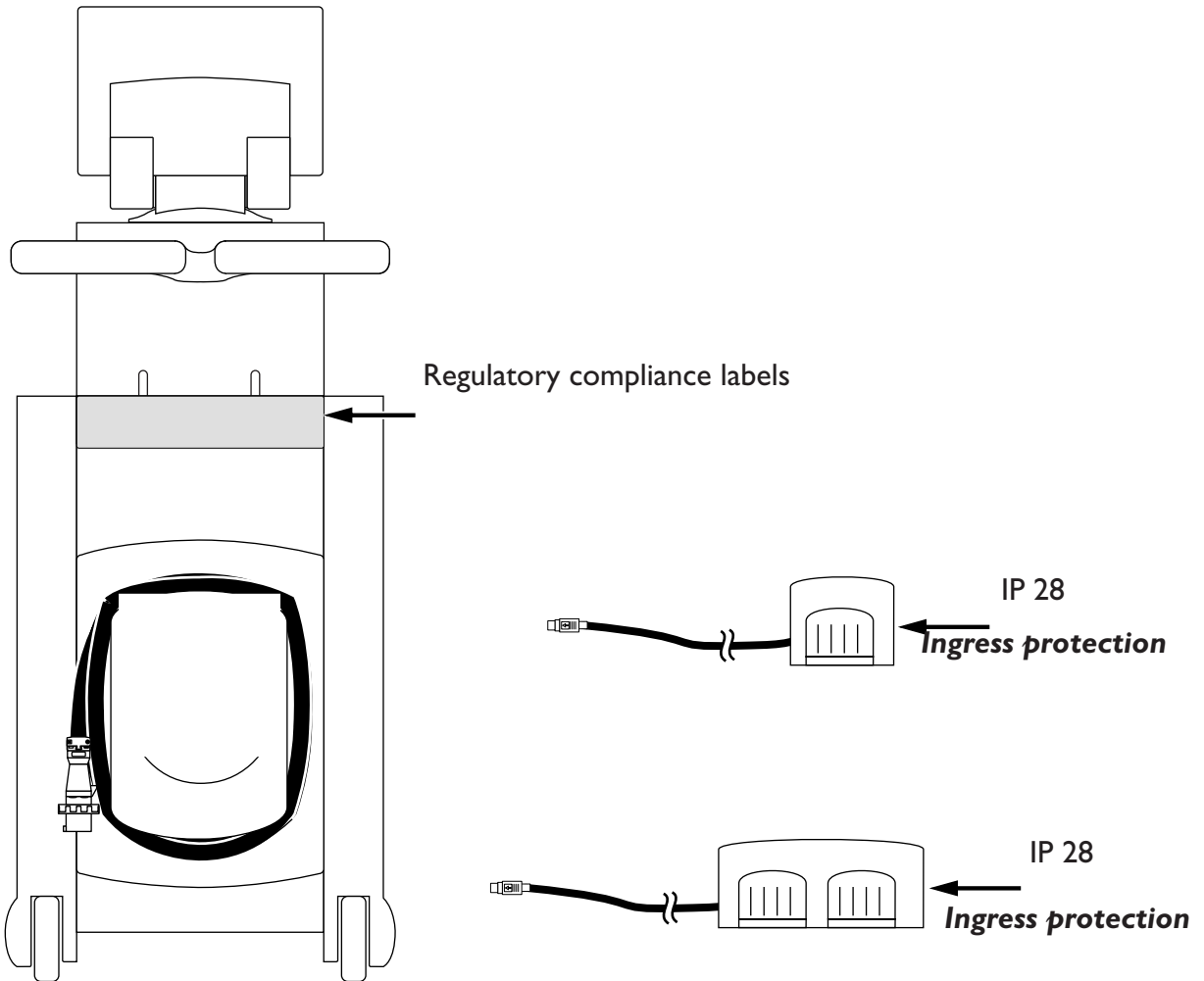
As required by national and international regulatory agencies, appropriate warning labels have been mounted in specified locations.



Location of regulatory compliance labels



Location of regulatory compliance labels



Location of regulatory compliance labels



MADE IN ISRAEL
U.S. AND INTERNATIONAL
PATENTS PENDING

CAUTION:
U.S. FEDERAL LAW RESTRICTS
THIS DEVICE TO SALE BY OR ON
ORDER OF A PHYSICIAN

Lumenis contact information

Patents pending

FDA sales restriction



(for products shipped under
the Medical Device Directive)

CE mark

REF

SN

**Model name, serial number, and
manufacturing date**

Domestic	208/230V~
	60 Hz 30A, 1φ
International	200/208/230V~
	50/60 Hz 32A, 1φ
Japan	200/208/230V~
	50/60 Hz 32A, 1φ

Electrical specification

THIS PRODUCT COMPLIES
WITH 21 CFR, CHAPTER I,
SUBCHAPTER J

(for FDA-compliant systems)

DHHS certification



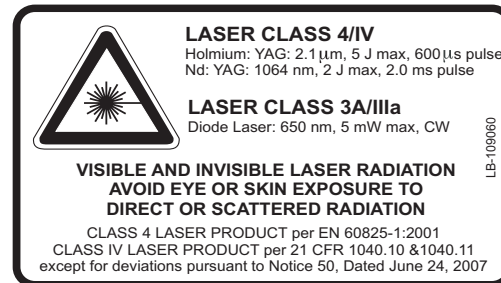
(for ETL approved products)

ETL label



(Holmium lasers)

or



(Dual Wavelength lasers)

Danger label

Regulatory compliance labels



Type BF electric shock protection



Mains switch



(Rated duty cycle: 80%)

Intermittent operation



(Read and comprehend the operator manual before use.)

Attention, read manual



(Danger. Possible explosion hazard if used in the presence of flammable anesthetics, oxygen, or nitrous oxide.)

Flammable anesthetics and gases warning



Remote receptacle



Remote interlock receptacle



Footswitch receptacle

IP 20

Ingress protection

Regulatory compliance labels

Indications for Use

General Warnings, Precautions, and Complications to consider when using the Holmium and Nd:YAG Wavelengths

This section contains warnings, precautions, and complications that apply to all of the wavelengths and surgical specialties described in this chapter. For important information specific to a particular surgical specialty, such as Urology, read the corresponding section later in this chapter.

CAUTION

Lumenis VersaPulse PowerSuite Holmium lasers are intended solely for use by physicians trained in the use of the Ho:YAG (2.1 μm) wavelength. VersaPulse PowerSuite Dual Wavelength lasers are intended solely for use by physicians trained in the use of Ho:YAG (2.1 μm) and Nd:YAG (1.06 μm) wavelengths.

NOTE

The use of a laser instrument for an application is at the physician's discretion except in cases where the indication has been contraindicated.

NOTE

Physicians should frequently consult current literature and information provided in advanced workshops to keep abreast of the most effective and up-to-date practices.

General laser warnings

- Refer to warnings specific to each surgical specialty and wavelength within this section.
- Incorrect treatment settings can cause serious tissue damage. Therefore, it is recommended that you use the lowest acceptable treatment settings until familiar with the instrument's capabilities. Use extreme caution until the biological interaction between the laser energy and tissue is thoroughly understood.
- As with conventional endoscopic surgery, the possibility of complications and adverse events, such as chills, fever, edema, hemorrhage, inflammation, tissue necrosis, or infection may occur following treatment. In extreme cases, death may occur due to procedural complications, concurrent illness, or laser application.
- Flash fire may occur. Flammable inhalation general anesthetics must not be used. Oxygen levels in the direct surgical area must not exceed 50 percent. The risks of combustion, perforation, and laser-induced hemorrhage, any of which could cause death, must be fully explained to the patient.
- The flammability of methane gas must be considered when treating in or near the perianal area.
- There is a risk of infection scarring associated with any surgical procedure. Therefore, appropriate pre and post-surgical care should always be practiced.
- The laser should be used only on tissues that are fully observable. Do not use the laser if the desired target is not visible.
- Use of the laser on anatomical structures in proximity to known critical structures, such as large arteries, veins, bowel, ureter, bladder, etc., should be performed carefully to avoid inadvertent or unintended treatment of such structures. In pre-treatment studies, screen tumors that are in close proximity to known arteries or veins to locate those circulatory structures.
- There is an increased risk of back scatter (reflection) and forward scatter (penetration) when using the laser if the laser is in the non-contact mode.

General laser precautions

- Refer to precautions specific to each surgical specialty and wavelength within this section.
- Use caution with patients who have had difficulty with previous endoscopic procedures.
- Blood vessels up to 1 millimeter in diameter can be effectively coagulated with the Ho:YAG wavelength.
- Electrocautery and/or suture (ligature) should be easily accessible in the event that a bleeding artery or vein is larger than possible to control with the laser.
- Use caution when treating patients who have recently undergone radiotherapy. Such patients may be at greater risk of tissue perforation or erosion.
- Discontinue laser treatment immediately if the patient develops any cardiopulmonary problems.
- Lumenis has no clinical information concerning the safety of laser treatment on pregnant or nursing women.
- Refer to the appropriate delivery system instruction guide for use instructions.

General laser complications

- Refer to complications specific to each surgical specialty and wavelength within this section.
- The potential complications encountered in endoscopic laser surgery are the same as those normally encountered in conventional endoscopic surgery.
- Acute pain may occur immediately following laser therapy and may persist for as long as 48 hours.
- Immediately following laser therapy, the patient may experience fever and leukocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment.
- Laser ablated tissue may become necrotic or infected after treatment. If a question of infection exists, appropriate treatment should be carried out.

The following complications could be serious and could result in death:

- Patients may experience bleeding at the site of laser therapy. Post-treatment hematocrits are recommended to identify this potential complication.
- Sepsis can result from performing any surgical procedure. If a question of sepsis exists, appropriate evaluations should be made.
- Perforation may occur as a result of laser treatment. To diagnose perforations, patients must be carefully followed post-operatively with appropriate tests.

Indications for Use Specific to the Ho:YAG Wavelength

The Ho:YAG (2.1 μm) wavelength is intended for use in surgical procedures involving open, laparoscopic and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including:

- Arthroscopy
- Urology
- Urinary lithotripsy
- Endonasal surgery
- Gynecological surgery
- General surgery
- Gastroenterological surgery

The Ho:YAG (2.1 μm) wavelength is indicated for use in specific surgical applications, as detailed in this chapter. Read and comprehend the previous section, titled “General Warnings, Precautions, and Complications to consider when using the Holmium and Nd:YAG Wavelengths”, before reading the sections that describe a particular surgical specialty.

Arthroscopy indications

The following applications are indicated for arthroscopic surgery in various joints of the body, excluding the spine, while using the Ho:YAG wavelength:

- Meniscectomy
- Plica removal
- Ligament and tendon release
- Contouring and sculpting of articular surfaces
- Debridement of inflamed synovial tissue (synovectomy)
- Loose body debridement
- Chondromalacia and tears
- Lateral retinacular release
- Capsulectomy in the knee
- Chondroplasty in the knee
- Chondromalacia ablation

Arthroscopy warnings, precautions, and complications

Read “General laser warnings”, “General laser precautions”, and “General laser complications” earlier in this chapter for further information.

Urology indications

The following applications are indicated for urology while using the Ho:YAG wavelength:

- Endoscopic transurethral incision of the prostate (TUIP), bladder neck incision of the prostate (BNI), holmium laser ablation of the prostate (HoLAP), holmium laser enucleation of the prostate (HoLEP), holmium laser resection of the prostate (HoLRP), hemostasis, vaporization and excision for treatment of benign prostatic hypertrophy (BPH). The clinical procedure for HoLRP, along with clinical study results, is described in Appendix A of this operator manual.
- Open and endoscopic urological surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including treatment of:
 - Superficial and invasive bladder, urethral and ureteral tumors
 - Condylomata
 - Lesions of external genitalia
 - Urethral and penile hemangiomas
 - Urethral strictures
 - Bladder neck obstructions

Urology contraindications

The Ho:YAG wavelength should not be used for HoLRP for treatment of BPH in patients with:

- Carcinoma of the prostate
- Desire for future fertility

The Ho:YAG wavelength should not be used in patients with the following conditions:

- Inability to receive endoscopic treatment
- Intolerance to anesthesia

Urology warnings

Good clinical judgement should be used prior to performing the HoLRP procedure on patients who are taking anticoagulants.

Read “General laser warnings” earlier in this chapter for a list of additional warnings.

Urology precautions

The following precautions are suggested when using the Ho:YAG wavelength in urology:

- Care should be exercised so as not to over distend the bladder when using the laser endoscopically. Excessive bladder distention could result in coagulative necrosis of the superficial and inner muscular region of the bladder wall.

The following precautions are recommended for HoLRP for treatment of BPH:

- Confirm that the tip of the fiber optic delivery device extends at least 1.25 centimeters beyond the end of the urethroscope or endoscope during laser treatment. Activating the laser when the tip of the delivery device is within the urethroscope or endoscope can result in penetration of holmium laser energy through the scope and destruction of the scope.
- Use caution during laser treatment near the verumontanum.
- The learning curve to obtain proficiency in HoLRP has been described by experienced urologists to be similar to that of learning TURP.

Read “General laser precautions” earlier in this chapter for a list of additional precautions.

Urology complications

Read “General laser complications” earlier in this chapter for a list of additional complications.

Urology clinical parameters

The Ho:YAG wavelength provides effective hemostasis without damaging surrounding or nontarget tissues. Coagulation can be effected by reducing the energy or power density incident on vascularized tissue in two ways. First, when the tip of the handpiece or fiber is in direct contact with the target tissue, the pulse energy and repetition rate settings on the control screen may be reduced. Second, the surgeon may elect to defocus the beam without changing the system controls by pulling the handpiece or fiber tip approximately 2 to 5 millimeters from the target tissue.

The following table shows the recommended pulse energy, repetition rate, and average power for endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in urological applications:

CLINICAL PARAMETERS ¹				
Application	Pulse Energy (Joules/pulse)	Repetition Rate (Hertz)	Average Power (Watts)	Recommended Fiber Size
Holmium laser resection of the prostate (HoLRP)	2.0	40 – 50	80 – 100	DuoTome or SlimLine 550 μm
Holmium laser enucleation of the prostate (HoLEP)	2.0	40 – 50	80 – 100	SlimLine 550 μm
Holmium laser ablation of the prostate (HoLAP)	2.0 – 3.5	40 – 50	80 – 100	DuoTome or SlimLine 550 – 1000 μm
Holmium laser incision of the prostate (BNI, TUIP)	2.0	40	80	SlimLine 365 – 550 μm or DuoTome
Bladder tumors	0.8 – 1.2	10 – 20	8 – 24	SlimLine 365 – 1000 μm
Ureteral tumors	0.6 – 1.2	10 – 16	6 – 19.2	SlimLine 365 – 550 μm
Incision of strictures	1.2 – 1.4	14 – 16	16.8 – 22.4	SlimLine 365 – 1000 μm
¹ Energy delivered endoscopically in a fluid medium Note: laser settings are guidelines only. Always start at low settings and increase to achieve desired tissue effect.				

Urology—recommended treatment parameters, for holmium only

Urinary lithotripsy indications

The following applications are indicated for urinary lithotripsy while using the Ho:YAG wavelength:

- Endoscopic fragmentation of urinary (urethral, ureteral, bladder and renal) calculi, including cystine, calcium oxalate, monohydrate and calcium oxalate dihydrate stones
- Treatment of distal impacted fragments of steinstrasse when guide wires cannot be passed

Urinary lithotripsy contraindications

The Ho:YAG wavelength must not be used in patients with the following conditions:

- Inability to receive endoscopic treatment
- Intolerance to anesthesia

Urinary lithotripsy warnings

Unexpected tissue damage may occur due to excessive power application. Refer to “Urinary lithotripsy clinical parameters” in this section for recommended initial power settings. Use of excessive power may result in inadvertent perforation of the ureter or damage to other urologic structures.

Read “General laser warnings” earlier in this chapter for a list of additional warnings.

Urinary lithotripsy precautions

- The laser should be used with an optical fiber delivery system in direct view and in direct contact with the target ureteral stone. To minimize the potential for migration up the ureter, laser energy should be directed to the side of the stone, if possible, rather than the leading edge.

NOTE

Maintaining low energy levels and repetition rates will reduce the potential for possible stone migration.

- Be aware of edematous folds of epithelium that may lie between the optical fiber and the stone; however, research suggests such folds are very rare.
- Baskets may be used with larger stone fragments that are relatively hard or tend to escape in a retrograde fashion up the ureter. Use of endoscopes in laser procedures allows excellent viewing and minimal trauma to the ureter during fragmentation.

NOTE

Baskets, guide wires, and other ureteroscopic accessories may be damaged by direct contact with the laser treatment beam.

- The use of irrigation is recommended throughout the lithotripsy procedure to absorb any heat produced, to carry stone fragments out of the urinary system, and to enhance direct visualization. The rate of irrigation should be carefully adjusted to avoid flux of calculi into the kidney.

Read “General laser precautions” earlier in this chapter for a list of additional precautions.

Urinary lithotripsy complications

- As with other endoscopic urologic procedures, there may be urine leakage following the laser procedure.
- The use of flexible endoscopes carries an equivalent incidence of stricture formation; these rates may improve with further advances in ureteroscope design.
- Although rare, loss of a kidney may occur as a result of the procedure or because of the stone, itself.

Read “General laser complications” earlier in this chapter for a list of additional complications.

Urinary lithotripsy clinical parameters

Preclinical and clinical testing have demonstrated that urinary calculi can be safely and effectively fragmented at power settings of 0.5 or 0.6 Joules and at a frequency of 5 or 6 Hertz. The use of higher power settings should be avoided, especially when the fiber tip is in close proximity to the ureteral walls, as perforation of the ureter may result.

For effective fragmentation, the tip of the optical fiber should be directly in contact with the stone. Whenever possible, laser energy should be directed at the side of, or at weaknesses in the stone. The stone should be progressively reduced in size by slowly removing small fragments. Continuous irrigation should be used to wash away stone fragments and to provide cooling of the treatment site. The following table shows recommended pulse energy, repetition rate and average power for endoscopic fragmentation of urinary calculi. The use of higher power settings should be avoided, especially when the fiber tip is in close proximity to the ureteral wall, as perforation of the ureter may result.

CLINICAL PARAMETERS ¹				
Application	Pulse Energy (Joules/pulse)	Repetition Rate (Hertz)	Average Power (Watts)	Recommended Fiber Size
Bladder calculi	0.5 – 2.0	5 – 40	3 – 80	DuoTome or SlimLine 365 – 1000 µm
Ureteral calculi	0.2 – 0.8	3 – 16	0.6 – 12.8	SlimLine 200 – 550 µm
Renal calculi	0.4 – 1.4	6 – 16	2.4 – 22.4	SlimLine 200 – 365 µm

¹ Energy delivered endoscopically in a fluid medium.
 Note: laser settings are guidelines only. Always start at low settings and increase to achieve desired tissue effect.

Urinary lithotripsy—recommended treatment parameters, for holmium only

E.N.T. surgery indications

The Ho:YAG wavelength is indicated for endoscopic vaporization, ablation, incision, and coagulation of soft tissue and cartilage during endonasal/sinus surgery procedures, including the following applications:

- Partial turbinectomy
- Ethmoidectomy
- Polypectomy
- Maxillary antrostomy
- Frontal sinusotomy
- Sphenoidotomy
- Dacryocystorhinostomy (DCR)
- Functional endoscopic sinus surgery (FESS)

E.N.T. surgery contraindications

The Ho:YAG wavelength should not be used in patients with any of the following conditions:

- Inappropriate candidates for endoscopic treatment
- Endonasal malignant neoplasm

E.N.T. surgery warnings

- Unexpected or uncontrolled tissue damage can sometimes occur due to excessive power application. Use low power and pulse rate settings until familiar with instrument capabilities. Extreme caution should be employed until the biological interaction of the laser energy with tissue is fully understood by the physician. The following initial power settings are recommended:

Ablation and excision using the SlimLine™ family of fiber optic delivery devices—An initial power setting of 0.5 Joules at 5 Hertz is recommended. Power should be increased until the desired tissue response is observed.

An increase of power and pulses per second is directly related to the speed at which tissue is removed. Therefore, extreme caution should be exercised around critical structures. The probe tip should be approximately 2 to 3 millimeters from the tissue for effective ablation and excision.

Coagulation—Tissue can be effectively coagulated by defocusing the fiber optic tip approximately 3 to 4 millimeters from the tissue, while maintaining the same treatment parameters used for ablating and excising tissue. The power density of the beam spot is reduced, effectively coagulating without further ablation of tissue.

- As with conventional endonasal surgery, damage to the orbit may occur, resulting in partial visual loss or blindness.
- Perforation of dura may result in leakage of cerebral spinal fluid with meningitis.

Read “General laser warnings” earlier in this chapter for a list of additional warnings.

E.N.T. surgery precautions

Read “General laser precautions” earlier in this chapter for a list of precautions.

E.N.T. surgery complications

- Swelling of the nasal membranes may cause nasal airway obstruction for up to one week. Patients should be followed posttreatment to clean debris from the nasal cavity.
- Perforation of the orbit or intracranial cavity may occur as a result of laser treatment. To diagnose perforations, patients must be carefully followed posttreatment with appropriate tests.

Read “General laser complications” earlier in this chapter for a list of additional complications.

E.N.T. surgery clinical parameters

The following table lists recommended energy and repetition rates for ablation, excision, and coagulation of soft tissue when using the SlimLine family of fiber optic delivery devices:

CLINICAL PARAMETERS			
Application	Energy (Joules)	Pulses (Hertz)	Average Power (Watts)
Ablation of Soft Tissue	0.5 - 1.0	5 - 15	2.5 - 15
Excision of Soft Tissue	1.0	10 - 15	10 - 15
Coagulation of Soft Tissue	0.5 - 1.0	5 - 15	2.5 - 15
Note: Laser settings are guidelines only. Always start at low settings and increase to achieve desired tissue effect.			

E.N.T. surgery—recommended holmium treatment parameters when using the SlimLine family of fiber optic delivery devices

Gynecology indications

The Ho:YAG wavelength is indicated for open and laparoscopic ablation, vaporization, incision, excision, and coagulation of soft tissues.

Gynecology contraindications

The Ho:YAG wavelength should not be used in patients with any of the following conditions:

- Inability to receive laparoscopic treatment
- Intolerance to anesthesia
- Septic peritonitis
- Intestinal obstruction
- Septic shock
- Resection or excision of large, highly vascularized organs

Gynecology relative contraindications

The Ho:YAG wavelength should not be used in patients with the following conditions:

- Recent myocardial infarction
- Multiple previous abdominal surgeries

Gynecology warnings

- With the use of gas to insufflate the abdomen, there is a possibility of gas embolus. In the extreme case, death may result from an embolus.
- Extreme caution should be used when insufflating the abdomen with gas. The use of carbon dioxide gas for insufflation will minimize patient risk, as it is highly soluble in blood. Insufflation pressure should be set to minimum settings for effective insufflation. ***The maximum safe intra-abdominal pressure setting is 15 to 20 mm Hg.***

Read “General laser warnings” earlier in this chapter for a list of additional warnings.

Gynecology precautions

Read “General laser precautions” earlier in this chapter for a list of additional precautions.

Gynecology complications

Read “General laser complications” earlier in this chapter for a list of additional complications.

Gynecology clinical parameters

The Ho:YAG wavelength has been shown to be a safe and effective tool for the ablation, excision, and coagulation of a variety of soft tissues. This has been demonstrated by both clinical and preclinical experience. The depth of the incision is determined by the amount of energy (in joules) applied. The rate at which the incision is made is dependent upon the rate of energy pulses being delivered to the target tissue (in pulses per second, or hertz). Optimum incision of tissue is accomplished by balancing the depth of the incision and the rate at which the incision is being formed. The physician may vary both the energy setting and the repetition rate of the laser, depending upon the specific type of soft tissue, the indication (excision, ablation, or coagulation), and the speed at which the physician wishes to work.

The Ho:YAG wavelength provides effective hemostasis without damaging the surrounding or nontarget tissues. Coagulation can be affected by reducing the power density incident on vascularized tissue in three ways. First, when the tip of the handpiece or fiber is in direct contact with the target tissue, the energy and repetition rate settings on the control screen may be reduced. Second, the physician may elect to defocus the beam without changing the system controls by moving the tip of the handpiece away from the target tissue approximately 2 to 5 millimeters. Third, if the beam is defocused at a distance greater than 5 millimeters, the surgeon may increase the treatment energy and, optionally, the repetition rate to effectively ablate and coagulate.

The Ho:YAG wavelength gives the physician the ability to customize the delivered power to fit the requirement of each soft tissue indication. Parameters recommended for near contact (<0.25 millimeters) and distant contact (1 to 2 millimeters) are provided in the following table:

CLINICAL PARAMETERS						
Tissue	Near Contact (<0.25 millimeters)			Distant Contact (1-2 millimeters)		
	Energy/ Pulse (Joules)	Repetition Rate (Hertz)	Average Power (Watts)	Energy/ Pulse (Joules)	Repetition Rate (Hertz)	Average Power (Watts)
Uterus	0.5 - 1.5	5 - 10	2.5 - 10	0.5 - 1.5	5 - 10	2.5 - 10
Ovary	0.5 - 1.5	5 - 20	2.5 - 10	0.5 - 1.5	5 - 15	2.5 - 15
Peritoneum	0.5 - 1.5	5 - 20	2.5 - 15	0.5 - 1.5	5 - 10	5 - 10
Bowel	0.5 - 1.0	5 - 10	2.5 - 10	0.5 - 1.0	5 - 15	5 - 15
Bladder	0.5 - 1.5	5 - 20	10 - 15	0.5 - 1.5	5 - 20	10 - 15

Note: Laser settings are guidelines only. Always start at low settings and increase to achieve desired tissue effect.

Gynecology—recommended treatment parameters, holmium only

General surgery indications

The following applications are indicated for open, laparoscopic, and endoscopic general surgery while using the Ho:YAG wavelength:

- Cholecystectomy
- Lysis of adhesions
- Appendectomy
- Pylorostenotomy
- Removal of rectal polyps of the sigmoid colon
- Skin incision
- Tissue dissection
- Excision of external tumors and lesions
- Complete or partial resection of internal organs, tumors, and lesions
- Mastectomy
- Hepatectomy
- Pancreatectomy
- Splenectomy
- Thyroidectomy
- Parathyroidectomy
- Herniorrhaphy
- Tonsillectomy
- Lymphadenectomy
- Partial nephrectomy
- Pilonidal cystectomy
- Resection of lipoma
- Debridement of decubitus ulcer
- Hemorrhoids
- Debridement of stasis ulcer
- Biopsy

General surgery contraindications

The Ho:YAG wavelength should not be used in patients with any of the following conditions:

- Inappropriate candidates for endoscopic or laparoscopic treatment
- Intolerance to anesthesia
- Septic peritonitis
- Intestinal obstruction
- Septic shock
- Resection or excision of large, highly vascularized organs (spleen, liver)

General surgery relative contraindications

The Ho:YAG wavelength should not be used in patients with any of the following conditions:

- Recent myocardial infarction
- Multiple previous abdominal surgeries

General surgery warnings

- With the use of gas to insufflate the abdomen, there is a possibility of gas embolus. In the extreme case, death may result from an embolus.
- Extreme caution should be used when insufflating the abdomen with gas. The use of carbon dioxide gas for insufflation will minimize patient risk, as it is highly soluble in blood. Insufflation pressure should be set to minimum settings for effective insufflation. ***The maximum safe intra-abdominal pressure setting is 15 to 20 mm Hg.***

Read “General laser warnings” earlier in this chapter for a list of additional warnings.

General surgery precautions

Read “General laser precautions” earlier in this chapter for a list of precautions.

General surgery complications

Air embolus is usually diagnosed intraoperatively. This condition requires rapid emergency treatment.

Read “General laser complications” earlier in this chapter for a list of additional complications.

General surgery clinical parameters

The Ho:YAG wavelength has been shown to be a safe and effective tool for the ablation, excision, and coagulation of a variety of soft tissues. This has been demonstrated by both clinical and preclinical experience. The depth of the incision is determined by the amount of energy (in joules) applied. The rate at which the incision is made is dependent upon the rate of energy pulses being delivered to the target tissue (in pulses per second, or hertz). Optimum incision of tissue is accomplished by balancing the depth of the incision and the rate at which the incision is being formed. The physician may vary both the energy setting and the repetition rate of the laser, depending upon the specific type of soft tissue, the indication (excision, ablation, or coagulation), and the speed at which the physician wishes to work.

Depending on the water content of the cells and other cell constituents, such as pigments, the depth of the thermal zone of injury has been shown to be less than 500 micrometers.

The Ho:YAG wavelength provides effective hemostasis without damaging surrounding or nontarget tissues. Coagulation can be affected by reducing the power density incident on vascularized tissue in two ways. First, when the tip of the handpiece or fiber is in direct contact with the target tissue, the energy and repetition rate settings on the control screen may be reduced. Second, the physician may elect to defocus the beam without changing the system controls by moving the tip of the handpiece away from the target tissue approximately 2 to 5 millimeters.

The Ho:YAG wavelength gives the physician the ability to customize the delivered power to fit the requirement of each soft tissue indication. The following table lists recommended energy and repetition rates for ablation, excision, and coagulation of soft tissue:

CLINICAL PARAMETERS			
Application	Energy (Joules)	Pulses (Hertz)	Average Power (Watts)
Ablation	0.5-1.0	5-15	2.5-15
Excision	1.0	10-15	10-15
Coagulation	0.5-1.0	5-15	2.5-15
Note: Laser settings are guidelines only. Always start at low settings and increase to achieve desired tissue effect.			

General Surgery—recommended treatment parameters, holmium only

Gastroenterology surgery indications

The following applications are indicated for open and endoscopic gastroenterology surgery (ablation, vaporization, incision, excision, resection, coagulation and hemostasis) while using the Ho:YAG wavelength:

- Gall bladder calculi
- Biliary/bile duct calculi
- Benign and malignant neoplasm
- Polyps
- Colitis
- Ulcers
- Angiodysplasia
- Hemorrhoids
- Varices
- Esophagitis
- Esophageal ulcer
- Mallory-Weiss tear
- Gastric ulcer
- Duodenal ulcer
- Non-bleeding ulcer
- Gastric erosions
- Colorectal cancer
- Gastritis
- Bleeding tumors
- Pancreatitis
- Vascular malformations
- Telangiectasias
- Telangiectasias of the Osler-Weber-Renu disease

Gastroenterology surgery contraindications

The Ho:YAG wavelength should not be used in patients with any of the following conditions:

- Inappropriate candidates for endoscopic or laparoscopic treatment
- Intolerance to anesthesia
- Intestinal obstruction

Gastroenterology surgery relative contraindications

The Ho:YAG wavelength should not be used in patients with any of the following conditions:

- Recent myocardial infarction
- Multiple previous abdominal surgeries

Gastroenterology surgery warnings

Read “General laser warnings” earlier in this chapter for a list of warnings.

Gastroenterology surgery precautions

- Use caution when treating patients who have had previous esophageal-tracheal fistulae or episodes of aspiration.

Read “General laser precautions” earlier in this chapter for a list of additional precautions.

Gastroenterology surgery complications

- Patients may experience gastrointestinal distension or pneumothorax during or after therapy.
- Swallowing may be worsened, rather than immediately improved, following esophageal procedures due to secondary tissue edema. This potential problem should be explained to the patient prior to therapy.

Read “General laser complications” earlier in this chapter for a list of additional complications.

Gastroenterology surgery clinical parameters

The Ho:YAG wavelength has been shown to be a safe and effective tool for the ablation, excision, and coagulation of a variety of soft tissues. This has been demonstrated by both clinical and preclinical experience. The depth of the incision is determined by the amount of energy (in joules) applied. The rate at which the incision is made is dependent upon the rate of energy pulses being delivered to the target tissue (in pulses per second, or hertz). Optimum incision of tissue is accomplished by balancing the depth of the incision and the rate at which the incision is being formed. The physician may vary both the energy setting and the repetition rate of the laser, depending upon the specific type of soft tissue, the indication (excision, ablation, or coagulation), and the speed at which the physician wishes to work.

Depending on the water content of the cells and other cell constituents, such as pigments, the depth of the thermal zone of injury has been shown to be less than 500 micrometers.

The Ho:YAG wavelength provides effective hemostasis without damaging surrounding or nontarget tissues. Coagulation can be affected by reducing the power density incident on vascularized tissue in two ways. First, when the tip of the handpiece or fiber is in direct contact with the target tissue, the energy and repetition rate settings on the control screen may be reduced. Second, the physician may elect to defocus the beam without changing the system controls by moving the tip of the handpiece away from the target tissue approximately 2 to 5 millimeters.

The Ho:YAG wavelength gives the physician the ability to customize the delivered power to fit the requirement of each soft tissue indication. The following table lists recommended energy and repetition rates for ablation, excision, and coagulation of soft tissue:

CLINICAL PARAMETERS			
Application	Energy (Joules)	Pulses (Hertz)	Average Power (Watts)
Ablation	0.5-1.0	5-15	2.5-15
Excision	1.0	10-15	10-15
Coagulation	0.5-1.0	5-15	2.5-15
Note: Laser settings are guidelines only. Always start at low settings and increase to achieve desired tissue effect.			

Gastroenterology Surgery—recommended treatment parameters, holmium only

Indications for Use Specific to the Nd:YAG Wavelength

CAUTION

The physician should be fully aware of the tissue effects of the Nd:YAG (1.06 μm) wavelength. Due to the increased tissue penetration of this wavelength, the physician must take precautions to avoid tissue perforation. Never activate laser emission unless the target tissue is in full view. Always use the lowest possible power setting necessary to achieve the desired tissue effect.

The Nd:YAG (1.06 μm) wavelength is intended for use in surgical procedures involving open, laparoscopic and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including:

- Urology
- General surgery
- Gastroenterology
- Thoracic and pulmonary surgery
- E.N.T. surgery
- Podiatry
- Gynecology—The use of the Nd:YAG wavelength in Gynecology is limited to specific indications. See “Gynecology indications” for a list of the indications.

The Nd:YAG (1.06 μm) wavelength is indicated for use in the performance of specific surgical applications, as detailed in this chapter. Read and comprehend “General Warnings, Precautions, and Complications to consider when using the Holmium and Nd:YAG Wavelengths” at the beginning of this chapter before reading the sections that describe a particular surgical specialty.

Urology indications

The Nd:YAG wavelength is indicated for ablation, vaporization, incision, excision, and coagulation of soft tissue during open and, where applicable, endoscopic procedures in urology. The following applications are indicated for urology while using the Nd:YAG wavelength:

- Removal of superficial bladder tumors
- Removal of invasive bladder carcinoma
- Removal of benign or malignant lesions of the external genitalia, including condyloma
- Urethral strictures
- Vascular lesions of the bladder wall
- Prostatectomy

NOTE

The safety and efficacy of the use of this wavelength for the treatment of benign prostatic hypertrophy (BPH) has not been demonstrated.

Urology contraindications

The Nd:YAG wavelength should not be used in patients with any of the following conditions:

- Intolerance to anesthesia
- Inappropriate candidates for laser surgery

Urology warnings

Read “General laser warnings” earlier in this chapter for a list of additional warnings.

Urology precautions

Care should be exercised so as not to over distend the bladder when using the laser endoscopically. Excessive bladder distention could result in coagulative necrosis of the superficial and inner muscular region of the bladder wall.

Read “General laser precautions” earlier in this chapter for a list of additional precautions.

Urology complications

Read “General laser complications” earlier in this chapter for a list of complications.

Urology clinical parameters

When delivering the laser energy, always start at low settings and increase power as necessary to achieve the desired clinical effect. In all cases, power levels should only be used as necessary and should be based on information from scientific studies, experience, training, and the particular procedure. The best indication of correct power is tissue effect; shrinkage and whitening of the tissue will occur as the laser energy is absorbed. Carbonization and vaporization will be seen at higher powers. Refer to the appropriate delivery system instruction guide for maximum power levels.

General surgery indications

The Nd:YAG wavelength is indicated for ablation, vaporization, incision, excision, and coagulation of soft tissue during general surgery procedures. The surgical method (open or laparoscopic) and the method of delivering the laser energy are left to the discretion of the physician.

The following applications are indicated when using the Nd:YAG wavelength in general surgery:

- Cholecystectomy
- Hepatectomy
- Splenectomy
- Thyroidectomy
- Herniorrhaphy
- Appendectomy
- Partial nephrectomy
- Resection of lipoma
- Removal of lesions
- Removal of tumors
- Debridement of decubitus ulcer
- Mastectomy
- Pancreatectomy
- Hemorrhoidectomy
- Parathyroidectomy
- Tonsillectomy
- Lymphadenectomy
- Pilonidal cystectomy
- Pelvic adhesiolysis
- Removal of polyps
- Tumor biopsy

General surgery contraindications

The Nd:YAG wavelength should not be used in patients with any of the following conditions:

- Intolerance to anesthesia
- Inappropriate candidates for laser surgery

General surgery warnings

Extreme caution should be used when insufflating the abdomen with gas during an endoscopic or laparoscopic procedure. The use of carbon dioxide gas for insufflation will minimize patient risk, as it is highly soluble in blood. Insufflation should be set to minimum settings for effective insufflation. **The maximum safe intra-abdominal pressure settings is 15 to 20 mm Hg.**

Read “General laser warnings” earlier in this chapter for a list of additional warnings.

General surgery precautions

Read “General laser precautions” earlier in this chapter for a list of precautions.

General surgery complications

Air embolus is usually diagnosed intraoperatively. This condition requires rapid emergency treatment.

Read “General laser complications” earlier in this chapter for a list of additional complications.

General surgery clinical parameters

When delivering the laser energy, start with power levels between 12 and 25 watts, and increase power as necessary to achieve the desired clinical effect. Refer to the appropriate delivery system instruction guide for maximum power levels.

In all cases, higher power levels should only be used as necessary and should be based on information from scientific studies, experience, training, and the particular procedure. The best indication of correct power is tissue effect; shrinkage and whitening of the tissue will occur as the laser energy is absorbed. Carbonization and vaporization will be seen at higher powers.

Gynecology indications

The Nd:YAG wavelength is indicated for the following applications in gynecology.

- Treatment of menorrhagia by the photocoagulation, vaporization, or ablation of the endometrial lining of the uterus under direct hysteroscopic visualization
- Intrauterine treatment of submucous fibroids, benign endometrial polyps, and uterine septum by incision, excision, ablation, and/or vessel coagulation
- Intra-abdominal treatment of endometriosis and/or peritoneal adhesions by laser contact tips
- Soft tissue excisional procedures, such as conization of the cervix

Gynecology contraindications

The Nd:YAG wavelength should not be used in patients with any of the following conditions:

- Intolerance to anesthesia
- Inappropriate candidates for laser surgery

When treating menorrhagia, the Nd:YAG wavelength should not be used in patients with any of the following conditions:

- Patients who desire child bearing potential
- Patients with any medical condition that contraindicates hysteroscopy, such as active pelvic inflammatory disease
- Patients in which there is an indication of precancerous pathology

Gynecology warnings

- It is essential that the physician and attending staff be trained in all aspects of these gynecological procedures. No physician should use this laser without first obtaining detailed instructions in laser use. In addition, this laser should not be used for hysteroscopic procedures until the physician or hysteroscopist also has obtained detailed instructions in hysteroscopy using a fluid distention medium.
- During intrauterine laser surgery, do not use gas or air for cooling the laser delivery system's fiber tip or for insufflation. The use of gas or air may cause a life-threatening gas or air embolism.

Read "General laser warnings" earlier in this chapter for a list of additional warnings.

Gynecology precautions

The following precautions are specific to the treatment of menorrhagia:

- Special precautions should be taken to monitor the patient fluid absorption from the hysteroscopic distention media. Excessive fluid absorption may be a problem if the procedure is prolonged. During the procedure, venous channels seem to be open, but bleeding is controlled by the pressure of the irrigating solution. There is a large, raw surface, and a large volume of fluid may be absorbed. Wider dilation of the cervix to allow irrigating fluid to flow more freely around the hysteroscope and reduce intrauterine pressure may reduce the risk. If excessive fluid is absorbed, appropriate therapy, such as diuretic administration, should be considered with subsequent electrolyte monitoring.
- Because of the risk of possible fluid absorption, patients with cardiovascular disorders should be carefully evaluated as candidates for this procedure.
- Consideration should be given to closing the fallopian tubes prior to the procedure. However, if the physician, after consultation with the patient, determines that sterilization is not indicated, the patient must be advised to utilize a contraceptive technique to avoid pregnancy. Although pregnancy is highly unlikely after this procedure, there is no data regarding the potential risks should pregnancy occur.

- Patients are urged to have a pap smear annually. There is a possibility that in a very small percentage of women who develop uterine cancer, their symptoms of bleeding may be hidden as a result of this treatment. And, while other symptoms would still be expected to occur, this precautionary step should be taken to reveal any possible cancerous development.

Read “General laser precautions” earlier in this chapter for a list of additional precautions.

Gynecology complications

- There is no guarantee that treatment with the Nd:YAG wavelength will entirely eliminate that disease entity. Repeat treatments or alternative therapies may be required.
- Formation of air emboli can occur if air or gas are used for cooling the laser fiber tip or for insufflation. Only use fluid coolant when performing hysteroscopic laser surgery.

Read “General laser complications” earlier in this chapter for a list of additional complications.

Gynecology clinical parameters

When delivering the laser energy, start with power levels between 12 and 25 watts, and increase power as necessary to achieve the desired clinical effect. Refer to the appropriate delivery system instruction guide for maximum power levels.

In all cases, higher power levels should only be used as necessary and should be based on information from scientific studies, experience, training, and the particular procedure. The best indication of correct power is tissue effect; shrinkage and whitening of the tissue will occur as the laser energy is absorbed. Carbonization and vaporization will be seen at higher powers.

Dermatology and plastic surgery indications

The Nd:YAG wavelength is indicated for ablation, vaporization, excision, incision, and photocoagulation of soft tissue in the following dermatology and plastic surgery procedures. The method of delivering the laser energy is left to the discretion of the physician.

- Lesions of skin and subcutaneous tissue
- Telangiectasia
- Port wine lesions
- Spider veins
- Hemangiomas
- Plantar warts
- Periungual and subungual warts
- Removal of tattoos
- Debridement of decubitus ulcer
- Keloids

NOTE

Lesion color may be affected by photocoagulation with the Nd:YAG wavelength.

Because of the deep penetrating tissue interaction of the Nd:YAG wavelength laser beam, the physician's patient selection criteria might include those patients with lesions that would potentially benefit from aggressive treatment. Those patients with lesions that have been refractory to other laser treatments might also be considered.

Dermatology and plastic surgery contraindications

The Nd:YAG wavelength should not be used in patients with any of the following conditions:

- Intolerance to anesthesia
- Inappropriate candidates for laser surgery

Dermatology and plastic surgery warnings

Read "General laser warnings" earlier in this chapter for a list of warnings.

Dermatology and plastic surgery precautions

- Dark skinned patients must be carefully evaluated by the physician for their risk of scarring versus the treatment benefit ratio.
- Lesions that have been previously treated with other laser wavelengths or with chemicals should be treated with caution and with the lowest possible power levels in order to avoid burns on the previously thinned skin.
- Treatment should be done in a “dot” fashion in areas where the skin is thin, such as the temple or scalp.

Read “General laser precautions” earlier in this chapter for a list of additional precautions.

Dermatology and plastic surgery complications

The treatment of colored vascular lesions with the Nd:YAG wavelength may result in no benefit or a decrease in lesion size and/or blanching of color. The lesion may also worsen due to scar formation. Potential complications of the laser treatment include the following:

- Scarring—hypertrophic and nonhypertrophic
- Burns—from superficial to full thickness
- Excessive tissue destruction
- Ulceration
- Hyperpigmentation
- Induced hemorrhage
- Edema
- Failure of the procedure—While clinical studies have shown efficacy in treating colored vascular lesions, it is possible that there may be regeneration of some ectatic vessels. Should this happen, further laser treatment may be necessary.

Read “General laser complications” earlier in this chapter for a list of additional complications.

Dermatology and plastic surgery clinical parameters

When delivering the laser energy, start with power levels between 12 and 25 watts, and increase power as necessary to achieve the desired clinical effect. Refer to the appropriate delivery system instruction guide for maximum power levels.

In all cases, higher power levels should only be used as necessary and should be based on information from scientific studies, experience, training, and the particular procedure. The best indication of correct power is tissue effect; shrinkage and whitening of the tissue will occur as the laser energy is absorbed. Carbonization and vaporization will be seen at higher powers.

E.N.T. surgery indications

The Nd:YAG wavelength is indicated for ablation, vaporization, excision, incision, and photocoagulation of soft tissue in E.N.T. surgery procedures. The surgical method and the method of delivering the laser energy are left to the discretion of the physician.

The following applications are indicated when using the Nd:YAG wavelength in E.N.T. surgery:

- Lesions or tumors of the oral, nasal, glossal, pharyngeal, and laryngeal soft tissue
- Tonsillectomy
- Adenoidectomy

E.N.T. surgery contraindications

The Nd:YAG wavelength should not be used in patients with any of the following conditions:

- Intolerance to anesthesia
- Inappropriate candidates for laser surgery

E.N.T. surgery warnings

Read “General laser warnings” earlier in this chapter for a list of warnings.

E.N.T. surgery precautions

Read “General laser precautions” earlier in this chapter for a list of precautions.

E.N.T. surgery complications

Read “General laser complications” earlier in this chapter for a list of complications.

E.N.T. surgery clinical parameters

When delivering the laser energy, start with power levels between 12 and 25 watts, and increase power as necessary to achieve the desired clinical effect. Refer to the appropriate delivery system instruction guide for maximum power levels.

In all cases, higher power levels should only be used as necessary and should be based on information from scientific studies, experience, training, and the particular procedure. The best indication of correct power is tissue effect; shrinkage and whitening of the tissue will occur as the laser energy is absorbed. Carbonization and vaporization will be seen at higher powers.

Podiatry indications

The Nd:YAG wavelength is indicated for ablation, vaporization, excision, incision, and photocoagulation of soft tissue in podiatry. The method of delivering the laser energy is left to the discretion of the physician.

The following applications are indicated when using the Nd:YAG wavelength in podiatry:

- Matrixectomy
- Plantar warts
- Neuromas
- Periungual and subungual warts
- Radical nail excision

Podiatry contraindications

The Nd:YAG wavelength should not be used in patients with any of the following conditions:

- Intolerance to anesthesia
- Inappropriate candidates for laser surgery

Podiatry warnings

Read “General laser warnings” earlier in this chapter for a list of warnings.

Podiatry precautions

Read “General laser precautions” earlier in this chapter for a list of precautions.

Podiatry complications

Read “General laser complications” earlier in this chapter for a list of complications.

Podiatry surgery clinical parameters

When delivering the laser energy, start with power levels between 12 and 25 watts, and increase power as necessary to achieve the desired clinical effect. Refer to the appropriate delivery system instruction guide for maximum power levels.

In all cases, higher power levels should only be used as necessary and should be based on information from scientific studies, experience, training, and the particular procedure. The best indication of correct power is tissue effect; shrinkage and whitening of the tissue will occur as the laser energy is absorbed. Carbonization and vaporization will be seen at higher powers.

Gastroenterology surgery indications

The Nd:YAG wavelength is indicated for ablation, vaporization, excision, incision, and photocoagulation of soft tissue in gastroenterology surgery. The surgical method and the method of delivering the laser energy are left to the discretion of the physician.

The following applications are indicated when using the Nd:YAG wavelength in gastroenterology surgery:

- Partial removal of neoplastic tissue in the management of esophageal obstruction for the symptomatic relief of dysphagia
- Gastrointestinal hemostasis, including:
 - Varices
 - Esophagitis
 - Esophageal ulcer
 - Mallory-Wiess tear
 - Gastric ulcer
 - Angiodysplasia
 - Stomal ulcers
 - Nonbleeding ulcers
 - Gastric erosions
- Gastrointestinal tissue ablation, including:
 - Benign and malignant neoplasm
 - Hemorrhoids
 - Polyps

Gastroenterology surgery contraindications

The Nd:YAG wavelength should not be used in patients with any of the following conditions:

- Intolerance to anesthesia
- Inappropriate candidates for laser surgery

Gastroenterology surgery warnings

Read “General laser warnings” earlier in this chapter for a list of warnings.

Gastroenterology surgery precautions

Use caution when treating patients who have had previous esophageal-tracheal fistulae or episodes of aspiration.

Read “General laser precautions” earlier in this chapter for a list of additional precautions.

Gastroenterology surgery complications

- Patients may experience gastrointestinal distension or pneumothorax during or after therapy.
- Swallowing may be worsened, rather than immediately improved, following esophageal procedures due to secondary tissue edema. This potential problem should be explained to the patient prior to therapy.

Read “General laser complications” earlier in this chapter for a list of additional complications.

Gastroenterology surgery clinical parameters

When delivering the laser energy, start with power levels between 12 and 25 watts, and increase power as necessary to achieve the desired clinical effect. Refer to the appropriate delivery system instruction guide for maximum power levels.

In all cases, higher power levels should only be used as necessary and should be based on information from scientific studies, experience, training, and the particular procedure. The best indication of correct power is tissue effect; shrinkage and whitening of the tissue will occur as the laser energy is absorbed. Carbonization and vaporization will be seen at higher powers.

Thoracic and pulmonary surgery indications

The Nd:YAG wavelength is indicated for ablation, vaporization, excision, incision, and photocoagulation of soft tissue in thoracic and pulmonary surgery. The surgical method and the method of delivering the laser energy are left to the discretion of the physician.

The following applications are indicated when using the Nd:YAG wavelength in thoracic and pulmonary surgery:

- Laryngeal lesions
- Airway obstructions including carcinoma, polyps, and granulomas
- Palliation of obstructing carcinomas of the tracheobronchial tree

Thoracic and pulmonary surgery contraindications

The Nd:YAG wavelength should not be used in patients with any of the following conditions:

- Intolerance to anesthesia
- Inappropriate candidates for laser surgery

Thoracic and pulmonary surgery warnings

Read “General laser warnings” earlier in this chapter for a list of warnings.

Thoracic and pulmonary surgery precautions

Use caution with patients who have had previous esophageal-tracheal fistulae or episodes of aspiration.

Read “General laser precautions” earlier in this chapter for a list of additional precautions.

Thoracic and pulmonary surgery complications

Read “General laser complications” earlier in this chapter for a list of complications.

Thoracic and pulmonary surgery clinical parameters

When delivering the laser energy, start with power levels between 12 and 25 watts, and increase power as necessary to achieve the desired clinical effect. Refer to the appropriate delivery system instruction guide for maximum power levels.

In all cases, higher power levels should only be used as necessary and should be based on information from scientific studies, experience, training, and the particular procedure. The best indication of correct power is tissue effect; shrinkage and whitening of the tissue will occur as the laser energy is absorbed. Carbonization and vaporization will be seen at higher powers.

Appendix A

Clinical Procedure for Holmium Laser Resection of the Prostate (HoLRP)

The holmium wavelength (2.1 μm) can be used to perform an endoscopic transurethral resection of the prostate. HoLRP produces an immediate TURP-like cavity and provides resected tissue samples for histologic analysis. Isotonic saline is used as the intraoperative transurethral irrigant, and minimal postoperative irrigation is required due to the hemostatic nature of the procedure. A 20 Fr two-way catheter is placed postoperatively and is removed once hematuria has settled, usually the morning after surgery.

Benign prostatic hyperplasia (BPH), or enlargement of the prostate gland (BPH) (also termed benign prostatic hypertrophy) is shown in Diagram 1.

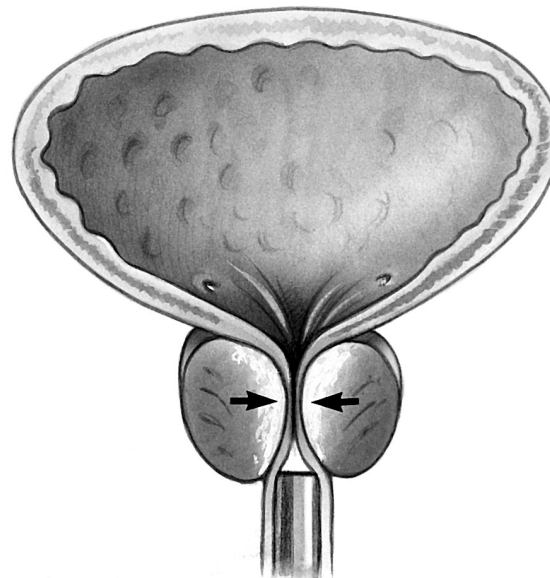


Diagram 1

Equipment Used

- VersaPulse Select Single Wavelength Ho:YAG or Dual Wavelength Ho:YAG/Nd:YAG Surgical laser system capable of 2.0 J/p, 40 Hz, and 80 W;
- 550 μm SlimLine™ Delivery Device ('bare' fiber)
- Karl Storz Endoscopy 26 Fr continuous flow resectoscope with Storz 'Fraundorfer' Inner Sheath (includes metal fiber guide at the tip of the inner sheath to stabilize the fiber tip and ensure that it remains in contact with the prostate tissue to be resected)
- 6 Fr ureteric catheter (threaded, together with the SlimLine fiber, through the metal fiber guide in the 'Fraundorfer' inner sheath to help stabilize the fiber tip and ensure that it remains in contact with the prostate tissue to be resected)
- Isotonic saline for intraoperative transurethral irrigation
- 100 mL Toomey glass syringe or Ellick evacuator to aspirate the majority of the resected prostate tissue from the bladder
- Mechanical grasping tool to remove any very large resected tissue fragments that cannot be evacuated via aspiration
- 20 Fr two-way catheter, placed postoperatively (to prevent clot formation and urinary retention) until hematuria settles

HoLRP Procedure

Resection of the Median Lobe

1. Once the resectoscope has been introduced, the urethral length is measured and the resection weight is estimated. The procedure begins with bilateral bladder neck incisions in the 5 and 7 o'clock positions. These extend from each ureteric orifice down to the level of the verumontanum. The incisions are then deepened down to the capsular fibers. These are important as they define the depth of the median lobe resection and form the lower margin of the lateral lobe resection.

NOTE

To incise the tissue, ensure that the tip of the laser fiber is in direct contact with the prostatic tissue. The incisional laser effect will be diminished, or not present, if the fiber tip is not maintained in contact with the tissue.

NOTE

If the prostate is large, keep the laser fiber close to the tip of the resectoscope - this will help keep the walls of the incision apart and aid in visualization during incision.

2. If the prostate is small and the median lobe can be removed as one or two fragments, the two bladder neck incisions can simply be joined transversely just above the verumontanum (or veru). The lobe can then be gradually undermined by working proximally from side to side, and pushing the tissue upwards towards the bladder. The resected lobe can easily be bivalved prior to disconnecting it from its attachments, if necessary.

If the median lobe is large, it must be incised transversely into multiple pieces (Diagram 2). If the pieces are too large, they will be difficult to remove later. The resection begins proximally and works towards the veru. These pieces can be made smaller by incising them into halves or thirds as required. The resection then gradually works back towards the veru until the entire median lobe has been removed.

NOTE

Small bleeding vessels can be coagulated by drawing the laser fiber 1 - 2 mm away from the tissue to defocus the

beam. At this distance, blanching and coagulation occur, rather than vaporization of tissue which occurs when the laser fiber is in direct tissue contact.

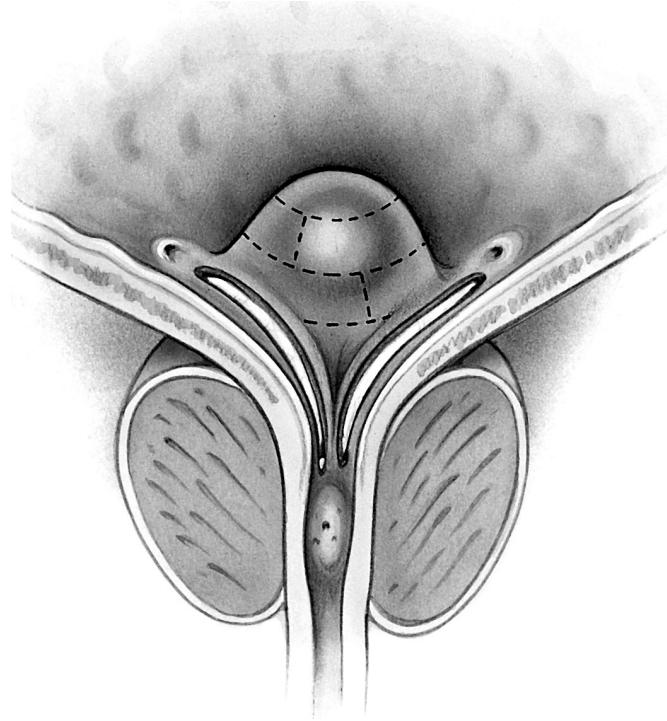


Diagram 2

Resection of the Lateral Lobe

1. Resection of the first lateral lobe begins with an incision to define the apical limit. This is done from 5 o'clock to 3 o'clock (left lobe) or from 7 o'clock to 9 o'clock (right lobe). The incision is deepened over a short distance to define the inferior/distal aspect of the resection (Diagram 3).

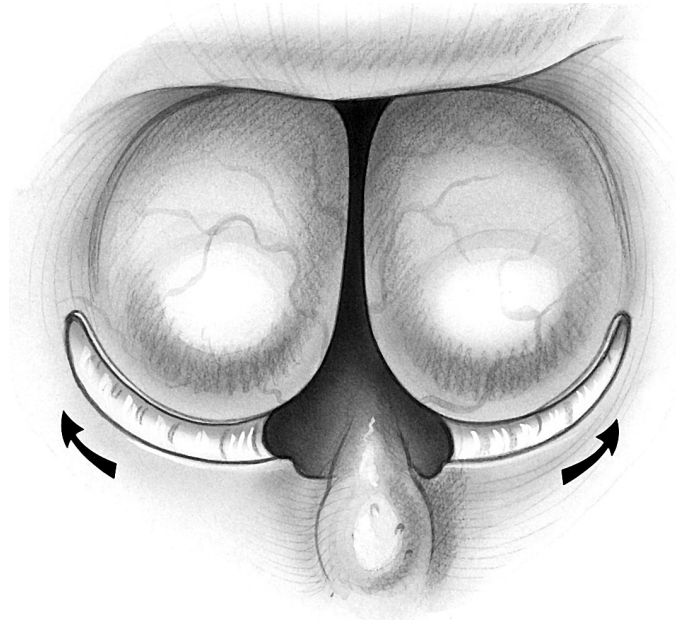


Diagram 3

2. A bladder neck incision is then performed at either the 1 o'clock (left lobe) or 11 o'clock (right lobe) position to define the upper margin of the resection (Diagram 4). This incision is deepened down to the capsular fibers and gradually extended distally until the distal limit (at the veru) is reached. To facilitate this incision in the larger prostate, the lateral lobe is gradually swept down off the prostatic capsule beginning at the proximal margin. The incision can then be easily brought distally.

NOTE

Again, it is useful to keep the laser fiber close to the tip of the resectoscope - this will help keep the walls of the incision apart and aid in visualization during incision.

3. Once the upper and lower incisions can clearly be seen near the apex of the dissection, they can simply be joined. This cleanly defines the apex of the resection. The distal incision can then be deepened to clearly outline the tissue to be removed.

NOTE

It is very tempting at this point to resect large pieces, but this should be avoided. Pieces too large to fit through the lumen of the resectoscope will be difficult and time-consuming to remove later.

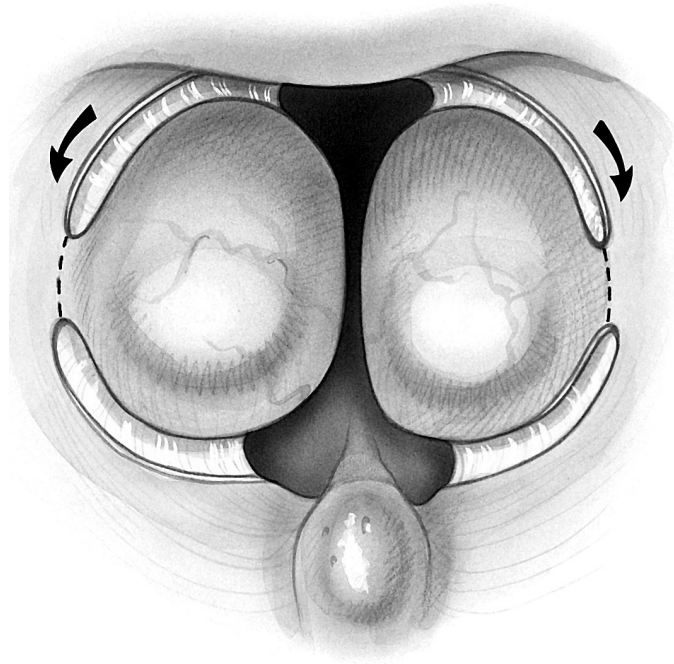


Diagram 4

4. If the prostate is small, the entire lateral lobe can be resected in one or two pieces. It is undermined distally using the laser to incise the cleavage plane between the adenoma and the prostatic capsule. The tip of the resectoscope is used to push the tissue ahead of the resection to open up this plane. If necessary, the lobe can be incised into two or three pieces prior to disconnecting it from the prostatic capsule.

If the lateral lobe is large it may be necessary to cut it into many pieces. This can be accomplished with a series of transverse incisions starting superiorly (Diagram 5). The superior bladder incision can then be brought down by sweeping the lateral lobe off the capsule. The lobe can then be removed in as many pieces as necessary.

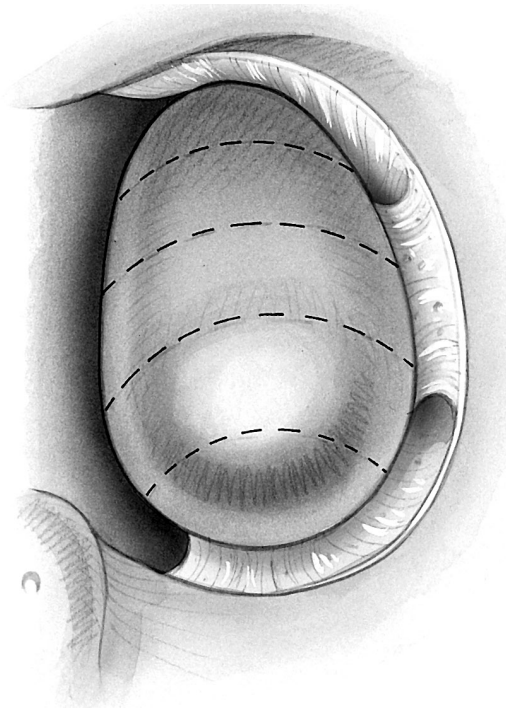


Diagram 5

The technique for the remaining lateral lobe is identical. It is generally easier to resect the second lateral lobe - as the large, open prostatic cavity allows the lobe to fall medially, opening up the planes of dissection.

5. Once the bulk of the prostate has been removed, any remaining prostatic tissue (ragged remnants) can be resected to tidy up the cavity. Small bleeding points can be coagulated by defocusing the beam (e.g., moving the tip of the laser fiber 1 - 2 mm away from the tissue). Any anterior tissue that is present can also be removed (Diagram 6).

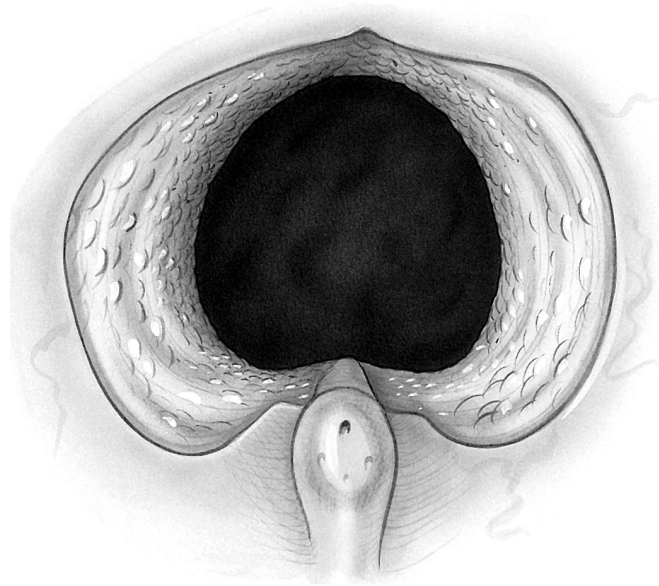


Diagram 6

Removal of the Resected Prostate Tissue Fragments

Most of the pieces can be evacuated with either a Toomey glass syringe or an Ellick evacuator. Fragments that are too large to be removed by aspiration, must be grasped with a mechanical grasping tool and removed manually through the resectoscope.

When fragments are too large to be removed through the urethra, they must be further divided within the bladder. This is a very difficult procedure and illustrates the importance of resecting the tissue into manageable pieces BEFORE disconnecting the entire lobe of the prostate from the capsule. Alternatively, a device such as the Lumenis VersaCut™ Tissue Morcellator can be used to morcellate and aspirate the resected tissue fragments from the bladder under endoscopic visualization.

WARNING

Care should be taken to ensure that all resected tissue fragments are removed. Any residual tissue fragments can become lodged at the bladder neck or in the urethra and cause urinary retention.

Postoperative HoLRP Patient Care

Once the tissue fragments have been removed, a 20 Fr two-way catheter can be placed until hematuria settles. Continuous bladder irrigation is not necessary. If bleeding occurs, a single intravenous 20 mg dose of Furosemide (Lasix) can be given to encourage brisk diuresis.

The two-way catheter can generally be removed the morning after surgery after hematuria has settled. The patient may be discharged once an adequate volume of urine is voided. HoLRP patients can be discharged to unrestricted activity.

Urology Clinical Parameters

The following table shows the recommended pulse energy, repetition rate, and average power for endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in urological applications:

CLINICAL PARAMETERS ¹			
Application	Pulse Energy (Joules/pulse)	Repetition Rate (Hertz)	Average Power (Watts)
Holmium laser resection of the prostate (HoLRP)	2.0	40	80
Bladder tumors	0.8 – 1.2	10 – 20	8 – 24
Ureteral tumors	0.6 – 1.2	10 – 16	6 – 19.2
Incision of strictures	1.2 – 1.4	14 – 16	16.8 – 22.4
¹ Energy delivered endoscopically in a fluid medium. Note: laser settings are guidelines only. Always start at low settings and increase to achieve desired tissue effect.			

Clinical Parameters

The Ho:YAG wavelength provides effective hemostasis without damaging surrounding or nontarget tissues. Coagulation can be effected by reducing the energy or power density incident on vascularized tissue in two ways. First, when the tip of the handpiece or fiber is in direct contact with the target tissue, the pulse energy and repetition rate settings on the control monitor may be reduced. Second, the surgeon may elect to defocus the beam without changing the system controls by pulling the handpiece or fiber tip approximately 2 to 5 millimeters from the target tissue.

Benign Prostatic Hypertrophy (BPH) Clinical Study Information

The performance of the Lumenis VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers were evaluated in 108 patients in a prospective, randomized, single-center clinical study. The study compared the safety and effectiveness of holmium laser resection of the prostate (HoLRP) with electro-surgical transurethral resection of the prostate (TURP) in the treatment of benign prostatic hypertrophy (BPH). Patients were evaluated through 6 months following prostatic resection.

Safety Results

The following table summarizes the postoperative complications and adverse events reported during the study. The complications and adverse events most commonly reported were urogenital system events, hypochromic anemia, fever, hypotension and diarrhea.

Complications and Adverse Events	Number of Events (Number of Patients* and %)	
	HoLRP (n=54)	TURP (n=54)
• Urogenital System Events Occurring in 7% of Patients:		
- Hematuria • average postoperative duration of hematuria	9 events (n*=8; 15%) • 18.6 hours/patient	24 events (n=18; 33%) • 49.3 hours/patient
- Dysuria	26 events (n=20; 37%)	23 events (n=16; 30%)
- Recatheterization	6 events (n=5; 9%)	13 events (n=11; 20%)
- Urinary retention**	6 events (n=5; 9%)	13 events (n=10; 19%)
- Urinary tract infection (UTI)	9 events (n=8; 15%)	7 events (n=7; 13%)
- Impaired urination	11 events (n=8; 15%)	8 events (n=7; 13%)
- Strangury	7 events (n=7; 13%)	7 events (n=7; 13%)
- Urethrostenosis	1 event (n=1; 2%)	7 events (n=6; 11%)
- Bladder spasm	2 events (n=2; 4%)	4 events (n=4; 7%)
- Urinary frequency	6 events (n=4; 7%)	3 events (n=3; 6%)
• Other Body System Events Occurring in 7% of Patients:		
- Hypochromic anemia	2 events (n=2; 4%)	7 events (n=6; 11%)
- Fever	2 events (n=2; 4%)	5 events (n=5; 9%)
- Hypotension	0 events (n=0; 0%)	5 events (n=5; 9%)
- Diarrhea	5 events (n=4; 7%)	1 event (n=1; 2%)
• All Other Events (7% of Patients)	32 events (n=18; 33%)	41 events (n=27; 50%)
Total All Events	118 events (n=39; 72%)	155 events (n=44; 81%)
* The sample size (n) represents the number of patients experiencing each type of event.		
** Prior to patient discharge: 13 events (5 HoLRP, 8 TURP) of urinary retention following removal of the indwelling catheter before patient was able to urinate freely. After patient discharge: 2 events (1 HoLRP at 1 month, 1 TURP at 10 days) of urinary retention requiring rehospitalization for recatheterization; 2 events (TURP at 3 months) of urinary retention requiring dilatation; and 2 events (TURP at 10 days and 4 months) of urinary retention requiring repeat BPH surgery.		

Postoperative complications and adverse events following prostate resection

The following table summarizes the total reported urogenital complications and adverse events, serious adverse events (for all body systems), and the requirement for blood transfusion.

Complications and Adverse Events	Number of Events (Number of Patients* and %)	
	HoLRP (n=54)	TURP (n=54)
• Complications and Adverse Events of the Urogenital System	87 events (n*=33; 61%)	105 events (n=40; 74%)
• Serious Adverse Events for All Body Systems	9 events (n=6; 11%)	15 events (n=13; 24%)
• Blood Transfusions Required	0 events (n=0; 0%)	6 events (n=4; 7%)

* The sample size (n) represents the number of patients experiencing each type of event.

**Postoperative complications and adverse events following prostate resection—
urogenital complications and adverse events, serious adverse events,
and blood transfusions**

The following table summarizes pre- and postoperative information regarding sexual function.

Sexual Function	HoLRP (Number and % of Patients)		TURP (Number and % of Patients)	
	Preoperative (n=54)	6 Months (n=50)	Preoperative (n=54)	6 Months (n=50)
Erectile Function				
- Normal/Functional	27 (50%)	17 (34%)	33 (61%)	21 (42%)
- Weak/Insufficient	10 (18%)	20 (40%)	8 (15%)	20 (40%)
- Absent/NA*	17 (32%)	13 (26%)	13 (24%)	9 (18%)
Total	54 (100%)	50 (100%)	54 (100%)	50 (100%)
Ejaculation				
- Normal/NA*	51 (94%)	27 (54%)	49 (91%)	18 (36%)
- Abnormal	3 (6%)	23 (46%)	5 (9%)	32 (64%)
Total	54 (100%)	50 (100%)	54 (100%)	50 (100%)
Dry (Retrograde) Ejaculation				
• Number of patients	• 0	• 22	• 2	• 30
- % of patients in group	- 0% HoLRP	- 44% HoLRP	- 4% TURP	- 60% TURP
- % of patients in group with abnormal ejaculation	- 0% abnormal HoLRP	- 96% abnormal HoLRP	- 40% abnormal TURP	- 94% abnormal TURP

* NA = not applicable; patient not sexually active.

Postoperative sexual function and complications following prostate resection

Decontamination Certificate

Under the provisions of Postal Law, Title 18, United States Code, Section 1716, and Department of Transportation regulations contained in CFR 49, Part 173.386 and 173.387, "etiologic agents, diagnostic specimens and biological products...are nonmailable..."

The undersigned therefore certifies that the Lumenis equipment being returned herein by

Individual/Institution

City, State

has undergone decontamination with a commercially available germicide cleared for use as a "Hospital Disinfectant" and is clean and free from biohazards, including - but not limited to - human or animal blood, tissue or tissue fluids or components thereof.

The undersigned also agrees to reimburse Lumenis for any costs incurred in cleaning the enclosed equipment, in the event said item(s) is/are received by Lumenis in a contaminated condition.

Model

Model

Serial Number

Serial Number

Lumenis RMR Number

Lumenis RMR Number

Typed/Printed Name

Position/Title

Signature

Date

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Addendum

*Updated Average Power Table for
100 Watt Holmium Laser Systems
in Selected Countries*

Average Power Table for VersaPulse PowerSuite 100 Watt Holmium systems operating in countries with an electrical supply of 220 VAC / 50 Hz.

When working with the holmium wavelength, the average power, measured in Watts, is determined by multiplying the selected energy, in Joules, by the selected rate, in pulses per second (Hz). The following table shows the relationship between energy, rate and power, and identify the maximum pulse rates available at different energy settings, for the 100 Watt Holmium laser system.

		Pulse Rate (pulses/second)											
		5	6	8	10	15	20	25	30	35	40	45	53
Energy (Joules)	0.2	1.0	1.2	1.6	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.6
	0.3	1.5	1.8	2.4	3.0	4.5	6.0	7.5	9.0	10.5	12.0	13.5	15.9
	0.4	2.0	2.4	3.2	4.0	6.0	8.0	10.0	12.0	14.0	16.0	18.0	21.2
	0.5	2.5	3.0	4.0	5.0	7.5	10.0	12.5	15.0	17.5	20.0	22.5	26.5
	0.6	3.0	3.6	4.8	6.0	9.0	12.0	15.0	18.0	21.0	24.0	27.0	31.8
	0.8	4.0	4.8	6.4	8.0	12.0	16.0	20.0	24.0	28.0	32.0	36.0	42.4
	1.0	5.0	6.0	8.0	10.0	15.0	20.0	25.0	30.0	35.0	40.0	45.0	53.0
	1.2	6.0	7.2	9.6	12.0	18.0	24.0	30.0	36.0	42.0	48.0	54.0	63.6
	1.4	7.0	8.4	11.2	14.0	21.0	28.0	35.0	42.0	49.0	56.0	63.0	74.2
	1.5	7.5	9.0	12.0	15.0	22.5	30.0	37.5	45.0	52.5	60.0	67.5	79.5
	1.6	8.0	9.6	12.8	16.0	24.0	32.0	40.0	48.0	56.0	64.0	72.0	84.8
	1.8	9.0	10.8	14.4	18.0	27.0	36.0	45.0	54.0	63.0	72.0	81.0	95.4
	1.9	9.5	11.4	15.2	19.0	28.5	38.0	47.5	57.0	66.5	76.0	85.5	100.7
	2.0	10.0	12.0	16.0	20.0	30.0	40.0	50.0	60.0	70.0	80.0	90.0	
	2.2	11.0	13.2	17.6	22.0	33.0	44.0	55.0	66.0	77.0	88.0		
	2.4	12.0	14.4	19.2	24.0	36.0	48.0	60.0	72.0	84.0	96.0		
	2.5	12.5	15.0	20.0	25.0	37.5	50.0	62.5	75.0	87.5	100.0		
	2.6	13.0	15.6	20.8	26.0	39.0	52.0	65.0	78.0				
	2.7	13.5	16.2	21.6	27.0	40.5	54.0	67.5	81.0				
	2.8	14.0	16.8	22.4	28.0	42.0	56.0	70.0	84.0				
3.0	15.0	18.0	24.0	30.0	45.0	60.0	75.0	90.0					
3.2	16.0	19.2	25.6	32.0	48.0	64.0	80.0	96.0					
3.5	17.5	21.0	28.0	35.0	52.5	70.0	87.5						