OPTIMEDICA®

PASCAL®
PHOTOCOAGULATOR

(SYSTEM SOFTWARE VERSION 5.XX)

OPERATOR MANUAL

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Precautions, Cautions, and Warnings

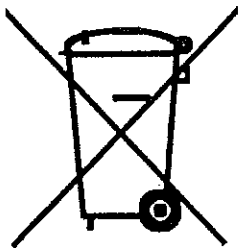
Disclaimer

Calibration is a service procedure to be done only by OPTIMEDICA certified Service Engineers or customers who have taken and passed an OPTIMEDICA Service Certification Training course on the Pascal system. Adjustment by anyone other than a trained OPTIMEDICA Certified Engineer or certified customer voids any existing manufacturer's warranty on the instrument.

Symbol Definitions

Please read this manual and follow its instructions carefully. The words **WARNING**, **CAUTION**, **PRECAUTION**, and **NOTE** carry special meanings and should be carefully reviewed.

 WARNING	The personal safety of the patient or physician may be involved. Disregarding this information could result in injury to the patient or physician.
 CAUTION	Disregarding this information may result in instrument failure or instrument damage.
 PRECAUTION	Possible instrument failure, instrument damage, or unintended outcome may occur when disregarding this information.
	An exclamation mark within a triangle is intended to alert the user to the presence of important operating and maintenance instructions in the literature accompanying the product.
NOTE	The word **NOTE** is to emphasize important information to the user.



WEEE ANNEX IV Symbol

THIS SYMBOL INDICATES THAT THE WASTE OF ELECTRICAL AND ELECTRONIC EQUIPMENT MUST NOT BE DISPOSED AS UNSORTED MUNICIPAL WASTE AND MUST BE COLLECTED SEPARATELY. PLEASE CONTACT THE MANUFACTURER OR OTHER AUTHORIZED DISPOSAL COMPANY TO DECOMMISSION YOUR EQUIPMENT.

WARNING

TO AVOID POTENTIAL INJURY TO THE USER AND THE PATIENT AND/OR DAMAGE TO THIS DEVICE, THE USER MUST:

READ THIS OPERATING MANUAL THOROUGHLY AND BE FAMILIAR WITH ITS CONTENTS PRIOR TO USING THIS EQUIPMENT.

BE A QUALIFIED PHYSICIAN, HAVING COMPLETE KNOWLEDGE OF THE USE OF THIS DEVICE.

TEST THIS DEVICE PRIOR TO A PROCEDURE.

ATTEMPT NO INTERNAL REPAIRS OR ADJUSTMENTS NOT SPECIFICALLY DETAILED IN THIS OPERATOR MANUAL.

DISCONNECT PASCAL FROM THE ELECTRICAL OUTLET WHEN INSPECTING THE FUSES.

OPTIMEDICA ACCEPTS FULL RESPONSIBILITY FOR SAFETY, RELIABILITY, AND PERFORMANCE OF THE DEVICE ONLY IF:

SERVICE, READJUSTMENTS, MODIFICATIONS, AND/OR REPAIRS ARE PERFORMED EXCLUSIVELY BY OPTIMEDICA.

THE ELECTRICAL INSTALLATION OF THE TREATMENT ROOM COMPLIES WITH THE APPLICABLE IEC, CEC, AND NEC REQUIREMENTS.

THE WARRANTY IS VOID IF ANY OF THESE WARNINGS ARE DISREGARDED.

OPTIMEDICA RESERVES THE RIGHT TO MAKE IMPROVEMENTS IN THE DEVICE(S) HEREIN. DEVICE(S), THEREFORE, MAY NOT AGREE IN DETAIL WITH THE PUBLISHED DESIGN OR SPECIFICATIONS. ALL SPECIFICATIONS ARE SUBJECT TO CHANGE WITHOUT NOTICE. PLEASE CONTACT OPTIMEDICA OR YOUR LOCAL OPTIMEDICA SALES REPRESENTATIVE FOR INFORMATION ON CHANGES AND NEW PRODUCTS.

WARNING

FEDERAL LAW (UNITED STATES OF AMERICA) RESTRICTS THIS DEVICE TO USE BY OR ON ORDER OF A PHYSICIAN.

WARNING

WHEN PASCAL IS INTERCONNECTED WITH OTHER MEDICAL ELECTRICAL EQUIPMENT, LEAKAGE CURRENTS MAY BE ADDITIVE. ENSURE ALL SYSTEMS ARE INSTALLED ACCORDING TO THE REQUIREMENTS OF IEC 60601-1-1.

WARNING

USE EXTREME CARE REGARDING CABLE ASSEMBLY TO/FROM THE DISPLAY ASSEMBLY TO/FROM THE SLIT LAMP ASSEMBLY. CABLE ASSEMBLY CONSISTS OF WIRING AND FIBER OPTICS CABLES. DO NOT PULL OR STRESS CABLE ASSEMBLY. DO NOT SET ITEMS ON OR UNDER CABLE ASSEMBLY. DAMAGE TO THE FIBER OPTIC CABLES MAY CAUSE UNINTENDED EXPOSURE.

CAUTION

USE OF CONTROLS OR ADJUSTMENTS OR PERFORMANCE OF PROCEDURES OTHER THAN THOSE SPECIFIED HEREIN MAY RESULT IN HAZARDOUS RADIATION EXPOSURE.

NOTE

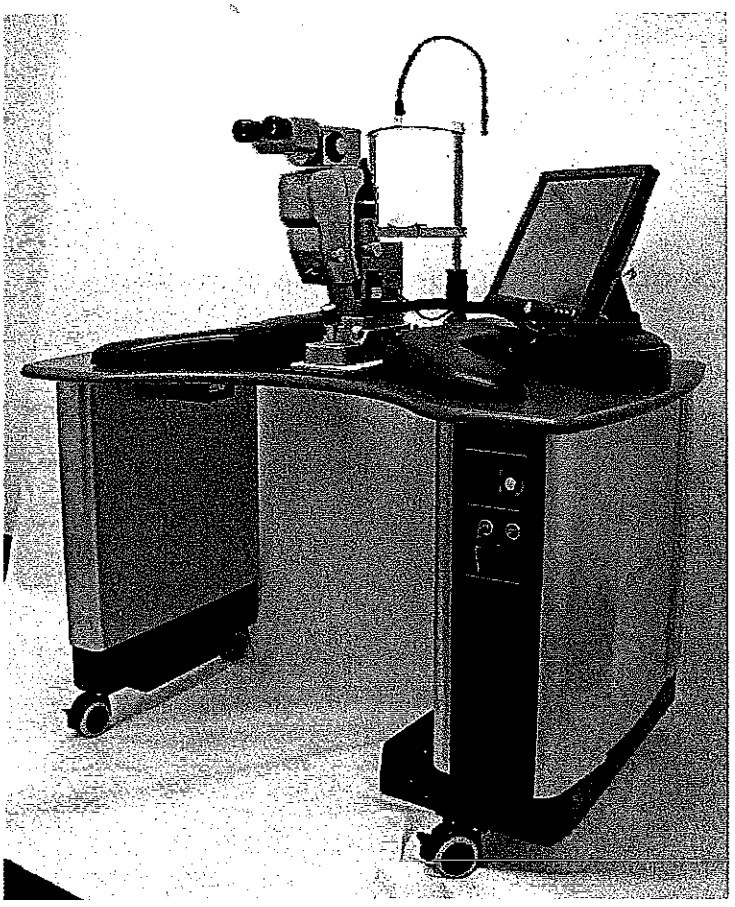
WHEN NOT IN USE, LASER EQUIPMENT SHOULD BE PROTECTED AGAINST UNQUALIFIED USE BY REMOVING THE KEY FROM THE KEY SWITCH.

SYSTEM DESCRIPTION

Pascal Photocoagulator Description

The Pascal Retinal Photocoagulator is a fully integrated laser photocoagulation system. **Pascal** is an acronym for **Pattern Scan Laser**. The system may be used for all standard single shot photocoagulation methods and, in addition, is equipped with proprietary laser scanning patterns that permit faster photocoagulation. The Pascal Retinal Photocoagulator consists of the following functional units:

- Slit lamp with integrated proprietary pattern generation system
- Wheelchair accessible table
- 532 nm laser photocoagulator console
- Touch-screen control panel



Indicated Use

The Pascal Photocoagulator is intended for use in the treatment of ocular pathology. Pascal is indicated for use in photocoagulation of both posterior and anterior segments including:

Retinal photocoagulation, pan-retinal, focal and macular grid photocoagulation for vascular and structural abnormalities of the retina and choroid including:

Proliferative and non-proliferative diabetic retinopathy
Choroidal neovascularization
Branch and central retinal vein occlusion
Age-related macular degeneration
Lattice degeneration
Retinal tears and detachments

In addition, the Pascal Method can be used to perform:

Iridotomy
Iridectomy
Trabeculoplasty in angle closure and/open angle glaucoma.

Pascal applications include:

Pan retinal photocoagulation
Macular grid laser treatment
Retinal tears
Retinal detachment
Focal treatment of juxtafoveal choroidal neovascularization

WARNING

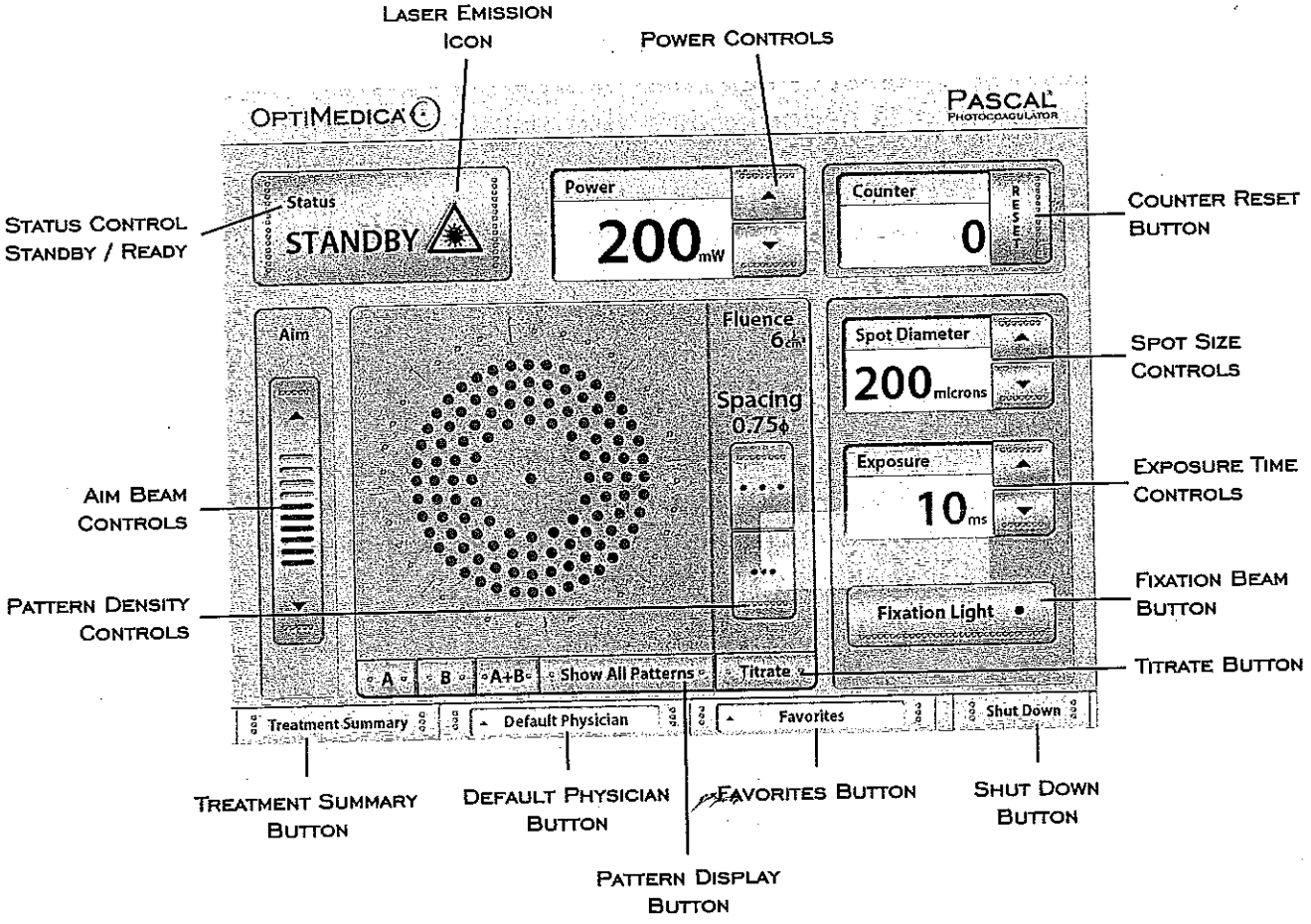
THE PASCAL PHOTOCOAGULATOR GENERATES A HIGHLY CONCENTRATED BEAM OF LASER LIGHT, WHICH MAY CAUSE INJURY IF IMPROPERLY USED. THIS ENTIRE MANUAL SHOULD BE CAREFULLY READ AND UNDERSTOOD BEFORE OPERATION. PRIOR TO TREATMENT IT IS RECOMMENDED THAT USERS FAMILIARIZE THEMSELVES WITH THE SYSTEM CONTROLS. IF YOU HAVE QUESTIONS REGARDING YOUR LASER SYSTEM, LASER SLIT LAMP, OR PATTERN GENERATOR DELIVERY SYSTEM, PLEASE CONTACT OPTIMEDICA AT +1(408) 850.8600.

CAUTIONS

FEDERAL LAW (UNITED STATES OF AMERICA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN. OPTIMEDICA MEDICAL DEVICES ARE SOLELY FOR USE BY PHYSICIANS TRAINED IN THE OPERATION OF LASER PHOTOCOAGULATORS AND ASSOCIATED DELIVERY DEVICES.

USE OF CONTROLS, ADJUSTMENTS, OR PERFORMANCE OF PROCEDURES OTHER THAN THOSE SPECIFIED IN THIS OPERATOR MANUAL MAY RESULT IN HAZARDOUS LASER RADIATION EXPOSURE.

CONTROL PANEL AND DISPLAYS



THE MAIN CONTROL PANEL IS LOCATED ON THE SLIT LAMP TABLE, AND TILT OF THE DISPLAY CAN BE POSITIONED AT A DESIRED ANGLE. THE KEY SWITCH AND EMERGENCY OFF SWITCH ARE LOCATED ON THE RIGHT-HAND SIDE OF THE TABLE. THE MAIN CONTROL PANEL IS A LIQUID CRYSTAL DISPLAY (LCD) WITH TOUCH-SCREEN CONTROLS FOR THE SELECTION OF SYSTEM PARAMETERS, SUCH AS AIM BEAM INTENSITY, POWER, EXPOSURE TIME, SYSTEM STATUS AND SHUT DOWN. AT ALL TIMES THE SYSTEM STATUS - STANDBY, READY, OR TREAT - IS DISPLAYED.

THE POSITION OF THE SLIT LAMP MICROSCOPE IS CONTROLLED BY A MECHANICAL JOYSTICK. THE SIZE OF THE PATTERN MAY BE ADJUSTED DEPENDING ON PHYSICIAN PREFERENCE. THERE ARE SOME LIMITATIONS FOR SAFETY. THE LASER EMISSION IS ULTIMATELY CONTROLLED BY THE FOOTSWITCH DEPRESSION.

CAUTIONS

THE LASER EMISSION ICON IS DISPLAYED TO WARN THE USER THAT THE SYSTEM IS CAPABLE OF EMITTING LASER ENERGY. APPROPRIATE PRECAUTIONS, SUCH AS WEARING APPROPRIATE EYE WEAR IN THE ROOM, SHOULD BE TAKEN.

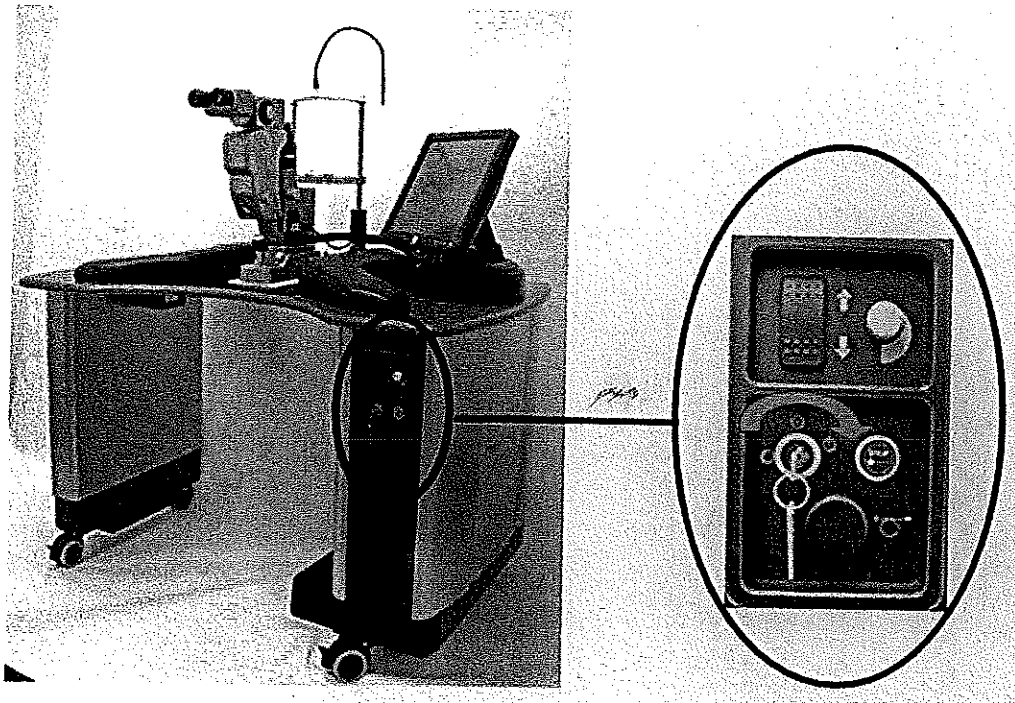
IF THE SCREEN APPEARS BLANK DO NOT USE THE SYSTEM. IF IT REMAINS BLANK FOR MORE THAN 30 SECONDS TURN THE SYSTEM OFF WITH THE KEY, WAIT OVER ONE MINUTE AND THEN RESTART THE SYSTEM.

System Start and Shut Down

System Start

Insert the key in the key switch; turn to the START position, and release.

A system self-test and start-up routine begins. At the beginning of start-up, the software revision is displayed and then the text START UP appears in the status display. The Laser Emission indicator is illuminated at start-up. When the start-up is complete, the system emits audible tones, and then the system enters STANDBY mode.



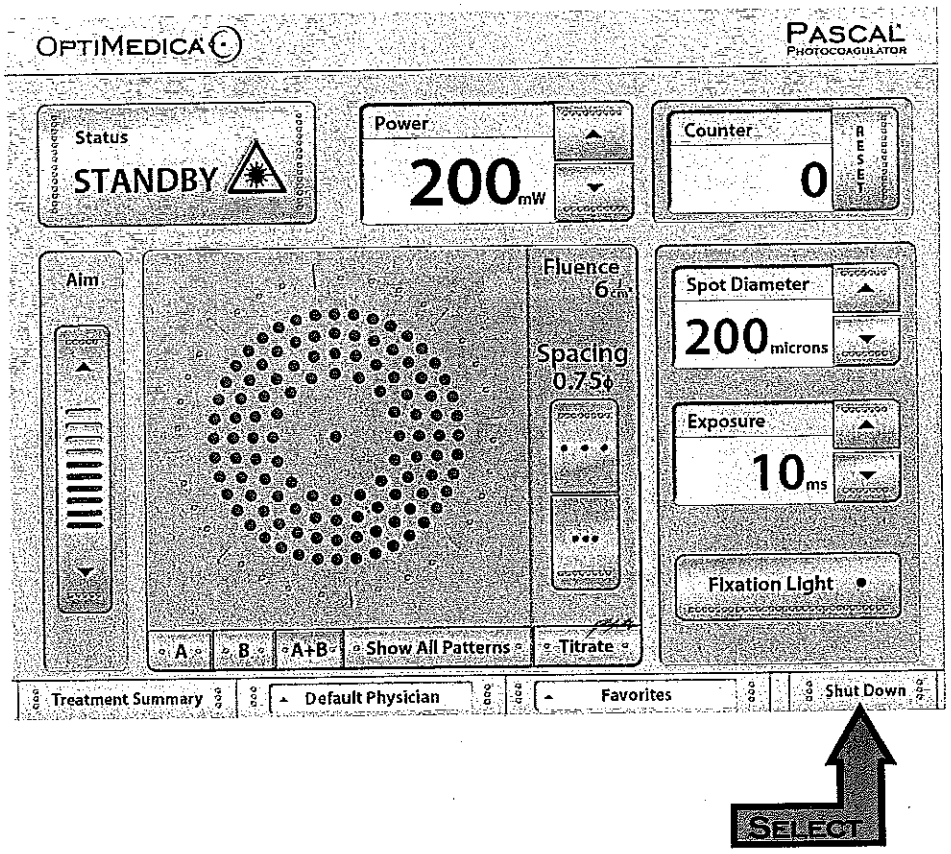
CAUTION

If the screen appears blank do not use the system. If it remains blank for more than 30 seconds turn the system off with the key, wait over one minute and then restart the system.

SYSTEM SHUT DOWN

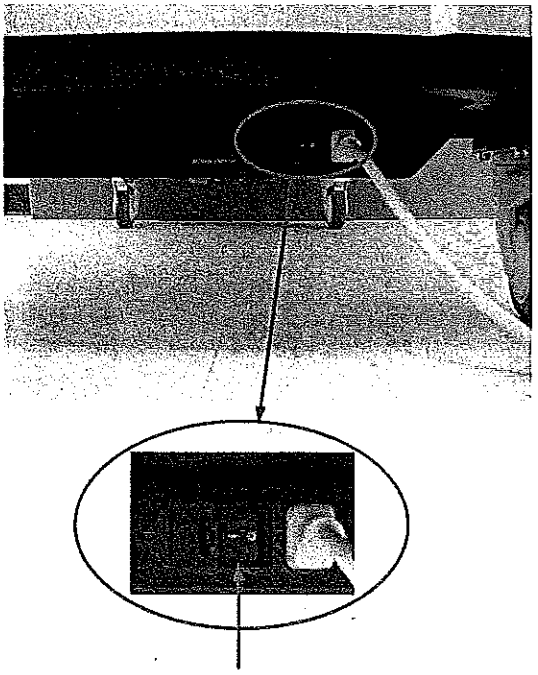
IF THE SYSTEM IS IN READY MODE, SELECT THE STATUS BUTTON LOCATED ON THE CONTROL PANEL DISPLAY TO PLACE THE SYSTEM IN STANDBY MODE AS INDICATED BY THE STANDBY STATUS INDICATOR.

SELECT THE SHUT DOWN BUTTON AND WAIT FOR THE SCREEN TO GO BLANK.



TURN THE KEY TO THE OFF POSITION, AND REMOVE IT TO PREVENT UNAUTHORIZED USE OF THE LASER SYSTEM.

If necessary, all the internal circuits may be de-energized by placing the system circuit breaker or the main wall power circuit breaker in the OFF position.

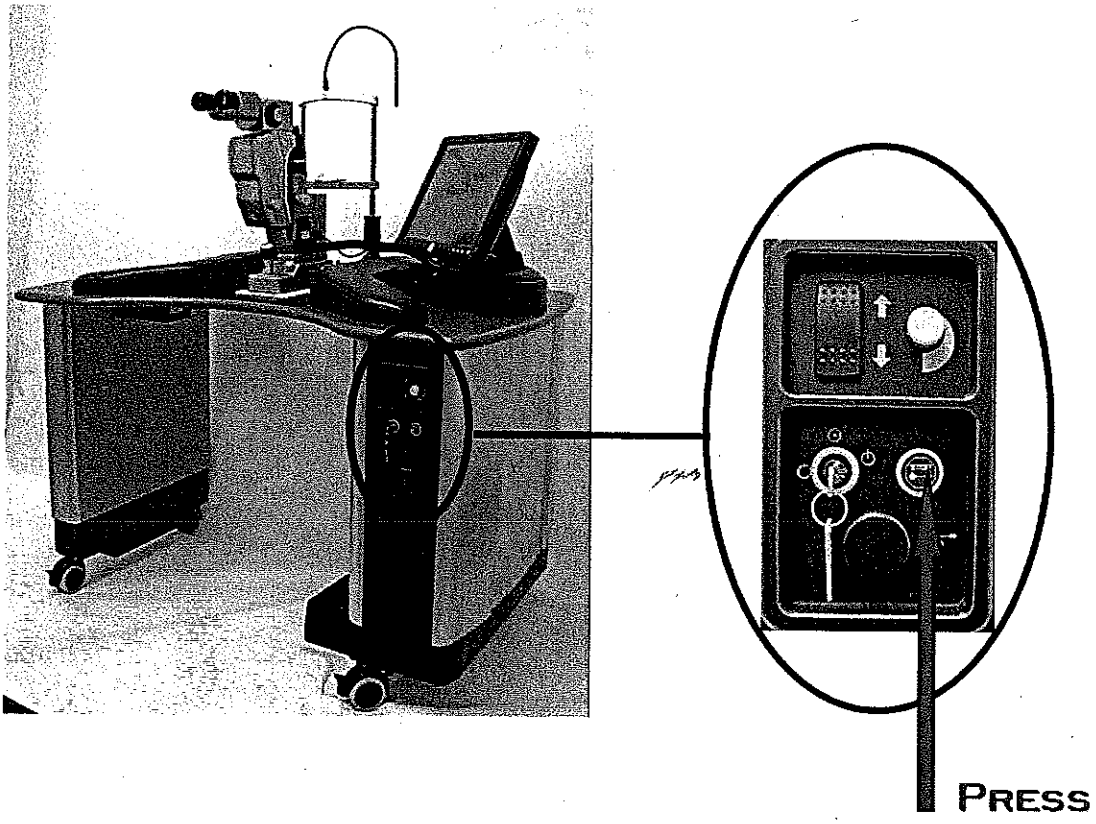


Circuit Breaker
"ON" Position

Emergency Shut Down

In an emergency situation, the system can be shut down rapidly by pressing the EMERGENCY STOP button located on the right hand side of the laser console next to the key switch.

If the power cord is still connected to the electrical source, some internal circuits remain energized. To de-energize all the internal circuits, place the device circuit breaker in the OFF position, and remove the power cord from the wall.



CAUTION

If the system is unresponsive turn the system off by pressing the emergency stop switch, wait over one minute and then restart the system using the key switch.

Slit Lamp and Pattern Generator Delivery System Operating Instructions

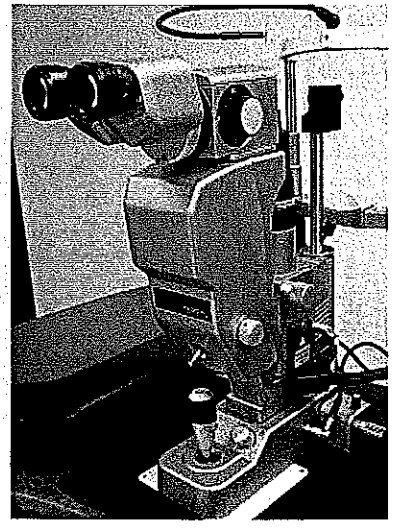
Slit Lamp Setup

The slit lamp is optimized for use as a laser delivery system specifically for laser treatment of the posterior segment of the eye. The lens system produces high-resolution color compensated images that enables the observation of fine details within the eye. The slit projector may be adjusted with either the right or left hand during treatment or observation.

In order to match the in-focus view of the retina with the laser beam focus (parfocality), the slit lamp must be adjusted properly. The slit lamp optics, the physician's individual refractive correction and accommodation, contact lens optics, and the laser beam focus working distance must all be considered when using the slit lamp as a laser delivery system. Failure to establish parfocality means that the viewer's focus is not in the same plane as the laser beam focus. This will result in the laser beam spot size and intensity profile being other than intended.

Slit Lamp Setup Procedure

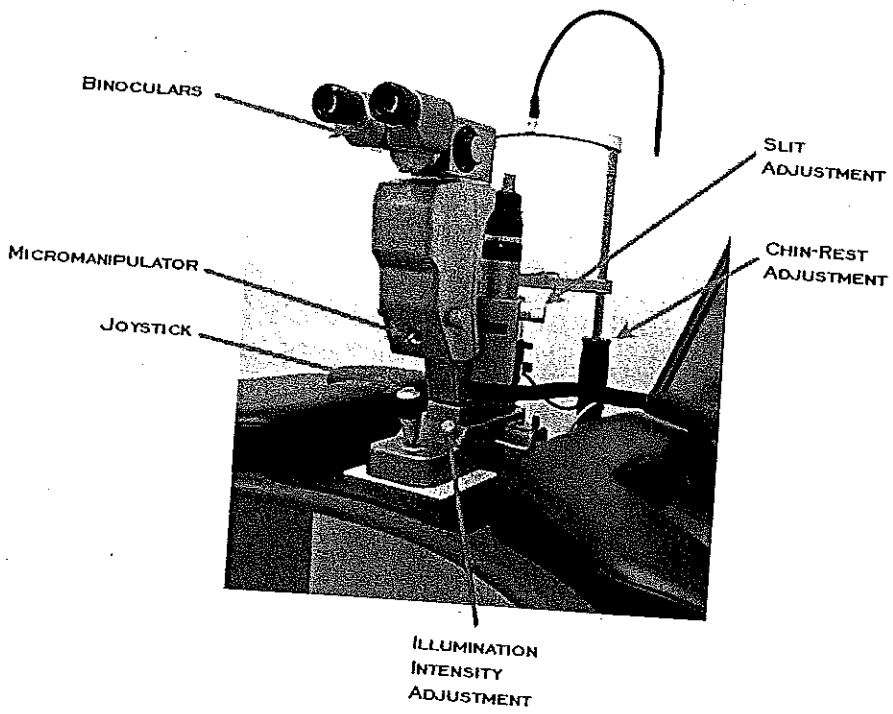
1. Ensure that the laser system is turned on.
2. Insert the focus post into the pivot hole of the slit lamp illumination assembly and set the fixation screw.
3. Turn on the slit lamp illumination and adjust the intensity.
4. Set the magnification to the highest setting and Adjust the pupillary distance of the eyepieces,
5. Defocus the eyepieces beyond "+5" or more.
6. Adjust the focus slowly from "+" to "−" until the image appears in focus. To eliminate natural accommodation of the eye, do not adjust from "−" to "+".
7. Make a note of the diopter setting and repeat steps 4 and 5 two more times and average your readings.
8. repeat steps 4-6 for other eye.
9. Make a note of your settings for future use.
10. Loosen the fixation screw of the focus post and remove post from the pivot hole.
11. It is a good habit to verify that the eyepieces are adjusted to your setting before each use of Pascal, especially in a multi user practice.



Focus Post

Slit Lamp Locking Thumb Screw

Note: There is an identical slit lamp Locking thumb screw on the Opposite side of slit lamp


BINOCULARS
SLIT ADJUSTMENT
MICROMANIPULATOR
CHIN-REST ADJUSTMENT
JOYSTICK
ILLUMINATION INTENSITY ADJUSTMENT

Procedure

1. Position the patient at the slit lamp.
2. Select the treatment parameters on the touch screen control panel.
3. Position the contact lens on the patient's cornea. Tilting the contact lens and/or positioning the illumination slightly off-axis helps to minimize glare from the illumination lamp.
4. Place the laser in READY mode.
5. Position the aiming beam on the target retinal tissue with the joystick and adjust focus by pushing the joystick toward or away from the patient.
6. Depress the footswitch to deliver the treatment beam.

CAUTION

Regardless of beam delivery mode, laser beam delivery will be interrupted if the footswitch is released before the entire pattern or pulse is concluded.

Delivery Systems

Achromatization

Pascal laser delivery is achromatic over the range of 500–700 nm, thus producing identical spots for both the treatment and aiming beams.

Laser Filter

There is a laser filter permanently mounted in the system. This is to protect the physician from exposure to the treatment laser beam. The filter selectively blocks back reflection of the treatment beam. The physician may see some minor fluorescing light when treating patients; this is the auto-fluorescence of the retina, and is not harmful.

CONTACT LENS COMPATIBILITY

WARNING

DO NOT USE ANY CONTACT LENS WITH A LASER SPOT MAGNIFICATION OF (LESS THAN) < 0.94.

PASCAL WILL WORK WITH ALL STANDARD OPHTHALMIC LASER LENSES, SUCH AS THE FOLLOWING:

NOTE

M = SPOT SIZE MAGNIFICATION

OCULAR, MAINSTER STANDARD (M= 1.05X)
OCULAR, FUNDUS LASER (M= 1.08X)
OCULAR, KARICHOFF LASER (M= 1.08X)
OCULAR, THREE MIRROR UNIVERSAL (M= 1.08X)
OCULAR, MAINSTER WIDE FIELD (M= 1.50X)
OCULAR, MAINSTER ULTRA FIELD (M-1.90X)
OCULAR, MAINSTER 165 PRP (M=2.00X)
RODENSTOCK SCHLEGEL PANFUNDOSCOPE (M=1.50X)
VOLK, G-3 GONIOFUNDUS (M=0.94X)
VOLK, AREA CENTRALIS (M= 1.04X)
VOLK, TRANS EQUATOR (M= 1.44X)
VOLK, SUPERQUAD 160 (M= 1.92X)
VOLK, QUADRA-SPHERIC (M=2.01X)
OR EQUIVALENTS.

THE SPOT SIZE AT THE RETINAL PLANE IS THE PRODUCT OF THE DEVICE LASER SPOT SIZE AND M, THE LASER SPOT MAGNIFICATION OF THE CONTACT LENS.

$$D_d \times M = D_r$$

FOR EXAMPLE, A 200 μM LASER SPOT DELIVERED THROUGH A CONTACT LENS WITH M EQUAL TO 1.9X, WOULD YIELD A SPOT OF 380 μM ON THE RETINA.

CAUTIONS

BE SURE TO KEEP ALL OPTICAL SURFACES SCRATCH FREE, CLEAN AND SMUDGE FREE. THIS WILL MINIMIZE LASER BEAM SCATTERING. IF REQUIRED, CLEAN WITH EITHER COMPRESSED AIR OR A DROP OF CAMERA LENS CLEANING SOLUTION APPLIED TO LENS TISSUE PAPER. CLEAN THE SURFACE USING A GENTLE CIRCULAR MOTION.

DO NOT DISINFECT WITH ISOPROPYL ALCOHOL. THIS CAN LEAD TO THE REMOVAL OF PROTECTIVE AND ANTI-REFLECTION COATINGS.

TO DISINFECT THE CONTACT LENS, SEE AND FOLLOW THE MANUFACTURER INSTRUCTIONS.

IF SCRATCHES ARE VISIBLE ON THE OPTICS, DO NOT USE THE DEVICE AND CONTACT OPTIMEDICA FOR REPLACEMENT COMPONENTS.

INTRAOPERATIVE INSTRUCTIONS

Position the Patient and Equipment

Position the patients at the slit lamp by having them sit comfortably behind the slit lamp table and place their chin on the chinrest and forehead on the headrest.

Select the status button to place the system in READY mode.

Position the contact lens on the patient's eye.

Focus the slit lamp and observe the red aiming beam on the patient's retina. Establish proper placement of the laser beam with the joystick.

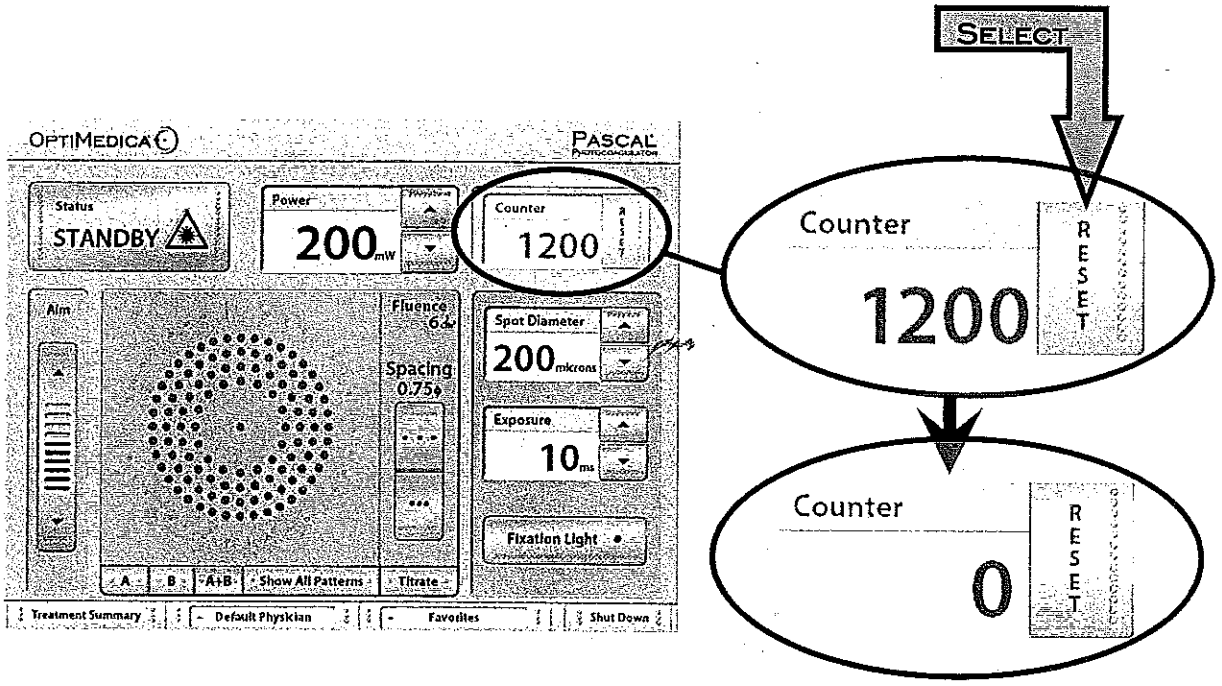
To deliver laser energy, depress the footswitch. Each footswitch depression will result in **ONE APPLICATION, UNLESS THE SYSTEM IS IN REPEAT MODE.** Treatment may be interrupted at any point by releasing the footswitch.

SELECT LASER TREATMENT PARAMETERS

COUNTER RESET

THE COUNTER DISPLAY RECORDS THE NUMBER OF EXPOSURES DELIVERED TO THE TARGET TISSUE. TURNING THE SYSTEM POWER OFF RESETS THE COUNTER TO ZERO.

IF APPROPRIATE, SELECT THE COUNTER RESET BUTTON LOCATED IN THE UPPER RIGHT CORNER OF THE CONTROL PANEL DISPLAY. THE COUNTER INDICATOR SHOULD READ "0." ENSURE THE FOOTSWITCH IS NOT DEPRESSED WHEN RESETTING THE COUNTER.



READY / STANDBY Mode

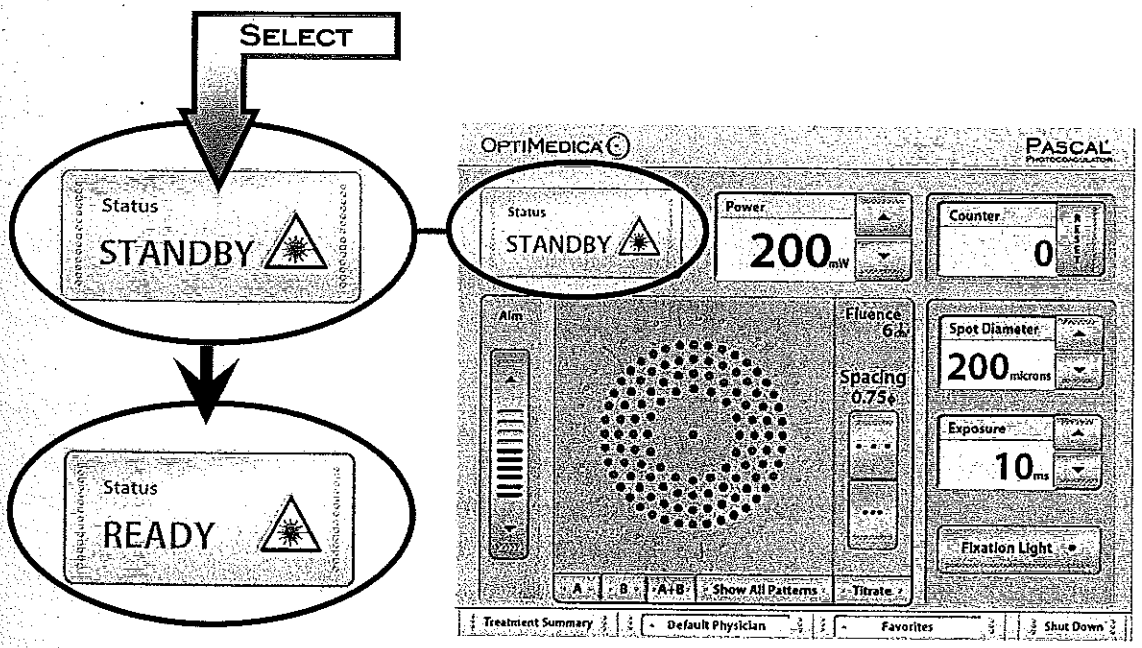
The Status button toggles the system between **READY** and **STANDBY** modes. The selected mode is shown in the adjacent status display.

CAUTION

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

The footswitch has been designed with a protective housing, to prevent inadvertent exposure. The footswitch is enabled only in **READY** mode. Depressing the footswitch will deliver the treatment beam to the target tissue. Likewise, the aiming beam is only available in the **READY** mode. Do not depress the footswitch unless laser exposure is intended.

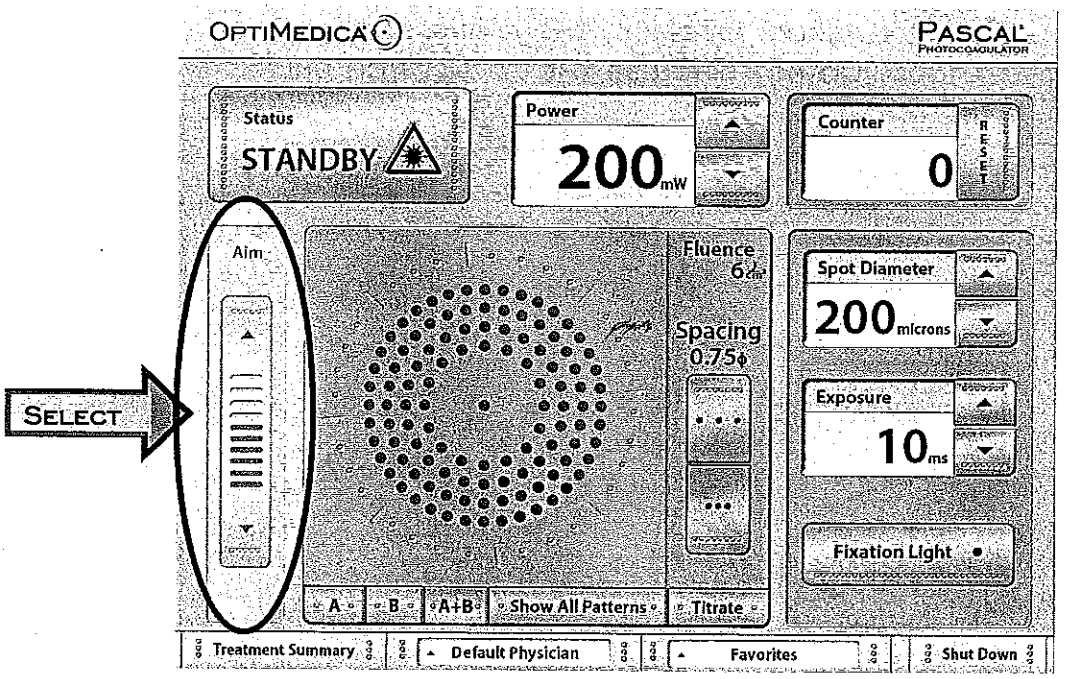
Select the **READY** mode with the Status push button as indicated by the **READY** status indicator.



Aiming Beam Intensity

The aiming beam intensity is variable from barely visible to a maximum average power of 1 mW. The lowest practical setting should always be used. See "Ocular Protection" in the Safety and Regulatory Compliance chapter.

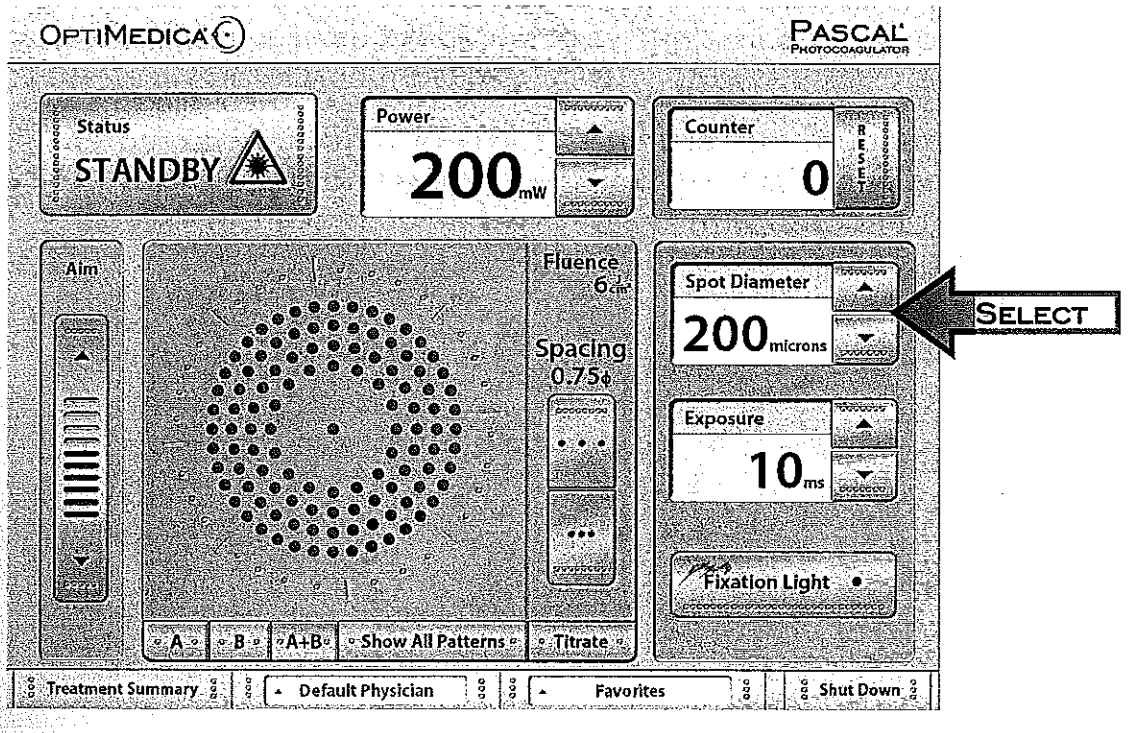
The Aim Beam up/down arrow indicators are located at the left section of the control panel. Select the UP arrow button (up-facing arrow) to increase the aiming intensity until the desired brightness is selected. Alternatively, select the DOWN arrow button (down-facing arrow), to decrease the aiming beam intensity. The relative aiming beam intensity is indicated on the bar indicator.



SPOT SIZE

THE SPOT SIZE AS MEASURED AT THE CORNEAL PLANE MAY BE CHANGED BY SELECTING THE SPOT SIZE INDICATORS LOCATED ON THE CONTROL PANEL AS SHOWN BELOW.

AVAILABLE SPOT SIZES ARE: 60 µM, 100 µM, 200 µM AND 400 µM.



CHOICE OF SPOT SIZE AVERAGE AND/OR AVERAGE POWER LEVEL DETERMINES THE POWER DENSITY (W/CM^2). POWER DENSITY = AVERAGE POWER (W) / SPOT SIZE AREA. TISSUE RESPONSE IS GOVERNED BY POWER DENSITY.

NOTE

THE SPOT SIZE AT THE RETINAL PLANE IS THE PRODUCT OF THE DEVICE LASER SPOT SIZE AND M, THE LASER SPOT MAGNIFICATION OF THE CONTACT LENS. FOR EXAMPLE, A 200 µM LASER SPOT DELIVERED THROUGH A CONTACT LENS WITH M EQUAL TO 1.9X, WOULD YIELD A SPOT OF 380 µM ON THE RETINA.

$$D_d \times M = D_r$$

WARNING

IT IS THE RESPONSIBILITY OF THE PHYSICIAN TO VERIFY THAT THE AIMING BEAM SPOT VISUALIZED THROUGH THE SLIT LAMP IS CIRCULAR AND NOT CLIPPED. A NONCIRCULAR AIMING BEAM COULD INDICATE A HARDWARE FAILURE. SHOULD THIS OCCUR, DISCONTINUE TREATMENT AND CONTACT OPTIMEDICA SERVICE.

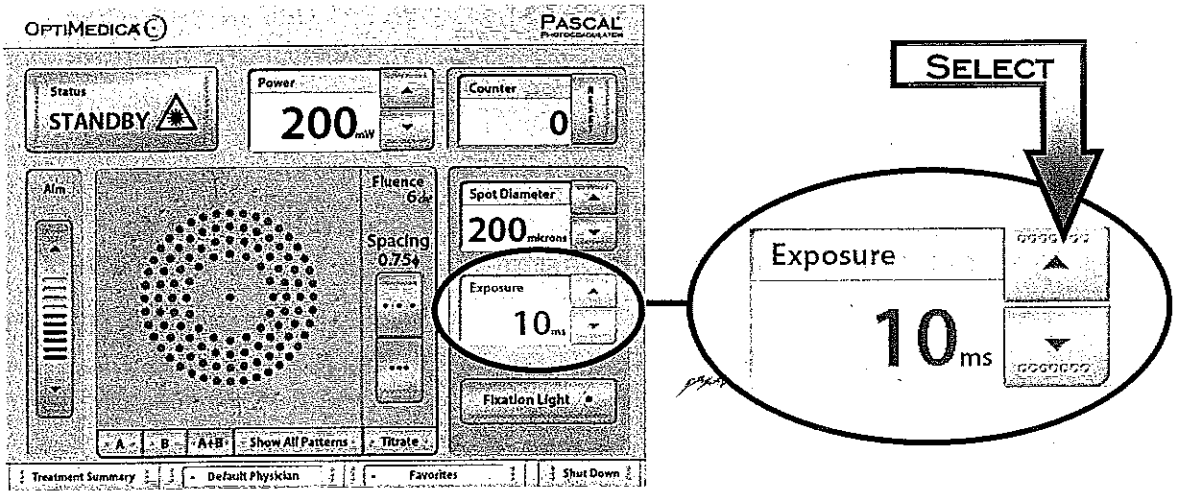
CAUTION

IT IS THE RESPONSIBILITY OF THE PHYSICIAN TO VERIFY THAT THE AIMING BEAM SPOT VISUALIZED THROUGH THE SLIT LAMP IS APPROXIMATELY THE EXPECTED SIZE. IF THE AIM BEAM SIZE OR PATTERN APPEARS INAPPROPRIATE OR DISTORTED DO NOT PROCEED WITH TREATMENT. READJUST SLIT LAMP FOCUS. IF PROBLEM PERSISTS CONTACT OPTIMEDICA SERVICE.

Treatment Exposure Time

Exposure time is the duration of the treatment laser pulse. It is measured in milliseconds (ms). Selections range from 10 – 1000 milliseconds for single spot delivery. Square array & arc pattern selections are 20 or 30 milliseconds. Macular patterns are fixed at 10 milliseconds. Early release of the footswitch will immediately terminate the treatment beam.

Use the UP and DOWN arrow buttons of the Exposure Time control to select the desired exposure time. The selected exposure time appears in the adjacent display.



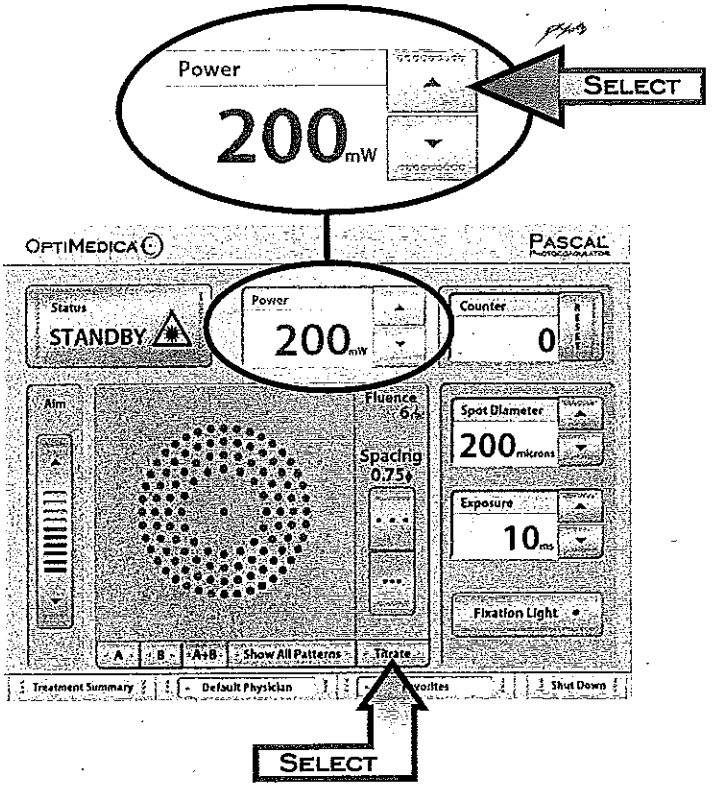
Laser Power

Press the Power UP arrow located on the touch screen control panel display to increase the average power of the laser beam delivered per pulse. Select the DOWN indicator to decrease the average power delivered in each laser pulse. The selected laser power appears in the adjacent display.

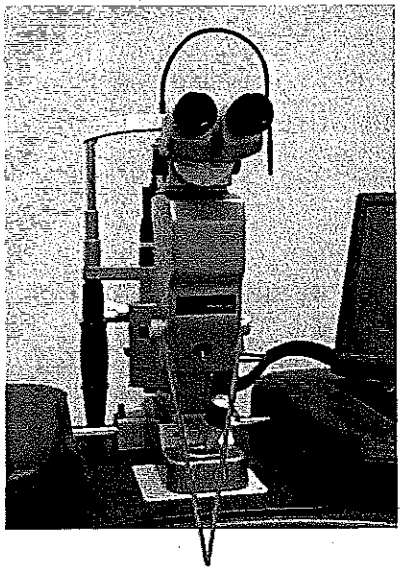
CAUTION

It is the responsibility of the physician to select the appropriate laser power and location of treatment. The lowest practical setting should always be used to achieve the desired clinical outcome. In order to determine the appropriate power level to use in the scan mode, single spot test burns should be delivered prior to pattern scan photocoagulation, in order to titrate the power to the desired level of burn.

Press the Titrate button on the touch screen control panel to switch to single spot mode to perform test burns. Press the Titrate button again to revert to scan mode.



The power can also be adjusted via the power control knobs located on the left and right side of the Slit Lamp Scanner. The selected laser power appears in the adjacent display.



Power Control Knobs

Power Accuracy: The difference in the absolute accuracy of the actual laser power delivered to the slit lamp focal plane versus the laser power displayed is less than 20%.

The laser power is displayed in milliwatts, mW (one milliwatt is equal to 1/1000 of a watt).

If there is a momentary variation in actual laser power of more than 20% but less than 50% of the displayed power, the system will beep. If the actual laser power variation is greater than 50% of the displayed power, the system will automatically stop treatment and return to **STANDBY** and display the error.

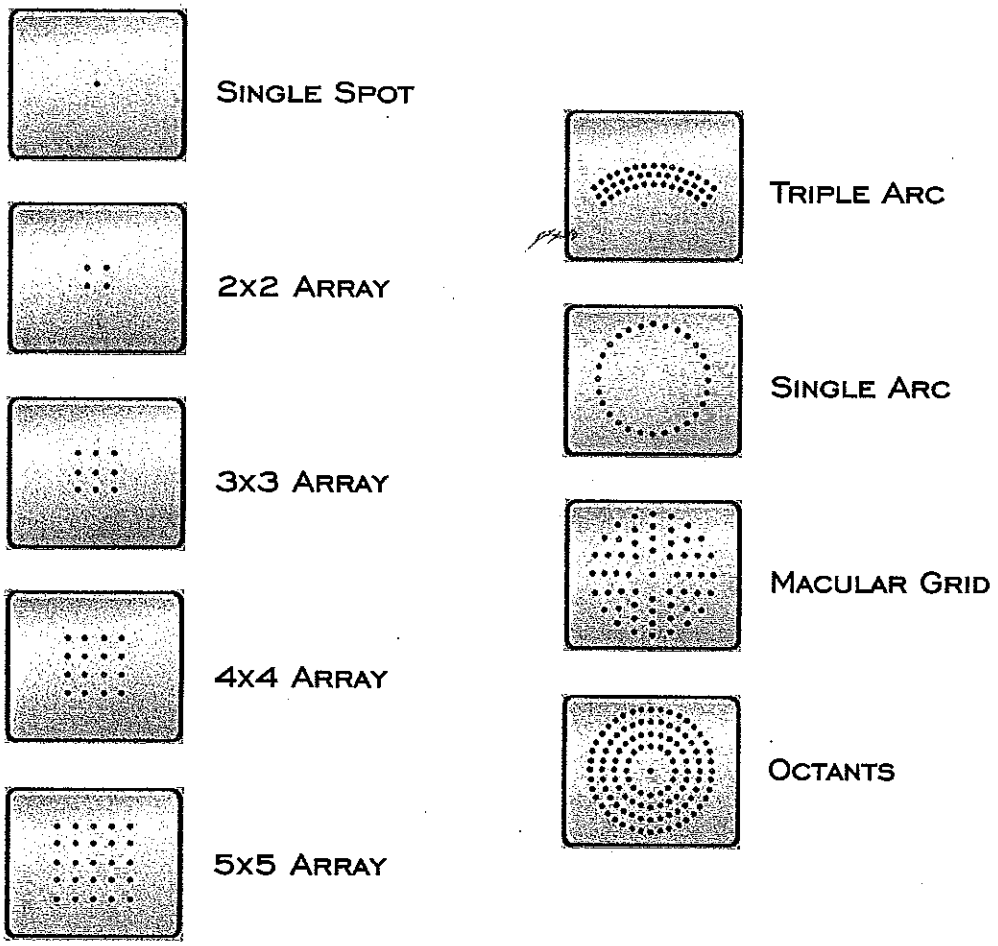
Pascal Method of Photocoagulation

The Pascal method of photocoagulation allows delivery of a predetermined pattern, by scanning the placement of the laser spots and controlling the emission of the laser light.

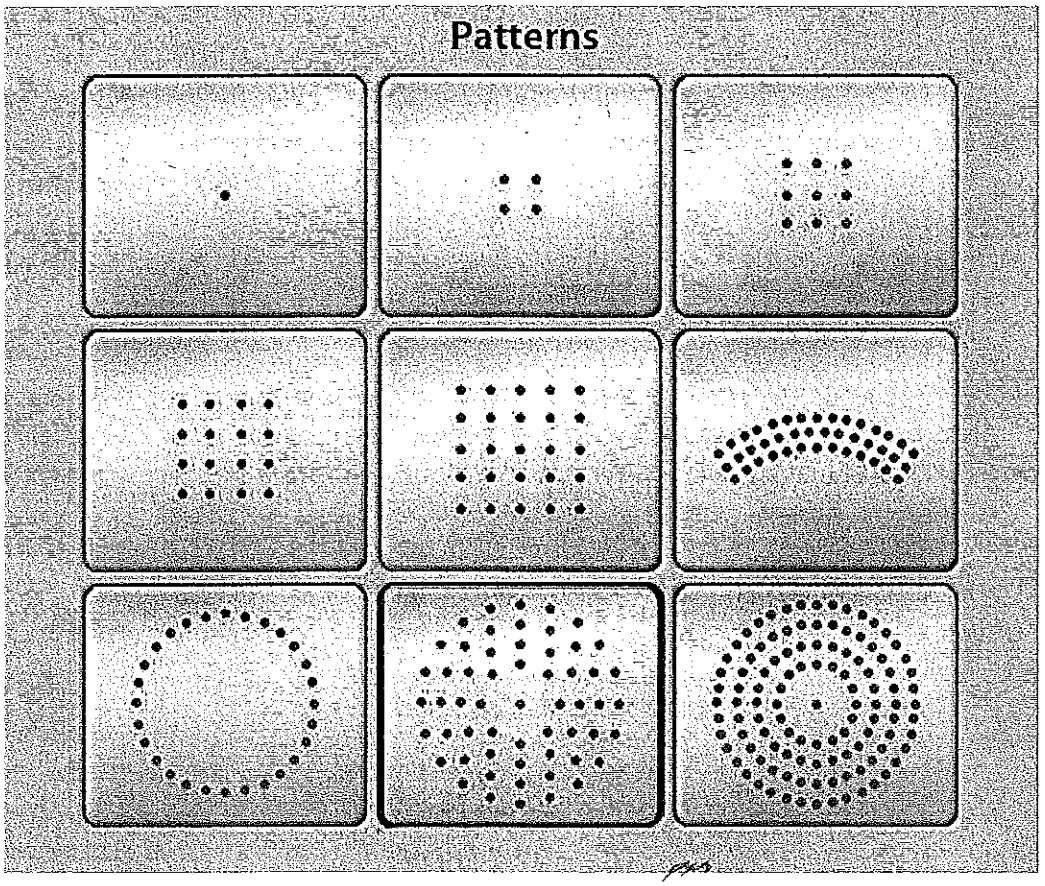
The Pascal Photocoagulator enables the physician to deliver multiple laser lesions with a single footswitch depression, by automating the emission of laser light with as much as 56 pulses within half a second.

With Pascal the pattern is selected by the physician. There are nine types of patterns available:

Pattern Types



Show All Patterns Screen

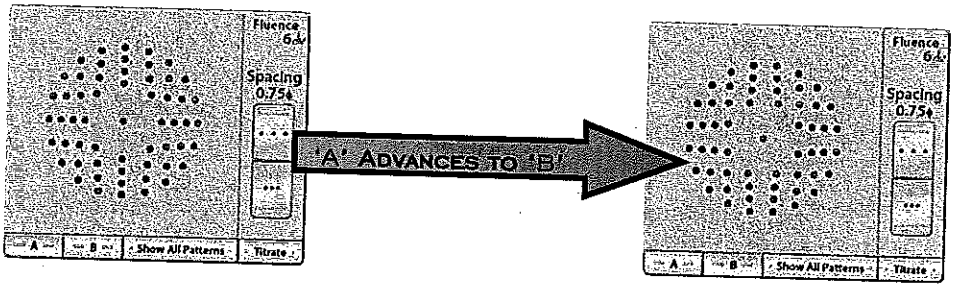


- Single spot — intended for all standard photocoagulation procedures.

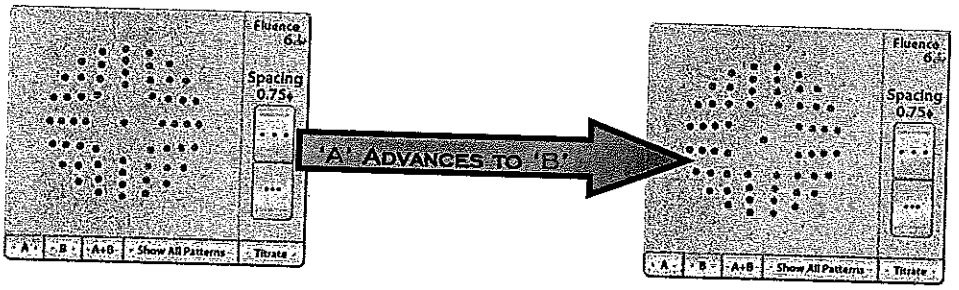
- Arrays — ranging from a square 2x2 to a 5x5 array. This is intended for highly efficient, scanning laser pattern delivery for Pan retinal photocoagulation.

- Macular Grids — a pattern consisting of fifty-six (56) spots of a 100 or 200 μm diameter in four concentric circles intended to surround the fovea. The inner circle diameter is greater than 2000 μM (the "safety zone"). A blinking red beam is provided as a fixation target for the patient. This is intended for highly efficient, scanning laser pattern delivery for macular grid photocoagulation.

WHEN THE 'A' FORMAT OF A GRID PATTERN IS SELECTED IT WILL ADVANCE TO THE 'B' FORMAT AUTOMATICALLY AFTER FIRING. IF YOU START WITH THE 'B' FORMAT, IT WILL NOT ADVANCE TO 'A' AFTER FIRING.



OR



- OCTANTS — A PATTERN COMPRISING CUSTOMIZABLE SUBSETS OF THE MACULAR GRID PATTERN, WITH 7 TO 56 SPOTS IN CONCENTRIC ARCS FOR MACULAR TREATMENTS.

- ARCS – A PATTERN CONSISTING OF A SINGLE OR TRIPLE ARC, SELECTABLE IN CUSTOMIZABLE ORIENTATIONS WITH ADJUSTABLE RADII, INTENDED FOR SURROUNDING TEARS OR LOCALIZED REGIONS.

NOTE

AFTER SELECTION OF THE TRIPLE ARC, THE SELECTION WILL APPEAR IN THE CENTER OF THE FIELD OF VIEW AND NOT IN THE PERIPHERY.

THE AIMING BEAM DISPLAYS THE PATTERN, ALLOWING THE PHYSICIAN TO PLACE IT IN THE APPROPRIATE LOCATION.

With the Pascal Photocoagulator, the scanned positioning of the laser spots results in a decrease of the overall treatment time, because over 50 pulses can be delivered per ½ second with a single footswitch depression.

The choice of pattern determines which control features are displayed.

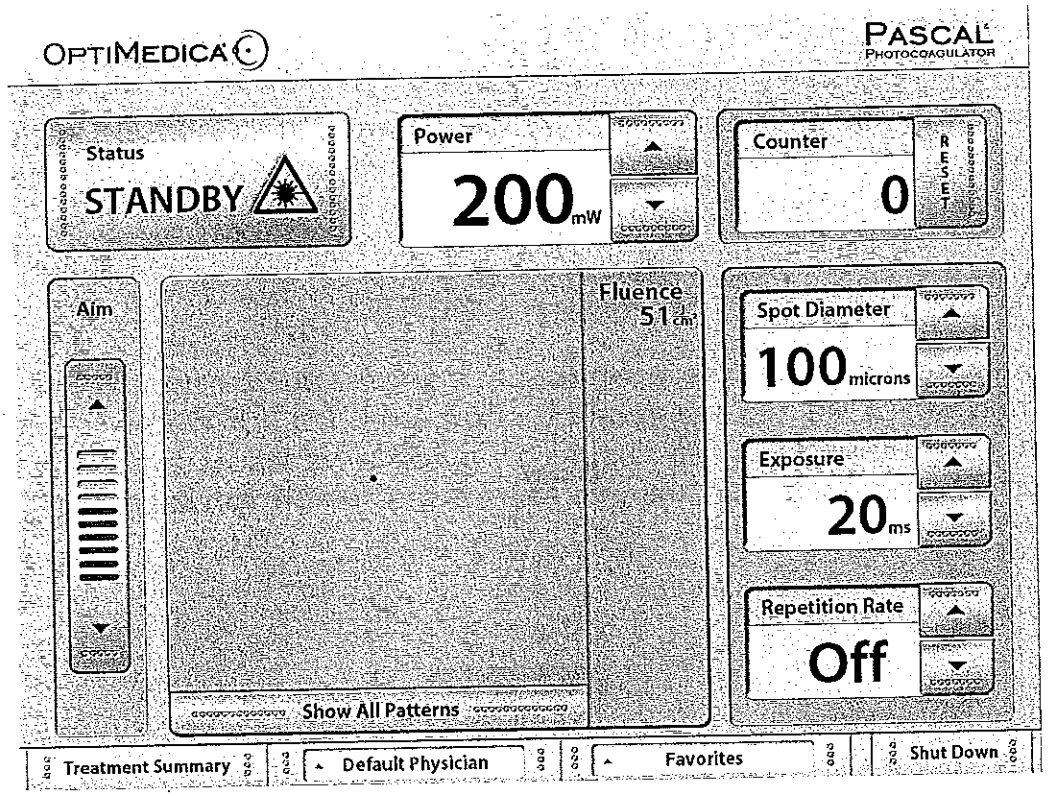
WARNING

When a pattern is selected with multiple spots, use caution when operating with a multiple mirror contact lens. Do not overfill the mirror with the pattern and ensure that you have visualization of the complete pattern and the area to be treated, prior to laser treatment.

NOTE

With the Macular Grid pattern, there is an optional blinking red spot located at the center of the pattern. This blinking red spot is provided as a patient fixation target. The patient should be instructed to look at the blinking red light to fixate the fovea when treating the macula. If the patient cannot resolve the blinking fixation light or is confused by it, turn the fixation light off.

SINGLE SPOT TREATMENT PROCEDURE



NOTE

WITH SINGLE SPOT SELECTION, THE REPEAT MODE CONTROLS APPEAR ON THE TOUCH SCREEN PANEL.

1. SELECT READY MODE. THE AIM BEAM TURNS ON.
2. SELECT THE AIM BEAM INTENSITY.
3. ADJUST THE LASER BEAM SPOT SIZE.
4. SELECT THE APPROPRIATE EXPOSURE TIME.
5. SELECT THE APPROPRIATE LASER POWER.
6. VISUALIZE THE TREATMENT AREA THROUGH THE SLIT LAMP.
7. DEPRESS THE FOOTSWITCH TO DELIVER THE TREATMENT LASER BEAM TO THE TISSUE.
8. IF THERE IS A PROLONGED PAUSE IN TREATMENT, IT IS RECOMMENDED THAT STANDBY MODE BE SELECTED.

WARNINGS

WHEN THE SYSTEM IS IN READY STATUS, IF THE AIMING BEAM IS NOT PRESENT, IS DISTORTED, OR IS INCOMPLETE DO NOT PROCEED WITH TREATMENT. TURN THE MACHINE OFF AND CONTACT OPTIMEDICA SERVICE.

EARLY RELEASE OF THE FOOTSWITCH WILL TERMINATE THE TREATMENT BEAM BEFORE THE INDICATED EXPOSURE TIME HAS ELAPSED. THIS WILL ALTER THE THERAPEUTIC EFFECT. IF THE FULL EXPOSURE TIME IS DESIRED, HOLD THE FOOTSWITCH DOWN UNTIL THE SELECTED EXPOSURE TIME HAS EXPIRED.

CAUTION

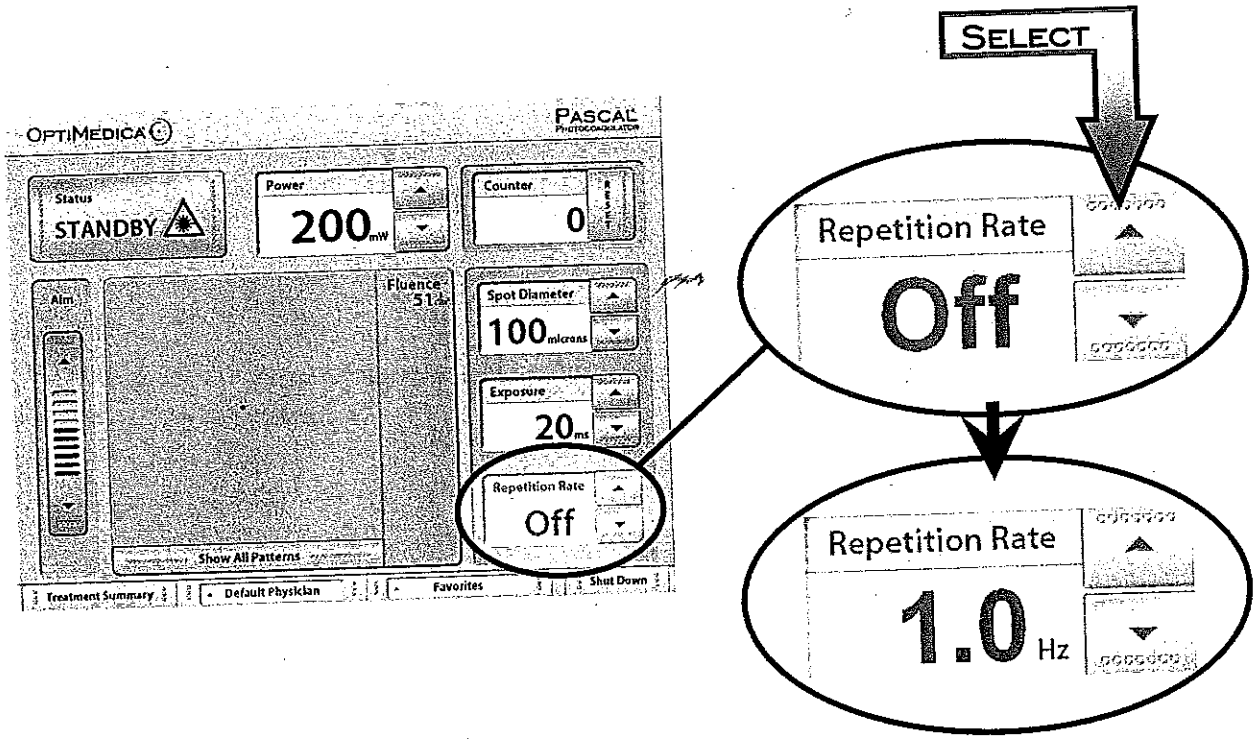
IT IS THE RESPONSIBILITY OF THE PHYSICIAN TO SELECT THE APPROPRIATE POWER AND TREATMENT LOCATION. THE LOWEST PRACTICAL SETTING SHOULD ALWAYS BE USED TO ACHIEVE THE DESIRED CLINICAL OUTCOME.

REPEAT MODE - AVAILABLE ONLY IN SINGLE SPOT MODE

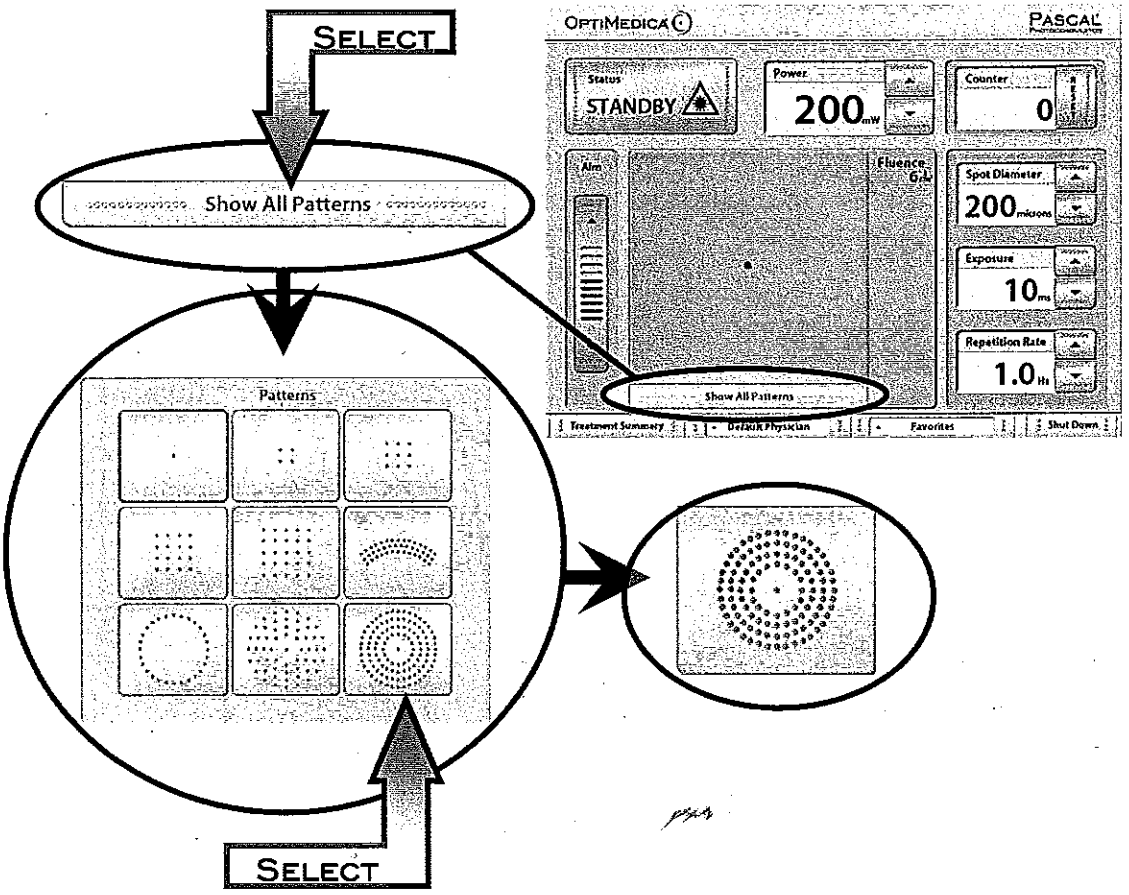
REPETITIVE EXPOSURES ARE AVAILABLE ONLY FOR SINGLE SPOT MODE. VARIABLE INTERVAL TIMES MAY BE ACHIEVED USING REPEAT MODE. WHEN ENABLED AND THE FOOTSWITCH IS DEPRESSED, REPETITIVE EXPOSURES WILL BE DELIVERED TO THE TARGET TISSUE.

REPETITION RATE IS MEASURED IN HERTZ. THE FORMULA IS 1 / T = Hz, WHERE T IS TIME IN SECONDS. TO FIRE EVERY 1/2 SECOND, 1 / 0.5s = 2 Hz.

TO SELECT REPETITION RATE, SELECT THE UP ARROW BUTTON LOCATED IN THE REPETITION RATE SECTION OF THE TOUCH SCREEN CONTROL PANEL. SELECT THE UP OR DOWN ARROW BUTTONS LOCATED ON THE CONTROL PANEL DISPLAY TO SET 1 Hz, 1.5 Hz, 2 Hz, OR 3 Hz.



PATTERN SCAN MODES



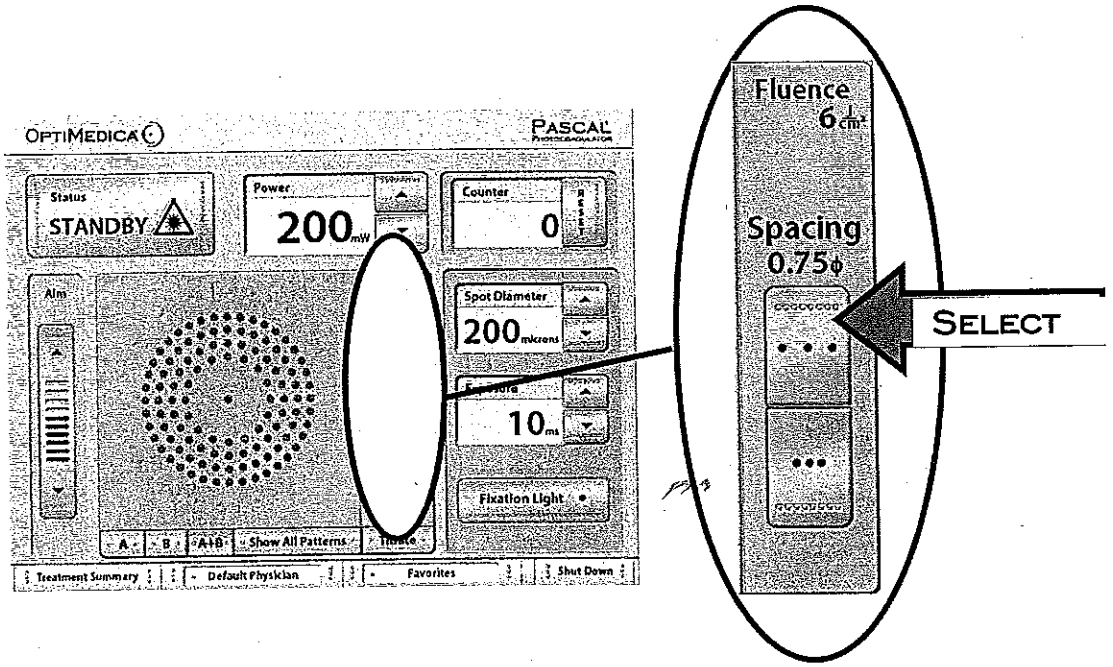
A PATTERN MAY BE SELECTED BY TOUCHING THE "SHOW ALL PATTERNS" BUTTON FOLLOWED BY SELECTION OF THE APPROPRIATE PATTERN ICON.

WARNING

IT IS THE RESPONSIBILITY OF THE PHYSICIAN TO VERIFY THAT THE PATTERN VISUALIZED THROUGH THE SLIT LAMP IS THE SAME AS THE PATTERN DISPLAYED ON THE CONTROL PANEL. A DISCREPANCY BETWEEN PATTERNS COULD INDICATE A HARDWARE FAILURE. SHOULD THIS OCCUR, DISCONTINUE TREATMENT AND CONTACT OPTIMEDICA SERVICE.

PATTERN SPACING

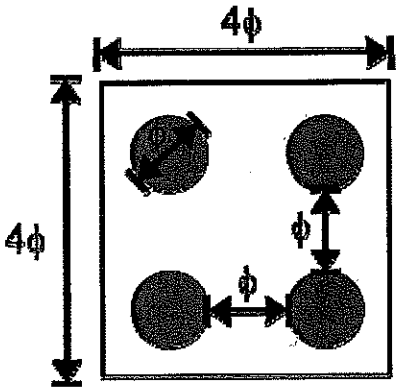
THE SPACING BUTTONS ARE LOCATED TO THE RIGHT OF THE PATTERN DISPLAY. SELECTING THE APPROPRIATE ICON ENABLES THE SPACING TO BE ADJUSTED TO THE APPROPRIATE LEVEL. THE CHANGE IN PATTERN SPACING AND RESULTANT SPOT SPACING MAY BE VISUALIZED BY VIEWING THE AIMING BEAM PATTERN ON THE TARGET THROUGH THE SLIT LAMP. THE SPOT SPACING IS VARIABLE FROM 0.25 SPOT DIAMETERS TO 3.0 SPOT DIAMETERS. DEPENDING ON THE TYPE OF PATTERN AND THE SPOT DIAMETER, SPACING SELECTION MAY BE LIMITED.



DEFAULT 'SPACING' VARIES BY PATTERN SELECTION

Pattern Density

Pattern density (or fill factor) is the measurement for the percentage of area directly irradiated by the laser compared with the total area of the pattern. (For square arrays, the total area of the pattern also includes consistent spacing between adjacent patterns). For example, in a medium density 2x2 Array, the laser spots are separated by one spot diameter, and the pattern density is calculated as follows:

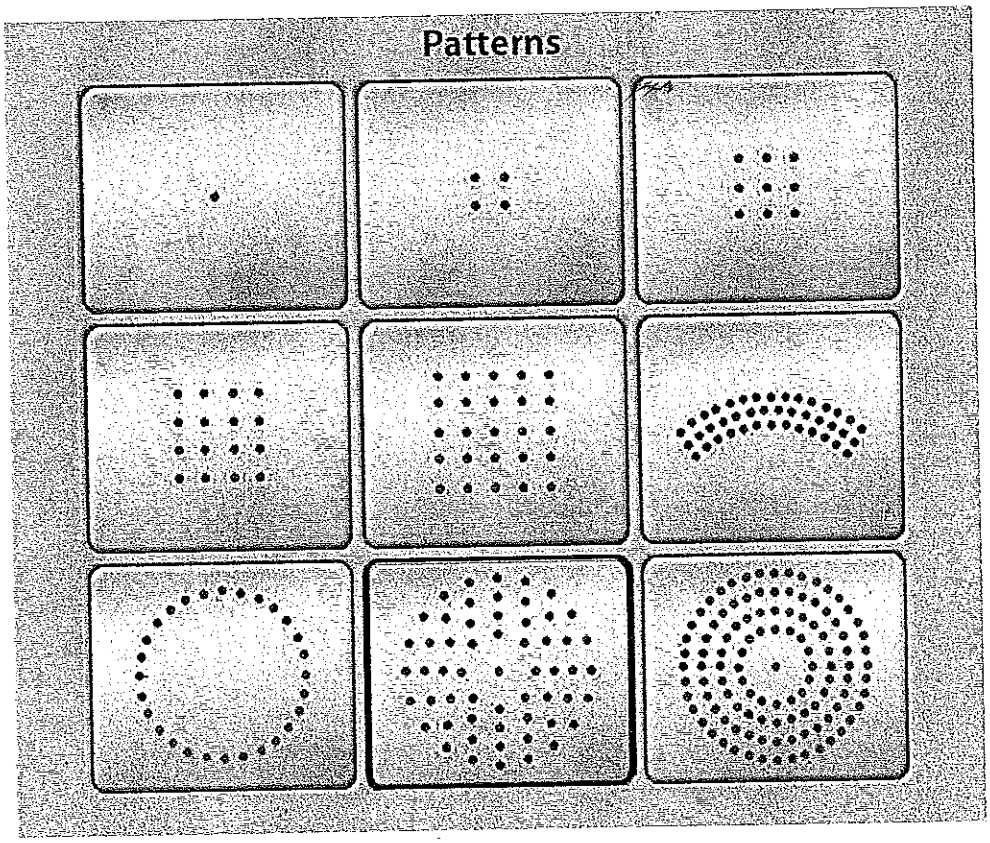


$$\text{Pattern density} = \frac{\text{area of the 4 spots}}{\text{area of the pattern}} = \frac{\pi\phi^2}{16\phi^2} = 20\%$$

Available Patterns

The available patterns are subject to the laser spot size selected as follows:

Patterns	Spot Size			
	60 microns	100 microns	200 microns	400 microns
1x1	□	□	□	□
2x2		□	□	□
3x3		□	□	□
4x4		□	□	□
5x5		□	□	□
Circle / Arc			□	□
Macular Grid		□	□	
Octant Array		□	□	



Pascal Treatment Procedure

1. Select READY mode. The aiming beam turns on.
2. Adjust the aiming beam intensity.
3. Adjust the laser treatment spot size.
4. Select the exposure time.
5. Select a pattern by pressing the appropriate Pattern icon located in the mid-left portion of the touch screen control display.
6. Adjust from pattern spacing 0.25 spot diameters to 3.0 spot diameters spacing by selecting the appropriate Spacing up/down indicators located on the touch screen panel.
7. Focus the slit lamp and observe the red aiming beam imaged on the patient's retina. Verify that the laser spots are round and that the pattern is undistorted. Establish proper placement of the laser beam with the slit lamp joystick.
8. Press the Titrate button to adjust the laser treatment power for therapeutic effect using a single spot.
9. Prior to treatment, verify that the power and other parameters are within acceptable ranges.
10. To deliver laser energy depress the footswitch. Each footswitch depression will result in **ONE SCANNED PATTERN.** Treatment may be interrupted at any point by releasing the footswitch.

CAUTIONS

It is the responsibility of the physician to select the appropriate power and treatment locations.

Early release of the footswitch will terminate the treatment beam before the complete pattern has been delivered. This results in delivery of a partial pattern; in this case, the pattern can be completed by delivering the burns individually. It is recommended that the full pattern be delivered.

Pascal Macular Grid Photocoagulation

The Pascal Macular Grid method of photocoagulation is intended for highly efficient macular grid treatment. There are two patterns, the Macular Grid and the Octant Array, which both cover the same area with the same numbers of laser spots, but differing orientations.

The inner circle diameter is always greater than 2000 µM (providing a wide "safety zone" around the fovea), and the diameter of the outer circle at its largest is 4300 µM, when contact lenses with an image magnification factor of 1.00 are used. This means for a pattern comprising 100 µM spots the total extent of the pattern is about 4100 µM, and if 200 µM spots are utilized the total extent is about 4300 µM. For reference, the center-to-center distance between the optic nerve and the fovea is about 4500 µM.

An optional centered blinking red beam is provided as a fixation target for the patient. This centered blinking red beam is enabled by touching the Fixation Light button on the control panel display. The patient should be directed to look at the blinking light. With the fovea identified, the Macular Grid or Octant aiming beam should be positioned symmetrically around the fovea.

NOTE

Advise the patient that the fixation light will turn off during treatment.

Pattern Orientation

Macular Grid Patterns with A and B are designed so that they can be used as individual patterns or as a combination, without overlapping of spots. The combination of patterns can be Pattern A, B, or A+B with 100 or 200 µM spots. This allows for re-treatment of the macula and also more precise control on the resultant pattern density.

OPTIMEDICA recommends that any of the following contact lenses be used for Pascal Photocoagulation of the Macular Grid:

Volk, Area Centralis (M= 1.04)
Ocular, Mainster Standard (M= 1.05)

Other equivalent lenses may be used if the image magnification factor $1.04 \leq (M) \leq 1.08$.

WARNING

Do not use wide field contact lenses for Macular Grid photocoagulation. Wide field lenses will enlarge the spot size and alter the Foveal Exclusion Zone ring diameter.

Pascal Macular Grid Treatment Procedure

1. Select READY mode. The aiming beam turns on.
2. Focus the slit lamp and adjust aiming beam intensity.
3. Adjust the laser spot size to 100 µM or 200 µM.
4. For Macular Grid treatment, an exposure of 10 milliseconds is required.
5. Select the *Macular Grid ring pattern* by pressing the appropriate Pattern icon located in the mid-left portion of the touch screen control panel. If desired, also turn on the fixation light.
6. Adjust the pattern spot spacing (and therefore the extent of the area to be treated) by observing the red aiming beam pattern on the targeted tissue and by selecting the appropriate spot spacing icons on the touch screen control panel. Verify that the individual laser spots are round and that the overall pattern is round.
7. Press the Titrate button to adjust the laser treatment power for therapeutic effect using a single spot at the periphery of the area to be treated.
8. Prior to treatment, verify that the power and other parameters are within acceptable ranges.
9. If using the optional fixation light, instruct the patient to look at the blinking red fixation light. The brightness of the blinking fixation light is controlled by touching the UP/DOWN indicators for the aiming beam.
10. Identify the fovea directly by reference to fluorescein angiography and fundus photographs (foveal avascular zone).
11. Surround the fovea with the inner Macular Grid, Octant, or Arc pattern.
12. Depress the footswitch. Up to four concentric rings of laser spots will be delivered in approximately ½ second. Be sure to keep the footswitch depressed to deliver the complete pattern to the targeted tissue unless the treatment should be aborted. The treatment may be interrupted by releasing the footswitch; in this case, the pattern can be completed by delivering the burns individually. **DO NOT repeat at the same targeted tissue as the pattern will start from the beginning, resulting in overlapping burns. Consider using the octant patterns.**

Pascal Octant Photocoagulation

The Pascal Octant photocoagulation is intended for efficient macular grid treatment. The octants are a subset of the macular grid pattern. These can be selected in a customizable pattern.

The A and B patterns correspond to the same spot locations as the A and B Macular Grid patterns respectively for the corresponding octants. The inner arc radius is always greater than 1000 µM (providing a wide "safety zone" around the fovea).

The method of treatment is similar to the Macular Grid patterns, with the exception that the number of spots is less and the pattern only partially encircles the fovea. The octants can be chosen by selecting the appropriate octants on the image. The patterns A, B, and A+B can also be selected in addition to the spot diameter.

OPTIMEDICA recommends that any of the following contact lenses be used for Pascal Photocoagulation of the Foveal Exclusion Zone:

Volk, Area Centralis (M= 1.04)
Ocular, Mainster Standard (M= 1.05)

Equivalent lenses may be used if the magnification factor is $1.04 \leq (M) \leq 1.08$.

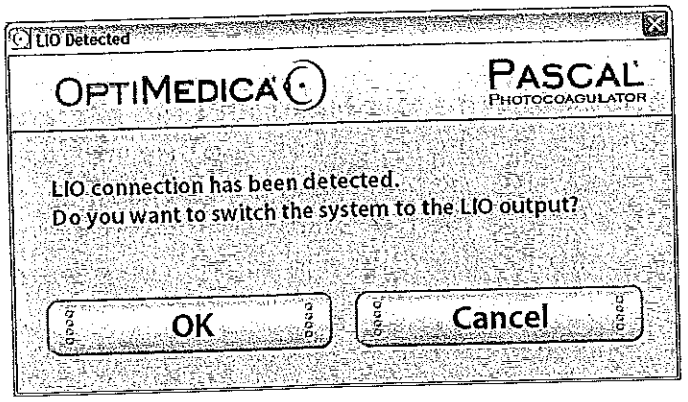
WARNING

Do not use wide field contact lenses for Macular Grid photocoagulation. Wide field lenses will enlarge the spot size and alter the Foveal Safety Zone ring diameter.

LIO TREATMENT PROCEDURE

PERFORM THE FOLLOWING PROCEDURE IN CONJUNCTION WITH THE INSTRUCTIONS IN THE LIO OPERATOR MANUAL.

1. CONNECT THE LIO TO THE PASCAL LASER, AS DESCRIBED IN THE LIO OPERATOR MANUAL. THE FOLLOWING WINDOW DISPLAYS ON THE TOUCH SCREEN CONTROL PANEL:



2. PRESS THE OK BUTTON TO CONTINUE WITH LIO OPERATION. "LIO" APPEARS IN THE SPOT DIAMETER DISPLAY, AND THE ONLY AVAILABLE PATTERN SETTING IS SINGLE SPOT.
3. SELECT READY MODE. THE AIM BEAM TURNS ON.
4. SELECT THE AIM BEAM INTENSITY.
5. SELECT THE APPROPRIATE EXPOSURE TIME.
6. SELECT THE APPROPRIATE LASER POWER.
7. MAKE ANY NECESSARY ADJUSTMENTS TO THE HEADSET TO ENSURE SAFE AND CLEAR VIEW OF THE RETINA, AS DESCRIBED IN THE LIO OPERATOR MANUAL.
8. POSITION THE ASPHERIC LENS AND SELECT THE SPOT SIZE, AS DESCRIBED IN THE LIO OPERATOR MANUAL.
9. TARGET THE AIMING BEAM ON THE DESIRED TREATMENT SITE.
10. DEPRESS THE FOOTSWITCH TO DELIVER THE TREATMENT LASER BEAM TO THE TISSUE.
11. IF THERE IS A PROLONGED PAUSE IN TREATMENT, IT IS RECOMMENDED THAT STANDBY MODE BE SELECTED.

WARNINGS

WHEN THE SYSTEM IS IN READY STATUS, IF THE AIMING BEAM IS NOT PRESENT, IS DISTORTED, OR IS INCOMPLETE DO NOT PROCEED WITH TREATMENT. TURN THE MACHINE OFF AND CONTACT OPTIMEDICA SERVICE.

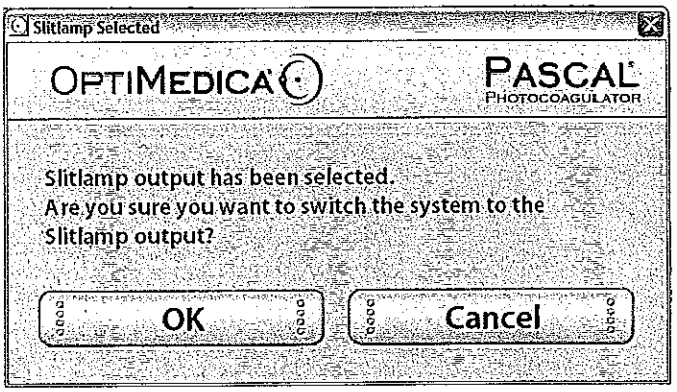
EARLY RELEASE OF THE FOOTSWITCH WILL TERMINATE THE TREATMENT BEAM BEFORE THE INDICATED EXPOSURE TIME HAS ELAPSED. THIS WILL ALTER THE THERAPEUTIC EFFECT. IF THE FULL EXPOSURE TIME IS DESIRED, HOLD THE FOOTSWITCH DOWN UNTIL THE SELECTED EXPOSURE TIME HAS EXPIRED.

CAUTIONS

IT IS THE RESPONSIBILITY OF THE PHYSICIAN TO SELECT THE APPROPRIATE POWER AND TREATMENT LOCATION. THE LOWEST PRACTICAL SETTING SHOULD ALWAYS BE USED TO ACHIEVE THE DESIRED CLINICAL OUTCOME.

WHEN USING THE LIO, THE LASER SPOT SIZE CANNOT BE SELECTED USING THE TOUCH SCREEN CONTROL PANEL. SPOT SIZE IS DETERMINED BY THE CHOICE OF ASPHERIC LENS AND THE POSITION OF THE LIO RELATIVE TO THE TARGET TISSUE. BEFORE SELECTING THE SPOT SIZE, YOU MUST THOROUGHLY UNDERSTAND THE RELATIONSHIP BETWEEN LASER POWER AND SPOT SIZE, AS WELL AS PROPER POSITIONING OF THE ASPHERIC LENS. REFER TO THE LIO OPERATOR MANUAL FOR DETAILED INFORMATION.

IF YOU ATTEMPT TO SELECT THE SPOT SIZE USING THE TOUCH SCREEN CONTROL PANEL, THE FOLLOWING WINDOW DISPLAYS:



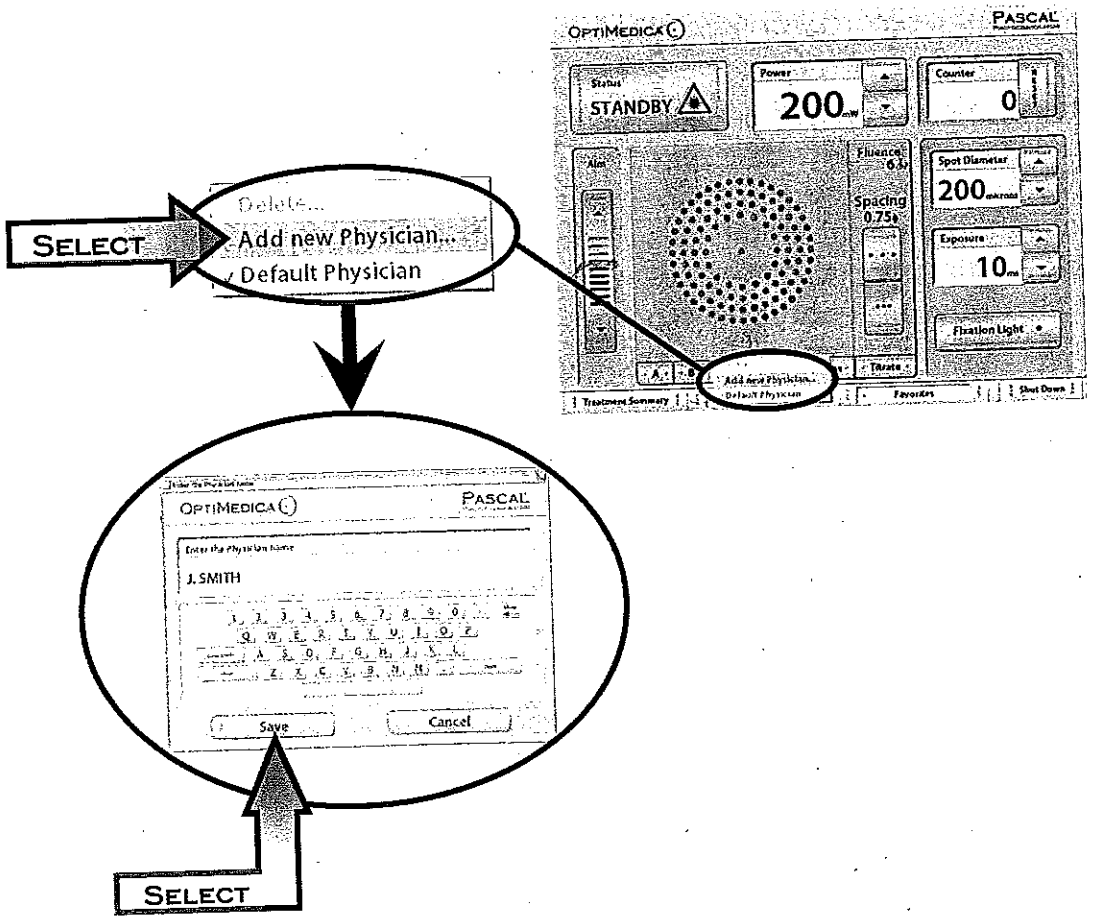
PRESS THE CANCEL BUTTON TO CONTINUE WITH LIO OPERATION.

Save Treatment Settings

If desired, you can save your preferred treatment settings, including power, spot size, exposure time, and pattern settings, to use for future treatments.

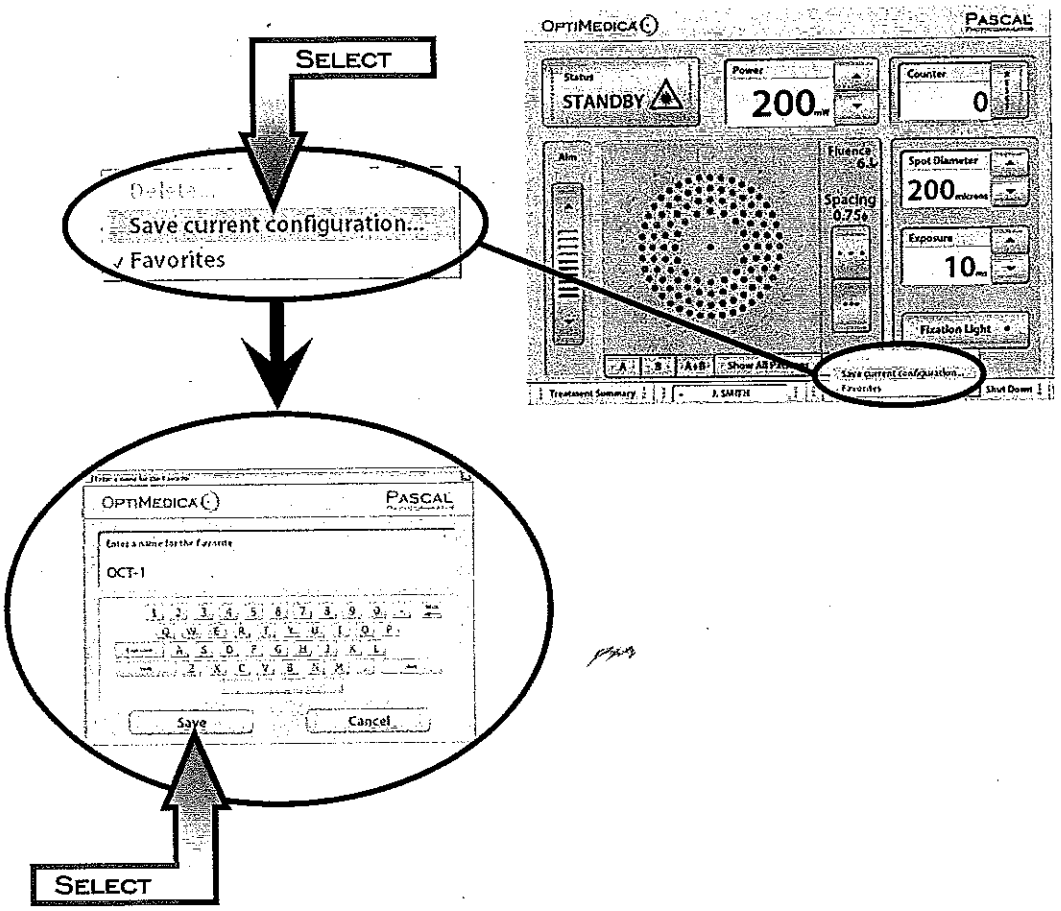
Before saving the current treatment settings, you must first enter your name:

1. Press the Default Physician button at the bottom of the touch screen control panel, then select "Add new Physician..." from the menu.
2. Type your name in the keyboard window, then press the Save button. Your name should display in the Default Physician button.



AFTER ENTERING YOUR NAME, SAVE THE CURRENT TREATMENT SETTINGS:

1. PRESS THE FAVORITES BUTTON, THEN SELECT "SAVE CURRENT CONFIGURATION..." FROM THE MENU.
2. TYPE A NAME FOR THE TREATMENT SETTINGS IN THE KEYBOARD WINDOW, THEN PRESS THE SAVE BUTTON.



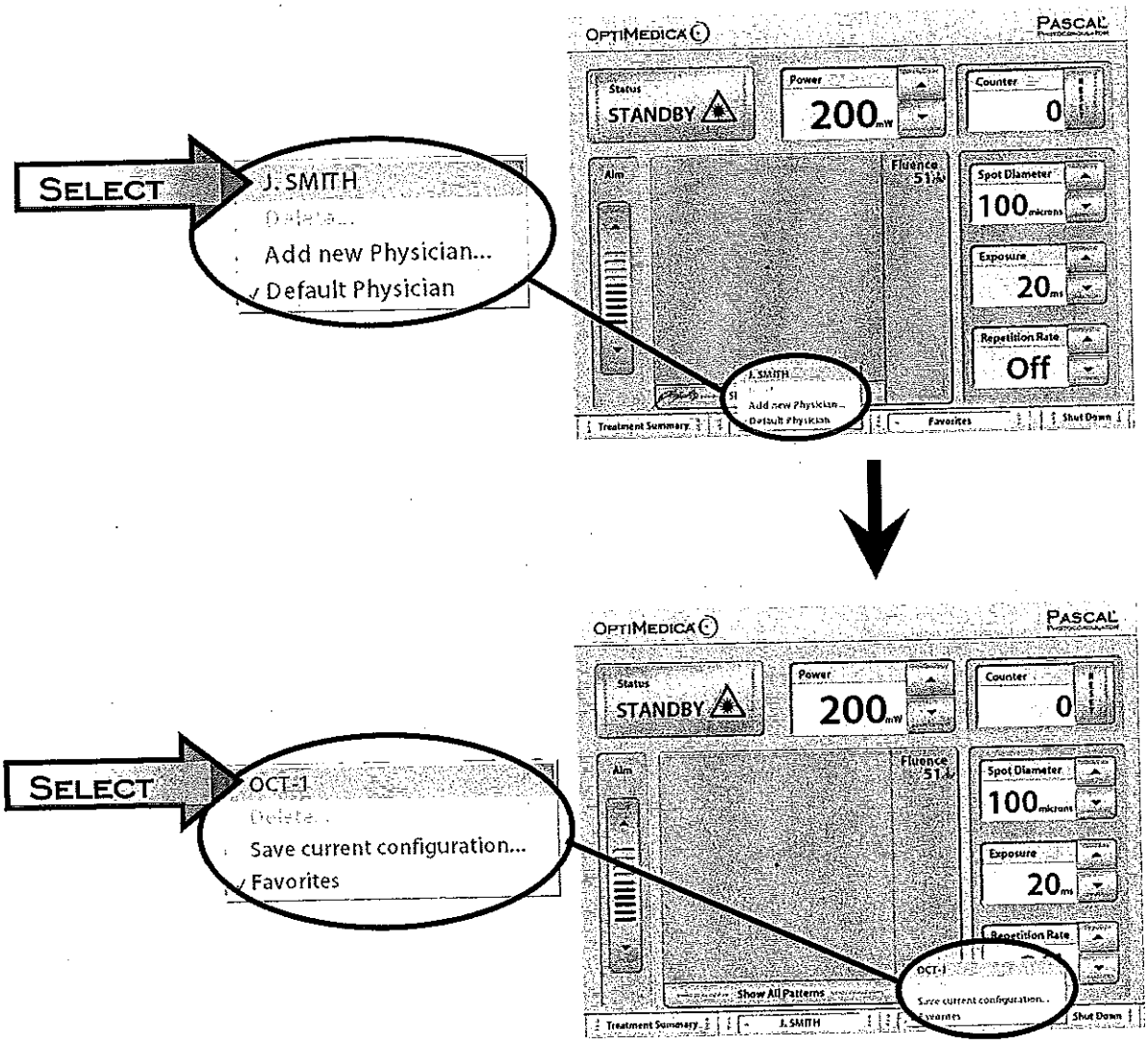
YOU CAN SAVE MULTIPLE SETS OF TREATMENT SETTINGS FOR FUTURE USE.

RECALL TREATMENT SETTINGS

TO RECALL YOUR SAVED TREATMENT SETTINGS, FIRST SELECT YOUR NAME FROM THE DEFAULT PHYSICIAN MENU, THEN SELECT THE DESIRED TREATMENT SETTINGS FROM THE FAVORITES MENU.

WARNING

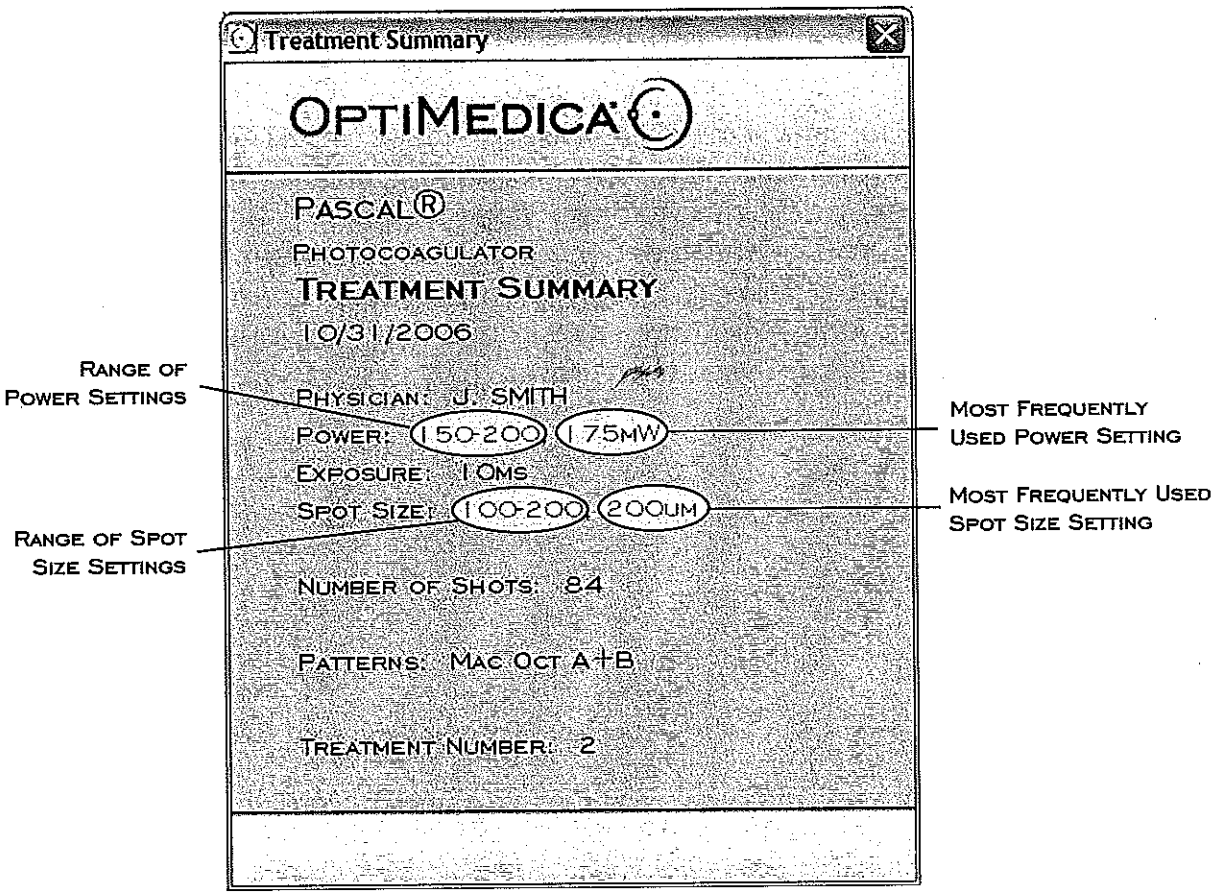
PRIOR TO TREATMENT, VERIFY THAT THE POWER, DURATION, AND OTHER PARAMETERS ARE WITHIN ACCEPTABLE RANGES.



View Treatment Summary

The Treatment Summary details the current treatment parameters, including power, exposure time, and spot size settings; the number of shots delivered; and the pattern(s) used. If more than one power, exposure time, or spot size setting was used, the range of settings is shown, followed by the most frequently used setting.

To view a summary of the current treatment parameters, press the Treatment Summary button at the bottom of the touch screen control panel. The Treatment Summary window displays in the middle of the control panel.



Between Patient Treatments

Once a treatment has concluded, either place the device in STANDBY mode or shut down the device by selecting the Shut Down button.

The Pascal system is designed for short term patient contact at the headrest and chinrest with uninjured skin. Disinfect the chinrest and headrest using mild soap and water. Dry with a soft cloth. Change the chinrest tissue after each patient.

Disinfect the contact lens, following the contact lens manufacturer instructions.

If the device is idle for 5 minutes and it is in READY mode, it will automatically revert to STANDBY mode.

If the device is idle for 30 minutes while in STANDBY mode the system will automatically revert to SLEEP mode. The display will become a light gray tint except for the Shut Down button. To resume activity touch the display at any point except the Shut Down button. When the display is touched, the Status control will display "Start Up" for approximately 90 seconds. If the Shut Down button is selected the system will shut down.

System Shutdown

1. Once treatment has concluded for the day, shut down the system by selecting the Shut Down button, located at the lower right portion of the control panel.

2. Wait while the system completes the power down sequence. Turn the key switch to the OFF position, fully counter clockwise after the screen goes blank.

3. Remove the key to prevent unauthorized use of the laser system.

4. Clean the laser console as instructed in the User Maintenance section of this manual.

5. Place a dust cover over the slit lamp.

6. Disinfect the chinrest using mild soap and water. Dry with a soft cloth.

7. Disinfect the contact lens, following the contact lens manufacturer instructions.

MAINTENANCE

User Maintenance

WARNING

Use extreme care regarding Cable Assembly to/from the Display Assembly and to/from the Slit Lamp Assembly. Cable Assembly consists of wiring and fiber optics cables. Do not pull or stress Cable Assembly. Do not set items on or under Cable Assembly. Damage to the fiber optic cables may cause unintended exposure to laser light.

The following maintenance procedures are to be performed by the user to ensure proper performance of your Pascal system.

Clean the Console External Surfaces

A cloth dampened with a non-caustic cleaning solution (such as soap and water) may be used to clean the external non-optical surfaces of the console and table. Dry with a clean cloth or allow to air dry. Do not spray or pour cleaning agents directly on the laser console.

Clean the Laser Control Panel

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

SCHEDULED MAINTENANCE AND REPAIR

THE FOLLOWING PROCEDURES ARE TO BE PERFORMED BY OPTIMEDICA-TRAINED PERSONNEL ONLY.

ANNUAL MAINTENANCE

PREVENTIVE MAINTENANCE, SAFETY, POWER AND CALIBRATION CHECKS SHOULD BE PERFORMED ANNUALLY BY AN OPTIMEDICA-CERTIFIED SERVICE ENGINEER TO ENSURE PROPER LASER PERFORMANCE.

LASER REPAIR

ALL LASER REPAIRS SHOULD BE PERFORMED BY AN OPTIMEDICA-CERTIFIED SERVICE ENGINEER TO ENSURE PROPER LASER PERFORMANCE.

ELECTRICAL REQUIREMENTS

THE PASCAL CONSOLE IS DESIGNED TO MEET UL2601-1, IEC 60601-1-1, 60601-1-2, 60601-1-4, 60825-1, AND CSA 22.2 NO. 601 REQUIREMENTS. THE LASER IS AVAILABLE AS A 100-120 V/5.0 A OR 220-240 V/2.5 A POWER INPUT CONFIGURATION.

WARNING

DO NOT USE POWER CORDS OTHER THAN THE POWER CORD PROVIDED WITH PASCAL. DO NOT USE EXTENSION CORDS WITH PASCAL.

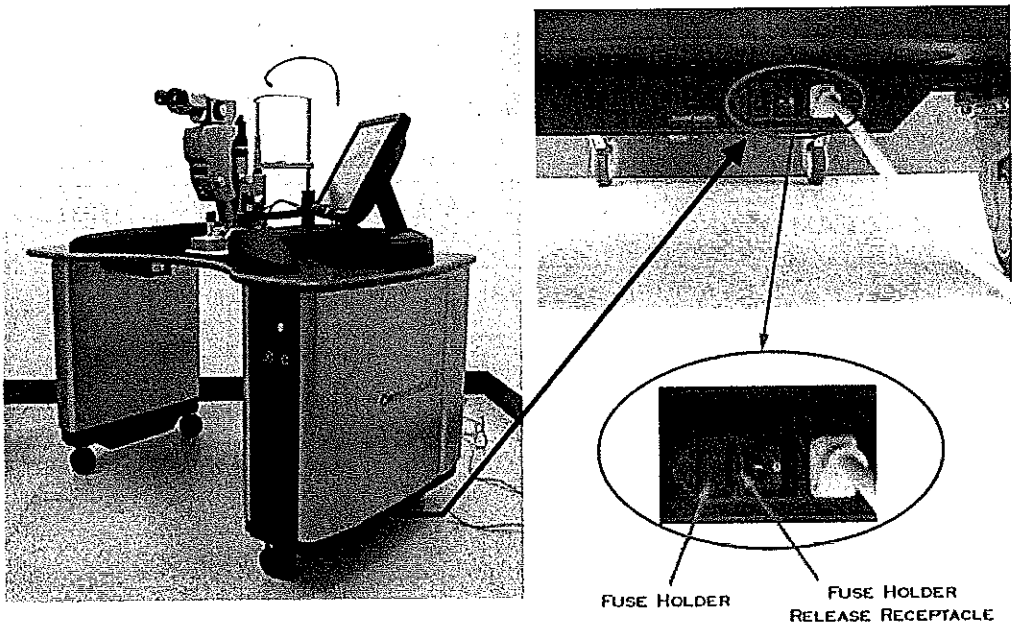
POWER RECEPTACLE FUSES

TO CHANGE THE POWER RECEPTACLE FUSES:

1. TURN OFF THE POWER TO THE LASER SYSTEM BY PLACING THE MAIN POWER CIRCUIT BREAKER OF THE SYSTEM IN THE OFF (DOWN) POSITION.

2. UNPLUG THE MAIN POWER CABLE FROM BOTH THE WALL OUTLET AND THE MAIN POWER RECEPTACLE ON THE PASCAL CONSOLE.

3. LOCATE THE FUSE HOLDER DIRECTLY BELOW THE MAIN POWER RECEPTACLE.



4. UNLOCK AND PULL OUT THE FUSE HOLDER BY INSERTING A SMALL, INSULATED FLATHEAD SCREWDRIVER INTO THE FUSE HOLDER RELEASE RECEPTACLE SLOT ON THE FUSE HOLDER.

5. REPLACE THE FUSES AS FOLLOWS:

FOR 100-120V SYSTEMS

TWO FUSES RATED FOR 250V/5.0A TYPE T SLO BLO (5MM X 20MM) (OPTIMEDICA PART # EC-01724)

FOR 220-240V SYSTEMS

TWO FUSES RATED FOR 250V/2.5A, TYPE T SLO BLO (5MM X 20MM) (OPTIMEDICA PART # EC-01740)

6. REINSERT THE FUSE HOLDER.

SPECIFICATIONS

[SPECIFICATIONS ARE SUBJECT TO CHANGE WITHOUT NOTICE]

PASCAL PHOTOCOAGULATOR	
TREATMENT BEAM	
TYPE	FREQUENCY-DOUBLED ND:YAG DIODE PUMPED SOLID-STATE
WAVELENGTH	532 ± 1 NM
POWER OUTPUT	0 – 2000 MW
DUTY CYCLE	100%
PULSE DURATIONS	10 – 1000 MS
PULSE INTERVAL	1 Hz, 1.5 Hz, 2 Hz, OR 3 Hz
PULSE COUNTER	0 – 99,999, RESET AVAILABLE
LASER BEAM DIAMETER MISSING INFORMATION	60 – 400 µM DELIVERED TO THE FOCAL PLANE OF THE SLIT LAMP IN AIR.
CDRH CLASSIFICATION	CLASS IV
EUROPEAN MDD LASER CLASSIFICATION	CLASS 4

Aim beam	
Type	Direct diode
Wavelength	635 ±10 nm
Power output	Adjustable to < 1 mW
CDRH classification	Class II
European MDD Laser Classification	Class 2

Electrical requirements	
Voltage	100-120V~50/60Hz 220-240V~50/60Hz 500VA
Fusing	100-120V 250V/T5A 220-240V 250V/ T2.5A

Product Classifications per IEC 60601-1
Class I Equipment
Type B Equipment
Ordinary Equipment, Footswitch is IPX1
Non-sterile product
Equipment not suitable for use in the presence of a Flammable Anesthetic Mixture with Air or with Oxygen or Nitrous Oxide
Continuous Operation

CLASSIFICATIONS & APPROVALS COMPLIES WITH MEDICAL SAFETY STANDARDS:	
IEC 60601-2-22	LASER SAFETY REQUIREMENTS FOR DIAGNOSTIC AND THERAPEUTIC LASER EQUIPMENT
CAN/CSA C22.2 NO.601.1-M90	CANADIAN SAFETY REQUIREMENTS FOR MEDICAL ELECTRICAL EQUIPMENT
IEC 60601-1	INTERNATIONAL SAFETY REQUIREMENTS FOR MEDICAL ELECTRICAL EQUIPMENT
IEC 60601-1-2:2001+A1:2004	EMC REQUIREMENTS FOR MEDICAL ELECTRICAL EQUIPMENT
IEC 60601-1-4	REQUIREMENTS FOR SAFETY PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS
ISO 14971:2000	RISK MANAGEMENT FOR MEDICAL DEVICES
UL 60601-1:2003	US SAFETY REQUIREMENTS FOR MEDICAL ELECTRICAL EQUIPMENT
FC	TESTED AND COMPLIES WITH FCC PART 15 CLASS B
 WEEE ANNEX IV Symbol	WEEE (WASTE OF ELECTRICAL AND ELECTRONIC EQUIPMENT) DIRECTIVE 2002/96/EC

ENVIRONMENTAL REQUIREMENTS (OPERATING)	
MAXIMUM ALTITUDE	3,900 M (13,000 FT)
OPERATING TEMPERATURE	15° - 32°C (59° – 90°F)
MAXIMUM HUMIDITY	UP TO 90% AT 32°C (90°F) NON-CONDENSING
ENVIRONMENTAL REQUIREMENTS (NON-OPERATING)	
MAXIMUM ALTITUDE	STANDARD COMMERCIAL SHIPPING ALTITUDE

NON-OPERATING TEMPERATURE	-10° - 55°C (14° – 131°F)
MAXIMUM HUMIDITY	UP TO 90% AT 55°C (131°F) NON-CONDENSING
PHYSICAL CHARACTERISTICS	
HEIGHT	ADJUSTABLE, 91 TO 122 ± 5 CM (36 TO 48 ± 2 IN)
LENGTH	122 ± 5 CM (48 ± 2 IN)
WIDTH	76 ± 5 CM (30 ± 2 IN)
WEIGHT	137 ± 5 KG (300 ± 10 LBS)
POWER CABLE LENGTH	IN THE US: APPROXIMATELY 10 FT (3 M) OUTSIDE THE US: APPROXIMATELY 2.5 M (8 FT)
FOOTSWITCH CABLE LENGTH	APPROXIMATELY 3 M (10 FT)
LATEX	THIS PRODUCT IS LATEX FREE
LASER SAFETY EYEWEAR	
NON-CE EYEWEAR	MINIMUM OD OF 4 AT 532 NM PER ANSI Z136.1
CE EYEWEAR	L4 AT 532 NM PER EN 207 PERSONAL EYE PROTECTION

TROUBLESHOOTING GUIDE

IF THE INSTRUMENT FAILS TO OPERATE PROPERLY, THIS TROUBLESHOOTING GUIDE WILL HELP YOU TO LOCATE AND CORRECT THE MALFUNCTION. SHOULD A MAJOR MALFUNCTION OCCUR, AN OPTIMEDICA SERVICE REPRESENTATIVE MUST BE CONTACTED.

FIRST, PLEASE CHECK FOR THE FOLLOWING ITEMS. IF NONE OF THESE SOLUTIONS REMEDIES THE PROBLEM, CONSULT THE TROUBLESHOOTING GUIDE:

1. VERIFY THAT THE WALL CIRCUIT BREAKER IS IN THE ON POSITION.
2. VERIFY THAT THE POWER CORD IS CORRECTLY ATTACHED TO THE CONSOLE AND THE WALL OUTLET.
3. VERIFY THAT THE POWER CIRCUIT BREAKER ON THE CONSOLE IS IN THE ON POSITION.
4. VERIFY THAT THE DOOR INTERLOCK PLUG IS SECURELY CONNECTED, AND IF DOOR INTERLOCK IS IN USE THAT THE DOOR SWITCH IS CLOSED.
5. VERIFY THAT THE FOOTSWITCH IS SECURELY CONNECTED TO THE CONSOLE.

SYSTEM DOES NOT TURN ON

PROBABLE CAUSE: SYSTEM NOT PLUGGED IN.

SUGGESTION: PLUG SYSTEM IN. VERIFY POWER CORD IS WELL SEATED INTO WALL RECEPTACLE AND SYSTEM POWER MODULE.

PROBABLE CAUSE: WALL CIRCUIT BREAKER IS IN THE OFF POSITION.

SUGGESTION: TURN ON WALL CIRCUIT BREAKER.

PROBABLE CAUSE: LASER CONSOLE MAIN POWER CIRCUIT BREAKER IS IN THE OFF POSITION.

SUGGESTION: PLACE THE MAIN POWER CIRCUIT BREAKER IN THE ON POSITION.

PROBABLE CAUSE: KEY ABSENT OR IN STANDBY POSITION.

SUGGESTION: INSERT KEY AND ROTATE TO START POSITION.

PROBABLE CAUSE: CHECK FOR STATUS MESSAGES ON THE CONTROL PANEL.

SUGGESTION: FOLLOW THE DIRECTIONS FOR SOLUTIONS TO SPECIFIC ERROR MESSAGES LATER IN THIS SECTION.

PROBABLE CAUSE: INTERNAL SYSTEM ERROR.

SUGGESTION: TURN THE LASER CONSOLE MAIN POWER CIRCUIT BREAKER TO THE OFF POSITION, WAIT 3 SECONDS, TURN THE CIRCUIT BREAKER ON, AND TURN THE KEY SWITCH TO START.

IF THE SYSTEM FAILS TO START, CONTACT OPTIMEDICA FOR SERVICE.

NO AIM BEAM IS PRESENT WHEN IN THE READY STATUS, AND/OR NO LASER TREATMENT LIGHT IS DELIVERED WHEN THE FOOTSWITCH IS DEPRESSED, AND/OR THE BEAMS ARE OF POOR QUALITY.

PROBABLE CAUSE:	LASER IS IN STANDBY MODE, NOT READY MODE.
SUGGESTION:	SELECT READY MODE.
PROBABLE CAUSE:	FOOTSWITCH NOT CONNECTED.
SUGGESTION:	CONNECT FOOTSWITCH.
PROBABLE CAUSE:	AIMING BEAM ON LOW INTENSITY SETTING.
SUGGESTION:	ADJUST AIMING BREAM INTENSITY ON THE LASER CONSOLE.
PROBABLE CAUSE:	AFTER 5 MINUTES OF SYSTEM NON-USE, THE LASER WILL GO INTO STANDBY AND THE SHUTTER CLOSES.
SUGGESTION:	SWITCH MODES FROM STANDBY TO READY.
PROBABLE CAUSE:	THE REMOTE INTERLOCK HAS BEEN ACTIVATED AND HAS DISABLED THE SYSTEM.
SUGGESTION:	ENSURE THAT THE ACTION THAT ACTIVATED THE REMOTE INTERLOCK HAS CEASED AND PROCEED. (FOR EXAMPLE, IF OPENING THE DOOR ACTIVATED THE INTERLOCK, CLOSE THE DOOR, AND GO FROM STANDBY TO READY MODE.)
PROBABLE CAUSE:	FOOTSWITCH AND CABLE ARE DAMAGED.
SUGGESTION:	INSPECT FOR DAMAGE, IF DETECTED ORDER A NEW FOOTSWITCH.
PROBABLE CAUSE:	INTERNAL SYSTEM ERROR.
SUGGESTION:	CONTACT OPTIMEDICA FOR SERVICE.

"FOOTSWITCH" IS DISPLAYED ON CONTROL SCREEN

PROBABLE CAUSE: FOOTSWITCH DEPRESSED WHILE SYSTEM IN STANDBY MODE.

SUGGESTION: SELECT THE STATUS BUTTON TO CLEAR THE ERROR AND RETURN TO STANDBY.

PROBABLE CAUSE: FOOTSWITCH AND/OR FOOTSWITCH CABLE DAMAGED.

SUGGESTION: INSPECT FOR DAMAGE, IF DETECTED ORDER A NEW FOOTSWITCH.

PROBABLE CAUSE: INTERNAL SYSTEM ERROR.

SUGGESTION: CONTACT OPTIMEDICA FOR SERVICE.

"INTERNAL ERROR" IS DISPLAYED ON CONTROL SCREEN

PROBABLE CAUSE: MINOR INTERNAL ERROR

SUGGESTION: SELECT THE STATUS BUTTON TO CLEAR THE ERROR AND RETURN TO STANDBY.

IF ERROR OCCURS ON A REGULAR BASIS, CONTACT OPTIMEDICA FOR SERVICE.

PROBABLE CAUSE: INTERNAL SYSTEM ERROR.

SUGGESTION: SHUT DOWN THE SYSTEM, WAIT 1 MINUTE AND RESTART. IF ERROR PERSISTS CONTACT OPTIMEDICA FOR SERVICE.

"50% OVER POWER" IS DISPLAYED ON CONTROL SCREEN

PROBABLE CAUSE: TEMPORARY SYSTEM FAILURE

SUGGESTION: SELECT THE STATUS BUTTON TO CLEAR THE ERROR AND RETURN TO STANDBY.

IF ERROR OCCURS ON A REGULAR BASIS, CONTACT OPTIMEDICA FOR SERVICE.

PROBABLE CAUSE: INTERNAL SYSTEM ERROR.

SUGGESTION: CONTACT OPTIMEDICA FOR SERVICE.

"50% Under Power" is displayed on control screen

Probable Cause: Temporary system failure.

Suggestion: Select the Status button to clear the error and return to STANDBY.

If error occurs on a regular basis, contact OPTIMEDICA for service.

Probable Cause: Internal system error.

Suggestion: contact OPTIMEDICA for service.

"Interlock" is displayed on control screen

Probable Cause: The remote interlock has been activated and has disabled the system.

Suggestion: Ensure that the action that activated the remote interlock has ceased and proceed. (For example, if opening the door activated the interlock, close the door, and go from STANDBY to READY mode.)

Probable Cause: Remote interlock connector has been disconnected.

Suggestion: Ensure that the remote interlock connector is securely connected to the system.

Probable Cause: Errors in the door interlock switch or external wiring.

Suggestion: Have a certified electrical professional check the operation of the door interlock switch, wiring, and external circuit.

Probable Cause: Internal system error.

Suggestion: Contact OPTIMEDICA for service.

Calibration Procedure

Regulatory agencies require that manufacturers of US FDA CDRH Class II and IV, and European IEC 60825 Class 2 and 4 medical lasers supply their customers with power calibration instructions.

Calibration must be performed by an engineer or technician qualified to work on energized electronic laser equipment. Questions regarding this procedure should be referred to the OPTIMEDICA Service Department.

Disclaimer warning

Calibration is a service procedure to be done only by OPTIMEDICA certified Service Engineers or customers who have taken and passed an OPTIMEDICA Service Certification Training course on the Pascal system. Adjustment by anyone other than a trained OPTIMEDICA Certified Engineer or certified customer voids any existing manufacturer's warranty on the instrument.

Calibration Instructions

Tools Required:

- 1 3/16" Allen wrench
- 1 Service/Calibration compact flash RAM
- 1 USB keyboard
- 1 NIST-traceable calibrated optical power meter
- 1 power meter to chinrest adapter
- 1 grounding strap

The system must be de-energized prior to this operation. Attach and wear the ground strap. Open the electronic subassembly covers to expose the CPU. Touch a hand to the chassis ground plane next to the TOUCH HERE sticker.

Connect the keyboard to the keyboard port. Attach the power meter to the chinrest adapter, and install the optical power meter.

RE-ENERGIZE THE SYSTEM AND BOOT-UP. NAVIGATE TO THE SERVICE / CALIBRATION SOFTWARE, AND ENTER SERVICE MODE. IF NECESSARY, ALIGN THE OPTICAL POWER METER USING THE AIMING BEAM. FOLLOW THE ON-SCREEN INSTRUCTIONS TO CALIBRATE THE SYSTEM.

SHUT DOWN THE SYSTEM AND DE-ENERGIZE. REMOVE THE SERVICE / CALIBRATION COMPACT FLASH RAM AND KEYBOARD. CLOSE THE ELECTRONICS SUBASSEMBLY COVERS, AND SECURE THE SYSTEM.

RE-ENERGIZE THE SYSTEM AND BOOT-UP. VERIFY THE CALIBRATION USING THE OPTICAL POWER METER.

IF NOT SUCCESSFUL, REPEAT THE CALIBRATION PROCEDURE.

IF SUCCESSFUL, SHUT DOWN THE SYSTEM AND REMOVE THE POWER METER AND CHINREST ADAPTER.

WARNINGS

AS A PRECAUTION AGAINST ACCIDENTAL EXPOSURE TO THE OUTPUT BEAM OR ITS REFLECTION, ANYONE CHECKING OR ADJUSTING CALIBRATION SHOULD WEAR APPROPRIATE LASER SAFETY EYEWEAR. FOR FURTHER INFORMATION ON LASER SAFETY EYEWEAR, SEE "OCULAR PROTECTION" IN THE SAFETY AND REGULATORY COMPLIANCE CHAPTER.

THERE IS POTENTIAL FOR EXPOSURE TO DANGEROUS LASER RADIATION AND HIGH VOLTAGES WHEN THE PROTECTIVE COVERS OF THE LASER CONSOLE ARE OPENED. ONLY OPTIMEDICA CORPORATION SERVICE REPRESENTATIVES OR OPTIMEDICA CORPORATION - CERTIFIED TECHNICIANS SHALL WORK ON THE LASER WITH THE PROTECTIVE COVERS OPENED.

System Relocation Instructions

Ensure that both the main wall circuit breaker and the device circuit breaker are in the OFF position. Remove the power cable from both the wall power receptacle and the laser console.

If a remote door interlock is utilized, remove the interlock plug and cable from the remote interlock receptacle and transport separately.

Place the footswitch on top of the laser console and contain the cable, or disconnect the footswitch cable from the receptacle and transport separately. Never drag the footswitch when moving the laser system.

Use the laser console handle to move the laser system and the Slit Lamp to the desired site.

Position the laser console a minimum of 15 cm (≈6 in) away from walls, furniture, or other equipment. Adequate space around the laser console will ensure proper air circulation for system cooling purposes.

CAUTION

The assistance of a second person is required when moving the system up or down an incline.

External Connections

Power cord: Connector on rear of unit mates with a supplied, hospital grade power cord. User accessible fuses are contained in the connector module.

Footswitch: Sturdy connector underneath the tabletop of unit.

Door Interlock: (also referred to as the CDRH Plug) Sturdy connector underneath the tabletop, next to the footswitch connection, with a supplied emulator plug.

CAUTION

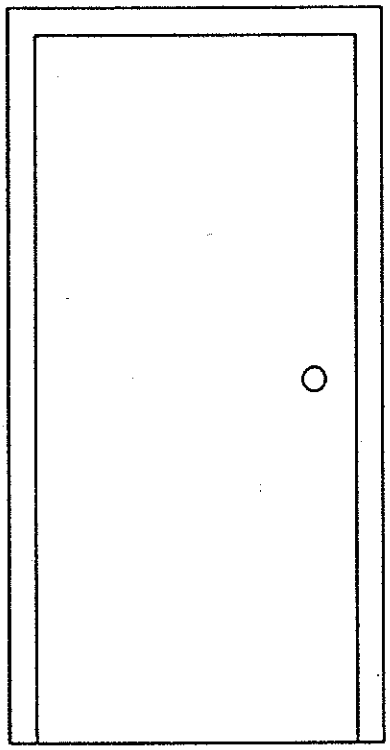
The power cord, footswitch and door interlock connectors should be correctly connected to the device prior to turning on the device circuit breaker.

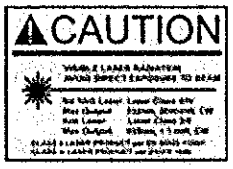
Room Preparation

Verify that the laser console electrical cord and plug are properly connected. For systems configured with an electrical wall circuit breaker, always place the electrical wall circuit breaker in the OFF position before inserting the plug into the receptacle.

Verify that the electrical service is turned on.

Verify that the "Laser in Use" warning sign has been posted outside of the treatment room door.





Ensure all attending personnel in the treatment room are wearing appropriate eye protection goggles or eyeglasses. (See "Ocular Protection" in the Safety and Regulatory Compliance chapter.)

Optional Door Interlock

An optional door interlock can be utilized. This is an added safety precaution that disables the laser if the door is opened.

Moreover, the laser can be set in READY mode ONLY when the door switch is closed. Breaking the connection by opening the door switch (or by removing the plug) during a treatment disables the laser. The system is then returned to STANDBY, and Door Interlock is displayed on the control panel.

The door interlock receptacle on the device must have the correct plug properly installed.

There are two situations:

1. If no door interlock system is utilized, an emulator plug is provided and is to remain in the device receptacle.

2. If a door interlock system is utilized, a qualified electrical professional is required to install the system and a specific door interlock plug is used to connect to the laser. The total length of cable should not exceed 5m (16 ft).

Safety and Regulatory Compliance

Introduction

OPTIMEDICA laser systems are precision medical instruments. The systems have undergone extensive testing. With proper handling, they are useful and reliable clinical instruments. To protect operating personnel and patients, this safety section and the appropriate slit lamp and pattern generator delivery system safety section should be read thoroughly before operation.

OPTIMEDICA lasers are classified as Class IV lasers by the National Center for Devices and Radiological Health. IV represents the highest power lasers; for this reason, the user must take precautions to prevent exposure of laser energy to the eye and skin from either direct or diffusely reflected laser beams, except as a therapeutic application. In addition, precautions must be taken in the surgical environment to prevent the hazards of fire and electrical injury.

OPTIMEDICA does not recommend specific clinical practices. The following precautions are extensive but may not be complete. Laser users are advised to supplement this information, with technological advances in surgical products and techniques as they become available to the medical laser user community through medical literature. See also the American National Standard (ANSI®) publications ANSI Z136.3-2005 "American National Standard for the Safe Use of Lasers in Health Care Facilities" and ANSI Z136.1-2000 "American National Standard for the Safe Use of Lasers", and other national standards as may be applicable for the country in which Pascal is used.

Classifications & Approvals Complies with Medical Safety Standards:	
IEC 60601-2-22	Laser Safety Requirements for Diagnostic and Therapeutic Laser Equipment
CAN/CSA C22.2 NO.601.1-M90	Canadian Safety requirements for Medical Electrical Equipment
IEC 60601-1-4	Requirements for Safety Programmable Electrical Medical Systems
IEC 60601-1	International Safety requirements for Medical Electrical Equipment
ISO 14971:2000	Risk Management for Medical Devices
UL 60601-1:2003	US Safety requirements for Medical Electrical Equipment
IEC 60601-1-2:2001+A1:2004 (Edition 2.1)	EMC Requirements For Medical Electrical Equipment
FC	Tested and Complies With FCC Part 15 Class B

Ocular Protection

WARNINGS

Never look directly into the laser aperture or scattered laser light from reflective surfaces when the treatment beam is activated. Severe eye damage could occur.

Never substitute glass prescription eyewear for the appropriate laser safety eyewear, as severe eye damage could occur. The glass in prescription eyewear can concentrate the laser light onto the retina of the eye. A high power density beam can also shatter glass prescription eyewear, resulting in possible severe eye damage.

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), and the Nominal Ocular Hazard Distance (NOHD) for each of the available laser wavelengths, as well as the wavelength itself and the configuration of the treatment room (usually within the controlled area).

The American National Standards Institute (ANSI) Standard Z136.1-2000 defines MPE as "the level of radiation to which a person may be exposed without hazardous effect or adverse biological changes in the eye or skin"; the NHZ as "the space within which the level of direct, reflected, or scattered radiation during normal operation is not expected to exceed the applicable MPE"; and, the NOHD as "the distance along the axis of the unobstructed beam from the laser to the human eye beyond which the irradiance or radiant exposure during operation is not expected to exceed the appropriate MPE."

THE NOHD IS MEASURED FROM THE SLIT LAMP AND PATTERN GENERATOR DELIVERY SYSTEM LASER APERTURE. ANSI DEFINES THE CONTROLLED AREAS AS "AN AREA WHERE THE OCCUPANCY AND ACTIVITY OF THOSE WITHIN IS SUBJECT TO CONTROL AND SUPERVISION FOR THE PURPOSE OF PROTECTION FROM RADIATION HAZARDS."

FOR PASCAL THE NOHD IS 3.73 M (12.24 FT).

ALL PERSONNEL WHO ARE WITHIN THE NOHD ARE CONSIDERED TO BE IN THE CONTROLLED AREA AND SHALL WEAR EYE PROTECTION WITH THE APPROPRIATE OPTICAL DENSITY.

EYEWEAR MUST BE RESISTANT TO PHYSICAL DAMAGE AND PHOTO-BLEACHING. THE MINIMUM OPTICAL DENSITY (OD) IS 4 AT 532 NM. FOR COUNTRIES INSIDE EUROPE AND THAT COMPLY WITH EN 207, THE EYEWEAR MUST HAVE A PROTECTION CLASS OF L4 AT 532 NM.

THE TYPE OF EYE PROTECTION RECOMMENDED FOR THE PHYSICIAN, THE PATIENT, AND/OR TREATMENT ROOM PERSONNEL WITHIN THE NHZ DEPENDS ON THE PLANNED PROCEDURE AND THE EQUIPMENT REQUIRED TO PERFORM THAT PROCEDURE.

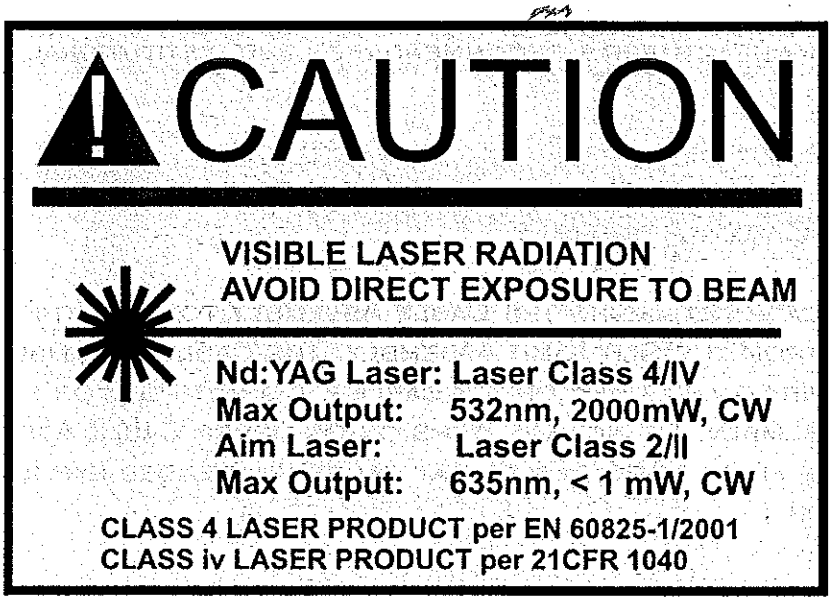
PASCAL IS FITTED WITH A LASER EYE FILTER, AND LASER SAFETY EYEWEAR IS NOT REQUIRED BY THE PHYSICIAN WHO VIEWS THE PROCEDURE THROUGH THE SLIT LAMP BINOCULARS. ALL OTHER PERSONNEL WITHIN THE NHZ MUST WEAR LASER SAFETY EYEWEAR WITH THE RECOMMENDED OPTICAL DENSITY.

DEPENDING ON THE PROCEDURE, THE PHYSICIAN MUST PROVIDE THE PATIENT WITH EITHER LASER SAFETY EYEWEAR OR ONE OF THE FOLLOWING ITEMS MOISTENED WITH A NON-FLAMMABLE SOLUTION: THICK CLOTH EYE PADS OR GAUZE PADS. IF THE TREATMENT SITE IS THE PATIENT'S EYELID, THE PHYSICIAN MUST PROVIDE DULLED METALLIC EYE SHIELDS TO PROTECT THE PATIENT'S EYE(S). ALL OTHER EYE SHIELDS MADE OF A MATERIAL OTHER THAN DULLED METAL SHOULD BE EVALUATED PRIOR TO USE FOR SAFETY AND DURABILITY WITH LASER ENERGY. ALONG WITH PROVIDING THE APPROPRIATE SAFETY EYEWEAR, THE FOLLOWING STEPS SHOULD BE TAKEN TO SECURE THE CONTROLLED AREA:

1. TREATMENT SHOULD BE CONDUCTED IN A DEDICATED, ENCLOSED ROOM.

2. A WARNING SIGN SHOULD BE PLACED ON THE OUTSIDE OF THE TREATMENT ROOM DOOR WHEN THE LASER IS IN USE. THE SIGN IS INTENDED TO ALERT PERSONNEL BEFORE THEY ENTER THE CONTROLLED AREA.

3. THE TREATMENT ROOM DOOR SHOULD BE KEPT CLOSED DURING TREATMENT.



AIMING BEAM OCULAR PROTECTION

CAUTION

THE LASER PRODUCES A RED DIODE LASER AIMING BEAM WITH AVERAGE POWER VARYING FROM BARELY VISIBLE TO 1 MW MAXIMUM. THE SAFE (CLASS II) EXPOSURE DURATION LIMIT AT A MAXIMUM POWER LEVEL OF 1 MW IS 3.9 SECONDS. TO PROTECT THE PATIENT FROM POSSIBLE RETINAL DAMAGE DURING TREATMENT, USE THE LOWEST PRACTICAL AIMING BEAM INTENSITY AND THE MINIMAL REQUIRED TIME DURATION.

ELECTRICAL HAZARDS

NEVER OPEN THE LASER CONSOLE PROTECTIVE COVERS. OPENING THE COVERS WILL EXPOSE YOU TO HIGH VOLTAGE COMPONENTS, THE LASER RESONATOR, AND POSSIBLE LASER RADIATION. ONLY OPTIMEDICA CERTIFIED SERVICE TECHNICIANS SHALL WORK INSIDE THE CONSOLE.

THE AREA AROUND THE LASER AND FOOTSWITCH SHALL 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 THE OPTIMEDICA MANUFACTURER'S RECOMMENDATION AND INSTITUTIONAL STANDARDS.

FIBER OPTIC CABLE ASSEMBLY

USE EXTREME CARE REGARDING THE CABLE ASSEMBLY TO/FROM THE DISPLAY ASSEMBLY TO/FROM THE SLIT LAMP ASSEMBLY. THE CABLE ASSEMBLY CONSISTS OF WIRING AND FIBER OPTICS CABLES. DO NOT PULL OR STRESS THE CABLE ASSEMBLY. DO NOT SET ITEMS ON OR UNDER CABLE ASSEMBLY. DAMAGE TO THE FIBER OPTIC CABLES MAY CAUSE UNINTENDED EXPOSURE TO LASER RADIATION.

Fire Hazard

WARNINGS

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

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 should be readily available.

Per IEC 601-2-22: The use of flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided. Some materials, for example cotton wool when saturated with oxygen may be ignited by the high temperatures produced in normal use of the Laser Equipment. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the Laser Equipment is used. Attention should also be drawn to the danger of ignition of endogenous gases.

Protecting Non-target Tissues

WARNING

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

CAUTIONS

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

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

Regulatory Compliance Safety Features

The Pascal Retinal Photocoagulator complies with 21 CFR subchapter J as administrated by the Center for Devices and Radiological Health of the Food and Drug Administration (FDA).

The following FDA compliance safety features are included:

Key Lock Switch

The system can be activated only with the proper key to operate the master key switch. The key cannot be removed in the ON position and the system will operate only with the key in place. When treatments are complete, always remove and secure the key to prevent unauthorized use of the laser system.

Laser Emission Indicator

The Laser Emission icon is displayed to warn the user that the system is capable of emitting laser energy and appropriate precautions should be taken, such as using the appropriate eye wear when in the treatment room.

Door Interlock

A door interlock may be used in conjunction with a remote switch to disable the laser in case of certain external events (e.g., the opening of a treatment room door). A remote switch or interlock can be wired to the interlock plug and connected to the laser console interlock receptacle. If a remote interlock is used, the laser can be set in the READY mode only when the remote switch is closed. Breaking the connection by opening the switch (door) or removing the plug disables the laser; and the system is returned to STANDBY mode with Door Interlock displayed on the control panel.

Emergency Stop

The system has an EMERGENCY STOP pushbutton that immediately turns off the device.

Protective Housing

The Pascal Retinal Photocoagulator laser has a protective housing which prevents unintended human access to laser radiation above Class 1 limits. This housing is to be opened only by an OPTIMEDICA certified technician.

Safety Interlocks

The protective housing is not designed to be removed by the user during operation or maintenance. Therefore, the laser does not have, and is not required to have, any safety interlock within the meaning of US FDA 21 CFR, Section 1040 or European EN 60825-1. However, the protective housing cannot be easily opened without special tools.

Location of Controls

Controls are located on the touch screen control panel and the slit lamp body. They are conveniently situated so the operator can make changes to the aiming beam without looking away from the patient.

Safety Shutter

The Pascal Retinal Photocoagulator includes a safety shutter, which prevents any laser radiation (including the aiming beam) from exiting the instrument. The safety shutter is activated when the system is off, during the self-test at turn-on, in STANDBY mode, or when the safety monitor detects a fault.

Manual Reset

If laser emission is externally interrupted during treatment by activation of the door interlock, the system will automatically go into STANDBY and the safety shutter will revert to a closed position. To resume treatment, reset the system by placing the laser in READY.

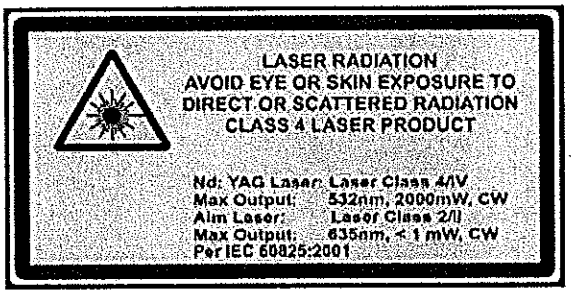
If laser emission is interrupted by main electrical power loss, the system will automatically turn off. To resume treatment after an electrical power loss, the system must first be manually restarted by rotating the key switch to START.

Electrical fault detection circuitry

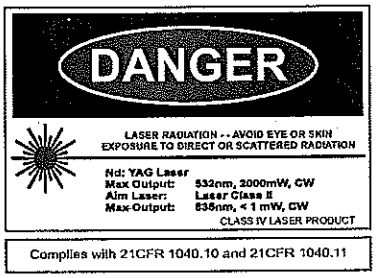
If the electronic system detects a fault condition, laser exposure cannot occur. The laser power supply is turned OFF, the safety shutter is closed, and the footswitch is disabled. Some fault conditions may be cleared by the operator. Refer to the Troubleshooting Guide in this manual for additional information.

LOCATION OF REGULATORY AND OTHER SYSTEM LABELS

AS REQUIRED BY THE FDA, CE, AND OTHER REGULATORY BODIES, APPROPRIATE WARNING LABELS HAVE BEEN MOUNTED IN SPECIFIED LOCATIONS ON THE INSTRUMENT TO INDICATE CONDITIONS UNDER WHICH THE USER COULD BE SUBJECTED TO LASER RADIATION. SEE THE FOLLOWING ILLUSTRATIONS FOR THE LOCATION OF THE LABELS.

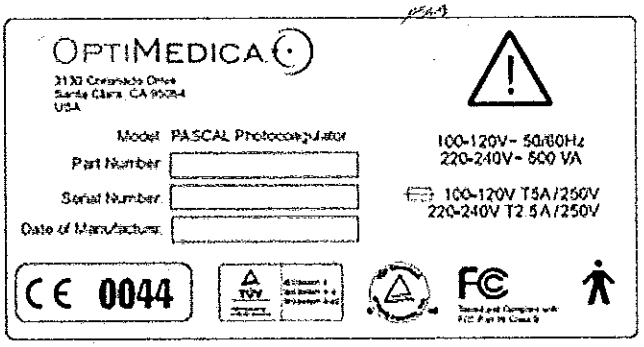


LASER RADIATION CAUTION LABEL



DANGER LABEL

LASER APERTURE LABEL



SYSTEM INFORMATION LABEL

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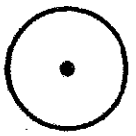
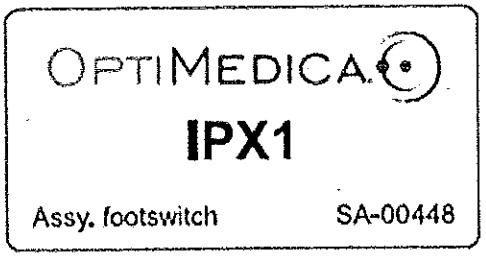


READY

START

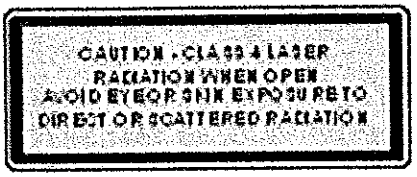
EMERGENCY STOP

LASER EMISSION WARNING

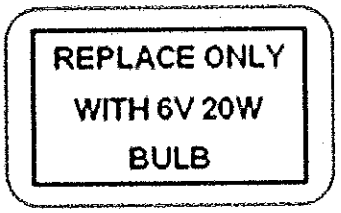


FOOTSWITCH LABEL

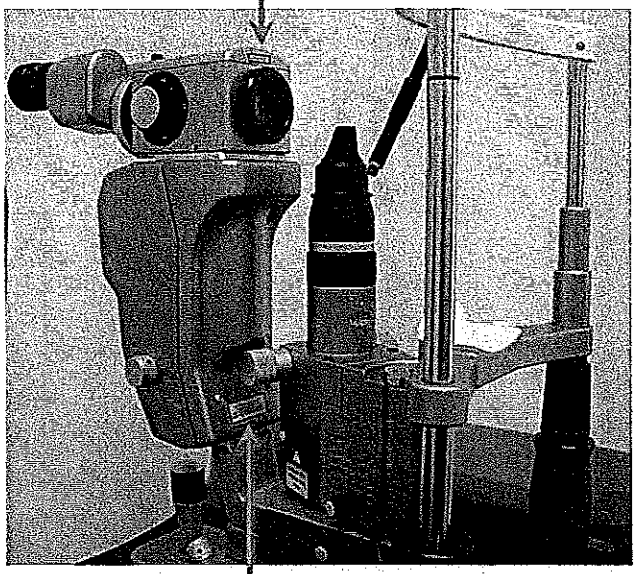
CAUTION SYMBOL LABEL

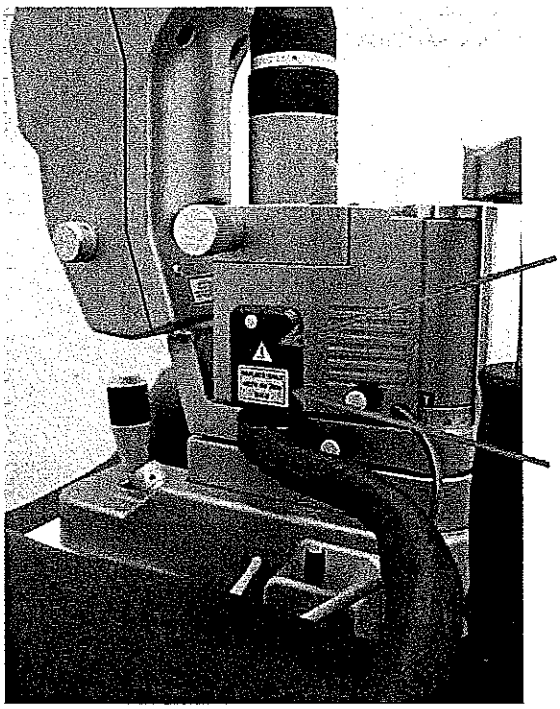


LASER CAUTION LABEL



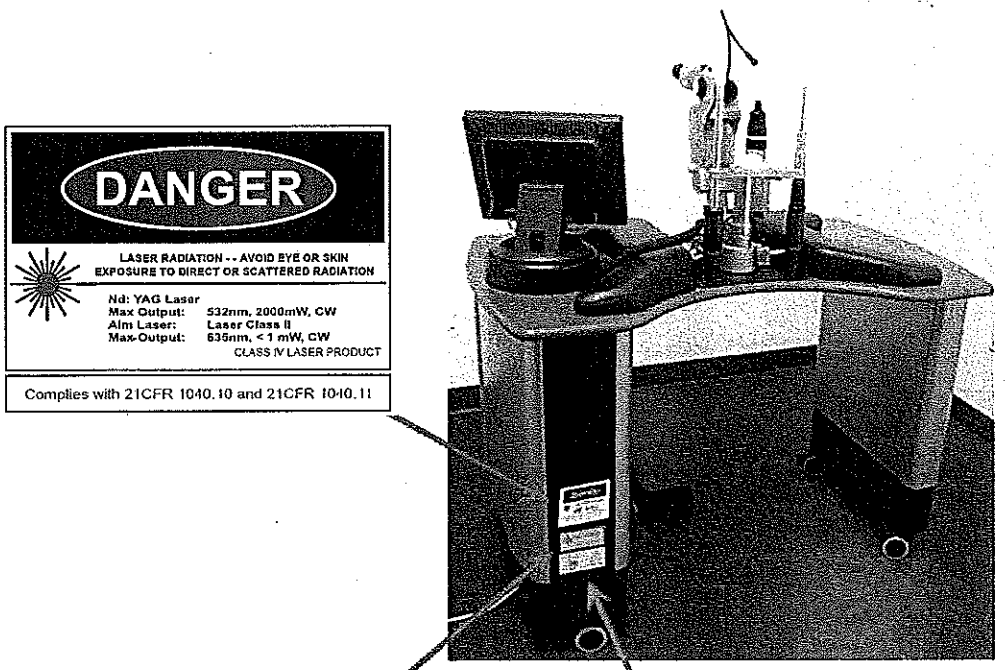
SLIT LAMP BULB LABEL





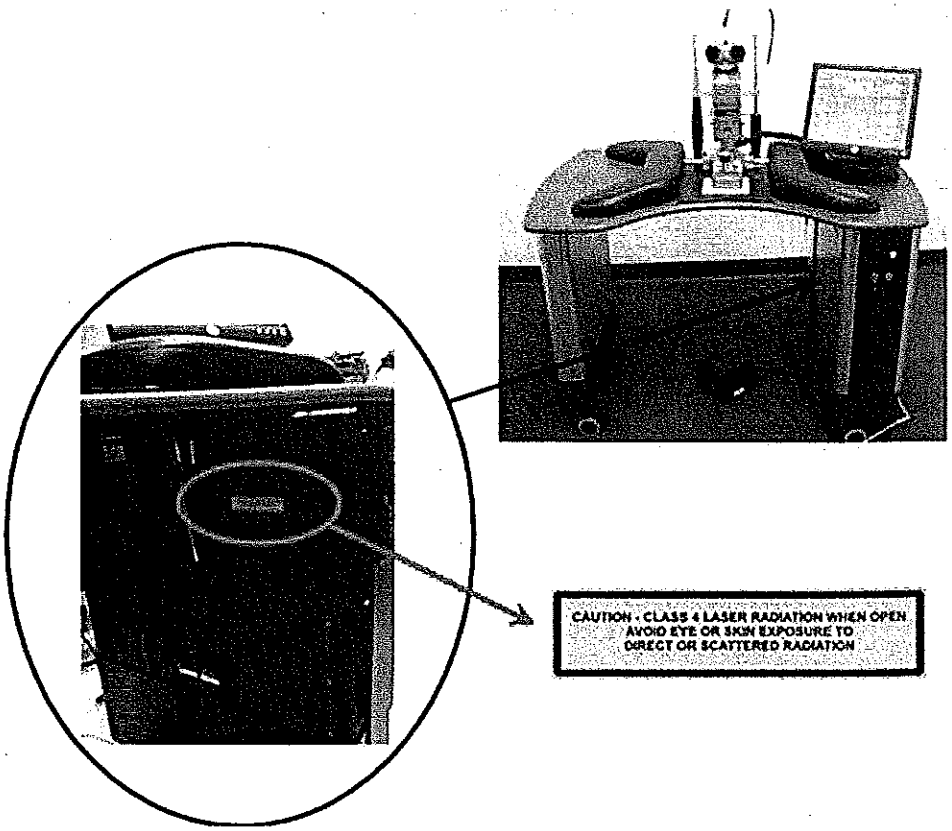
CAUTION SYMBOL LABEL

SLIT LAMP BULB LABEL

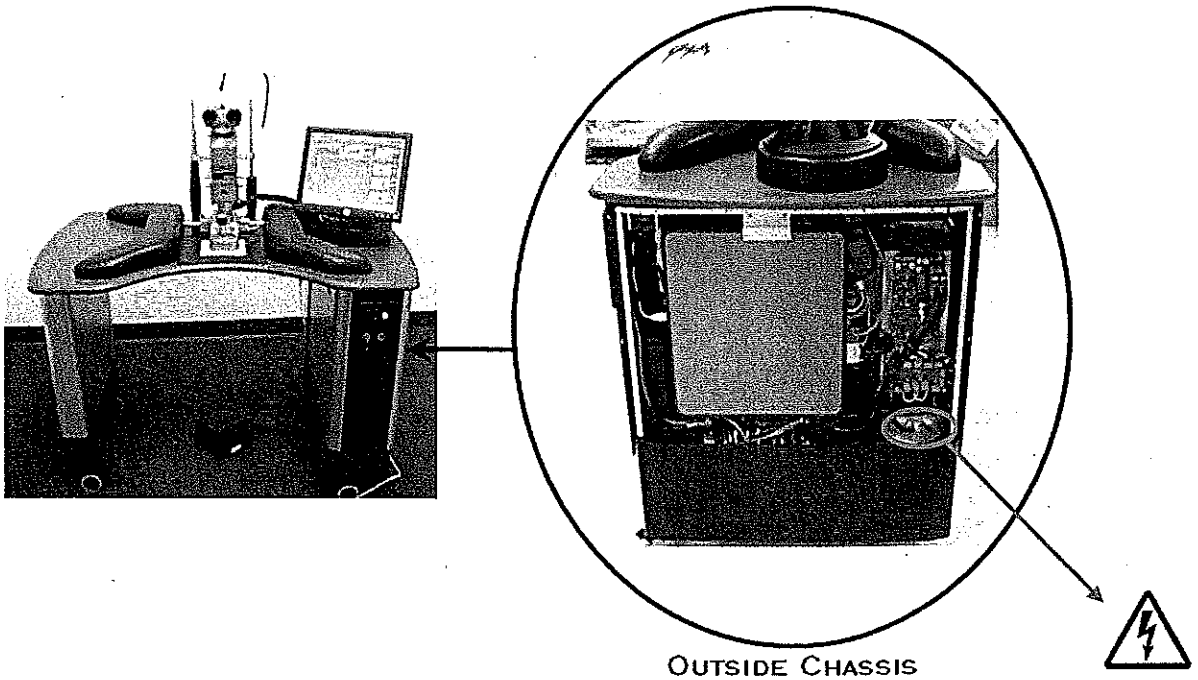


LASER RADIATION CAUTION LABEL

SYSTEM INFORMATION LABEL



INSIDE CHASSIS
COVER REMOVED



OUTSIDE CHASSIS
COVER REMOVED

Electromagnetic Compatibility

Like other electrical medical devices, Pascal requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure electromagnetic compatibility (EMC), Pascal must be installed and operated according to the EMC information provided in the manual.

NOTE

Pascal has been designed and tested to comply with IEC 60601-1-2:2001+A1:2004 (Edition 2.1) requirements for EMC with other devices.

CAUTION

Portable and mobile RF communications equipment may affect normal function of Pascal.

WARNING

Do not use cables or accessories other than those provided with Pascal, as this may result in the increased electromagnetic emissions or decreased immunity to such emissions.

WARNING

If Pascal is used adjacent to or stacked with other equipment, observe and verify normal operation of Pascal in the configuration in which it will be used prior to use.

CONSULT THE TABLES BELOW FOR GUIDANCE IN PLACING PASCAL.

GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC EMISSIONS		
PASCAL IS INTENDED FOR USE IN THE ELECTROMAGNETIC ENVIRONMENT SPECIFIED BELOW. THE CUSTOMER OR THE USER OF PASCAL SHOULD ENSURE THAT IT IS USED IN SUCH AN ENVIRONMENT.		
EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF EMISSIONS CISPR 11	GROUP 1	PASCAL USES RF ENERGY ONLY FOR ITS INTERNAL FUNCTION; THEREFORE, ITS RF EMISSIONS ARE VERY LOW AND ARE NOT LIKELY TO CAUSE ANY INTERFERENCE IN NEARBY ELECTRONIC EQUIPMENT.
RF EMISSIONS CISPR 11	CLASS B	PASCAL IS SUITABLE FOR USE IN ALL ESTABLISHMENTS, INCLUDING DOMESTIC ESTABLISHMENTS AND THOSE DIRECTLY CONNECTED TO THE PUBLIC LOW-VOLTAGE POWER SUPPLY NETWORK THAT SUPPLIES BUILDINGS USED FOR DOMESTIC PURPOSES.
HARMONIC EMISSIONS IEC61000-3-2	CLASS A	
VOLTAGE FLUCTUATIONS/ FLICKER EMISSIONS IEC61000-3-3	COMPLIES	

GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC IMMUNITY			
PASCAL IS INTENDED FOR USE IN THE ELECTROMAGNETIC ENVIRONMENT SPECIFIED BELOW. THE CUSTOMER OR THE USER OF PASCAL SHOULD ENSURE THAT IT IS USED IN SUCH AN ENVIRONMENT.			
IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT: GUIDANCE
ELECTROSTATIC DISCHARGE (ESD) IEC61000-4-2	±6KV CONTACT ±8KV AIR	±2,4,6KV CONTACT ±2,4,8KV AIR	FLOORS SHOULD BE WOOD, CONCRETE, OR CERAMIC TILE. IF FLOORS ARE COVERED WITH SYNTHETIC MATERIAL, THE RELATIVE HUMIDITY SHOULD BE AT LEAST 30%.
ELECTRICAL FAST TRANSIENT/ BURST IEC61000-4-4	±2KV FOR POWER SUPPLY LINES ±1KV FOR INPUT/OUTPUT LINES	±2KV LINE TO GROUND ±1KV LINE TO LINE	MAINS POWER QUALITY SHOULD BE THAT OF A TYPICAL COMMERCIAL OR HOSPITAL ENVIRONMENT.
SURGE IEC61000-4-5	±1KV DIFFERENTIAL MODE ±2KV COMMON MODE	±0.5, 1KV DIFFERENTIAL MODE ±0.5, 1, 2KV COMMON MODE	MAINS POWER QUALITY SHOULD BE THAT OF A TYPICAL COMMERCIAL OR HOSPITAL ENVIRONMENT.
VOLTAGE DIPS, SHORT INTERRUPTIONS AND VOLTAGE VARIATIONS ON POWER SUPPLY INPUT LINES IEC61000-4-11	<5% UT (>95% DIP IN UT) FOR 0.5 CYCLE 40% UT (60% DIP IN UT) FOR 5 CYCLES 70% UT (30% DIP IN UT) FOR 25 CYCLES <5% UT (>95% DIP IN UT) FOR 5	<5% UT (>95% DIP IN UT) FOR 0.5 CYCLE 40% UT (60% DIP IN UT) FOR 5 CYCLES 70% UT (30% DIP IN UT) FOR 25 CYCLES <5% UT (>95% DIP IN UT) FOR 5 SEC.	MAINS POWER QUALITY SHOULD BE THAT OF A TYPICAL COMMERCIAL OR HOSPITAL ENVIRONMENT. IF THE USER OF PASCAL REQUIRES CONTINUED OPERATION DURING POWER MAINS INTERRUPTIONS, IT IS RECOMMENDED THAT PASCAL BE POWERED FROM AN UNINTERRUPTIBLE POWER SUPPLY OR A BATTERY.
POWER FREQUENCY (50/60HZ) MAGNETIC FIELD IEC 61000-4-8	3 A/M	N/A	POWER-FREQUENCY MAGNETIC FIELDS SHOULD BE AT LEVELS CHARACTERISTIC OF A TYPICAL LOCATION IN A TYPICAL COMMERCIAL OR HOSPITAL ENVIRONMENT.
NOTE: UT IS THE A.C. MAINS VOLTAGE PRIOR TO APPLICATION OF THE TEST LEVEL.			

GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC IMMUNITY			
GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC IMMUNITY			
PASCAL IS INTENDED FOR USE IN THE ELECTROMAGNETIC ENVIRONMENT SPECIFIED BELOW. THE CUSTOMER OR THE USER OF PASCAL SHOULD ENSURE THAT IT IS USED IN SUCH AN ENVIRONMENT.			
IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT: GUIDANCE
CONDUCTED RF IEC 61000-4-6	3 VRMS 150 KHZ TO 80 MHZ	3 V	PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT SHOULD BE USED NO CLOSER TO ANY PART OF THE PASCAL SYSTEM, INCLUDING ITS CABLES, THAN THE RECOMMENDED SEPARATION DISTANCE CALCULATED FROM THE EQUATION APPLICABLE TO THE FREQUENCY OF THE TRANSMITTER. RECOMMENDED SEPARATION DISTANCE D = 1.17 / P
RADIATED RF IEC 61000-4-3	3 V/M 80MHZ TO 2.5 GHZ	3 V/M	D = 1.17 / P 80 MHZ TO 800 MHZ D = 2.33 / P 800 MHZ TO 2.5 GHZ WHERE P IS THE MAXIMUM OUTPUT POWER RATING OF THE TRANSMITTER IN WATTS (W) ACCORDING TO THE TRANSMITTER MANUFACTURER AND D IS THE RECOMMENDED SEPARATION DISTANCE IN METERS (M). FIELD STRENGTHS FROM FIXED RF TRANSMITTERS, AS DETERMINED BY AN ELECTROMAGNETIC SITE SURVEY (A), SHOULD BE LESS THAN THE COMPLIANCE LEVEL IN EACH FREQUENCY RANGE(B). INTERFERENCE MAY OCCUR IN THE VICINITY OF EQUIPMENT MARKED WITH THE FOLLOWING SYMBOL:

NOTE 1: AT 80 MHZ AND 800 MHZ, THE HIGHER FREQUENCY RANGE APPLIES.

NOTE 2: THESE GUIDELINES MAY NOT APPLY IN ALL SITUATIONS. ELECTROMAGNETIC PROPAGATION IS AFFECTED BY ABSORPTION AND REFLECTION FROM STRUCTURES, OBJECTS, AND PEOPLE.

(A) FIELD STRENGTHS FROM FIXED TRANSMITTERS, SUCH AS BASE STATIONS FOR RADIO (CELLULAR/CORDLESS) TELEPHONES AND LAND MOBILE RADIOS, AMATEUR RADIO, AM AND FM RADIO BROADCAST, AND TV BROADCAST, CANNOT BE PREDICTED THEORETICALLY WITH ACCURACY. TO ASSESS THE ELECTROMAGNETIC ENVIRONMENT DUE TO FIXED RF TRANSMITTERS, AN ELECTROMAGNETIC SITE SURVEY SHOULD BE CONSIDERED. IF THE MEASURED FIELD STRENGTH IN THE LOCATION IN WHICH THE PASCAL SYSTEM IS USED EXCEEDS THE APPLICABLE RF COMPLIANCE LEVEL ABOVE, THE PASCAL SYSTEM SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION. IF ABNORMAL PERFORMANCE IS OBSERVED, ADDITIONAL MEASURES MAY BE NECESSARY, SUCH AS REORIENTING OR RELOCATING THE PASCAL SYSTEM.

(B) OVER THE FREQUENCY RANGE 150 KHZ TO 80 MHZ, FIELD STRENGTHS SHOULD BE LESS THAN 3 V/M.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE PASCAL SYSTEM			
THE PASCAL SYSTEM IS INTENDED FOR USE IN AN ELECTROMAGNETIC ENVIRONMENT IN WHICH RADIATED RF DISTURBANCES ARE CONTROLLED. THE USER OF THE PASCAL SYSTEM CAN HELP PREVENT ELECTROMAGNETIC INTERFERENCE BY MAINTAINING A MINIMUM DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT (TRANSMITTERS) AND THE PASCAL SYSTEM AS RECOMMENDED BELOW, ACCORDING TO THE MAXIMUM OUTPUT POWER OF THE COMMUNICATIONS EQUIPMENT.			
RATED MAXIMUM OUTPUT POWER (W) OF TRANSMITTER	SEPARATION DISTANCE (M) ACCORDING TO FREQUENCY OF TRANSMITTER		
	150KHZ TO 80MHZ $d = 1.17\ P$	80MHZ TO 800MHZ $d = 1.17\ P$	800 MHZ TO 2.5 GHZ $d = 2.33\ P$
0.	0.12	0.12	0.23
0.	0.37	0.37	0.74
1	1.17	1.17	2.33
1	3.70	3.70	7.37
10	11.70	11.70	23.30
FOR TRANSMITTERS RATED AT A MAXIMUM OUTPUT POWER NOT LISTED ABOVE, THE RECOMMENDED SEPARATION DISTANCE (D) IN METERS (M) CAN BE ESTIMATED USING THE EQUATION APPLICABLE TO THE FREQUENCY OF THE TRANSMITTER, WHERE P IS THE MAXIMUM OUTPUT POWER RATING OF THE TRANSMITTER IN WATTS (W) ACCORDING TO THE TRANSMITTER MANUFACTURER.			
NOTE 1: AT 80 MHZ AND 800 MHZ, THE SEPARATION DISTANCE FOR THE HIGHER FREQUENCY RANGE APPLIES.			
NOTE 2: THESE GUIDELINES MAY NOT APPLY IN ALL SITUATIONS. ELECTROMAGNETIC PROPAGATION IS AFFECTED BY ABSORPTION AND REFLECTION FROM STRUCTURES, OBJECTS, AND PEOPLE.			

Indications for Use

Indications for Use

Ophthalmic Applications of the Pascal Photocoagulator

Pascal is used to treat ocular diseases in both the posterior and anterior chambers of the eye. Pascal is particularly well suited for treating the eye because it has minimal effect on transparent tissues and materials. This means that Pascal can be efficiently delivered to opaque structures of the eye through the transparent cornea, aqueous humor, lens, and vitreous humor. This allows many conditions to be treated by non-invasive techniques.

Laser energy is delivered to opaque structures within the eye by means of a slit lamp that has been specially adapted for use as a laser delivery system.

The delivery system includes a lens system to focus the laser energy and vary the size of the laser spot in the plane of observation of the slit lamp. It includes a mechanism to manipulate the position of the laser beam without moving the slit lamp. Laser energy is delivered to the slit lamp by means of a flexible fiber optic.

For most procedures, a laser contact lens is used to direct laser energy to the part of the eye being treated. The contact lens may have mirrors so that laser energy can be delivered to areas of the retina behind the iris, or into the angle so that the Trabecular meshwork can be treated. The contact lens also helps to hold the eye open and still so that laser energy can be delivered effectively.

Pascal may be used for procedures performed in a hospital or in a physician's office, for in-patient or out-patient procedures. The use of Pascal is not a contributing factor in deciding whether a procedure is done on an in- or an out-patient basis.

Posterior Segment Laser Procedures

CAUTIONS

Users should be aware of general laser warning, precautions, and adverse effects listed in "General Information" in this chapter.

Please see "Ophthalmology References" in this chapter for literature regarding the use of Pascal in retinal laser procedures.

Indications for use

Pascal is indicated for posterior chamber procedures involving the retina.

Retinal photocoagulation, pan retinal, focal and macular grid photocoagulation for vascular and structural abnormalities of the retina and choroids, including:

- proliferative and non-proliferative diabetic retinopathy
- choroidal neovascularization
- branch and central retinal vein occlusion
- age-related macular degeneration
- lattice degeneration
- retinal tears and detachments

In addition, Pascal can be used to perform:

- Iridotomy
- Iridectomy
- trabeculoplasty in angle closure and open angle glaucoma

Adverse effects and complications

WARNINGS

The most common complication of panretinal photocoagulation is increased macular edema usually with a concurrent decrease in visual acuity. In addition, blowout hemorrhages from the areas of neovascularization, particularly on the optic nerve have been observed, and may be caused by an increase in peripheral resistance secondary to photocoagulation, or by an inadvertent Valsalva maneuver by the patient.

Only a contact lens specifically designed for use with laser energy should be used. Use of a standard diagnostic contact lens will result in a power loss due to reflection from the surface of the lens. The reflected energy may pose a hazard to both the patient and the physician.

PRECAUTIONS

Following photocoagulation, patients should be cautioned against any activity that could increase the venous pressure in the head, neck, or eyes, such as straining, lifting, or holding their breath. Patients should be advised to sleep with the head of their bed elevated 15 degrees to 20 degrees.

Patients should be cautioned against stifling a sneeze, because this raises the blood pressure within the eyes to a high level. Vigorous nose blowing should also be discouraged. Rubbing the eyes following photocoagulation may disrupt blood vessels inside the eyes. Sneezing and coughing should be controlled with cough syrup or other medications.

Immediately following treatment, patients should avoid altitudes over 2500 M (~8000 ft).

Anterior Segment Laser Procedures

Users should be aware of general laser warnings, precautions, and adverse events listed in this chapter.

Indications for use

Iridotomy, iridectomy and trabeculoplasty in angle closure and open angle glaucoma.

Contraindications

The following conditions are contraindications for performing laser trabeculoplasty:

- Aphakic eye with vitreous in the anterior chamber
- Neovascular glaucoma
- Glaucoma caused by congenital abnormalities of the angle
- Less than 90° of open angle or extensive low-lying peripheral anterior synechiae present circumferentially around the angle
- Significant corneal edema or a diminished aqueous clarity obscuring visualization of the angle detail
- Glaucoma secondary to active uveitis

⚠ WARNINGS

Intraocular pressure should be closely monitored following laser iridotomy or trabeculoplasty.

Hemorrhage from the Trabecular Meshwork occasionally occurs as an ooze of blood from Schlemm's canal to the site of laser impact. This is easily stopped by increasing the pressure on the gonio lens on the cornea or by coagulating the bleeding site by application of a laser burn.

Pupillary distortion may be encountered if the iris root or peripheral iris has been treated. This distortion may or may not be permanent, depending on the severity of the accidental damage.

PRECAUTIONS

Intraocular pressure elevations have been reported to occur in up to 53% of eyes when 360° of the Trabecular Meshwork has been treated with 100 spots at the initial session. Intraocular pressure rises occur most frequently from 1 to 2 hours following laser treatment, although they may occur several hours afterward. For this reason it is imperative to monitor patient intraocular pressure after laser treatment for up to 24 hours.

Peripheral anterior synechiae may occur when the posterior portion of the Trabecular Meshwork or other structures posterior to the meshwork are treated. These are best avoided by meticulous delivery of a well-focused laser beam.

Transient corneal epithelial burns have reportedly been resolved within 1 week without scarring. Endothelial burns are rarely encountered when careful focusing is employed.

Rarely, severe iritis may occur, related to either an unusual patient response or improper spot location.

Ophthalmology References

1. The Diabetic Retinopathy Study Research Group. Photocoagulation Treatment of Proliferative Diabetic Retinopathy Clinical application of diabetic retinopathy-study (DRS) findings, DRS report number 8. Ophthalmology 1981; 88:583-600.

2. Quigley HA. Long Term Follow-up of Laser Iridotomy. Ophthalmology 1981;88:218-114

3. Fleischman JA, Swartz MA, Dixon JA. Krypton Laser Endophotocoagulation An Intraoperative Trans-Pars Plana Technique Archives of Ophthalmology, 99: 1610-1612, 1981

4. Ritch R, Podos SM. Krypton Laser Treatment of Angle Closure Glaucoma Perspectives in Ophthalmology Vol.4, No.4, June, 1980

5. Schwartz AL, et al. AL. Krypton Laser Trabecular Surgery in Uncontrolled Phakic Open Angle Glaucoma Ophthalmology Vol.88 No.3, March 1981.

6. Ophthalmic Laser Therapy Posterior Segment Laser Section Current Techniques Proliferative Diabetic Retinopathy. Edited by Michael J.Bradbury, Vol.1,No.2, 121-129

7. L'Esperance FA, Ophthalmic Lasers Third Edition Photocoagulation of Ocular Disease: Application and Technique. (1988)

8. Kurata F, et al. Intraocular pressure the day of Krypton Laser Trabeculoplasty in Primary Open-angle Glaucoma Ophthalmology 89:338, 1980

9. Thomas JV, Simmons R, and Belcher CD III. Complications of Krypton Laser Trabeculoplasty Glaucoma 4:50, 1982

10. Wise JB, Errors in Laser Spot Size in Laser Trabeculoplasty Ophthalmology, 91:186, 1984

11. Kanski JJ, Clinical Ophthalmology, Second Edition. Butterworths, 1989

Warranty and Decontamination Information

Warranty Information

OPTIMEDICA warrants the Pascal Photocoagulator to be free from defects in material and workmanship, at the original purchaser's location for 12 months.

In order to comply with this warranty, all internal adjustments or modifications must be made by an OPTIMEDICA-certified field engineer or with the express permission of the OPTIMEDICA Service Department. The warranty does not apply in the event of misuse, negligence or accidental damage.

The liability of OPTIMEDICA under valid warranty claims is limited to repair or replacement at OPTIMEDICA's plant or purchaser's place of business (or, if not practicable, a refund of the purchase price, all at the option of OPTIMEDICA).

There are certain other limitations that apply to OPTIMEDICA's warranty. Reference should be made to the terms and conditions of sale attached to OPTIMEDICA's invoice included with each product.

Warranty Shipments, Returns, and Adjustments

A warranty claim must be made promptly and must be received during the applicable warranty period by OPTIMEDICA. If it becomes necessary to return a product for repair and/or adjustments, authorization from OPTIMEDICA must be obtained. Instructions as to how and where products should be shipped will be provided by OPTIMEDICA. Any product or component returned for examination and/or warranty repair shall be sent insured and prepaid via the means of transportation specified by OPTIMEDICA. Shipping charges for all products or components replaced or repaired under warranty shall be the sole responsibility of the purchaser. In all cases, OPTIMEDICA has sole responsibility for determining the cause and nature of failure, and OPTIMEDICA's determination with regard thereto will be final.

The foregoing Warranty is exclusive and in lieu of all other warranties, whether written, oral, or implied, and shall be the purchaser's sole remedy and OPTIMEDICA's sole liability on contract or warranty or otherwise for the product. OPTIMEDICA disclaims any implied warranty or merchantability or fitness for a particular purpose. In no event shall OPTIMEDICA be liable for any incidental or consequential damages arising out of or in connection with the use or performance of the goods delivered hereunder. The essential purpose of this provision is to limit OPTIMEDICA's potential liability arising out of this sale.

Decontamination of Returned Equipment

To comply with United States postal and transportation law, equipment shipped to OPTIMEDICA Corp. for repair or return must be properly decontaminated with a chemical germicide that is commercially available and cleared for sale as a Hospital Disinfectant. To ensure that all equipment has been properly decontaminated, a signed Decontamination Certificate (provided in this section) must be enclosed in the package.

If equipment is received without a Decontamination Certificate, OPTIMEDICA will assume the product is contaminated and will assess the customer with decontamination costs.

Any inquiries should be directed to the OPTIMEDICA Service Department. These include service of a device, assistance with troubleshooting the device, and ordering accessories.

Service Information

OPTIMEDICA Corporation
3130 Coronado Drive
Santa Clara, California 95054
USA
Phone: +1 (408) 850-8600
Fax: +1 (408) 850-8595
Service@Optimedica.com

DECONTAMINATION CERTIFICATION

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 OPTIMEDICA EQUIPMENT BEING RETURNED HEREIN BY

_____ _____

INDIVIDUAL / INSTITUTION CITY, STATE/PROVINCE, COUNTRY

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 – HUMAN OR ANIMAL BLOOD, TISSUE, OR TISSUE FLUIDS, OR COMPONENTS THEREOF.

THE UNDERSIGNED ALSO AGREES TO REIMBURSE OPTIMEDICA FOR ANY COSTS INCURRED IN DECONTAMINATING THE ENCLOSED EQUIPMENT, IN THE EVENT SAID ITEM IS RECEIVED BY OPTIMEDICA IN A CONTAMINATED CONDITION.

MODEL: PASCAL® PHOTOCOAGULATOR

SERIAL NUMBER: _____

OPTIMEDICA
RMA NUMBER: _____

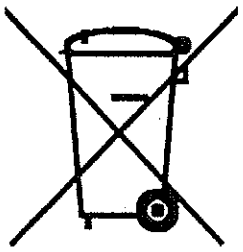
POSITION/TITLE: _____

NAME (PRINTED): _____

SIGNATURE: _____

DATE(MM/DD/YY): _____

END OF LIFE DISPOSAL – ENVIRONMENTAL INFORMATION



WEEE ANNEX IV Symbol

THERE ARE NO DISPOSABLE OR WASTE PRODUCTS USED WITH THE PASCAL SYSTEM. THE PASCAL MUST BE DISPOSED OF ACCORDING TO LOCAL LAWS AND HOSPITAL PRACTICES. THIS PRODUCT IS CONSIDERED ELECTRONIC EQUIPMENT AND MUST NOT BE DISPOSED OF AS UNSORTED MUNICIPAL WASTE AND MUST BE COLLECTED SEPARATELY. PLEASE CONTACT THE MANUFACTURER OR OTHER AUTHORIZED DISPOSAL COMPANY TO DECOMMISSION YOUR EQUIPMENT.