PHILIPS

Laser System

Operator’s manual

Contents

Notice

The Philips Laser System contains no user serviceable parts or assemblies.

Service of the Philips Laser System must be performed only by a Philips certified field service engineer in order to avoid risks to individuals, customers and/or patients. Service of the Philips Laser System requires special tools, equipment and/or gases, some of which may not be commercially available, or may only be available to or from Koninklijke Philips N.V.

Philips assumes no responsibility or liability for any service provided by non-certified representatives. Service performed by anyone other than a Philips certified field service engineer voids all warranties (if any) to the System and/or the disposable laser catheter delivery device.

Philips reserves the rights to refuse to sell products or services to any customer not in compliance with manufacturers recommended service requirements.

Limited warranty

Notice: Manufacturer's Specifications and Policies Subject to Change. Philips reserves the right to make changes to the products described in this manual in order to improve design or performance. Reproduction or distribution of any portion of this manual without the prior written consent of Philips is prohibited.

Subject to the conditions and limitations on liability stated herein, Philips ("Philips") warrants that the Philips Laser System (the "System") as so delivered, shall materially conform to Philips's then current specifications for the System, for a period of one year from the date of delivery. **Any liability of Philips with respect to the System or the performance thereof under any warranty, negligence, strict liability or other theory will be limited exclusively to system repair, replacement or, if replacement is inadequate as a remedy or, in the opinion of Philips, impractical, to refund of the price paid for the System. Except for the foregoing, The System is provided "as is" without warranty of any kind, express or implied, including without limitation, any warranty of fitness, merchantability, fitness for a particular purpose or non-infringement. Further, Philips does not warrant, guarantee, or make any representations regarding the use, or the results of the use, of the System or written materials in terms of correctness, accuracy, reliability, or otherwise.** Buyer understands that Philips is not responsible for and will have no liability for any items or any services provided by any persons other than Philips certified service personnel. Philips shall have no liability for delays or failures beyond its reasonable control.

Additionally, this warranty does not apply if:

1. The System is operated in other than a manner prescribed by Philips in the Operator's Manual, and/or supplements.
2. The System is operated in a manner that is not in conformance with purchase specifications and specifications contained in the Operator's Manual, and/or supplements.
3. The System is not maintained in accordance with procedures in the Operator's Manual, and/or supplements.
4. The System is repaired, altered, or modified in any way by other than Philips authorized personnel, or without Philips authorization.

Contact Philips field service for instructions and issuance of a return material authorization if claims under this warranty become necessary and if the System or components of the System are to be returned. The System or components will not be accepted for warranty purposes unless the return has been authorized by Philips. System parts or components repaired or replaced under warranty bear the same warranty expiration date as the original equipment, or 90 days, whichever is longer. Consumable parts (data disks, batteries, among others) are warranted only against defects in materials and workmanship. System parts purchased outside the original warranty period are warranted for a period of 90 days, subject to all of the restrictions contained in this Limited Warranty. Use of unauthorized replacement parts may void the warranty. In all cases, Philips will be the sole judge as to what constitutes warrantable damage.

In no event will Philips be liable for any indirect, special, incidental, punitive, or consequential damages, including, but not limited to, loss of profits and/or loss of business, arising out of or resulting from use of the Laser or its failure to meet the terms of this warranty, even if Philips has been advised of the possibility of such damages.

This limited warranty covers only the System. Information on Philips' warranty relating to disposable items used with the System can be found in the documentation relating to those products.

Warnings and responsibility

Important

Read the Operator's manual thoroughly before operating the System. Pay particular attention to the **notes, cautions**, and **warnings** throughout this manual to ensure safe operating conditions at all times. Also, refer to the **Instructions for use,** which accompanies Philips fiber-optic catheters. Indications and contraindications are included in individual instructions for use for the fiber-optic catheters

Warning

The System contains a Class IV laser that produces an invisible beam of high-energy ultraviolet radiation. Improper use of the System could result in serious personal injury. Observe all safety precautions for use of Class IV laser equipment.

Warning

The System contains high voltages, which are potentially lethal. To avoid electrical shock, do not open the System cabinet. Internal maintenance must be performed solely by a Philips certified field service engineer.

Warning

System is not intended to be used during a defibrillation event.

Danger

Possible explosion hazard if used in the presence of flammable anesthetics.

Warning

Skin exposure to excimer radiation should be avoided.

Warning

Move the System carefully, and avoid jarring or sudden impacts. Disconnect and store the footswitch and power cable before moving the System. Do not run over cables with the System. Depress the brake levers on the rear wheels to lock the Philips Laser System once the System is positioned for use. Lift up on the brake levers to release wheels. Lift up on the brake levers to allow for lateral movement.

Caution

Use of the System or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Warning

Use only fibers and catheters approved by Philips with the System. The Philips laser fiber-optic catheters are supplied sterile. Sterility is guaranteed only if the package is unopened and undamaged.

Warning

Use care when handling the fiber-optic catheter to ensure the distal or proximal fibers are not chipped or scratched.

Notice

The System is intended for use only by licensed physicians. All persons who operate and service this equipment must be properly trained.

Caution

The System is designed for continuous operation with intermittent loading. The System will provide a warning if internal temperatures get too high. Reduce the usage of the System if this occurs. If the System's internal temperature continues to increase, the System will fault. The System will recover once internal temperatures reduce to normal levels.

Notice

The System contains a gas mixture that is 0.05% HCl, a respiratory irritant. To avoid injury, only a trained and certified Philips field service engineer should handle the laser gas.

Caution

Federal law restricts this device to the sale or on the order of a physician.

Responsibility

Philips is not responsible for injury or damage resulting from improper use of the System. If there is any doubt concerning the use of the System, or the Operator's manual, contact Philips immediately for assistance.

Reporting of a serious incident, customer complaints and feedback

If a serious incident (death or any intervention) has occurred and the device was in use at any time, it should be reported to the manufacturer and/or the competent authority of the member state in which the user and/or patient is established. A serious incident means any incident that directly or indirectly led, might have led, or in case of recurrence, could lead to any of the following:

- Intervention to prevent a serious injury,
- The death of a patient, user or other person,
- The temporary or permanent deterioration of a patient's, user's, fetus or other person's state of health,
- A serious public health threat.

Any complaints against the devices that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a conformance to a specification of a Philips medical device, should be reported to the post market department at SPNC-ComplaintsDL@philips.com.

Any other device feedback can be reported to the post market department at SPNC-ComplaintsDL@philips.com.

Customer understands that the **equipment** is manufactured with substances that are considered hazardous to the environment and cannot be disposed of directly. In the unlikely event, that **customer** wishes to remove the **equipment** from service; they may elect to return the System (at their expense) to Philips. Once the **equipment** is received, Philips will bear the cost of properly disposing of and/or recycling the raw components according to law.

Overview

Introduction

The System is an Excimer laser system used in minimally invasive interventional procedures within the cardiovascular system, and for the removal of problematic pacemaker and defibrillator cardiac leads. The System produces pulsed excimer radiation, which is delivered to the target site with proprietary fiber-optic catheter technology, or other approved instruments or accessories, to complete the system. This photoablation is enabled by a light pulse, sonic wave and vapor cavitation bubble expansion and contraction.

Indications for use

Refer to the Instructions for Use that accompanies the Philips fiber-optic catheters. Indications are included in individual instructions for use for the fiber-optic catheters.

Contraindications

Refer to the Instructions for use that accompanies the Philips fiber-optic catheters. Contraindications are included in individual instructions for use for the fiber-optic catheters.

System description

Specifications

The System is a pulsed Excimer laser with the following nominal specifications:

Active medium	XeCl
Wavelength	308 nm
Catheter output fluence*	30 - 80 mJ/mm^2
Repetition rate range*	25 - 80 Hz
Pulse width	125-200 ns, FWHM**
Weight	480 lbs / 217 kg
Length	52 in / 132 cm
Height	42 in / 107 cm - unit 7-9 in / 18-23 cm - control panel
Width	19 in / 48 cm (all dimensions approximate)
Power requirements	100 – 240 V ~ - single phase 50/60 Hz 16 Amp
IPX rating	Footswitch: IPX8

*** Dependent on fiber-optic catheter in use; see the Instructions for use documentation supplied with each fiber-optic catheter for specific information.**

**** FWHM: Full width half max**

The System should be operated and stored within the following Environmental Conditions

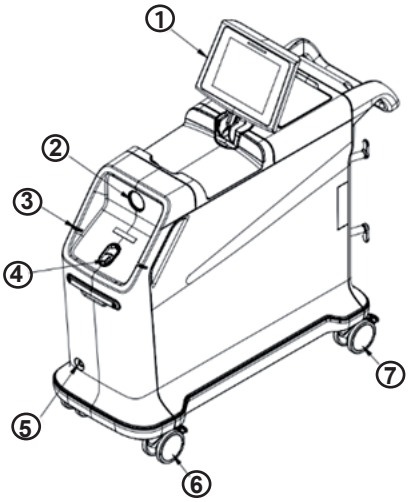
- Operating temperature: 12 °C to 30 °C (54 °F to 86 °F)
- Storage temperature: 0 °C to 50 °C (32 °F to 122 °F)
- Operating humidity: 20 to 80% relative humidity, non-condensing
- Storage humidity: 5 to 60% relative humidity, non-condensing

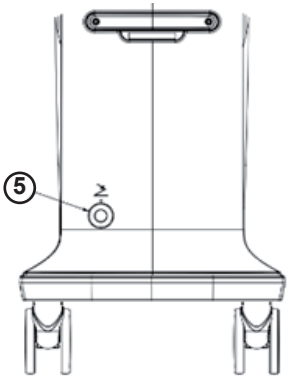
Avoid exposing the System to temperatures and humidity levels beyond the specified ranges. If the System is exposed to conditions outside of the listed ranges, a service visit may be required prior to returning the System to use.

System components

Component diagram

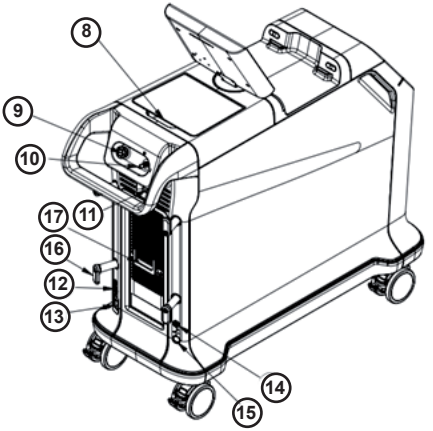
1. Control panel
2. Energy detector
3. Catheter retainer
4. Catheter connector
5. Front footswitch connector
6. Front directional locking casters
7. Rear total locking casters

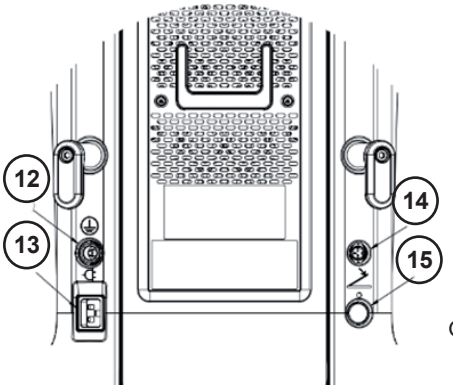




Detailed view of
connections (Front)

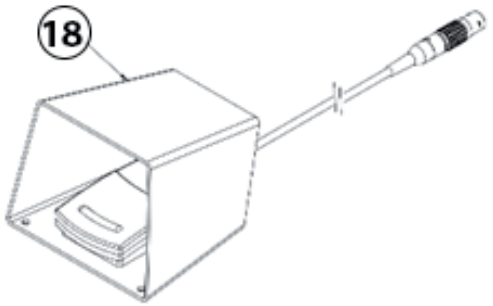
8. Storage compartment
9. Emergency stop button
10. Keyswitch (Power switch)
11. Main circuit breaker
12. Potential equalization (PE)
    (Optional PE cable provided based on destination country)
13. Power connector
14. Interlock plug
15. Rear footswitch connector
16. Cable management wraps
17. Footswitch storage bracket





Detailed View of Connections (Rear)

18. Footswitch



Component descriptions

1. Control panel

The System has a stowable control panel. To use, lift the control panel from the stowed position. The control panel may be positioned (rotation and elevation) to see the information displayed. Return the panel to the stowed position when done by positioning the face of the screen to the front of the unit, then lowering to stow.

2. Energy detector

The Energy Detector is located above the catheter connector. The Energy Detector is used to calibrate fiber-optic catheters prior to use.

3. Catheter retainer

A catheter retainer is provided to hold the catheter out of the way of the energy detector to ensure sterility during calibration.

4. Catheter connector

The catheter connector is the location where the fiber-optic catheters are inserted. Slide open the cover (if necessary), and fully seat the catheter within the device.

5. Front footswitch connector

Footswitch connectors are provided in the front, and the rear, of the device. Align the red dot on the System with the red dot on the cable connector to insert. If there is no footswitch plugged in, the System will advise the user to insert one. In the event that there are two footswitches plugged in the System will advise the user to remove one.

6. Front directional locking casters

The front casters provide the option to lock (prevent turning) or unlock (allow for lateral movement). Lock the front casters when moving the System from room to room. Un-lock the casters once the System is close to the desired position to allow for fine positioning of the System.

7. Rear total locking casters

The rear casters lock the System in place. Prior to moving the System unlock the rear casters. Once the System is in place, lock the rear casters to ensure the System does not move.

8. Storage compartment

The storage compartment located on the top of the System can store laser safety glasses, the operator's manual, etc. Storage for the footswitch and the power cable is provided on the rear of the System.

9. Emergency stop button

In an emergency, the emergency stop button should be depressed. Depressing the button will de-energize the System and beep until the button has been rotated to release.

10. Key/keyswitch (power switch)

The key turns the System on and off. If the System loses power, the key needs to be cycled (turned off, then back on) in order to restore power.

11. Main circuit breaker

The main circuit breaker is provided in case of a system overload. The circuit breaker should remain in the "ON (I)" position.

12. Potential equalization (PE)

Optional PE cable provided based on destination country. Cord may connect the System to a grounding location.

13. Power connector

The power cord connects to the power connector. The cord has a locking feature (pull the red switches on the connector housing) to release.

14. Interlock plug

Optional, plug provided to make a cable based on facility needs. Removal of the interlock plug will disable laser output. When in use, connect the door interlock plug into the interlock socket.

15. Rear footswitch connector

Footswitch connectors are provided in the front and the rear of the device. Align the red dot on the System with the red dot on the cable connector to insert. If there is no footswitch plugged in, the System will advise the user to insert one. In the event that there are two footswitches plugged in, the System will advise the user to remove one.

16. Cable management wraps

The cables for the power cord (left side cable wraps) and the footswitch (right side cable wraps) should be wound around the cable wraps when the System is not in use.

17. Footswitch storage bracket

Slide the footswitch over the storage bracket hook when the System is not in use.

18. Footswitch (IPX8 rated)

The footswitch is provided to operate laser output from the System. The laser will generate light when the footswitch is depressed while the device is in Ready mode. Release the footswitch to stop lasing.

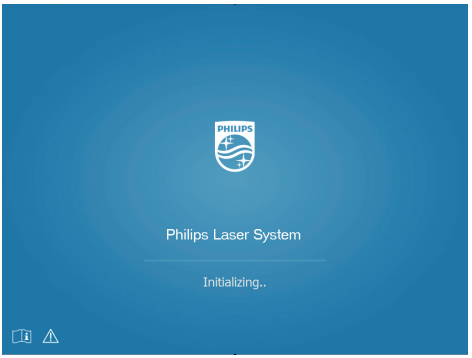
System workflow and control

Setup

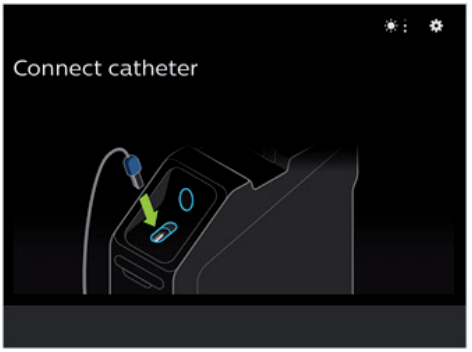
1. Position the System in the desired location. The front wheels can be unlocked to allow lateral movement for final positioning. Lock rear wheels once in desired location.
2. Remove the footswitch from the rear storage location. Connect the footswitch plug into the receptacle located on the front or rear panel.
    - Connection points provided in the front and rear of the System. To insert, align the red dot on the connector to the red dot on the System.
    - Only one footswitch may be plugged in at a time.
3. Connect the end of the power cord into the receptacle located on the rear of the System. Ensure power cord is fully seated into the power receptacle. Insert the other end of the power cord into a wall receptacle with the proper output voltage.
4. Insert the key in the keyswitch on the rear panel. Turn the keyswitch clockwise to activate the System.
5. When the System is activated, it enters **Testing** mode.
6. Inspect the energy detector. If it is dirty, clean the surface of the energy detector with an alcohol prep before and after each use.
7. Once the System is powered on, follow the guidance provided on the screen.

Screen guided workflow

Initialization screen



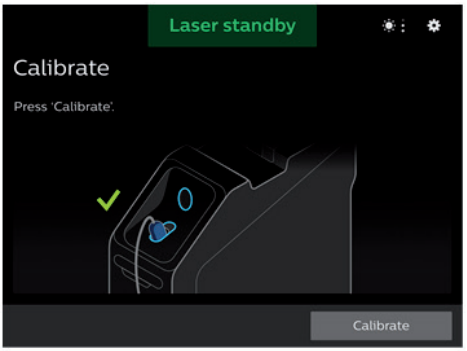
Once initialization completes, the System will present the following screen prompt.



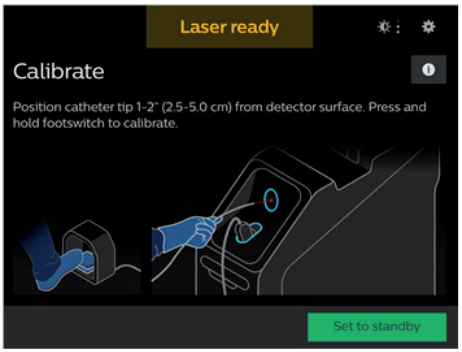
Insert the desired catheter for the procedure.

*Note: Use the provided catheter retaining-feature to hold catheter away from the detector during calibration to provide more clearance from the sterile area.

To **calibrate** the catheter, select the **calibrate** button on the screen.



Once the **calibrate** button is pressed, the System enters **ready** mode. The System will lase only when the footswitch is pressed while in **ready** mode.



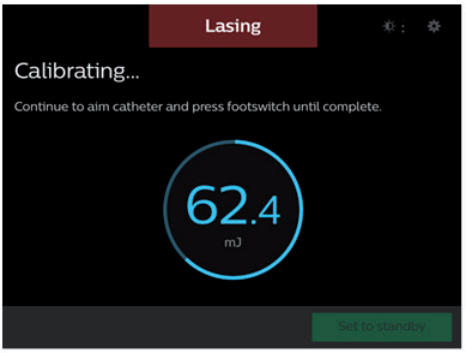
Note: To enter into **standby** mode press "**Set to standby**". This will disable the footswitch. To continue with calibration press "**Set to ready**".

Follow the instruction on the screen.

Point the distal tip of the fiber-optic catheter directly at the center of the energy detector. Ensure that the catheter is no less than one inch (2.5 cm) and no more than two inches (5 cm) away from the front surface. Then depress the footswitch until calibration is complete. This will take approximately 5 seconds. The end of the catheter will illuminate with a red light to aid in aiming the catheter. Wear laser safety glasses while calibrating the catheter.

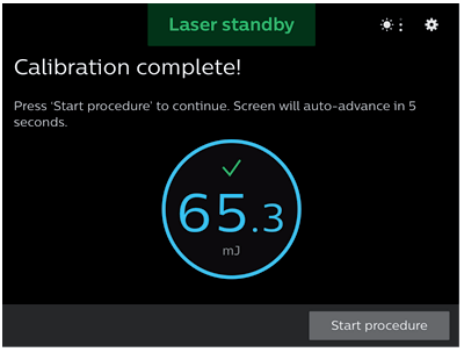
Warning: **System may not pass calibration if the catheter is not perpendicular to and/or at the proper distance (one inch (2.5 cm) and no more than two inches (5 cm) from the detector surface during calibration).**

While calibrating, the System will display its progress. The circular progress bar will fill as calibration progresses. Energy readings will be displayed during the process.



Once calibration is complete, the System will display the following screen.

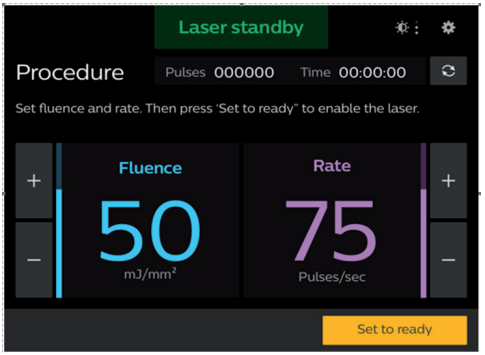
Note: The System will auto advance to the procedure screen in 5 seconds. This may be bypassed by pressing “Start procedure” button.



The calibration energy is displayed to compare the calibration energy reading with the energy range for the fiber-optic catheter selected. (See catheter package for appropriate ranges.)

Note: If the calibration energy at the end of the calibration step was not read, or if an energy reading is desired at any other time during the operation of the System, check the energy out of the fiber-optic catheter by selecting the **Ready** mode, tapping the **Read energy** button, aiming the distal tip of the fiber-optic catheter at the energy detector, and depressing the footswitch.

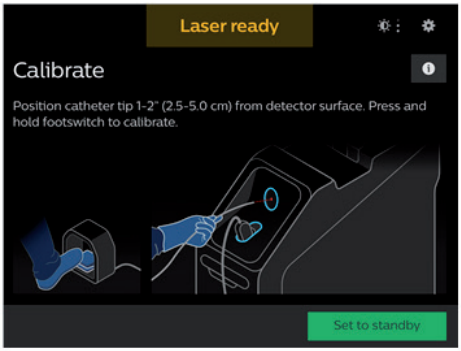
Procedure screen



Fluence: The **Fluence (+ and -)** buttons adjust the output energy (in increments of 5). The fluence value is increased or decreased by pressing the appropriate **Fluence (+ and -)** button. The current fluence value is visible in the display window in **mJ/mm²**.

Rate: The **Rate (+ and -)** buttons adjust the pulse repetition rate (in increments of 5). The rate is increased or decreased by pressing the appropriate **Rate (+ and -)** button. The repetition rate is visible in the display window in **Pulses/Second**. A brief press of either the increase or decrease **Rate** button while in other operating modes shows the current repetition rate. Pressing either the increase or decrease, **Rate** button for one second or longer changes the repetition rate accordingly.

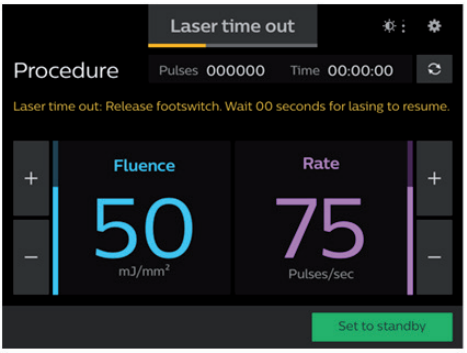
Ready: Pressing the "Set to ready" button places the System in **Ready** mode. If the System has not been calibrated, the **Ready** button is not active.



Lasing: While in **Ready** mode, the footswitch will be active. Once the catheter is in the desired location, depress the footswitch to activate the laser.

Catheter timeout: If a catheter is inserted that has a timeout (coronary or lead removal fiber-catheters), the System will provide a visual display of the remaining time left in the timeout. Once the timeout is complete, the System will provide audible feedback to notify the user.

Note: The foot pedal will need to be released prior to re-starting lasing.

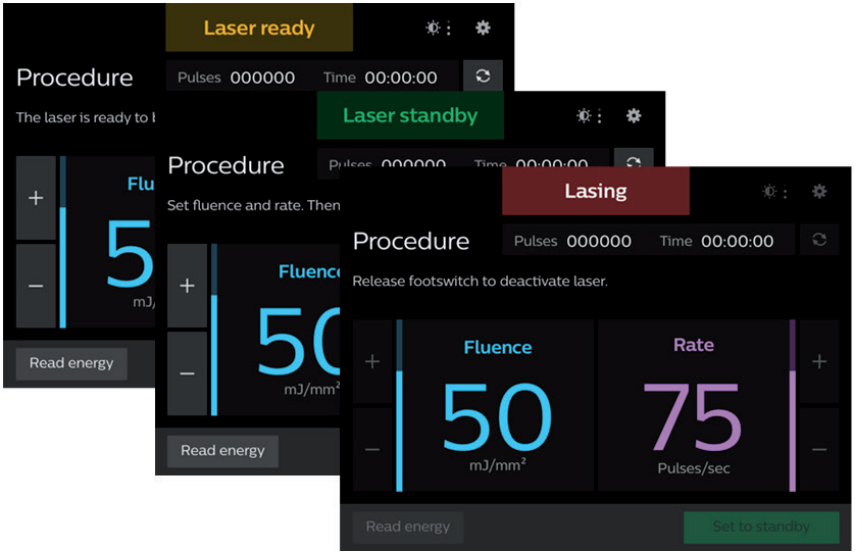


Pulses: The total number of pulses during a procedure is visible on the display.

Reset: The **Reset** button is used to reset **Pulses** delivered and treatment **Time**. The reset button is located to the right of the Time display.

Time: Displays the total lasing time of the procedure to be visible in the display window.

Screen advisory, indicator and status information



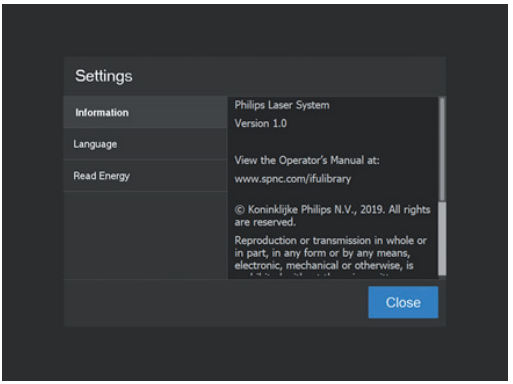
Green when in **Standby** mode

Yellow when in **Ready** mode

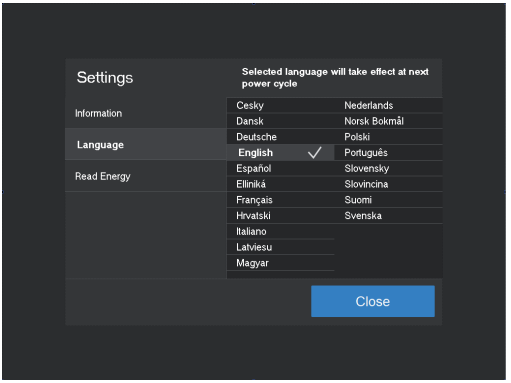
Red when the System is **Lasing**

Screen brightness adjustment
The screen's brightness can be adjusted to one of three present brightness levels, as indicated by the dots next to the brightness adjustment.

Settings
Settings provides information about the System, allows the user to change language, and turns on the Read energy function.

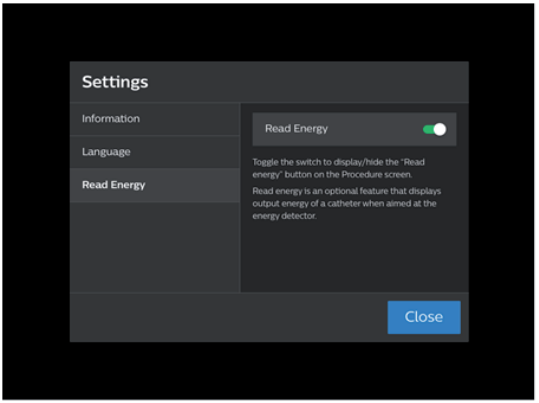


Language Selection:



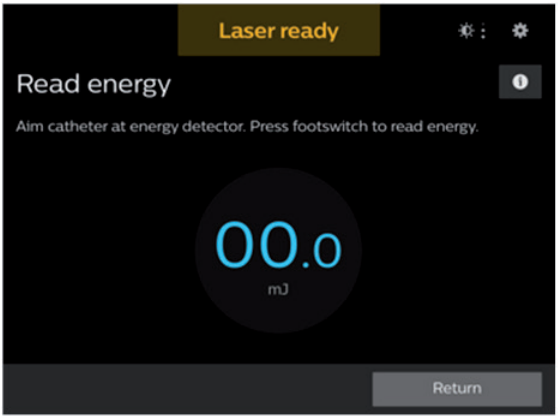
To change the language settings scroll through the options, select the desired language. Selected language will take effect at next power cycle. **Note:** if there is a catheter inserted it will need to be recalibrated after power cycle.

Read energy:



Read energy mode can be used to test the energy exiting the catheter connected to the Philips Laser System.

The **Read energy** button can be enabled in the settings screen. By default the **Read energy** button is not displayed, and will need to be re-enabled after each power cycle. When enabled, tapping the **Read energy** button enables the fiber output energy read by the calibration energy detector to be visible in the display window. The **Read energy** button will be displayed on the procedure screens.



Power down

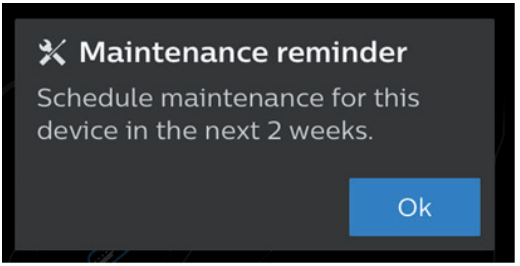
1. Press “Set to standby” button.
2. Turn the keyswitch to the OFF (◯) position.
3. Disconnect the power cord from the wall receptacle and store on the cord wraps in the rear of the System.
4. Disconnect and store the Footswitch and store on the cord wraps in the rear of the System.
5. Close the catheter connector door.
6. Clean detector face with alcohol prep.
7. Remove the key to protect from unqualified use.
8. Return to storage location and lock the rear wheels.

Error codes

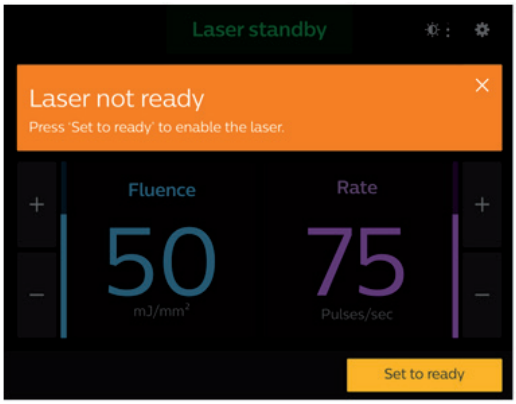
When a fault is detected by the System, a code number is displayed in the middle of the display window corresponding to the appropriate error. Refer to the Troubleshooting Section of this manual for code descriptions. Always record the fault code number and report it to Philips customer service.

System maintenance reminder:

The reminder appears when the System needs routine maintenance. Time indicated is approximate from the first time the message is displayed. Call customer service to schedule routine maintenance.

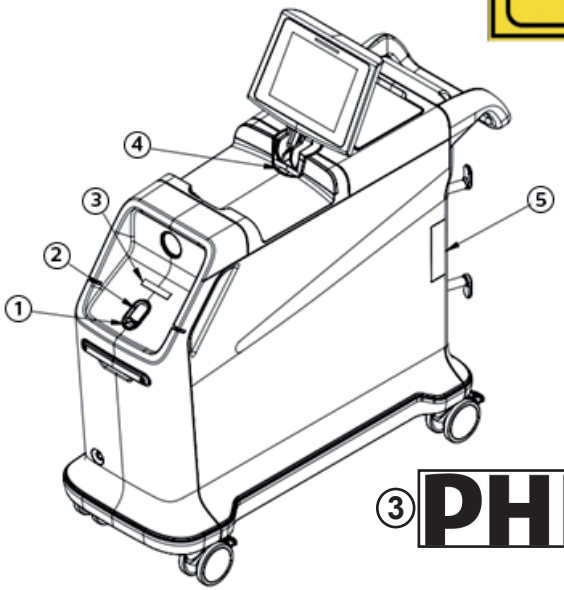


Alerts: Alerts appear to provide guidance to the user during workflow. Follow the instructions displayed on the screen to resolve alert.



Errors: Error screens appear when there is a fault with the System. Follow the instructions provided.

System labeling



1

2

LASER APERTURE
INVISIBLE RADIATION
EMITTED AT END
OF CATHETER

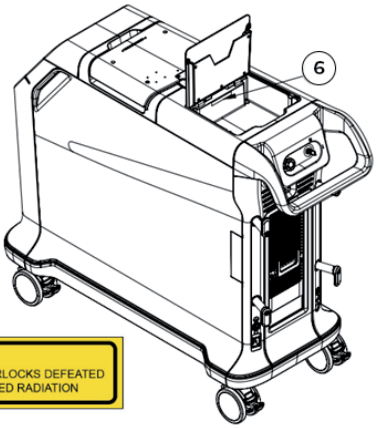
CAUTION
DIRT AND LIQUIDS
MAY DAMAGE OPTICAL
SYSTEM. KEEP FREE
OF CONTAMINATION

3 PHILIPS

5 Laser System

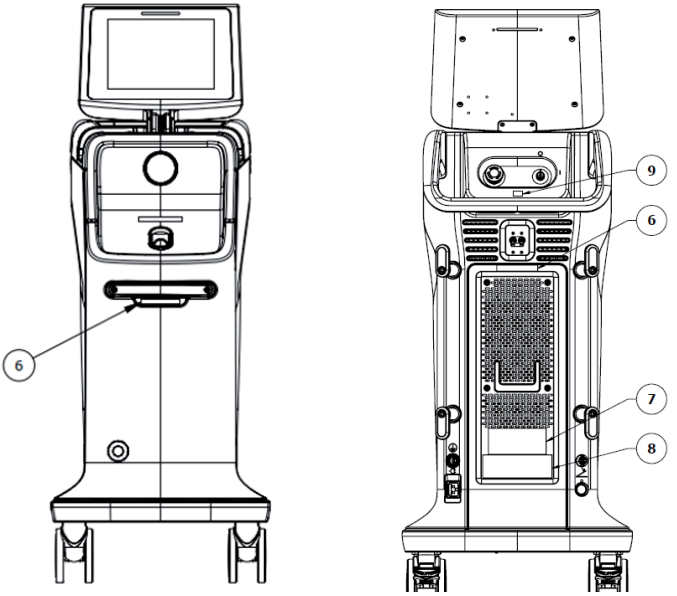
4

PHILIPS
Customer Service - Sales
- Field Service
1-800-231-0978



6

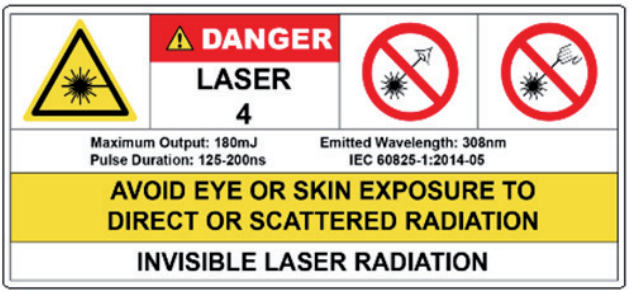
DANGER
CLASS 4 INVISIBLE LASER RADIATION WHEN OPEN AND INTERLOCKS DEFEATED
AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION



⑥

DANGER
CLASS 4 INVISIBLE LASER RADIATION WHEN OPEN AND INTERLOCKS DEFEATED
AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION

⑦



⑧

REF LAS-100
SN XXXXXXXX
YYYY-MM-DD

Philips Laser System
INTERMITTENT OPERATION
Duty cycle dependent upon device in use
100 - 240 VAC, 50/60HZ, 16 AMP

Complies with 21 CFR 1040.10 and 1040.11 except for conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1, as described in Laser Notice No. 56, dated May 8, 2019.

UDI
(01)00813132027452(11)000000(21)XXXXXXXX

Philips use

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9965 Federal Drive, Colorado Springs, CO 80921 USA
Tel: 1-800-231-0978 Fax: 719-447-2022
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EC REP Spectranetics International B.V.
Plesmanstraat 6 3833 LA Leusden, The Netherlands
Tel: +31 33 43 47 050 Fax: +31 33 43 47 051

CE 2797
50° c
0° c
60%
5%
MD

⑨

Safety precautions

1. The laser must be operated only by trained personnel.
2. Establish a controlled-access laser operating area to limit access to persons instructed in the safe operation of lasers.
3. Post "**Laser in operation**" warning signs at all entries to the laser operating area.
4. Persons in the laser operating area including doctors, nurses, observers and the patient must wear the appropriate protective eyewear and protective gloves. Protective eyewear of 5 or greater at a 308 nanometer (nm) wave-length must be worn during calibration, read energy, or any other time when laser light may be exposed. The laser safety glasses must state the OD rating and wavelength on the lens or on the side shields. Philips offers safety glasses that may be purchased by calling customer service. Sources of information about eye protection include Rockwell Laser Institute (rli.com) and Ultra-Violet Products (uvex.com).
5. Never look directly into the laser beam.
6. Avoid uncontrolled reflections of the laser beam.
7. Skin exposure to excimer laser radiation should be avoided.
8. Do not allow direct or reflected laser radiation to go beyond the laser operating area.
9. When not in use, the Philips Laser System should be protected against unauthorized use by removing the key.

Nominal ocular hazard distance (NOHD)

The nominal ocular hazard distance (NOHD) is defined by the American National Standard (ANSI) Z136.1 as the distance along the axis of the unobstructed beam from a laser, fiber end, or connector to the human eye beyond which the irradiance or radiant exposure is not expected to exceed the applicable maximum permissible exposure (MPE) limits.

All laser energy produced by the System, when operated in accordance with this manual, is enclosed within the System, the fiber-optic catheter or within the body except during the calibration of the catheter (refer to the laser System Operating Instructions and precautions in this manual).

During these short calibration periods, the energy output from the laser is not contained and the operator should be aware of the NOHD from the tip of the fiber. A 2.5 mm fiber-optic device emits the highest amount of energy during calibration.

The Fiber NOHD was calculated with the System in the normal operating mode during calibration utilizing the following values;

Exposure time	20 seconds
Energy at tip of catheter	76.5 mJ
Fiber tip diameter	2.5 mm
Repetition rate (calibration)	25 Hz
Numerical aperture of the fiber-optic	0.22
Wavelength	308 nM
Pulse width	135 nS
Repetitively pulsed	Yes

Using the ANSI Z136.1 standard, the fiber NOHD can be calculated as 1.35 meters (53.1 inches) from the distal tip of the 2.5 mm reference catheter device during calibration.

Always wear the appropriate laser safety glasses when using this equipment and follow all safety precautions as outlined within this manual.

EMC precautions

Special precautions are required regarding the electromagnetic compatibility (EMC) of the System. The laser needs to be installed and put into service according the EMC information provided in this manual.

Portable and mobile radio frequency (RF) communications equipment can affect any medical electrical equipment including the Philips Laser System.

Warning

Only cables and accessories provided by Philips may be used with the System. The use of any other cable or accessories may have an adverse effect on the electromagnetic capability of the System, such as increased emissions or decreased immunity.

Warning

The System should not be used adjacent to or stacked with other equipment. Should use adjacent to other equipment become necessary, the System should be observed to verify normal operation in that configuration.

Guidance and Manufacturer's declaration - Electromagnetic emissions		
The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The System 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 A	Class A equipment is equipment suitable for use in all locations other than those allocated in residential environments and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ flicker emissions IEC 61000-3-3	Complies	
Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.		

Guidance and Manufacturer's declaration - Electromagnetic immunity			
The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.			
Immunity test	**Test level**	**Compliance level**	**Electromagnetic environment- guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 2, 4, 8, 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients/Bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV 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. IEC 61000-4-11	0% UT; 0.5 Cycle At 0, 45, 90, 135, 180, 225, 270, and 315 0% UT; 1 Cycle70% UT; 25/30 Cycles Single phase: at 0 0% UT; 250/300 Cycle	100% dip for 0.5 cycles 100% dip for 1 cycles 30% dip for 25 cycles 100% dip for 5 seconds	Mains power quality should be that of a typical commercial of hospital environment. If the user of the System requires continued operation during power mains interruptions, it is recommended that the System be powered from an uninterruptible power supply or a battery.

Guidance and Manufacturer's declaration - Electromagnetic immunity			
The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.			
Immunity test	**Test level**	**Compliance level**	**Electromagnetic environment- guidance**
Rated power Frequency (50/60 Hz) magnetic fields IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's declaration - Electromagnetic immunity			
The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.			
Immunity test	**Test level**	**Compliance level**	**Electromagnetic environment- guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 150 kHz and 80 MHz 80% AM at 1kHz	3 Vrms 6 Vrms	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Philips Laser System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7GHz Proximity fields (see below table for proximity field characteristics)	3 V/m Proximity fields (see below table for proximity field characteristics) RF Wireless Communications, Table 9	

Guidance and Manufacturer's declaration - Electromagnetic immunity			
The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.			
Immunity test	**Test level**	**Compliance level**	**Electromagnetic environment- guidance**
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. Note 3: Common RF emitters that may cause electromagnetic disturbances include diathermy, lithotripsy, electrocautery, and RFID devices, and fixed transmitters such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast and TV broadcast. Electromagnetic disturbance from these and other RF emitters cannot be predicted with accuracy. To assess the electromagnetic environment of such devices, an electromagnetic site survey should be considered. If the measured field strength in the location in which the System is used exceeds the applicable RF compliance level above, the System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the System. Note 4: 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 System

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

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
0,01	0.12	0.12	0.23
0,1	0.37	0.37	0.74
1	1.2	1.2	2.0
10	3.7	3.7	7.4
100	12	12	12

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.

Adhering to the separation distances and other recommendations above will reduce disturbances. When intsalled and operated as specified herein, the System will maintain its essential performance as described below.

Essential performance of the Philips laser system

The essential performance of the System is specified below:

- The System must not deliver an inappropriate amount of energy.
- The System must not pose an electrical hazard to the patient or user.
- The System must not interfere with the operation of the other equipment.

Maintenance

Clean the face of the energy detector with an alcohol prep before and after each use. The System should be stored in a secure place, protected from freezing or extremely high temperatures, and draped with a protective cover when not in use. Never store the System in areas that may be below 32 °F (0 °C) or above 122°F (50°C). **Relative humidity must be between 5% and 60% non-condensing.** The same conditions should be observed when transporting the System.

When moving the System, avoid traversing large bumps or extremely rough surfaces. The System requires regular maintenance and calibration to ensure problem-free operation. Philips recommends that preventive maintenance be performed yearly at a minimum. Internal maintenance must be solely performed by a Philips certified field service engineer. Internally, the System contains no user serviceable parts. Product safety tests in the form of current leakage and ground testing should be performed by a Biomedical engineer according to generally recognized technical rules.

Only cables and power cords supplied by Philips should be used on the System. Use of alternate parts may affect EMC compliance.

Prior to use, the operator should perform the following checks on the System:

1. Visually inspect the System for damage of the laser covers.
2. Visually inspect the power cord to ensure connections on both ends are not damaged.
3. Visually inspect the power cord jacket to ensure the insulation is not damaged.
4. Visually inspect the ground connection to insure it is intact.
5. Clean the face of the energy detector with an alcohol prep.
6. Turn the System on and calibrate the laser with a Reference Catheter.

If any of the above do not pass visual inspection or the Reference Catheter does not calibrate, contact Philips prior to using the laser.

Caution

Warning

The System contains a Class IV laser that produces an invisible beam. Potentially lethal high voltages are present inside the System. The gas mixture utilized inside the laser contains 0.05% HCl, a respiratory irritant.

Warning

Failure to service the equipment properly may result in personal injury or death. Service should only be completed by a Philips certified field service engineer.

In the event that the laser has exceeded its useful life, contact Philips to return the laser or for information regarding disposal of the equipment. See Instructions for Use for each single-use device for disposal of the fiber-optic catheters.

Cleaning and disinfection

Clean and disinfect the external surfaces of the System after each use with Super Sani-Cloth® wipes or product with equivalent active ingredients and concentration*.

Cleaning:

Wipe the System with Super Sani-Cloth® wipes for 2 minutes to remove any visible soil, using additional wipes as needed. Special attention should be given to cracks, crevices, seams, and hard to reach areas. Dry the System by wiping with a clean, dry, lint-free cloth for 30 seconds.

Disinfection:

Using fresh Super Sani-Cloth® wipes, ensure the System stays wet for 2 minutes, using additional wipes as needed.

*If using and equivalent product, determine equivalency and follow the manufacturer's recommendations for use.

Accessories and replacement parts

Power cord, footswitch, interlock plug, safety glasses, potential equalization conductor, dust cover, and Philips approved fiber-optic catheters.

Verification of calibration

Philips energy detector circuit

The energy monitor on the System requires verification during routine maintenance to ensure that the laser radiation output is within specification. This procedure may be performed more frequently if desired. Always wear the appropriate laser safety glasses when using this equipment and follow the safety precautions as outlined within this manual.

Safety glasses specific to the System are available for purchase from Philips by calling our Customer service department.

Equipment required

- Laser safety glasses
- The System
- A commercially available National Institute of Standards and Technology (NIST) calibrated Joule Meter and Energy Detector rated at 308 nM, 120 nS, 0-100 mJ, and directions for use
- Philips reference catheter

This procedure requires that the System is operational and functions properly and that the operator has been trained by Philips on the proper use, safety and operation of the System. This procedure also requires that the operator has been trained on the use, safety and operation of the NIST calibrated Joule Meter.

Energy monitor verification procedure

1. Connect the power cord to the rear panel of the System. Ensure power cord is fully seated into the power receptacle. Insert the other end of the power cord into the appropriate receptacle with the proper output voltage.
2. Insert the key in the switch located on the rear panel and rotate it clockwise to turn the System ON (|). The System will energize and enter the self-test mode.
3. Remove the Footswitch from storage and connect it.
4. Allow the System to complete the warm-up period.
5. Insert the reference catheter's proximal end into the System connector. The appropriate calibration Fluence and Rate will automatically be displayed when the 2.5 mm reference catheter is inserted into the connector.
6. Ensure that all personnel in the room are wearing the appropriate laser safety glasses.
7. Aim the distal end of the reference catheter directly at the center and one to two inches away from the front surface of the energy detector on the front of the System.

8. Tap the calibrate button on the display.
9. Depress and hold the Footswitch down until the laser stops.
10. Record the energy reading in mJ shown on the display.
11. Once in Procedure screen, tap the “Set to ready” button on the display panel.
12. Aim the reference catheter directly at the center of the NIST Detector and Joule Meter.
13. Depress the footswitch and record the energy.
14. Compare the recorded energy value in step 10 with the recorded energy value in step 13.
15. The difference in the two recorded energy values should be less than 20% (CFR 21 1040.11 Section 1) when using the following equation

    (energy value in step 10 – energy value in step 13)

    / energy value in step 13
16. Notify the Philips customer service department immediately if the difference in the recorded energy values are greater than or equal to 20%.
17. Press the Standby button, turn the key switch to the OFF (◯) position, remove the key and store it in a safe place, disconnect the footswitch and store it in the front compartment, disconnect the power cord from the power source and the laser, close the catheter connector door, cover the System with the protective cover.

Troubleshooting

In case of emergency, the Philips Laser System can be powered down by depressing the **Emergency stop button** located on the back panel. Caution should be taken not to activate the **Emergency stop button** accidentally. To reactivate the System, rotate the Emergency stop button clockwise until it ascends and turn the keyswitch to the OFF (◯) position and then to the ON (|) position.

Keyswitch: The keyswitch is the power control for the System.

*The keyswitch will not turn ON (	) the System.*	• Ensure the Philips power cord is connected to the proper source. • Ensure the main circuit breaker, located on the lower back panel, is in the ON (	) position.
The buzzer sounds when Philips power cord is plugged in.	• Release the emergency stop button by turning it in a clockwise direction. • Power cycle the key
The Philips Laser System will not enter Calibrate mode.	• Allow the System time to complete the warm-up mode. • Insert a fiber-optic catheter into the coupler. • Plug in the footswitch.
The System does not complete calibration.	• **Depress and hold** the footswitch down until lasing stops.
*Keyswitch is ON (	) but the System will not come on after the emergency stop button has been reset.*	• Turn the keyswitch to the OFF (◯) position and then to the ON (	) position to reset the System.
Service warning indicator is shown on screen.	• Call Philips customer service to schedule a service.
A fault occurs during Warm-up or Calibration, the fault indicator is illuminated and a fault code number is shown in the middle of the display window.	• Refer to the Fault Code Table at the end of this section.
The laser gives an odor of HCl gas (like bleach).	• Place the laser in a well-ventilated, yet isolated room. Call Philips customer service to schedule an emergency service visit.

Troubleshooting: Fault codes

Philips exception ID	Exception type	Description	Try this
101	Alert	No energy detected at sensor	Position catheter tip 1-2" (2.5-5.0cm) from detector surface
102	Warning	Requested Fluence level unavailable	Lower the requested Fluence setting and try again. Contact customer service to schedule maintenance.
103	Error	Error 103: System Failure	Contact customer service if problem continues.
105	Error	Error 105: System Failure	Contact customer service for assistance.
106	Error	Error 106: System Failure	Contact customer service for assistance.
107	Error	Error 107: System Failure	Contact customer service for assistance.
108	Error	Error 108: System Failure	Contact customer service for assistance.
109	Warning	Maintenance reminder	Schedule maintenance for this device in the next 2 weeks.
110	Error	Error 110: System Failure	Contact customer service for assistance.
200	Error	Error 200: System Failure	Remove and reinsert catheter. Contact customer service if problem continues.
201	Error	Error 201: System Failure	Contact customer service for assistance.
210	Error	Error 210: System Failure	Contact customer service for assistance.
211	Error	Error 211: System Failure	Contact customer service for assistance.
220	Error	Error 220: System Failure	Contact customer service for assistance.
221	Error	Error 221: System Failure	Contact customer service for assistance.
230	Error	Error 230: System Failure	Contact customer service for assistance.

Philips exception ID	Exception type	Description	Try this
231	Error	Error 231: System Failure	Contact customer service for assistance.
240	Error	Error 240: System Failure	Contact customer service for assistance.
250	Error	Error 250: System Failure	Insert a footswitch plug into either connection point. Contact customer service if the problem continues.
251	Error	Error 251: System Failure	Two footswitches detected. Remove one footswitch to continue. Contact customer service if problem continues.
252	Error	Error 252: System Failure	Remove and re-connect footswitch. Contact customer service if problem continues.
260	Error	Error 260: System Failure	Contact customer service for assistance.
270	Error	Error 270: System Failure	Contact customer service for assistance.
300	Error	Error 300: System Failure	Contact customer service for assistance.
301	Error	Error 301: System Failure	Contact customer service for assistance.
302	Error	Error 302: System Failure	Contact customer service for assistance.
303	Error	Error 303: System Failure	Contact customer service for assistance.

Philips exception ID	Exception type	Description	Try this
310	Error	Error 310: System Failure	Contact customer service for assistance.
320	Alert	Laser not ready	Release footswitch and press “Calibrate” to enable the laser.
321	Alert	Laser not ready	Release footswitch and press “Set to ready” to enable the laser.
322	Alert	Laser not ready	Release footswitch and press “Try again” to enable the laser.
400	Error	Error 400: System Failure	Contact customer service for assistance.
401	Error	Error 401: System Failure	Contact customer service for assistance.
402	Error	Error 402: System Failure	Contact customer service for assistance.
403	Error	Error 403: System Failure	Contact customer service for assistance.
404	Error	Error 404: System Failure	Contact customer service for assistance.
500	Error	Error 500: System Failure	Contact customer service for assistance.
501	Error	Error 501: System Failure	Contact customer service for assistance.
502	Error	Error 502: System Failure	Contact customer service for assistance.
503	Error	Error 503: System Failure	Contact customer service for assistance.
504	Error	Error 504: System Failure	Contact customer service for assistance.

Philips exception ID	Exception type	Description	Try this
505	Error	Error 505: System Failure	Contact customer service for assistance.
600	Alert	Approaching temperature Error (600)	Allow the System to cool and try again. If problem continues contact customer service.
601	Alert	Approaching temperature Error (601)	Limit pulse count, or allow the System to cool to avoid Error.
602	Alert	Approaching temperature Error (602)	Limit pulse count, or allow the System to cool to avoid Error.
610	Error	Error 610: System Failure	Contact customer service for assistance.
611	Error	Error 611: System Failure	Contact customer service for assistance.
612	Error	Error 612: System Failure	Allow the System to cool and try again. Contact customer service if problem persists.
613	Error	Error 613: System Failure	Allow the System to cool and try again. Contact customer service if problem persists.

Glossary

Terms and definitions

Align

To adjust the components of a system for proper interrelationship.

Circuit breaker

An electromagnetic device, which opens a circuit automatically when the current exceeds a pre-determined value.

Distal

Located away from the point of origin or attachment.

Energy

The capacity for doing work and overcoming resistance. Heat, light, and electricity are examples of energy. Energy is measured in joules.

Excimer

Contraction of **EXCI**ted and di**MER**.

Excimer laser

A pulsed, gas laser which lases when two atoms form a temporary excited molecule.

Excimer radiation

Electromagnetic radiation emitted from the **System,** which includes all reflected radiation and any other form of energy resulting from the primary beam.

Excitation

The addition of energy to a particle or system of particles to produce an excited state.

FDA

The Food and Drug Administration.

Fiber-optic

Transparent, glass or quartz fibers used for conducting light.

Fluence

Fiber-optic catheter output energy density usually expressed in millijoules/square millimeter.

Hydrogen Chloride (HCl)

A gaseous compound, which is the source of the excimer laser chlorine atom.

Hertz

One cycle per second; a unit of frequency. Abbreviated Hz.

IPX8

The degree of protection rating given the footswitch, which means it is enclosed such that it is usable under water.

Joule

One Watt second; a unit of energy.

Laser

(An acronym) **L**ight **A**mplification by **S**timulated **E**mission of **R**adiation: a device, which amplifies light, then releases it in a coherent powerful beam.

Non-Ionizing Radiation

Electromagnetic radiation that does not have sufficient energy to remove electrons from the outer shells of atoms. Types of non-ionizing radiation are ultraviolet (UV), visible light, infrared (IR), microwave, radio (and television), and extremely low frequency (ELF, sometimes referred to as EMF or ELF-EMF).

Neon (Ne)

A rare, inert gas occurring in the atmosphere. It is colorless, but glows reddish orange in an electrical discharge.

Proximal

Nearest to the point of attachment or origin.

Pulsed laser

A laser, which delivers energy in short bursts.

Repetition rate

The rate at which the laser delivers pulses, usually expressed as pulses per second.

Type CF

Classification indicating direct conductive contact with the heart.

Ultraviolet

Pertains to electromagnetic radiation at wavelengths shorter than visible light.

Watt

One joule per second; a unit of power.

Wavelength

The distance between corresponding points on two successive waves.

WEEE (Waste from Electrical & Electronic Equipment)

Directive that mandates the collection and treatment of electronic and electrical equipment at end-of-life.

Xenon (Xe)

A noble gas.

Symbols

Outside:

“ON” (power)

“OFF” (power)

Protective earth (ground)

Footswitch connector

Power plug

Laser radiation

Laser aperture

Caution

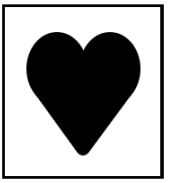
Warning

Consult instruction for use

Follow instructions for use

WEEE

(Waste from electrical and electronic equipment)



Type CF

Laser radiation, avoid eye exposure

Laser radiation, avoid skin exposure

Humidity limitation

Temperature limitation

Medical device

Catalogue number, reference number

Serial number

Authorized representative
in the European community

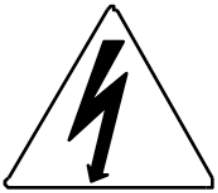
Unique device identifier

Manufacturer

Date of manufacture

Inside:

Protective earth (ground)



Dangerous voltage

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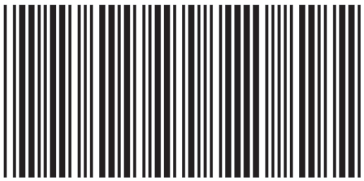

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