CLEAR + BRILLIANT®

Laser System

Operator Manual

For 1440 nm and Perméa™ (1927 nm) Handpieces

EC REP

CE 0197

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Patents that cover CLEAR + BRILLIANT Laser System can be found at www.clearandbrilliant.com/patents.

Ratings:

Entire handpiece is Type BF Applied Part, Class 1

100 – 240 VAC, 50 / 60Hz, 2 – 1A

Output: Max. Power (average) = 2.5 W (Laser, 1440 ±20 nm)

Output: Max. Power (average) = 0.9 W (Laser, 1927 ±20 nm)

PLEASE READ THE OPERATOR MANUAL IN ITS ENTIRETY PRIOR TO USE. PLEASE CONTACT SOLTA MEDICAL CUSTOMER SERVICE AT 510-782-2286 OR YOUR LOCAL AUTHORIZED DISTRIBUTOR OF SOLTA MEDICAL PRODUCTS IF YOU HAVE ANY QUESTIONS.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

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1.0 Warnings, Cautions and Notes

This operator manual contains certain warnings, cautions and notes designed to alert the operator to the proper care and use of the CLEAR + BRILLIANT Laser System and accessories. The following illustrates each of these messages and how to recognize them.

	Message The "Warning:" message alerts the operator about safety and non-compliance issues that are of the highest importance. Failure to observe the instructions in these alerts could result in serious injury, fire, or damage to the laser system or surrounding equipment.

CAUTION: A "CAUTION:" box alerts the operator to proper operation and proper use of CLEAR + BRILLIANT and its accessories.

Note: A "Note:" box designates information of special interest.

	The CLEAR + BRILLIANT Laser System is intended for use by authorized staff trained in the operation of this device.
	Do not use this device in the presence of critical concentrations of flammables or explosives, such as volatile anesthetics, alcohol, certain surgical preparation solutions, flammable solutions used for cleaning / disinfecting, flammable anesthetics or oxidizing gases such as nitrous oxide (N2O) and oxygen, an airway (endotracheal) oxygen tube, and other substances known to have these fire hazards. An explosion and/or fire could occur and severe injury could result if these precautions are not observed.
	Severe damage to the unit may result from immediate power-up following movement of the unit from a cold environment into a warm environment. The unit must be allowed to equilibrate with its surroundings for a minimum of 90 minutes following a change of environment prior to use. Failure to observe these precautions may result in the warranty of the unit being voided.

	Laser equipment not in use should be protected against unauthorized operation by removing the treatment tip from the handpiece. Keep the treatment tip in a designated place accessible only to authorized and trained personnel to avoid unauthorized use by untrained personnel and the possibility of injury or fire.
	To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.
	The tones generated by the system indicate normal function. If the tone is unchanging but hand velocity is changing, stop treatment to reduce the risk of injury to the individual receiving treatment. Restart the laser, and if the fault persists, call Solta Customer Service.
	Do not move the handpiece in a direction parallel to the long axis of the treatment tip. Do not twist the handpiece in a circular motion while treating. Failure to observe these precautions may result in increased risk of injury to the individual receiving treatment.
	Inspect the handpiece cable for damage on a routine basis. Do not use the device if the handpiece cable is damaged.
	Never move the unit by pulling on the handpiece or handpiece cable. Do not utilize an undersized cart to move the system.
	Maintenance is not to be performed while system is in use with the patient.
	Do not immerse or soak the handpiece or the handpiece cable.
	If the handpiece sealing window is cleaned with alcohol prior to use, allow time for the alcohol to evaporate before restarting the laser to mitigate the risk of fire and injury.
	Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
	The use of accessories, transducers and cables other than those specified or provided by Solta could result in increased electromagnetic emissions or decreased electromagnetic immunity of the CLEAR + BRILLIANT Laser System and result in improper operation.
	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 CLEAR + BRILLIANT Laser System, including cables specified by Solta. Otherwise, degradation of the performance of this equipment could result.

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

CAUTION: Prior to use of the CLEAR + BRILLIANT Laser System, this manual must be thoroughly read and understood by the personnel involved with operating the System. Improper use may cause personal injury and/or damage to the System and may invalidate any warranty agreement.

CAUTION: Unauthorized calibration of this device or the use of controls or adjustments to performance not specified or approved by Solta Medical could cause injury or harm, or may result in unintentional laser exposure, and/or may void any warranty.

CAUTION: Any changes in accessories or additional equipment connected to the CLEAR + BRILLIANT Laser System not specifically allowed by Solta Medical must be evaluated according to IEC 60601-1 by the end user.

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

CAUTION: The system is pre-calibrated and does not require any Operator set-up or calibration once the system is installed. Improper service, repair or modifications performed by unauthorized personnel may pose a hazard and will invalidate any warranty agreement.

CAUTION: The Treatment Tip must be attached to the distal portion of the handpiece prior to any treatment. If this is not done, the laser system will not function.

CAUTION: Take precautions to ensure that the handpiece exit window does not become contaminated before, during, or after the self-test procedure as this may result in poor clinical outcome, damage to the machine or injury to persons nearby.

CAUTION: Do not substitute another power cord for the one supplied with the unit. Do not use the power cord if it becomes frayed or damaged in any way. Contact Solta Medical or your local authorized distributor of Solta Medical products for a replacement if necessary. Do not pull on the cord to pull the plug out of the socket.

CAUTION: Do not position the device so that the rear panel is inaccessible for disconnecting the power cord from the CLEAR + BRILLIANT system.

CAUTION: Use of controls, adjustments, or procedures other than those specified may result in hazardous electromagnetic radiation which may cause personal injury or damage to other equipment.

CAUTION: The availability of electronic alerts does not relieve operators of their obligation to carefully monitor the entire system during operation.

CAUTION: While the CLEAR + BRILLIANT laser cannot fire unless the treatment tip rollers are in contact with the skin, it is recommended not to look into the handpiece exit window if the system is turned on. Turn off the power to the system before inspecting any of the optical components.

NOTE: Do not attempt to disassemble or service the CLEAR + BRILLIANT Laser System without Solta professional support. Please call your local Customer Service Representative for further instruction.

NOTE: Never block the cooling system vents on the system console. Ensure adequate space around the unit at all times to facilitate system cooling.

NOTE: As a Class B emission and Class A immunity product, there is no potential electromagnetic, or other, interference between the operation of the CLEAR + BRILLIANT system and other devices.

2.0 CLEAR + BRILLIANT Laser System Overview

This manual provides operating instructions for the CLEAR + BRILLIANT Laser System for treatment providers.

CLEAR + BRILLIANT is a non-ablative laser designed for use in dermatological procedures. This device is part of the family of Solta Medical products utilizing the Fractional Photothermolysis principle. This device consists of a Console and a base handpiece (1440 nm) with the option of purchasing additional add-on handpieces. Currently, the Perméa (1927 nm) handpiece is available.

The 1440 nm handpiece is an infrared diode laser with a wavelength of 1440 ± 20 nm. The laser coagulates the epidermis and dermis with up to 0.4 mm depth of penetration.

The Perméa (1927 nm) handpiece is an infrared diode laser with a wavelength of 1927 ± 20 nm. The laser coagulates the epidermis and dermis with up to 0.17 mm depth of penetration.

The solid state design of CLEAR + BRILLIANT is designed with limited maintenance and minimal utilities requirements. The output of the laser is focused onto the skin using lenses contained within the handpiece. Computer controlled motors within the handpiece and the software system architecture direct the laser system to deliver focused spots and an evenly spaced treatment pattern. These advanced features allow for precisely controlled delivery of the fractional laser treatment.

This manual is intended to help you get the most from your system as you make CLEAR + BRILLIANT an integral part of the treatments you provide. It is our intention that this information assists the operator in successful use of this product. If you have additional questions, please do not hesitate to contact your local Solta Customer Service representative.

2.1 Indications for use

The CLEAR + BRILLIANT System is indicated for use in dermatological procedures requiring the coagulation of soft tissue and general skin resurfacing procedures.

3.0 Features of the CLEAR + BRILLIANT Laser System

The CLEAR + BRILLIANT Laser System contains a laser source in the handpiece. The console is electrically connected to the facility power source. Laser energy produced by the unit is delivered to the tissue through the handpiece. Contact with the tissue is maintained by removable, disposable contact treatment tips which attach to the handpiece.

The features of CLEAR + BRILLIANT are described below.

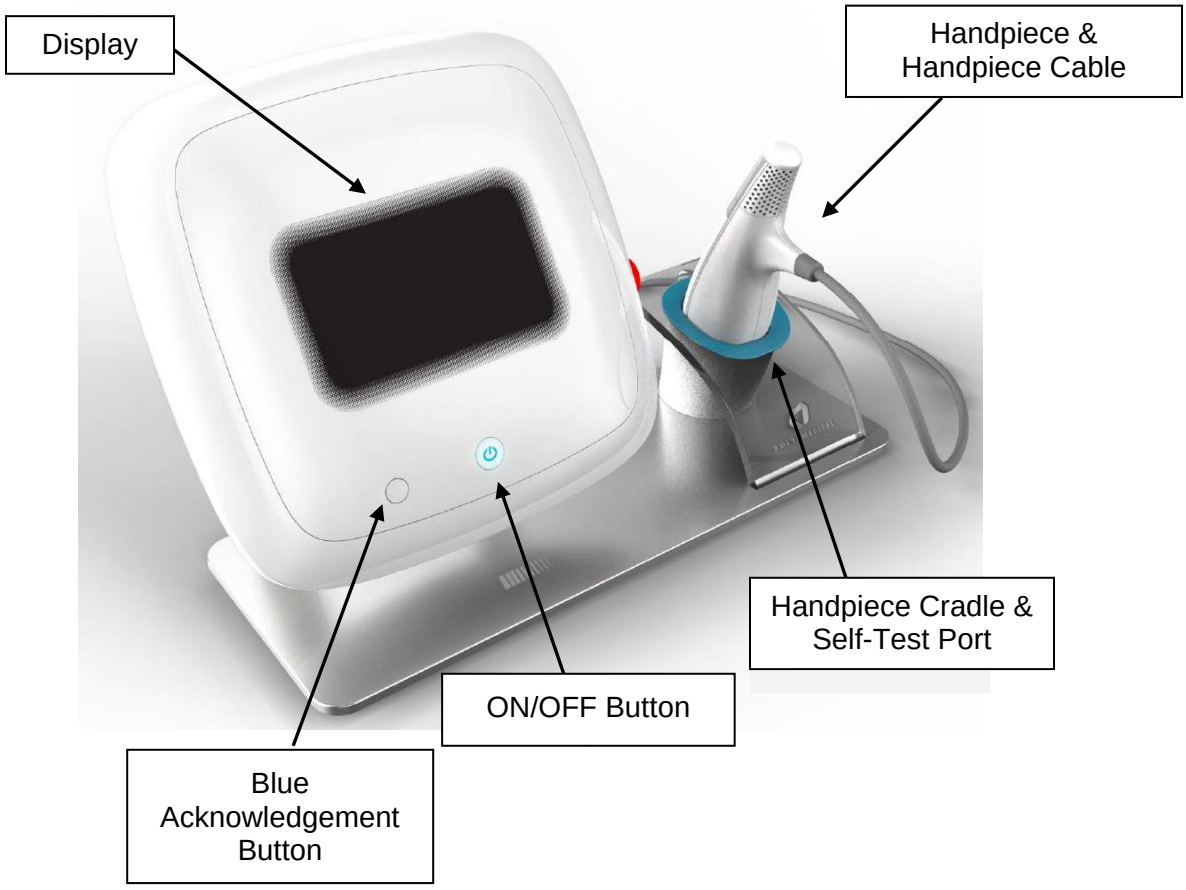
3.1 Front View of the CLEAR + BRILLIANT Laser System Console

The features of the CLEAR + BRILLIANT Laser System console include:

- **On / Off Button:** turns the laser system on and off. The device should always remain in the Off position when not in use to avoid unauthorized use by untrained personnel and the possibility of injury or fire.
- **Display:** The display serves as the information interface for CLEAR + BRILLIANT. It displays the information associated with the operating conditions, including: Laser On/Off, system status, progress and completion of the self-test, step-by-step instructions for treatment procedures, general messages and error messages.
- **Handpiece and Handpiece Cable:** Two handpieces are available for the Clear + Brilliant laser system: the Original (1440 nm) handpiece and the Perméa (1927 nm) handpiece. The handpiece (laser) should always be resting in the cradle when not in use. The cable connects the handpiece to the console. Ensure that there are no kinks in the cable.

ATTENTION! THE CONSOLE MUST BE TURNED OFF PRIOR TO CHANGING FROM ONE HANDPIECE TO THE OTHER AND THEN TURNED ON ONCE DESIRED HANDPIECE IS PROPERLY CONNECTED TO THE CONSOLE. FAILURE TO DO THIS WILL RESULT IN IRREPARABLE DAMAGE TO THE HANDPIECE.

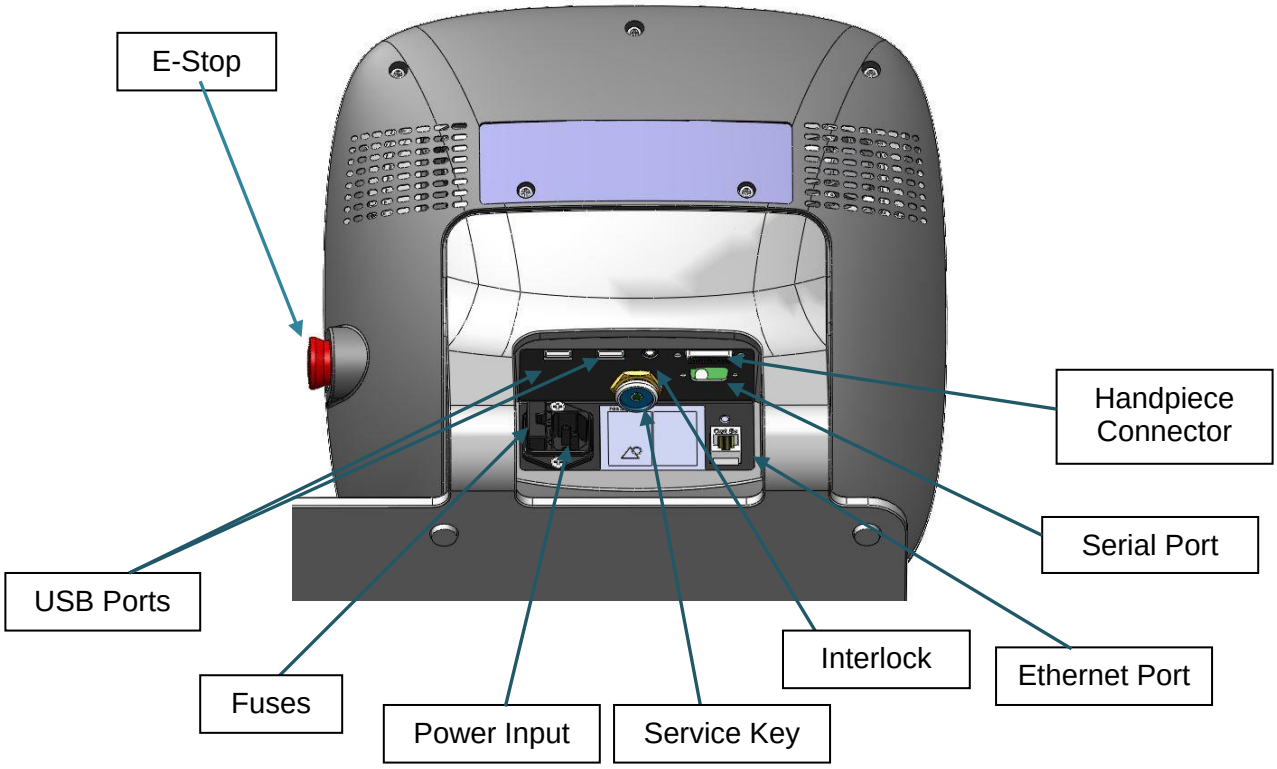
- **Handpiece Cradle and Self-Test Port:** The handpiece (laser) should always be resting in the cradle when not in use. The cradle also serves as the self-test port during initialization of the system. The laser self-test procedure is automatically controlled by the software.
- Ensure the console is placed on a flat and steady surface to prevent movement or tipping.


Display
Handpiece &
Handpiece Cable
Handpiece Cradle &
Self-Test Port
ON/OFF Button
Blue
Acknowledgement
Button

3.2 Back View of the System Console

The back of the system includes:

- **Power Input:** A power cord connects the system to the electrical outlet. The power input on the back of the console is a standard IEC 60320 type C14 male connector (within the U.S.), or a hospital grade, grounded power cord.
- **E-Stop Button:** located on the right side of the console (if viewing from the front). Press this button during an emergency to stop the laser treatment beam. To restart, twist the button and release it from the latched OFF position.
- **Service Key:** Provides service access to the system. For service use only.
- **Interlock:** Access to the remote door interlock is through this plug and socket. The system is delivered with this plug shorted internally. Do not connect other power supplies to this interlock.
- **Serial Port:** For service and maintenance use only.
- **Handpiece Connector:** The handpiece connector connects the handpiece and handpiece cable to the system console. The cable plugs into the connector.
- **USB and Ethernet Ports:** For external communication and maintenance purposes.
- **Fuse:** To remove and/or install the replaceable fuse in the back panel of the system console, press on the center tab to release the fuse enclosure, pull up gently and replace the fuse. Place the new fuse back into the pocket until is snaps into place.



3.3 System Configuration Screen

A mini keyboard with touchpad, see image below, is provided for use with the Clear + Brilliant laser system. The keyboard allows customization of the system by providing access to the system configuration screen. Customers can adjust the system volume and choose preferred language and time zone. Please note that any keyboard will work with the Clear + Brilliant system once it is connected to the console via a USB port.

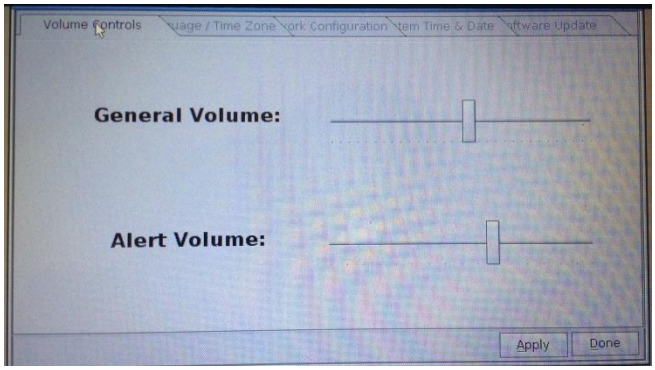
3.3.1 Keyboard Instructions

Connect keyboard to the available USB port in back of the console. Keyboard may be connected before powering system on or after system has been turned on, completed the system self-test, and successfully reached the home screen.

From the home screen, press the space bar on the keyboard to access the system configuration screen.

Customizable system features are accessible through 5 tabs. At this time only 3 tabs are active: Volume Control, Language/Time Zone, and System Time & Date. The Network Configuration and Software Update tabs are currently inactive by design and may be activated by Solta in the future if necessary.

The first customizable tab is **Volume Control**, see image below. The tracking pad is used to adjust the General Volume and/or the Alert Volume by moving the slide bars left or right. Once you have selected your desired volume settings, press the APPLY button located on the bottom right-hand side of the display. **Please ensure volume levels selected are audible with background noise, especially the Alert Volume.**



The language and time zone can be adjusted in the **Language/ Time Zone** tab, see image below. Preferred language and time zone can be selected via drop-down menus using the tracking pad. Press APPLY when you have made desired choices.

Press DONE button when all desired adjustments are complete.

Although the **System Time & Date** tab is active and accessible, it is not necessary to configure any of this information as this is currently set by Solta upon system shipment and only used for service purposes.

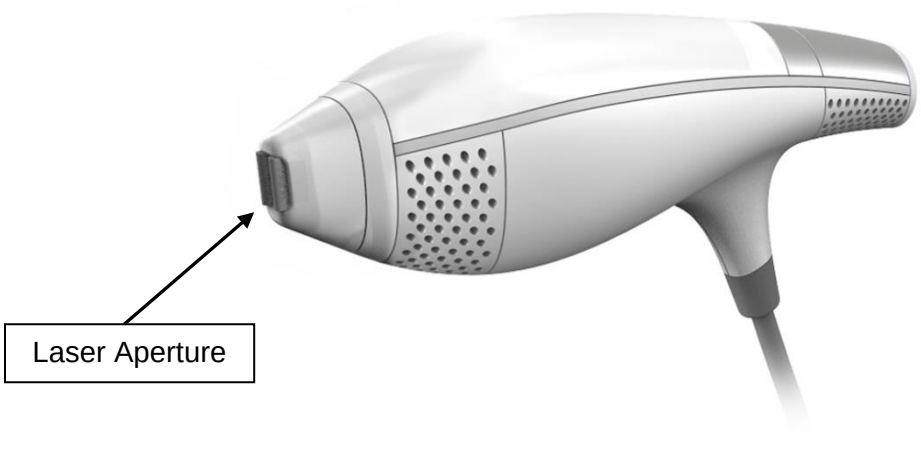
3.4 Handpiece and Treatment Tip

Two handpieces are available for the Clear + Brilliant laser system: the Original (1440 nm) handpiece and the Perméa (1927 nm) handpiece. The handpiece delivers the laser energy to the surface of the skin through the laser aperture, only if the required treatment tip is in place. The activation and selector buttons (for low, medium, or high treatment settings) and light indicators can be found at the top side of the handpiece.

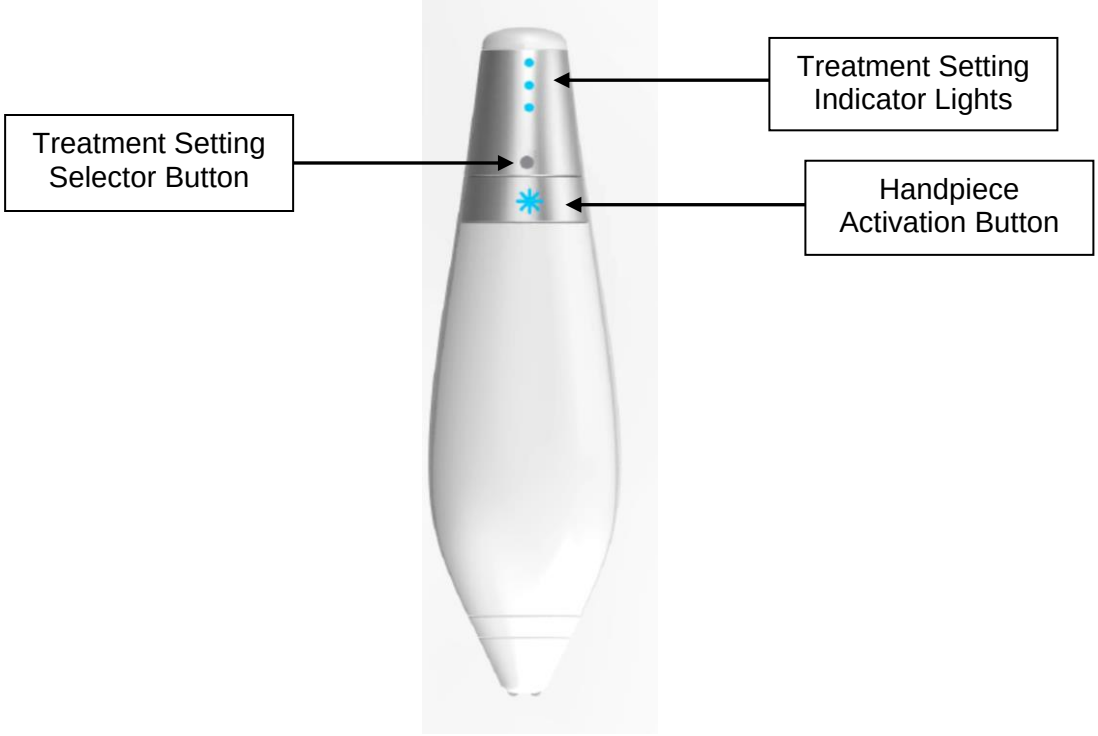
ATTENTION! THE CONSOLE MUST BE TURNED OFF PRIOR TO CHANGING FROM ONE HANDPIECE TO THE OTHER AND THEN TURNED ON ONCE DESIRED HANDPIECE IS PROPERLY CONNECTED TO THE CONSOLE. FAILURE TO DO THIS WILL RESULT IN IRREPARABLE DAMAGE TO THE HANDPIECE.

The handpiece should always be resting in the handpiece cradle when not in use.

Side view of Handpiece (with Tip Installed)



Top view of Handpiece (with Tip Installed)



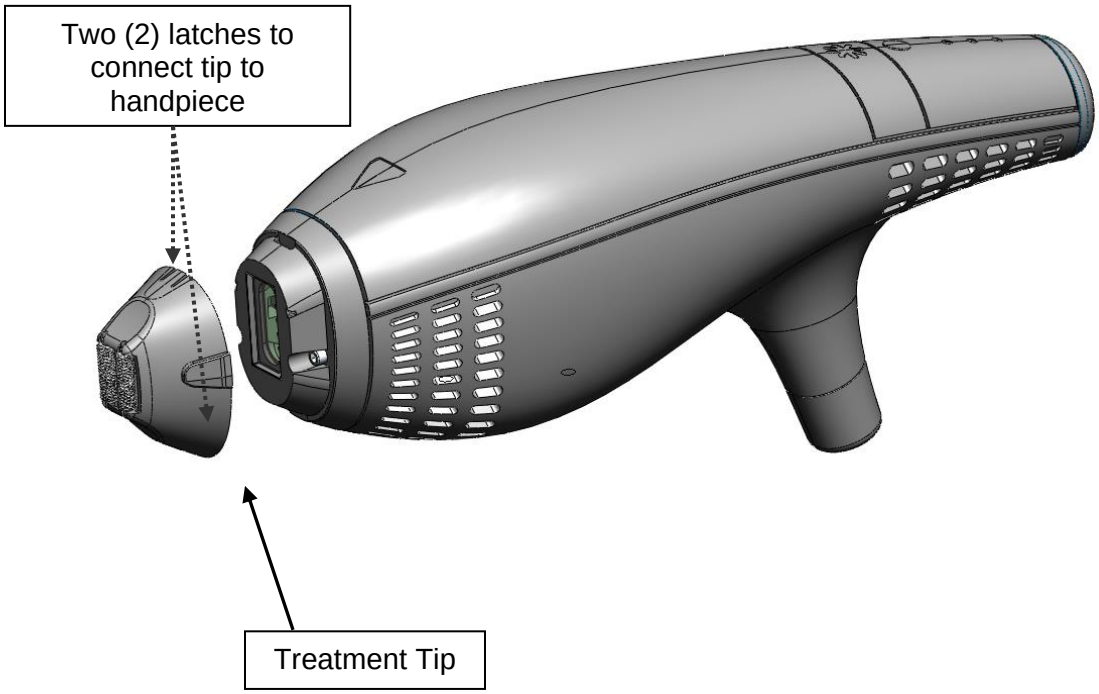
3.5 Treatment Tip

A disposable treatment tip attaches to the distal portion of the handpiece and MUST be in place prior to any treatment. The system detects contact between the tip and the skin and translates handpiece motion into velocity information.

The treatment tips are biocompatible in accordance with ISO 10993 for contact with skin.

The treatment tip will latch mechanically and magnetically when properly positioned and will remain latched throughout treatment, with appropriate handling.

Each treatment tip is single-use and therefore will have a tip life of one treatment. Treatment tips are disposable. Do not reuse. Multiple patient use may create the potential risk of cross contamination of biological agents from one patient to another.


Two (2) latches to connect tip to handpiece
Treatment Tip

4.0 CLEAR + BRILLIANT Operating Instructions

4.1 Overview

This section provides a general guideline for the operation of the CLEAR + BRILLIANT Laser System. This laser system has specific operating requirements. It is the responsibility of the treatment provider to fulfill these requirements. Failure to do so can result in incorrect and/or intermittent operation or damage to the laser.

4.2 Routine Pre-Cautions Prior to Treatment | Before Turning System ON

4.2.1 Take precautions to mitigate the fire hazards associated with the laser system.

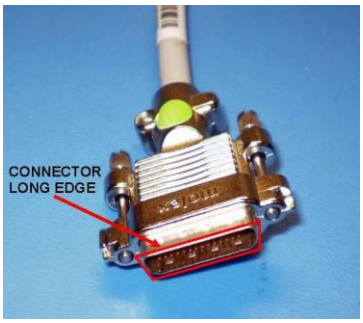
ATTENTION! THE CONSOLE MUST BE TURNED OFF PRIOR TO CHANGING FROM ONE HANDPIECE TO THE OTHER AND THEN TURNED ON ONCE DESIRED HANDPIECE IS PROPERLY CONNECTED TO THE CONSOLE. FAILURE TO DO THIS WILL RESULT IN IRREPARABLE DAMAGE TO THE HANDPIECE.

4.2.2 Connecting handpiece directly to the console:

Select the desired handpiece. Identify the green dot on the handpiece connector and ensure it is facing upwards, if the console is upright on a flat surface.

CAUTION: Inserting handpiece incorrectly may result in system failure!

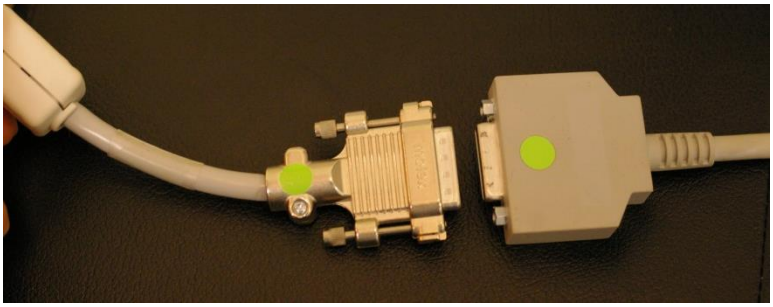
Attach the handpiece connector to the back of the console and tighten the screws completely into the console. **It is important the connector is attached correctly.** If the screws do not tighten all the way, the connector may be attached in reverse. Remove the connector and reattach, ***before switching console ON***.



Connecting handpiece to the console via the extension cable:

Select the desired handpiece. Identify the green dots on the handpiece connector and the mating connector. Align connection ports and tighten the screws to secure connection.

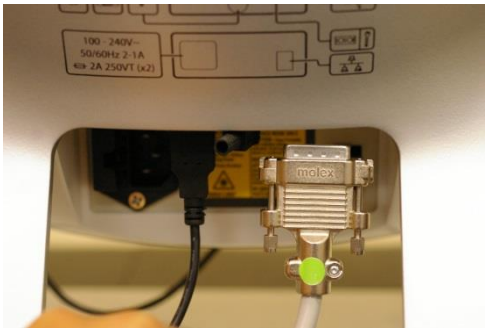
CAUTION: Connecting handpiece incorrectly to the extension cable may result in system failure!



Identify the green dot on the other end of the extension cable and ensure it is facing upwards, if the console is upright on a flat surface.

CAUTION: Inserting extension cable incorrectly may result in system failure!

Attach the other end of the extension cable to the back of the console and tighten the screws completely into the console. **It is important the connector is attached correctly.** If the screws do not tighten all the way, the connector may be attached in reverse.



Remove the connector and reattach, ***before switching console ON***.

4.2.3 Check the power cord for damage. Ensure the appropriate electrical utilities are available in the treatment room. Connect the power cord to the laser and to the wall socket before turning system ON.

4.2.4 Ensure the handpiece cable is not excessively twisted from the unit. Do not tape the cable to any structure.

4.2.5 Check handpiece and tip integrity. Do not use tips or handpiece if any damage is visible.

4.2.6 Ensure Card Reader is attached to the back of the console via USB port prior to turning system ON.

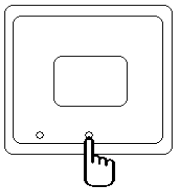
4.3 Step-by-Step Operating Instructions

ATTENTION! THE CONSOLE MUST BE TURNED OFF PRIOR TO CHANGING FROM ONE HANDPIECE TO THE OTHER AND THEN TURNED ON ONCE DESIRED HANDPIECE IS PROPERLY CONNECTED TO THE CONSOLE. FAILURE TO DO THIS WILL RESULT IN IRREPARABLE DAMAGE TO THE HANDPIECE.

4.3.1 Turn the System ON

ON/OFF Button: turns the laser system on and off. The device should always remain in the OFF position when not in use to avoid unauthorized use by untrained personnel and the possibility of injury or fire.

Turn the unit ON and verify that the unit powers up normally with no error messages. Instructions will appear on the screen to guide the operation of the system.



4.3.2 Place the Handpiece in the Cradle

CAUTION: Handpiece should ONLY be placed in cradle with cord oriented toward the front of the console as shown in image below. Placing handpiece in cradle in any other orientation may lead to handpiece/system malfunction.

Upon completion of the system power-up, the system will enter the System Self-Test mode. Please follow the instructions as they appear on the display and place the handpiece in the cradle on the system console. The display will indicate when testing has initiated.

If the testing is not successful, check the handpiece window for visible damage. If there is no visible damage, try again. If you see damage to the tip, please call Solta Medical Customer Service. If the system does not pass self-test after three tries, contact Solta Medical Customer Service.

If the system fails to pass the System Self-Test, it will not allow further treatment. Solta Medical then requires that the system be serviced. Contact Solta Medical Customer Service to schedule service.

4.3.3 Treatment Initiation | Insert Treatment Card

Upon successful completion of the System Self-Test, the display will immediately transition to the home screen and treatment scan mode (see screen shots below).

Original (1440 nm) Handpiece

Perméa (1927 nm) Handpiece

During this mode, the user will insert the treatment card into the card reader, wait for the card to be validated, and press the blue button (left button) on the front of the console when prompted to use a treatment credit.

CAUTION: Please ensure card inserted is correct for handpiece attached. Cards are handpiece-specific and must be properly matched in order to activate a treatment. If the incorrect card is inserted, the message “Invalid Treatment Card. Please contact Customer Service.” will appear on screen. You can remove invalid card and insert the correct card to proceed without the need to contact Customer Service.

Once the treatment card is successfully validated and a treatment credit properly authorized, a treatment credit will be deducted from the treatment card. A treatment card with valid treatment credits is required to activate the device for treatment and is available only to authorized users of the device. Treatment cards are handpiece-specific. The treatment card used must match the handpiece attached. Please **do not remove treatment card from card reader until notified you are allowed to do so on-screen.**

4.3.4 Connect Treatment Tip to Handpiece

Once the treatment credit has been authenticated, the display will instruct the user to connect the treatment tip to the handpiece, as shown in the screen shot below.

As mentioned in Section 2.5, the treatment tip contains two latches which mechanically, and magnetically, attach to the distal part of the handpiece. Ensure that these latches line up with the corresponding grooves on the handpiece. If the tip does not click into place, the positioning may be incorrect. Turn the tip to ensure the top latch lines up with the top interconnect on the handpiece.

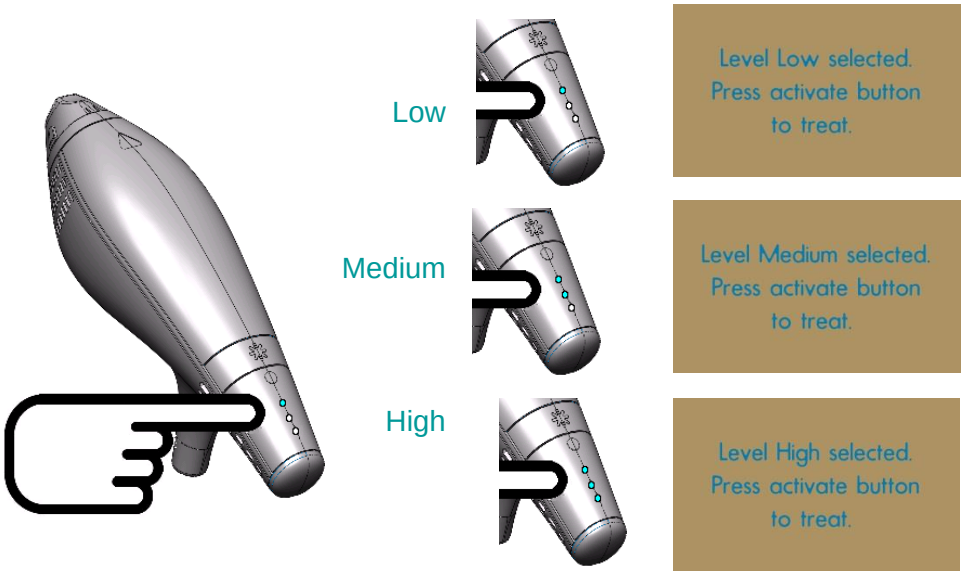
If proper connection between the treatment tip and the handpiece is not made, the laser will not fire and treatment will not proceed.

If the treatment tip is disconnected at any time, the system will not allow any energy delivery to the tip and the display screen will instruct the user to connect the treatment tip to the handpiece.

4.3.5 Select Treatment Level

When the treatment tip is securely in place, the screen will display the following message:

The user will press the Treatment Setting Selector Button on top of the handpiece to select the treatment setting (low, medium, or high). Push the button once to select the low setting, twice to select the medium setting, and three times to select the high setting. If the button is pushed a fourth time, the treatment setting will reset back to the low setting. The corresponding blue activator lights will turn on and will identify the treatment setting selection. One light corresponds to the low setting, two lights to the medium setting, and three lights to the high setting. The screen will display the level selected and instruct the user that treatment may proceed.



4.3.5.1. Parameter Selection

All operators should be adequately trained in laser safety and should make informed and appropriate selection of treatment parameters. CLEAR + BRILLIANT treatment parameters range from low to high settings, as shown in the table below. The decision to increase or decrease treatment setting should be based on patient feedback.

Treatment Setting	Handpiece Activator Button	Number of Activated Lights on Handpiece	Energy (mJ) CB-HANDPIECE/ CB-HP-1440	CB-HANDPIECE/ CB-HP-1440	Energy (mJ) CB-HP-1927 (Perméa)	CB-HP-1927 (Perméa)
Spot Size (µm)			**110-180 µm**	**Spot Density**	**110-180 µm**	**Spot Density**
LOW	**Push 1x**	**1**	**4**	50 laser spots per cm^2	**5**	17 laser spots per cm^2
MEDIUM	**Push 2x**	**2**	**7**	40 laser spots per cm^2	**5**	25 laser spots per cm^2
HIGH	**Push 3x**	**3**	**9**	40 laser spots per cm^2	**5**	34 laser spots per cm^2

Handpiece	CB-HANDPIECE/CB-HP-1440			CB-HP-1927 (Perméa)		
Treatment Setting	**Pulse Energy (mJ)**	**Lesion Depth (µm)**	**Lesion Width (µm)**	**Pulse Energy (mJ)**	**Lesion Depth (µm)**	**Lesion Width (µm)**
Low	**4**	**281.82 ± 22.89**	**119.46 ± 9.43**	**5**	**167.4 ± 21.33**	**220.7 ± 15.64**
Medium	**7**	**339.32 ± 29.82**	**163.07 ±13.34**	**5**	**167.4 ± 21.33**	**220.7 ± 15.64**
High	**9**	**384.16 ± 37.74**	**201.57 ± 12.82**	**5**	**167.4 ± 21.33**	**220.7 ± 15.64**

4.3.6 Activate Handpiece

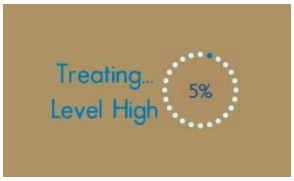
Once the treatment setting has been chosen, the user will press the handpiece Activator Button, located on top of the handpiece, to activate the laser as instructed on the display screen. After pushing the button, the laser is in emission state and is ready to begin treatment.

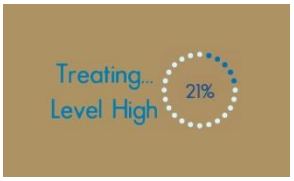
4.3.7 Treat

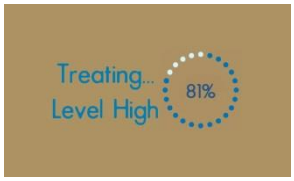
After pressing the handpiece activator button, the user will bring the handpiece with treatment tip in contact with the area to be treated. The laser will fire once it is placed in contact with the skin and moved across the skin. The optical mouse provides a proximity sensor for sensing skin contact and movement. When the system is actively treating, audible indicators will reflect that laser energy is being emitted and treatment is occurring.

In order to change treatment parameters during treatment, or to interrupt treatment, the user must press the laser activation button to deactivate the laser or place it in the handpiece cradle. The display screen will return to the Level Selection screen.

The display screen will indicate treatment progress showing the time remaining as well as a percentage of surface area remaining to complete the intended treatment.





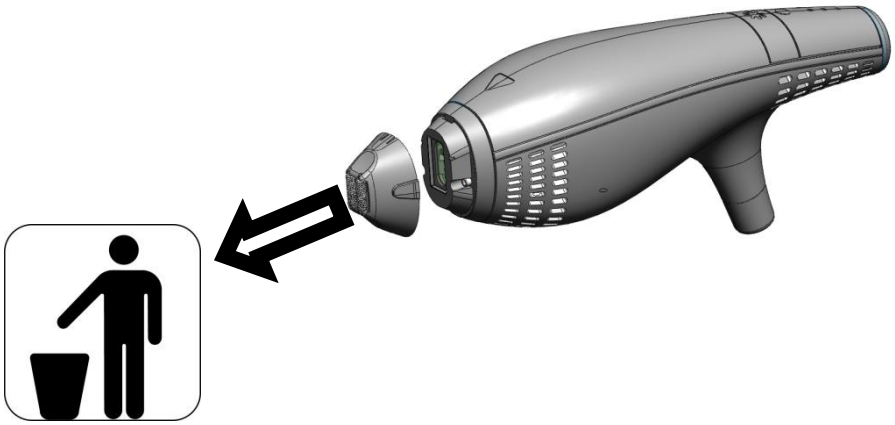


When the treatment has been completed, the following message will be displayed:

4.3.8 Remove and Discard Treatment Tip

When treatment is complete, remove the treatment tip by squeezing the sides of the treatment tip to unhinge from the handpiece. Discard the treatment tip according to your local regulations.

The CLEAR + BRILLIANT treatment tips are single-use tips and are to be disposed of after each treatment. They are not to be re-used. Re-use may create the potential risk of cross contamination of biological agents from one patient to another.

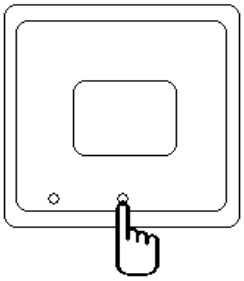


Secure the handpiece back in the handpiece cradle.

4.3.9 Turn the System OFF

Upon treatment completion, the system will return to the treatment authentication stage. Additional treatments can proceed by repeating the treatment authentication process and using additional treatment credits. If another treatment will be performed immediately after the previous treatment, the above steps can be repeated, beginning with pressing the blue button on the console to use another treatment credit to authenticate the next treatment.

To turn the system off, deactivate the laser, or place it in the cradle, then press the green On/Off button on the system console. The system provides a prompt asking you if you really wish to turn off the console. Press the green button again to confirm.



4.3.10 Turning System OFF Before Treatment is Complete

If the green On/Off button on the system console is pressed before treatment completion, user will be asked to confirm request to turn system off. If the system is turned off before treatment is complete, the **treatment credit will be lost**. Press the green On/Off button to confirm request and proceed to turn system off. Waiting 5 seconds without taking any action will return the system to its previous screen and allow for treatment continuation.

5.0 Definitions

This section of the manual should familiarize the treatment provider with terminology which describes aspects of the Fractional Photothermolysis process. It is the responsibility of the treatment provider to fully understand the indications for use, safety considerations and laser function associated with CLEAR + BRILLIANT, and to make decisions regarding the specific application of the Laser System to the individual receiving treatment.

MTZ – An MTZ is a Microscopic Treatment Zone, the region of coagulated tissue resulting from one pulse from the handpiece.

Pass – A "pass" is a single, unidirectional hand motion laying down one segment of MTZs.

MEND – A MEND is a Micro-Epidermal Necrotic Debris particle. This is a compact accretion of necrotic epidermal debris which is pushed up from the Dermal/Epidermal junction and expelled as a part of the healing process. MENDS produced by the non-ablative CLEAR + BRILLIANT system typically flake off after 4 – 14 days. During the flaking process they give the skin a slightly bronzed appearance.

5.1 Handpiece Tracking (IOTS – Intelligent Optical Tracking® System)

The CLEAR + BRILLIANT Laser System includes an Intelligent Optical Tracking System (IOTS) that senses skin contact with the treatment tip rollers, and the motion of the tip relative to the skin surface.

Contact and motion detection is accomplished by analyzing the image of the skin's surface located at the center of the aperture between the treatment tip rollers. It works in much the same way as a computer optical mouse does, in that it senses motion by analyzing the change in an image.

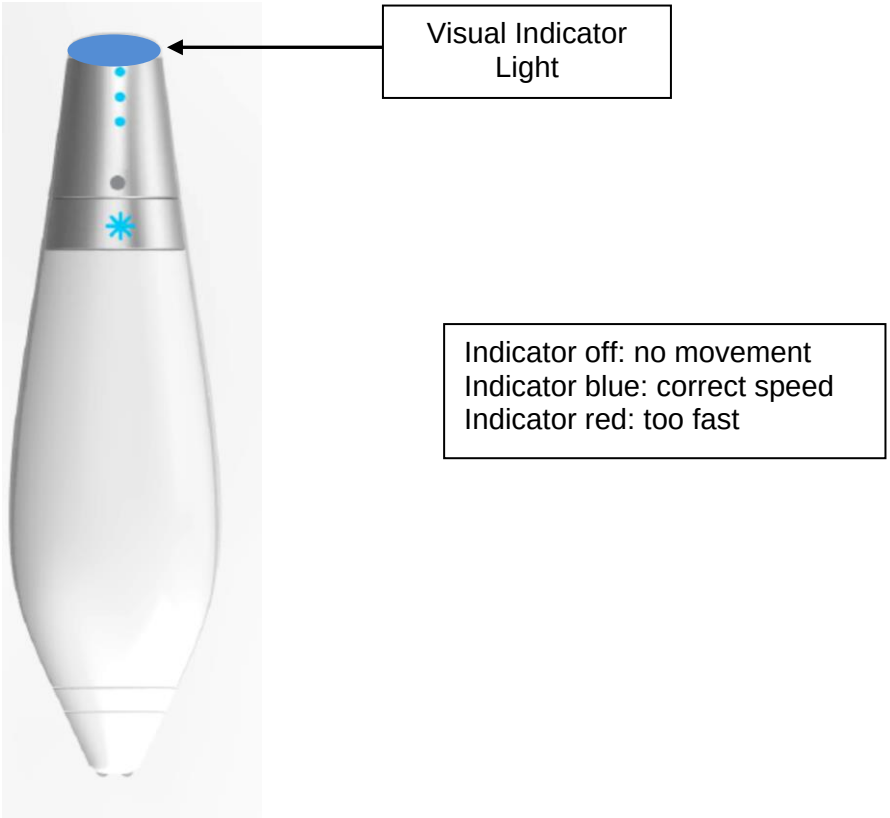
The system calculates hand motion velocity during treatment to ensure uniform delivery of the laser spots. The IOTS controls the delivery of a specified number of laser spots per unit area of treatment surface. The specified number of laser spots per square centimeter (spot density) is dependent on the treatment level setting:

Handpiece	CB-HANDPIECE/ CB-HP-1440	CB-HP-1927 (Perméa)
Level Low	50 laser spots per cm^2	17 laser spots per cm^2
Level Medium	40 laser spots per cm^2	25 laser spots per cm^2
Level High	40 laser spots per cm^2	34 laser spots per cm^2

The IOTS also defines a minimum and maximum velocity of the handpiece to ensure the delivery of the appropriate spot density. These velocity limits are dependent on the treatment level setting.

Setting	CB-HANDPIECE/ CB-HP-1440	CB-HP-1927 (Perméa)
Low	Min Hand Speed = 0.5 cm/sec Max Hand Speed = 8.0 cm/sec	Min Hand Speed = 0.7 cm/sec Max Hand Speed = 8.0 cm/sec
Medium	Min Hand Speed = 0.5 cm/sec Max Hand Speed = 8.0 cm/sec	Min Hand Speed = 0.4 cm/sec Max Hand Speed = 5.9 cm/sec
High	Min Hand Speed = 0.4 cm/sec Max Hand Speed = 6.2 cm/sec	Min Hand Speed = 0.4 cm/sec Max Hand Speed = 4.3 cm/sec

There are audible (see Section 5.2) and visual indicators for the user to ensure that the correct hand-piece velocity is used during treatment. The visual indicator light is located on the distal end of the handpiece. The light will turn blue when the handpiece velocity is within limits, turn red if the handpiece velocity is over the maximum hand speed limit, and will be off when the handpiece velocity is under the minimum hand speed limit or not moving.



The IOTS allows treatment to be bidirectional. The handpiece may be stopped after one pass and the direction of motion reversed without loss of function.

NOTE: It is important that the tip stay in good physical contact and approximately perpendicular to the skin for the IOTS to provide accurate information about contact and velocity.

5.2 System Audible Feedback

The system will generate audible tones during treatment indicating proper delivery of the laser spots on the skin. Treatment providers should practice with the system to gain an understanding of the relationship between handpiece velocity and audible tones. (See Pattern Preview Test in next sub-section).

If the handpiece is moved at a velocity in the range between minimum and maximum hand speed limits, the system will produce a constant tone in a frequency equivalent to the delivery of laser spots. The sound will change to a higher-pitched tone, designed to alert the operator when the hand speed is over the maximum limit indicating that the system is not delivering laser spots. Slowing down to the correct speed will restore the audible tones to normal. Slowing down under the minimum limit or stopping the handpiece will stop the audible feedback.

The indicator light is blue when the device is operating at the correct speed but turns red when the handpiece is moving too fast. This light is intended to notify the user when the appropriate speed is reached. If the user moves the handpiece across the skin too fast, the audible system will also provide a higher pitched beep. If the user is moving within the recommended speed, the tones will be in the default range. These two feedback systems are intended to notify the user when the appropriate speed is used.

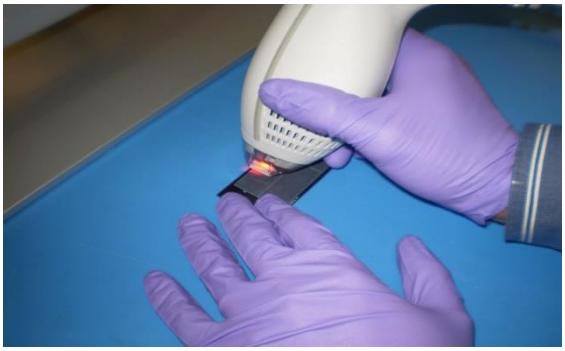
If the hand speed is too fast, the patient will not receive the correct dosage of treatment chosen.

5.3 Pattern Preview Test

It is important for the user to become familiar with the system's visual and audible feedback indicators. For this purpose, Solta Medical provides "burn paper" with each box of CLEAR + BRILLIANT tips in order for the user to produce a pattern preview test. For this test, the user performs a pass of the handpiece onto the burn paper – just use one of the four quadrants on the burn paper to perform the test, to minimize waste. The burn paper can be used up to four times – one quadrant for each tip tested. You can see the pattern of the laser through the clear laminate on the burn paper. If you desire, you can peel back the top film of the burn paper to reveal a clearer view of the laser pattern. (Additional burn paper is available as an accessory from Solta Customer Service.)

When energy is delivered to the paper, a pattern of microscopic thermal zones shows up on the paper in the same way it would be delivered to the skin. The user can understand the visual cues from the indicator light and also become familiarized with the audible tones as they relate to handpiece speed.

If lines do not appear on the burn paper after attempting the Pattern Preview Test, do not perform treatment and contact Solta Medical Customer Service.



Performing Pattern Preview Test

Burn paper before test

Burn paper after test

6.0 Contraindication and Risk Information

The information which follows is provided by Solta only as an information service to treatment providers and is made available with the understanding that it does not constitute the rendering of medical advice. It also does not constitute an endorsement or warranty of the safety or efficacy of these products. Treatment providers should make their own assessment of and decision on the use of any of the information.

6.1 Indications for Use

The CLEAR + BRILLIANT Laser System is indicated for use in dermatological procedures requiring the coagulation of soft tissue, as well as for general skin resurfacing procedures.

6.2 Pre-Treatment Inspection

Do not use CLEAR + BRILLIANT on individuals if contraindicated, as described below.

6.3 Contraindications

6.3.1 Not all individuals will necessarily react the same way to the laser treatment. Appropriate judgment should be exercised at all times.

6.3.2 The following contraindications are routine for many laser treatments and may also be associated with non-ablative CLEAR + BRILLIANT treatment. Pre-screening and informed consent should include, (but not be limited to):

(a) diagnosis / possibility of actinic keratosis, melasma, rosacea, or other significant skin conditions (e.g. skin cancer, active infections, cold sores, open wounds, rashes, burns, inflammation, eczema, psoriasis),

(b) predisposition to keloid formation or excessive scarring,

(c) diagnosis of a condition that may compromise the immune system, such as HIV, lupus, scleroderma, and/or systemic infections,

(d) known sensitivity to light or if photosensitizing agents/medications are being taken,

(e) systemic steroids (e.g. prednisone, dexamethasone), which should be rigorously avoided prior to and throughout the course of treatment,

(f) use of retinoids should be avoided for at least 2 weeks prior to and during treatment,

(g) individuals undergoing Accutane™ treatment or with drugs in a similar class,

(h) if skin is still recovering from a cosmetic procedure, such as a chemical or mechanical peel, or laser resurfacing,

(i) if Botox injections, or dermal fillers (such as collagen) have occurred within the past 2 weeks.

6.3.3 Solta has no clinical information or experience concerning the use of CLEAR + BRILLIANT on pregnant women or nursing mothers.

6.4 Tissue Interaction

In skin, water is the primary absorber (chromophore) of the laser wavelength used in CLEAR + BRILLIANT. Tissue damage can occur with the incorrect use of the handpiece and its settings. Caution should be exercised until you are familiar with the system.

6.5 Post - Treatment Information

6.5.1 Protecting New Skin

For treatment associated with CLEAR + BRILLIANT, new epithelium (new skin) will start to form within 24 hours but will remain covered by the old stratum corneum and MENDS for 4 -14 days, for some skin types. During that time, normal / accelerated exfoliation will reveal the repaired epidermal tissue and new stratum corneum.

Sun Protection: Sun exposure before and during treatment can increase the risk of unwanted pigmentation. After treatment the skin is more sensitive to the sun, which can increase the risk of unwanted pigmentation and sunburn. Post-treatment individuals should plan to use a high SPF sunscreen on a regular basis whenever they are outside. Ideally, a dual UVA/UVB sunscreen should be applied containing both a physical sun block (either or both zinc oxide or titanium dioxide) with a sun protection factor of 15 of above. Applying sunscreen helps maintain good results. In general, it is recommended that direct sunlight is avoided and to wear sun-protective clothing (i.e. a wide-brimmed hat) when possible.

6.5.2 Routine Skin Care

Most skin care products can be used the day after treatment. Avoid the use of retinoids and topical corticosteroids for 1 – 2 weeks before and after treatment. Avoid systemic steroids (e.g., prednisone, dexamethasone) throughout the course of the CLEAR + BRILLIANT treatment.

6.5.3 Expected Responses to Treatment

Expected Responses	Description
Erythema (Redness)	Mild to moderate erythema (redness) typically develops immediately after treatment and diminishes or resolves within 12 to 24 hours after treatment. A small degree of redness may last longer in some cases.
Edema (Swelling)	Mild to moderate edema (swelling) typically develops immediately after treatment and diminishes or resolves within 12 to 24 hours after treatment. A small degree of swelling may last longer in some cases.
Itching / Dryness	These are common symptoms once the skin has healed initially. Flakiness and dry crusting will gradually clear. Use of bland moisturizers and/or sunscreens that have previously been shown to not cause irritation should help this condition.
Increased Skin Sensitivity	The skin can become more sensitive to touch and temperature changes. This is a sign that the skin is regenerating and daily use skin care products may be applied to soothe the skin. These sensations typically diminish within a few days after treatment.
Pain or Discomfort	Post-treatment cooling gels, cooling masks, or handheld fans may be used to alleviate discomfort. Over-the-counter itch and pain relievers may be used if necessary (e.g., Benadryl®, Claritin®, Tylenol®, etc.). Solta has no knowledge of the effects of NSAIDS (e.g. Motrin®) on the outcome of treatment.
Pinpoint Bleeding/ Petechiae	Although rare, may occur and typically self-resolve without sequelae.

6.6 Complications

Clinical studies have shown that CLEAR + BRILLIANT treatments are safe. There is a very low incidence of side effects and complications associated with treatment. The following complications are very rare but may be associated with non-ablative laser treatments. This is not intended to be an all-inclusive list, nor a substitute for informed consent, which should be provided by every individual.

Complication	Description of Complication
Discoloration	The possibility of temporary and permanent skin color change is known to exist with any laser treatment. Post-inflammatory hypo-pigmentation and hyper-pigmentation are known complications of many laser treatments and may occur with CLEAR + BRILLIANT laser treatment. Following appropriate instructions for sun protection will lower the risk for pigmentation changes.
Infection	A risk of infection exists whenever the skin is wounded. The possibility for infection exists even with non-ablative fractional laser devices such as CLEAR + BRILLIANT. If observed, infection should be treated appropriately with topical and/or systemic medications.
Prolonged Redness	Mild-moderate transient erythema is an expected response with any laser treatment. However, if erythema is severe or persists significantly longer than expected, re-treatment should be avoided until the condition resolves. Reaction may vary on a person-to-person basis.

Complication	Description of Complication
Scarring	The possibility for scarring exists with any laser treatment, even with non-ablative laser devices such as CLEAR + BRILLIANT. Local scarring may occur directly from laser exposure if treatment procedures are not followed properly, or from infection or physical irritation such as picking and rubbing.
Delayed Wound Healing / Skin Textural Changes	Following any laser treatment, re-epithelialization may not occur as expected due to an individual's physiology (i.e. poor wound healing ability, or post-treatment care). This may result in undesirable textural changes.
Temporary Bruising	Temporary bruising may develop over the treated areas.

6.7 Complaints and Adverse Events

Solta Customer Service should be contacted if CLEAR + BRILLIANT is involved in a complaint or adverse event.

7.0 CLEAR + BRILLIANT Laser System Safety Information

CLEAR + BRILLIANT is classified as a Class 3R laser according to IEC/EN 60825-1. Operators and staff must take precautions to prevent direct exposure of laser energy to the eyes. In addition, precautions must be taken to prevent hazards of fire and electrical injury.

This section discusses the primary safety concerns when operating the CLEAR + BRILLIANT Laser System. The instructions are intended to raise awareness of the safety issues and provide insight so that hazardous optical, mechanical, electrical, and chemical risks may be minimized.

CAUTION: Do not open handpiece as there are no serviceable parts contained within. For assistance contact customer service.

7.1 General Considerations and Hazard Potential

Laser light presents a potential eye and burn hazard if handled inappropriately, and has a potential for starting a fire. To prevent injury, avoid unintentional exposure to the laser beam. Take all necessary protective measures and follow appropriate procedures for safety and heed the warnings, cautions, notes and guidelines in this manual. Failure to do so could result in increased risk of injury or fire or damage to equipment.

7.2 Fire Precautions

7.2.1 A fire extinguisher should always be available to extinguish any flames. Know the location of the nearest fire extinguisher in case of fire.

7.2.2 Exercise great care around oxygen anesthetics, or any other flammable substance. In the event of fire, oxygen and other flammable substances will accelerate the progress of a fire, which could cause serious injury.

7.2.3 If alcohol is used for cleaning and disinfection of the skin, allow the area to dry completely before using the laser in order to reduce the possibility of alcohol fuelling a fire. Replace the cover on the alcohol container and remove the alcohol from the immediate area prior to initiating treatment to reduce the possibility of alcohol fuelling a fire, which could cause serious injury.

7.3 Optical Safety

7.3.1 Review, become familiar with, and follow the local regulations for the use of lasers and laser safety.

7.3.2 A designated and laser-trained individual(s) and/or treatment provider shall be responsible for enforcing safety guidelines during operation.

7.3.3 All operators should attend the appropriate laser training course and receive certification and/or credentialing prior to patient treatment.

7.3.4 The treatment room door should be kept closed during operation of the laser. Door interlocks can optionally be installed to automatically disable the laser when the treatment room door is open.

7.3.5 Use extra caution when treating close to the eyes. The laser wavelengths used in the Clear + Brilliant laser systems are extremely hazardous to the cornea and soft tissue around the eye. All operators must have a comprehensive understanding of the risks involved and knowledge of the safety precautions required for these lasers to ensure the safety of the patients and others within the NOHD (Nominal Occular Hazard Distance).

7.3.6 Keep reflective objects out of the treatment field to avoid accidental reflection. Remember that stainless steel eye shields may cause some reflection of the laser beam.

7.4 Laser Safety Eyewear

7.4.1 The CLEAR + BRILLIANT laser cannot fire unless the treatment tip rollers are in contact with the skin, making it safe for use without protective eyewear. Laser light is only emitted when the tip is in intimate contact with skin which precludes the emission of errant light energy. The laser will not fire unless the sensors indicate skin contact has been made and the tracking system indicates there is motion.

7.4.2 Should treatment providers choose to use protective eyewear during the laser procedure, it is recommended that glasses or goggles with the appropriate protection range for the CLEAR + BRILLIANT laser wavelengths (1440 nm ± 20 nm and 1927 ± 20 nm) and optical density of 1 or greater, be used.

7.4.3 It is prudent to provide appropriate eye protection for patients (even though the laser cannot fire unless the treatment tip rollers are in contact with the skin). Examples of patient-specific eye protection used by practitioners skilled with the use of this and similar lasers include: disposable laser eye shields and non-disposable laser eye shields (Glendale Laser, Kentek Corporation, Lasermet Limited, Oculo-Plastik, Inc.).

7.5 Operation of the Laser System

CAUTION: Solta does not and cannot recommend standard operating practice. The following guidelines are suggested as a starting point from which operators may become familiar with good laser technique.

7.5.1 Check the laser prior to every procedure before admitting the individual receiving treatment into the room.

ATTENTION! THE CONSOLE MUST BE TURNED OFF PRIOR TO CHANGING FROM ONE HANDPIECE TO THE OTHER AND THEN TURNED ON ONCE DESIRED HANDPIECE IS PROPERLY CONNECTED TO THE CONSOLE. FAILURE TO DO THIS WILL RESULT IN IRREPARABLE DAMAGE TO THE HANDPIECE.

7.5.2 The laser is designed to fire only when:

(a) A treatment tip is properly installed on the handpiece,

(b) The treatment level has been selected on the handpiece,

(c) The laser has been activated by pressing the handpiece activator button and,

(d) The Intelligent Optical Tracking System (IOTS) senses handpiece motion across the surface of the skin. See Section 5.1 of this manual for a more detailed explanation of the IOTS.

7.5.3 Do not allow the tip to lose contact with the skin during treatment.

7.5.4 The audible tones emitted by the unit during treatment are an indication of handpiece velocity. If the handpiece is moved at an unsustainable velocity, i.e. above that where the system will produce the correct pulse energy and repetition rate, the sound will change to a higher-pitched tone designed to alert the operator. Slowing down will restore the audible tones to normal.

7.5.5 Refer to the list of “Indications for Use” and “Contraindications” before treatment.

7.5.6 Do not use if visible damage is observed on the system, handpiece and/or handpiece cable.

7.6 Electrical Safety

7.6.1 Electrical hazards with the laser are similar to any high-powered electrical device. Care should be taken when plugging the unit into the wall outlet. The area must be free of water and your hands must be dry to avoid electric shock. Always disconnect the laser by grasping and pulling the plug and not the power cord.

7.6.2 Place the power cord where it cannot become a hazard.

7.6.3 The system is pre-calibrated and does not require any Operator set-up or calibration once the system is installed. Improper service, repair or modifications performed by unauthorized personnel may pose a hazard and will invalidate any warranty agreement.

7.6.4 Servicing CLEAR + BRILLIANT is to be done only by Solta authorized personnel. If service is required call Solta Customer Service or your local authorized distributor of Solta Medical products.

CAUTION: Do not position the device so that the rear panel is inaccessible for disconnecting the power cord from the CLEAR + BRILLIANT system.

7.7 Laser Room Access and Remote Door Interlock

7.7.1 Always limit personnel in the treatment room to those essential to the procedure. To protect personnel from possible injury due to entry into the procedure room during treatment, an optional remote door interlock can be connected from the laser system to the procedure room entrance door.

7.7.2 When connected, the interlock will automatically disable the laser if the door is opened during the procedure. When the door is closed, the interlock is reconnected and treatment can resume once the message is acknowledged.

7.7.3 Access to the remote door interlock is through a plug and socket located on the back panel of the system. The system is delivered with this plug shorted internally. Contact Solta Customer Service for more instructions on installing the remote door interlock.

7.7.4 Do not connect other power supplies to this interlock. Connecting devices to the unit other than instructed may cause severe damage to the unit and will result in voiding of the device warranty.

7.8 Proper Laser Routine Maintenance, Handling, and Storage

7.8.1 Only Solta personnel or personnel approved and trained by Solta shall install or adjust the CLEAR + BRILLIANT Laser System.

7.8.2 Do not use acetone on the tip as this may cause damage preventing the tip from functioning properly.

7.8.3 To clean the handpiece sealing window, carefully use an alcohol prep pad or gauze moistened (do not soak) with 70% alcohol. Allow the window to dry before initiating treatment in order to mitigate the risk of fire from which serious injury could result.

7.8.4 Do not set liquids of any kind on top of the laser. Do not allow any solid or liquid substances to get inside of the handpiece or console.

7.8.5 Minimize the presence of dust particles and corrosive substances such as salts and acids in the storage environment in order to extend the lifetime of the laser system.

7.8.6 Do not store the laser outside.

7.8.7 Do not allow the plastic or metal parts of the handpiece to come into prolonged contact with chemically aggressive cleaning solutions.

7.8.8 The exterior chassis of the laser system can be cleaned with a soft cloth dampened with mild cleansing solution.

7.8.9 Do not move/transport laser system with handpiece attached as handpiece may fall and crack or become damaged. If system needs to be moved/transported, handpiece should be detached and transported separately.

7.9 Regulatory Compliance and Device Safety Information

7.9.1 Safety Features

CLEAR + BRILLIANT provides a means for setting and measuring the laser output of the laser source, and also contains the required interlock connector, a treatment credit processing system and a removable treatment tip to limit unauthorized access, and labeling.

7.9.2 Emergency Stop Button

The laser has an emergency stop button that, when pushed, turns off (de-energizes) the laser in emergency situations.

7.9.3 Restricting Access to Authorized Users

The treatment card authentication system and treatment tip can be used to restrict access to the device to authorized users ONLY. Laser light can be produced by the system only when there a valid treatment card with available treatment credits is inserted in the card reader and the treatment tip is properly installed.

7.9.4 Laser Emission Indicator

After a self-test, treatment can only begin when the laser is in the activated state by pushing the handpiece activator button. The laser also emits an audible sound when the treatment is being delivered.

7.9.5 The laser can only fire when the following conditions are met:

(a) The tip is installed correctly,

(b) Treatment setting has been selected,

(c) Laser has been activated, and the handpiece senses motion across the skin.

7.9.6 Remote Interlock Connector

The remote interlock connector permits the operator to connect a remote barrier interlock. The interlock is wired internally such that, when the terminals of the connector are open, the laser is disabled to prevent laser emission.

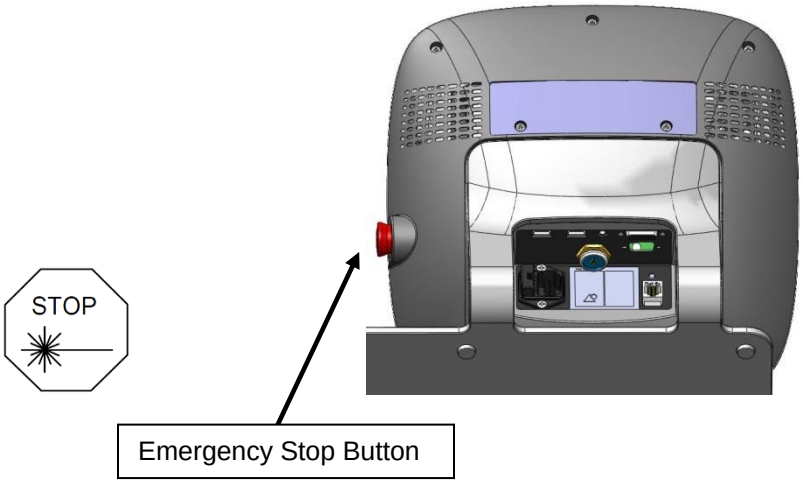
7.9.7 Protective Housing

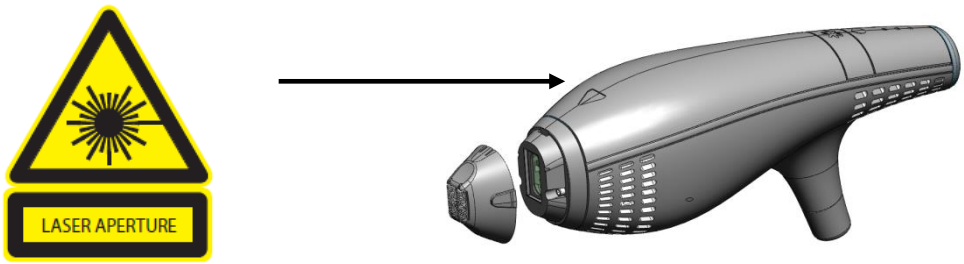
The laser has a protective housing which prevents unintended access to laser radiation. The laser optical path is enclosed in the handpiece. The only exposed laser portal is the laser aperture between the tip rollers when the treatment tip is in place on the handpiece. No sections of the housing can be removed without specialized tooling, except for the treatment tip which is interlocked to prevent laser operation when the tip is not properly attached.

7.10 Labeling

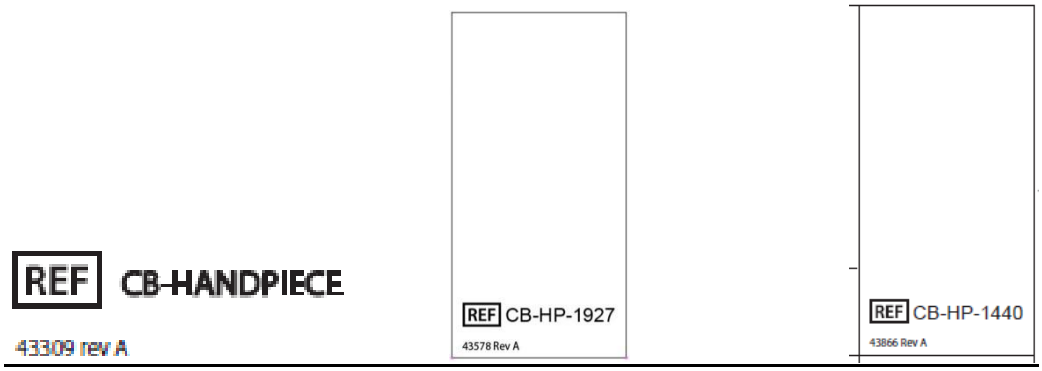
The CLEAR + BRILLIANT Laser System bears the required manufacturing warning labels.

The location, positioning and formatting of labels are subject to change.





Labels on Handpieces (Catalog Numbers)



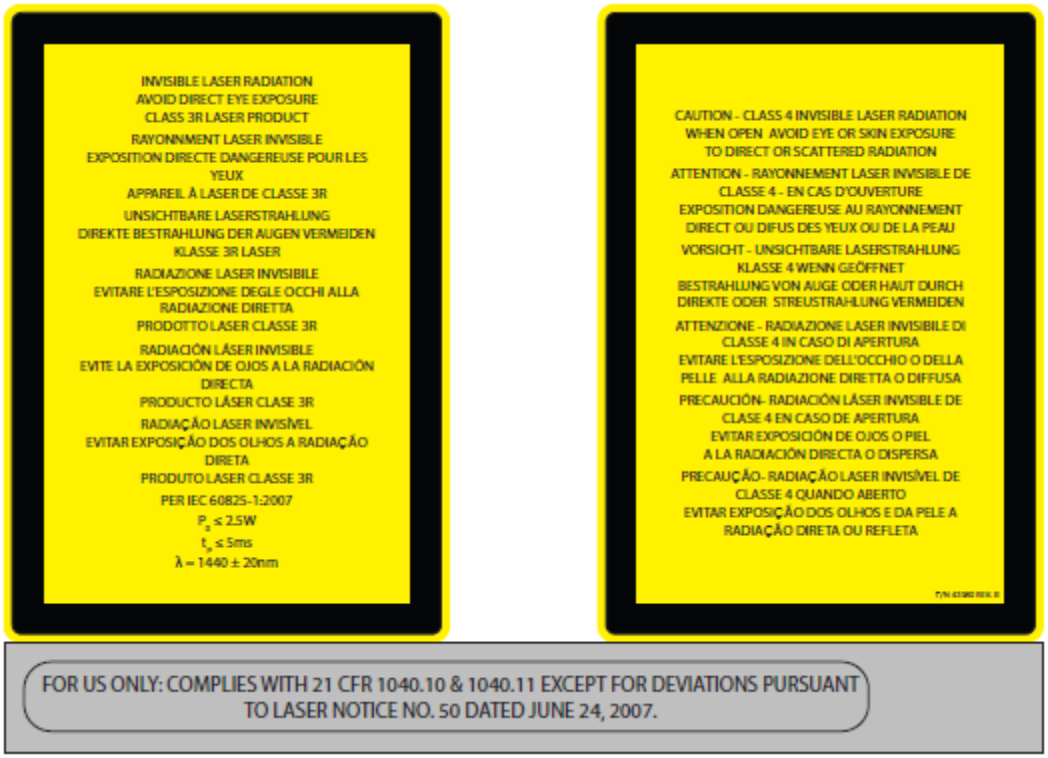
Labels on Tips Packaging

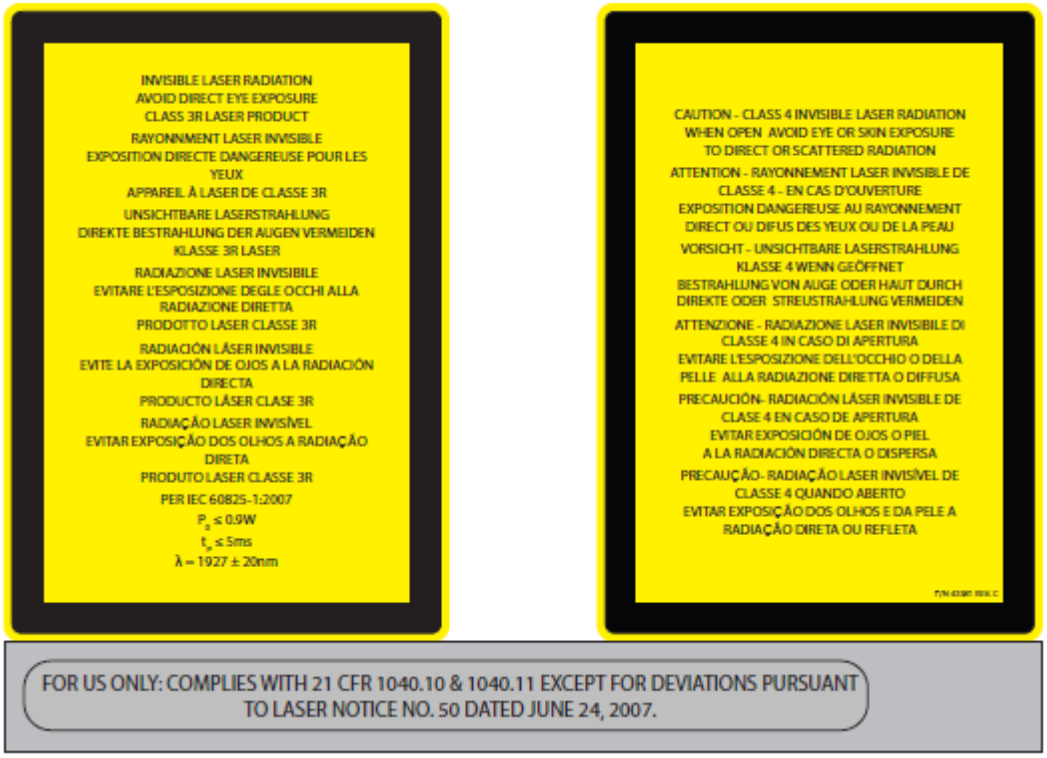
P009336-01

P009338-01

Regulatory Compliance Labels

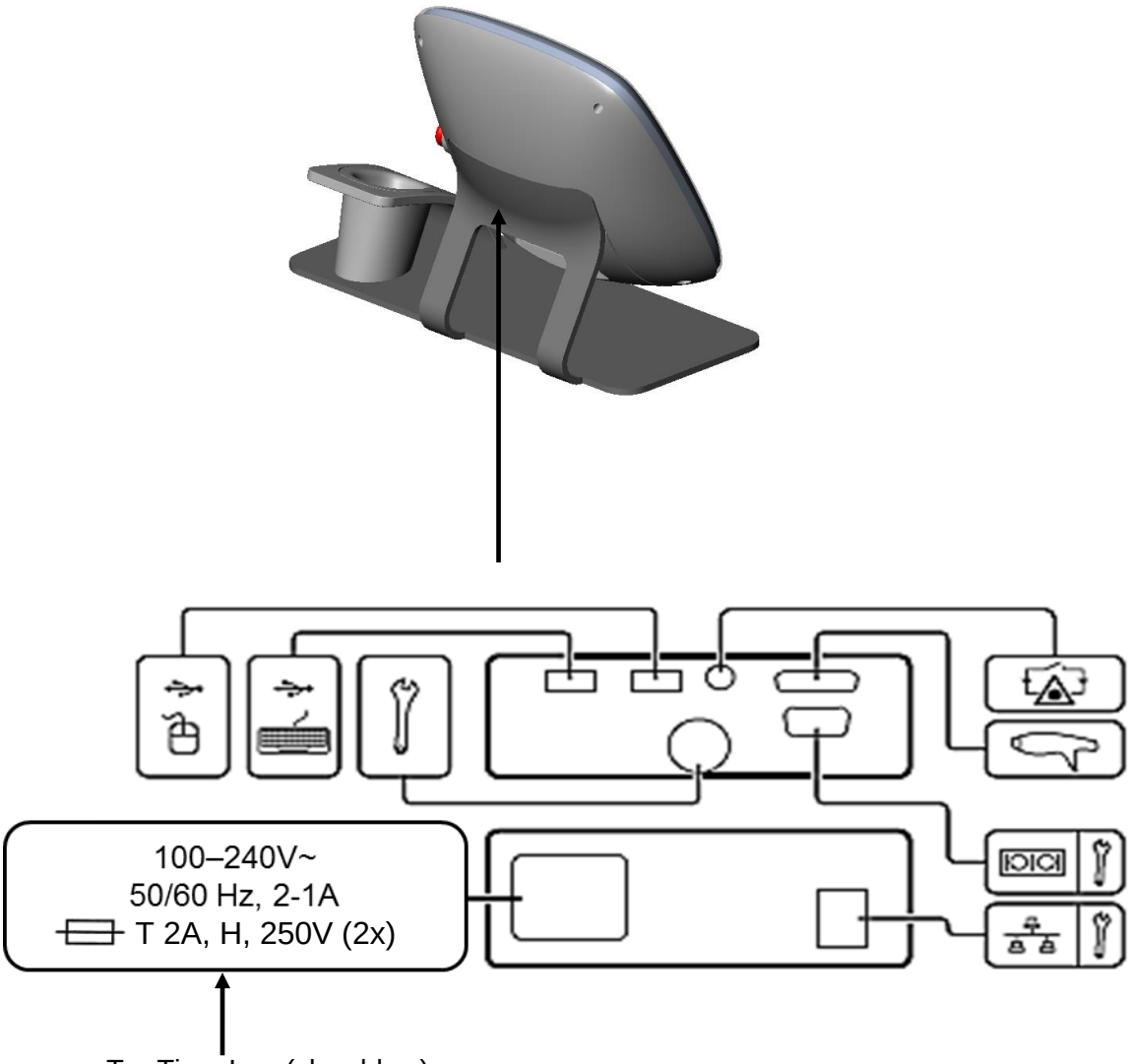
The location, positioning and formatting of labels are subject to change.





Regulatory Compliance Labels

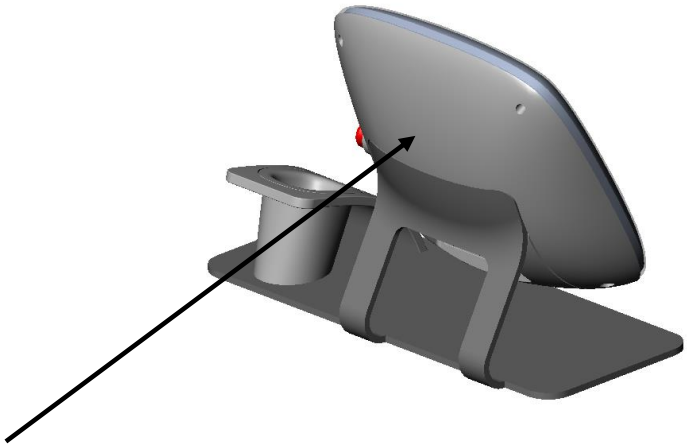
The location, positioning and formatting of labels are subject to change.

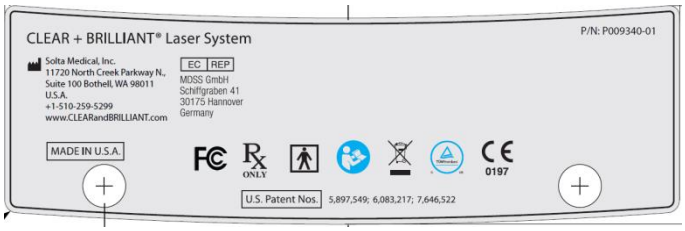


T = Time Lag (slow blow)

H = High Breaking Capacity 1500A

2x = Two Fuses




CLEAR + BRILLIANT® Laser System
P/N: P009340-01
Solta Medical, Inc.
11720 North Creek Parkway N.,
Suite 100 Bothell, WA 98011
U.S.A.
+1-510-259-5299
www.CLEARandBRILLIANT.com
EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany
MADE IN U.S.A.
Rx ONLY
CE 0197
U.S. Patent Nos. 5,897,549; 6,083,217; 7,646,522

8.0 CLEAR + BRILLIANT Laser System Safety Specifications

8.1 Technical Specifications – Original (1440 nm) Handpiece

	Invisible Laser Radiation
IEC 60825-1 Classification	Class 3R
Wavelength	1440 ± 20 nm; min:1420 max:1460
Maximum Power (average)	2.5 W
Maximum Pulse Energy	9 mJ
Maximum Pulse width	3 ms
Pulse Repetition Rate	< 400 Hz

Technical Specifications - Perméa (1927 nm) Handpiece

	Invisible Laser Radiation
IEC 60825-1 Classification	Class 3R
Wavelength	1927 ± 20 nm; min:1907 max:1947
Maximum Power (average)	0.9 W
Maximum Pulse Energy	5 mJ
Maximum Pulse width	5 ms
Pulse Repetition Rate	< 150 Hz

8.2 Console

Dimensions / in	17.62w x 12.47h x 8.03d
(/cm)	44.76w x 31.67h x 20.4d
Weight	~ 15 lbs

8.3 Operating Conditions

Maximum Recommended Ambient Air Temperature for Treatment	30°C / 86°F
Operating Temperature Range	15 to 30°C, 59 to 86°F
Humidity	30 – 75% Non-condensing
Altitude	< 10000 feet / 3075 meters

8.4 Shipping and Storage (Non-Operational)

Temperature Range	-15 to 45°C, 5 to 113°F
Humidity	30 – 75% Non-condensing
Altitude	< 45000 feet / 13846 meters

8.5 Compatible Delivery Devices

Only use original CLEAR + BRILLIANT Disposable Tips. Contact Solta Customer Service or your local authorized distributor of Solta Medical products for more information.

8.6 Electromagnetic Compatibility and Immunity

This guidance and manufacturer's declaration information pertain to the CLEAR + BRILLIANT

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment.

All medical electrical equipment must be installed and put into service in accordance with the EMC information provided in this document.

Portable and mobile RF communications equipment can affect the behavior of medical electrical equipment.

The CLEAR + BRILLIANT Laser System is intended to be used in a Professional healthcare facility environment (e.g.; single physician medical office or outpatient clinical facility). It does not include areas where there are sources of intense electromagnetic disturbances, such as a RF shielded room of magnetic resonance imaging, or in operating rooms near active HF surgical equipment.

It is essential the CLEAR + BRILLIANT Laser System not deliver an excessive amount of energy to the patient per the selected treatment setting. Placing the system in areas where intense electromagnetic disturbances could be present may result in excessive energy delivered to the patient, or unexpected changes in treatment levels that could lead to possible burns to the patient.

The CLEAR + BRILLIANT complies with applicable and required standards for electromagnetic interference:

- The CLEAR + BRILLIANT does not normally affect nearby equipment and devices.
- The CLEAR + BRILLIANT is not normally affected by nearby equipment and devices.
- It is not safe to operate the CLEAR + BRILLIANT in the presence of high-frequency medical equipment.
- It is good practice to avoid using the CLEAR + BRILLIANT and in close proximity to other equipment.

Guidance and manufacturer's declaration – electromagnetic emissions

The CLEAR + BRILLIANT is intended for use in the electromagnetic environment specified below. The customer or user of the CLEAR + BRILLIANT should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Class A Group 1	The CLEAR + BRILLIANT Laser 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 Group 1	The CLEAR + BRILLIANT system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network which supplies buildings used for domestic purposes. **WARNING**: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the CLEAR + BRILLIANT Laser System or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker IEC 61000-3-3	Complies	

NOTE 1: The Emission characteristics of this equipment make is suitable for the use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential/domestic 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 re-orienting the equipment.

NOTE 2: There were no test level or compliance deviations to IEC 60601-1-2, 4th edition.

Guidance and manufacturer's declaration – electromagnetic immunity

The CLEAR + BRILLIANT is intended for use in the electromagnetic environment specified below. The customer or user of the CLEAR + BRILLIANT should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ± 8kV, ±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 transient / burst IEC 61000-4-4	± 2 kV on AC mains lines ± 1 kV for signal input / output lines, 100kHz	± 2 kV on AC mains lines ± 1 kV for signal input / output lines, 100kHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	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 cycle and 70% UT; 25/30 cycles Single phase: at 0°	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CLEAR + BRILLIANT requires continued operation during power mains interruptions, it is recommended that the CLEAR + BRILLIANT be powered from an uninterruptible power supply or a battery.
Power frequency (50/ 60Hz) magnetic field 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 1: U_T is the a.c. mains voltage prior to application of the test level. NOTE 2: There were no test level or compliance deviation to IEC 60601-1-2, 4th edition			

Guidance and manufacturer's declaration – electromagnetic immunity (continued)

The CLEAR + BRILLIANT is intended for use in the electromagnetic environment specified below. The customer or user of the CLEAR + BRILLIANT should assure 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 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	**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 CLEAR + BRILLIANT Laser System, including cables specified by Solta. Otherwise, degradation of the performance of this equipment could result.
Radiated RF IEC 61000-4-3	3 V / m 80 MHz to 2,7 GHz	3 V / m	
NOTE: There were no test level or compliance deviations to IEC 60601-1-2, 4th edition.			

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The CLEAR + BRILLIANT Laser System is intended for use in the electromagnetic environment specified below. The customer or the user of the CLEAR + BRILLIANT Laser System should assure that it is used in such an environment.			
IMMUNITY Test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Proximity field from RF wireless communications equipment IEC 61000-4-3	See table 9 in IEC 60601-1-2, 4th Edition	See table 9 in IEC 60601-1-2, 4th Edition	
NOTE: There were no test level or compliance deviations to IEC 60601-1-2, 4th edition.			

Table 9: IEC 60601-1-2, 4th Ed, - Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment.

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900 TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1,720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1,845						
1,970						

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
2,450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5,240	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5,500						
5,785						
Note: if necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the CLEAR + BRILLIANT may be reduced to 1 m. The test distance is permitted by IEC 61000-4-3.						
[a] For some services, only the uplink frequencies are included. [b] The carrier shall be modulated using a 50% duty cycle square wave signal. [c] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

9.0 Regulatory Compliance

9.1 Laser Safety and Electrical Product Safety Standards

CLEAR + BRILLIANT meets applicable electrical and laser safety standards (per IEC 60601 series and IEC 60825-1) for a Class 3R laser.

The CLEAR + BRILLIANT Laser System contains a Class 3R laser, according to IEC/EN 60825-1:2007 standards. The treatment provider and associated staff must take precautions to prevent direct exposure of laser energy to the eyes.

10.0 Maintenance and Warranty

The CLEAR + BRILLIANT Laser System should not require any specific maintenance by the operator. Routine regular preventative maintenance should be performed on the system as described in this manual. The device is covered by the warranty described in the Solta Master Purchase Agreement and the included attachments thereto, such as the Terms and Conditions of Sale.

10.1 Warranty Information

Please refer to the Terms and Conditions of Sale document attached to the Master Purchase Agreement. Specific warranty terms and procedures are discussed in this document.

10.2 Cleaning Procedures

10.2.1 Exterior Surfaces

The exterior surfaces of the laser console may be cleaned with a soft cloth damped using a mild cleansing solution – e.g. 70% alcohol solution. Do not use harsh detergents or acetone to clean the exterior surfaces, including the console. The display screen should be cleaned with antistatic glass or plastic cleaner. Do not pour cleaning products directly on the system and/or handpiece, as this could cause damage to the system.

10.2.2 Handpiece

ATTENTION! THE CONSOLE MUST BE TURNED OFF PRIOR TO CHANGING FROM ONE HANDPIECE TO THE OTHER AND THEN TURNED ON ONCE DESIRED HANDPIECE IS PROPERLY CONNECTED TO THE CONSOLE. FAILURE TO DO THIS WILL RESULT IN IRREPARABLE DAMAGE TO THE HANDPIECE.

Wipe the exterior surface of the handpiece with a gauze pad moistened with a small amount of 70% alcohol solution. The handpiece must be thoroughly dried prior to initiation of treatment. Do not use harsh detergents or acetone to clean the handpiece. The handpiece can be cleaned with or without the treatment tip attached.

10.2.3 Component Replacement/Service

Solta Medical, Inc. offers a full service warranty to cover all necessary modifications, replacements, and repairs for CLEAR + BRILLIANT. Contact Solta Medical Customer Service to confirm return of the device for these purposes.

To remove and/or install the replaceable fuse in the back panel of the system console, press on the center tab to release the fuse

enclosure, pull up gently and replace the fuse. Place the new fuse back into the pocket until is snaps into place.

CAUTION: All equipment should be properly cleaned or decontaminated before return to Solta. Failure to do this will result in delays and charges to the customer.

10.3 Disposal and Recycling

Do not dispose of the laser console as unsorted municipal waste. End of life electrical / electronic equipment must be collected separately to prevent effects to the environment and human health.

Follow local governing ordinances and recycling plans regarding the recycling or disposal of this equipment and its accessories.

11.0 Re-order Information

To reorder accessory or device related items, contact Solta Customer Service or your local authorized distributor of Solta Medical® products.

Device Model/Type Reference: CLEAR + BRILLIANT Laser System

Ratings:

100 – 240 VAC, 50 / 60Hz, 2 – 1A

Output: Max. Power (average) = 2.5 W (Laser, 1440 ±20 nm)

Output: Max. Power (average) = 0.9 W (Laser, 1927 ±20 nm)

11.1 Components

The components are as follows:

- CB-CONSOLE-SC: system display console and cradle with SmartCard
- CB-HANDPIECE/CB-HP-1440: treatment handpiece with 1440 nm diode laser
- CB-HP-1927 (Perméa): treatment handpiece with 1927 nm diode laser
- CB-TIP-SC: disposable treatment tip with smartcard for 1440nm handpiece
- CB-TIP-SCP: disposable treatment tip with smartcard for 1927nm (Perméa) handpiece

11.2 Accessories

Accessory items include:

- CB-HP-CASE: Storage case for 2 handpieces
- CB-BURNPAPER: Pattern paper to test laser array
- Solta PN 44863, Extension cable

12.0 Shipping, Installation and Set-Up Requirements

12.1 Shipping

The CLEAR + BRILLIANT Laser System will be shipped in a specially designed container. When the shipment is received, inspect the exterior container for damage. If there is exterior damage, DO NOT ACCEPT OR UNPACK THE SYSTEM. Contact Solta Customer Service or your local representative of Solta Medical products and the shipping company immediately.

Store the system indoors and at a temperature similar to the temperature of the facility in which it is to be installed.

12.2 Space Requirements

The dimensions of CLEAR + BRILLIANT are listed in the specifications above. Allow adequate space for ventilation (at least a 12 inch perimeter all around the laser system console) to prevent overheating.

12.3 Environmental

The temperature in the laser room and the ambient operating temperature should ideally remain within the range defined in section 8.3.

12.4 Electrical

CLEAR + BRILLIANT contains a universal, medical grade, power-factor corrected power supply. The line voltage and power switch amperage requirements are given in the specifications section of the manual. Solta recommends a dedicated circuit for the laser system. Place the power cord where it cannot become a hazard, for example by being tripped over or having sharp objects dropped on it.

The worst-case current draw is anticipated to be: 2A (steady state) at 100V line voltage.

12.5 Moving the Laser System:

12.5.1 Shut down the laser and then remove the power cord plug from the wall and from the power switch housing in the laser.

12.5.2 Disconnect handpiece from the system console and transport separately. Handpiece may fall and crack if transported in cradle.

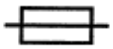
12.5.3 Move the system to the new location.

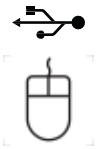
12.5.4 When the system is placed in its final working location, ensure that the surface is sturdy and that the system has adequate breathing room.

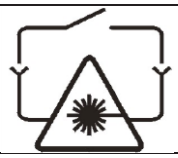
13.0 Labeling Symbols

BS EN ISO 15223-1: 2012 Medical devices—Symbols to be used with medical device labels, labeling and information to be supplied. Part 1: General requirements			
Symbol	**Symbol Ref. No.**	**Symbol Title**	**Additional Information**
	5.1.1	Manufacturer	The date of manufacture, as well as the name and address of the manufacturer, can be combined in one symbol. Additional reference ISO 7000-3082.
	5.1.2	Authorized representative in the European Community	
	5.1.3	Date of manufacture	This symbol can be filled or unfilled. If filled, the date of manufacture as well as the name and address of the manufacturer can be combined in one symbol. Additional reference ISO 7000-2497.
	5.1.5	Batch code	Synonyms for “batch code” are “lot number” and “batch number.” Additional reference ISO 7000-2492.
	5.1.6	Catalogue number	Synonyms for “catalogue number” are “reference number” and “reorder number.” Additional reference ISO 7000-2493.
	5.1.7	Serial number	Additional reference ISO 7000-2498.
	5.2.8	Do not use if package is damaged	This symbol may also mean “Do not use if the product sterile barrier system or its packaging is compromised.” Additional reference ISO 7000-2506.
	5.3.1	Fragile, handle with care	Additional reference ISO 7000-0621.
	5.3.4	Keep dry	Additional reference ISO 7000-0626.
	5.3.7	Temperature limit	Additional reference ISO 7000-0632.
	5.3.8	Humidity limitation	Additional reference ISO 7000-2620
	5.4.2	Do not re-use	Synonyms for “Do not re-use” are “single use” and “use only once.” Additional reference ISO 7000-1051.
	5.4.3	Consult instructions for use	Synonym for “Consult instructions for use” is “Consult operating instructions.” Additional reference ISO 7000-1641.

BS EN 50419:2006 Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC		
Symbol	**Symbol Title**	**Additional Information**
	WEEE wheeled bin	This product contains electrical and electronic components that may contain materials which, if disposed with general waste, could be damaging to the environment. Residents of the European Union must follow specific disposal or recycling instructions for this product. Residents outside the European Union must dispose or recycle this product in accordance with local laws or regulations that apply.

IEC TR 60878 Ed. 3.0 b:2015 Graphical symbols for electrical equipment in medical practice			
Symbol	**Symbol Ref. No.**	**Symbol Title**	**Additional Information**
	ISO 7010-W001 (2011-06)	General warning sign	To signify a general warning. *Note - This safety sign cannot be used on its own and requires a supplementary sign to give further information about the hazard.* *IEC TR 60878 note: On medical equipment, this safety sign shall only be used if there is no other safety sign for the corresponding hazard. If possible, the hazard or the appropriate precaution should be indicated.*
	6197	Emergency Laser Stop	The laser emergency stop button turns off (de-energizes) the laser in emergency situations
	5152	Laser Aperture	Laser Aperture, avoid exposure. Invisible laser radiation
	ISO 7010-M002 (2011-06)	Refer to instruction manual/booklet	To signify that the instruction manual/booklet must be read.
	5334	Type BF applied part	To identify a type BF part complying with IEC 60601-1. Additional reference IEC 60417-5334 (2002-10) *Note 1 – B = Body.* *Note 2 – F = Floating applied part.*
	5016	Fuse	To identify fuse (fuse boxes) or their location Additional reference IEC 60417-5016 (2002-10).

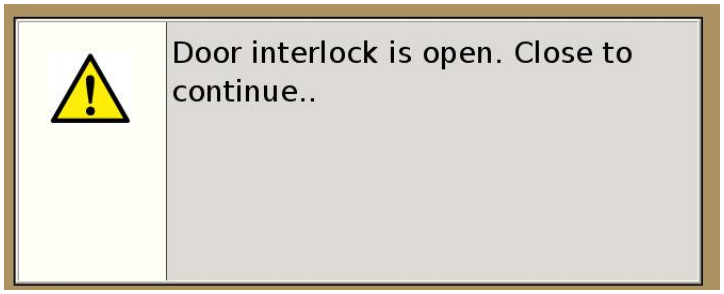
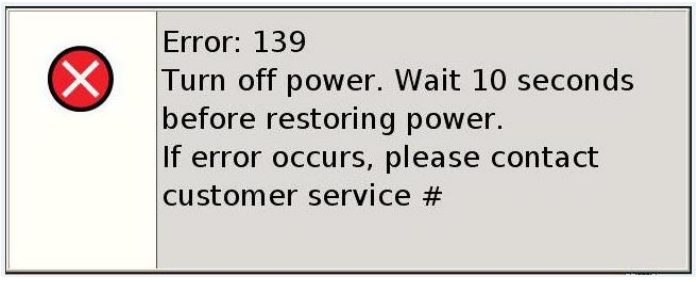
IEC TR 60878 Ed. 3.0 b:2015 Graphical symbols for electrical equipment in medical practice			
Symbol	**Symbol Ref. No.**	**Symbol Title**	**Additional Information**
	5032	Alternating current	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals. Additional reference IEC 60417-5032 (2002-10).
	5140	Non-ionizing electromagnetic radiation	To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems, e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment. Additional reference IEC 60417-5140 (2003-04)
	ISO 7000-2794 (2011-06)	Packaging unit	To indicate the number of pieces in the package. Additional reference ISO 7000-2794 (2009-02) *Note – A number is inserted in the symbol to indicate the number of parts in the package.*
	ISO 7000-2403 (2011-06)	Stacking limit by number	To indicate that the items shall not be vertically stacked beyond the specified number, either because of the nature of the transport packaging or because of the nature of the items themselves.
	5850	Serial Interface	Communication Connectors (These ports are used in case a system error has occurred. This port is utilized by qualified Service Technicians Only) Do not insert any cable or wires to any of the service ports as this may potentially cause damage to the equipment
	5988	Computer network	**For Service Use Only.** To identify the computer network itself or to indicate the connecting terminals of the computer network.
	5990 and Universal serial bus (USB) symbol	USB Mouse connection port	This port is used for system updates/upgrades.
	5991 and Universal serial bus (USB) symbol	USB Keyboard connection port	This port is used for system configuration and operation. The keyboard provides access to the system configuration screen. Customers can adjust the system volume and choose preferred language and time zone. During operation, the card reader is connected to this port.

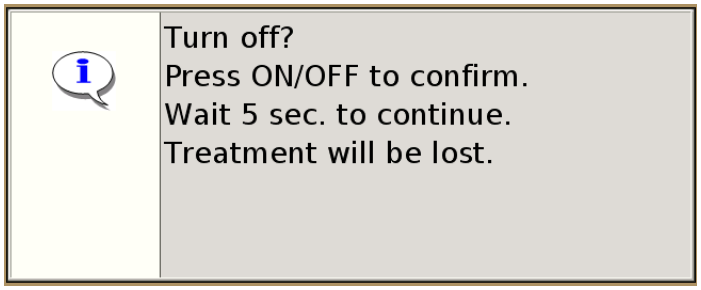
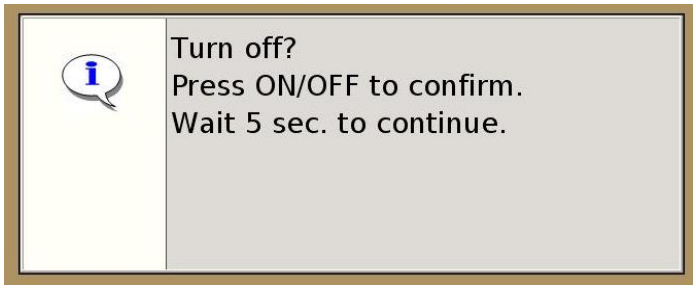
Other Marks and Symbols		
Symbol	**Symbol Description**	**Additional Information**
	On/Off (push/push)	Based on IEC 60417-5009 (2002-10) Stand-By Symbol
CE	European Conformity mark Notified Body: TUV Rheinland (0197)	The product conforms to European Medical Directive 93/42/EEC and meets applicable health, safety and environmental requirements. If the mark is accompanied by a number, conformity is verified by the indicated notified body.
	TUV Rheinland classification mark	TUV Rheinland of North America classification mark that indicates compliance with both U.S. and Canadian National Standards.
℞Only	For U.S. Only: Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician or licensed health care professional.	USA Code of Federal Regulations 21 CFR Part 801 § 801.109(b)(1)
FC	The Federal Communications Commission (FCC) Declaration of Conformity mark	For U.S. Only: This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: 1. This device may not cause harmful interference and, 2. This device must accept any interference received, including interference that may cause undesired operation.
MADE IN USA	MADE IN USA	Country of origin symbol
	Important information (software symbol)	Important information. Please read and follow instructions
	System Fault (software symbol)	System Fault. Discontinue treatment and reboot system. If the system is still not functioning, contact Customer Service.
	Handpiece Connector	Attach the handpiece to this connector
	Remote Interlock Connector	Laser safety interlock can be used to automatically disable the laser if the door is opened during the procedure.
	Treatment Card	The treatment card is required for treatment validation and system activation.

Other Marks and Symbols		
Symbol	**Symbol Description**	**Additional Information**
	Service Key (For Service Technicians Only)	Based on ISO 7000:0717 (2004-01)
	Clear + Brilliant Product Logo	Clear + Brilliant Registered Trademark
	Clear + Brilliant Perméa Product Logo	Clear + Brilliant Registered Trademark
	Clear + Brilliant Laser System	Clear + Brilliant (registered trademark) product name

14.0 Error Messages and Troubleshooting

	SmartCard must remain inside the card Reader.
	Remove SmartCard from Reader and re-insert into Reader verifying proper card orientation and that light on top of Reader turns green.
	It is safe to remove SmartCard from the Reader.
	The Reader cannot read SmartCard properly. Re-insert SmartCard and verify proper insertion by ensuring green light on top of the Reader is lit. Also, verify that SmartCard matches the handpiece attached to the console. Additionally, please ensure valid treatments are available on the SmartCard.
	If the error message above – “Invalid Read. Please re-insert card and try again.” - appears 2 times, the third invalid read will lead to this message. Please contact Customer Service.
	All treatment credits have been used up. Insert a SmartCard with available treatment credits.

	Handpiece temperature must not exceed 40°C. This message will disappear once handpiece temperature is below 40°C. Treatment should continue uninterrupted.
	If you wish to cancel a treatment, proceed to press blue button on the console. If you reach this message in error, press any button on the handpiece to return to stand-by mode.
	If treatment is complete, proceed to press blue button on the console. If you reach this message in error, press any button on the handpiece to return to stand-by mode.
	The door interlock is a safety feature located on the back of the console. It must be properly engaged in order to activate laser. Verify door interlock is in proper position. If it is not, push door interlock until it is properly seated in system.
	Turn the system off and restart after 10 seconds. If the system is still not functioning, please contact Customer Service. This message not specific to Error: 139. This is just one example for various Error codes.

	If the ON/OFF button is pressed before a treatment is completed, user is asked to confirm request to turn system off by pressing ON/OFF button again. Please note, if system is turned off before a treatment is complete, the treatment will not be available for future use
	If you'd like to power system OFF, press the ON/OFF button to proceed. If you reach this message in error, wait 5 seconds to return to previous screen.