



Sapphire[®] plus

Instructions for Use

Dental Curing Light with Optional Tooth Whitening

Conforms to AAMI Std ES60601-1, IEC Stds60601-1-6, 80601-2-60 & 62366
Certified to SCA Std C22.2 NO. 60601-1-6



Table of Contents

Warnings and Precautions	1-2
Electromagnetic Compatibility	3
Important Start-up/Set-up Instructions	4
Device Description and Intended Use	5-6
Controls and Functions	6
Control Panel	7
Accessories.....	7
Set-up and Operation Instructions.....	8
Light Meter (Radiometer)	9
Curing Mode	9-10
Curing Instructions.....	10
Bleach (Whitening) Mode	11-12
Whitening Instructions	12-15
Sanitizing and Sterilizing	16
Replacement Parts	16
Service.....	16
Troubleshooting	17
Lamp Replacement Instructions	18
Fuse Replacement	19
Transportation	19
Storage	19
System Warranty.....	20
Contact and Order Information.....	21

Warnings and Precautions

(Read completely through and understand before proceeding)

Each statement in this section is a WARNING

Before connecting and operating the Sapphire® Plus, read all safety instructions. When used properly and with normal precautions, the Sapphire Plus is a safe and effective multi-purpose light system. However, the Sapphire Plus is a source of high electrical voltage, intense light, and heat. This product must only be used as indicated in this manual.

This device must be used by Dental professional such as Board Certified Dentist or Orthodontist. Must have specific training in use of light curing systems. Must be familiar with complete instructions for use (especially all warnings, precautions and alerts).

Do not shine light from the tip on anything other than indicated use (restorative materials which cure using photo-initiators). Shining light on combustible materials may CAUSE FIRE. Use only as directed. Maintain this practice even when you believe the lamp is off and cannot come back on.

Before connecting the Sapphire Plus to the mains (the AC wall outlet), verify that the voltage to be applied is within the range of that specified on the identification label on the backside of the instrument. If you have any questions concerning the proper voltage, call the factory for clarification.

To avoid risk of electric shock, disconnect the power cord before opening the lamp access door. Never remove the product cover. All repairs other than lamp and fuse replacement must be made by a factory authorized representative. Lamp replacement and fuse replacement must be done by a qualified service technician or by factory authorized representative. Do not touch or probe other electronic components inside the product. There is a risk of electric shock, even when the unit is disconnected from the AC wall outlet.

Do not modify this equipment. It is unsafe and voids the warranty.

Do not simultaneously touch the Sapphire main unit and the patient, either directly or through your body.

The unit generates high intensity light. The light travels down the light cable (warming the cable) and come out the end of the light guide. High-intensity light can be harmful to the eyes. When the system is in use, the patient, operator, and assistant(s) must all wear protective eyewear. Caution should be used to avoid accidentally starting the light outside of the mouth. To avoid possible injury, never look directly into the end of the light guide or directly into the light output on the front panel (even with protective eyewear). Never shine the light into the eyes. The provided Orange Safety Glasses Must be Worn at all times (Clinician and User) when using this equipment.

PRECAUTION: When not in use, immediately turn off the power switch at the back of the device. Remove the tip from the end of the light guide handle. Remove the light guide from the light guide receptacle. This reduces risks associated with the light coming on expectantly.

Never look into the light guide receptacle of the main Sapphire unit. Interlocks in the system are designed to prevent light from coming out of the receptacle, but if the system fails, intense light could come out of the receptacle.

High-intensity dental lights should not be used by operators or on patients who may be photo-sensitive.

Also use extreme caution with patients who have any conditions which may make any portions of their mouths heat sensitive.

Do not expose soft oral tissues directly to the tip of the light or to the light coming out of the tip at close proximity.

Do not direct the light on to unprotected gingiva or skin. Even a portion of the beam directed on unprotected gingiva or skin can cause a rapid rise in temperature. While the reflective surface of the teeth is less prone to this effect, the condition of oral tissue must be monitored closely during exposure to the light.

Use the correct curing tip to ensure the light is focused on the tooth. The intense light can quickly blister gums or unprotected skin. Council patient to immediate notify you if they experience discomfort associated with a temperature rise or heat. Apply the light for only as long is needed to achieve required cure or bleaching. Do not over expose.

Use the 2 mm and 4 mm Ceri-Taper™ Tacking Tips only for tacking of restoratives. They may also be used for curing of lumineers but only for 1 to 2 seconds exposure times. Extreme care must be used with use of the 2 mm and 4 mm Ceri-Taper Tacking Tips. The smaller tips focus all of the lamp energy output into a smaller focused area.

Only use the light guide supplied with the Sapphire® Plus. Other light guides may not be effective and may damage the light. Do not cause excessive bending in the light guide. Do not drop the light guide or tip. Do not autoclave the light shield provided with the unit. Do not autoclave the light guide. Removable curing tip is autoclavable.

Do not use abrasives or liquid chemicals to clean the tip or the light housing.

The fan at the rear of the light provides cooling when the system is on. Obstructing the air flow will cause heat buildup and will damage the system. If the system fan does not come on, do not use the device and contact DenMat for repair.

Do not store liquid above the Sapphire Plus. Disconnect the Sapphire Plus power cord from the power outlet and contact the factory for service instructions if the light or the main unit has been exposed to liquid spills, dropped, or otherwise damaged (including the power cord), or otherwise malfunctions.

Do not use in the presence of flammable materials, including but not limited to flammable mixtures of anesthetic gases. Do not use in an oxygen rich environment. Equipment is non-AP

In a power outage or for failure of this equipment, it is the dental professional's judgment with respect to how to proceed. If the unit is being used to cure, dental restoratives are "dual cure" and will slowly cure without the photo initiation from the blue light (consult Instructions for Use of the restorative material). Maintain back-up equipment where possible.

Periodically inspect the power cord to ensure it is not worn or frayed. Also inspect it each time the unit is plugged in to ensure it has not been damaged. Replace per instructions in this User's Manual if needed.

RISK GROUP 2

**CAUTION: Possibly hazardous optical radiation emitted from this product.
Do not stare at operating lamp. May be harmful to the eyes.**

Caution: US Federal Law restricts the use of this device to use by or on the order of a dentist

Electromagnetic Compatibility For Sapphire Plus

WARNING: The Sapphire Plus (and in general all medical electrical equipment) needs to be installed, put into service, and operated in taking special precautions with respect to EMC (Electromagnetic compatibility).

WARNING: As a preventive measure, separate all electrical equipment from the Sapphire Plus. If space constraints make this a challenge, determine by observation and testing, if the Sapphire Plus or the other electrical medical devices are being affected by electromagnetic coupling.

WARNING: the Sapphire Plus is intended for use by Dental professionals only. The Sapphire Plus may cause Radio Interference. If this happens, take appropriate measures such as re-orienting, relocating or shielding the Sapphire Plus or filtering the connection to the public mains network.

NOTE: CE marked equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/32/EEC [EN 55011 Class A and EN 60601-1-2:2001].

The limits in these standards are intended and designed to provide reasonable protection against harmful interference in a typical dental / medical installation. The equipment generates radio frequency energy. If not installed properly, the Sapphire Plus may interfere with other medical devices. Since there is no guarantee in a particular installation that other device that interference will not occur, test the installation prior to use. Ensure that other devices in the vicinity operate without interference and also ensure that the Sapphire Plus operations correctly. Test all functions. Correct any interference by one or more of the following mean:

- Reorient or relocate the affected device
- Increase the distance between the devices
- Connect the equipment into an outlet on a different circuit
- Consult the manufacturer or field service technical for help

WARNING: Other mobile or portable RF equipment may impact the Sapphire Plus and other medical device equipment.

WARNING: Do not modify or use unapproved accessories with the Sapphire Plus. This may increase emissions or decrease immunity of the Sapphire Plus. If unapproved accessories are used, it becomes the user's responsibility to assess EN 60601-1-2 compatibility.

The DenMat Holdings, LLC Sapphire Plus Specification

Input Voltage: 100-240 Vac, 50/60 Hz, 6/3A

Wavelength Range: 400-500 nm

Light Intensity (curing mode): 1975 - 2320 mW/cm² (at time of manufacturing)

Dimensions: 131.5 (W) x 234.9 (D) x 263.3 (H) (mm)

Weight: 5.8 kg / 12.8 lbs

Basic System Contents

Sapphire Light Source

Operator's Manual

Light Guide and Tip

AC Power Cord

Curing Light Protective Glasses (2 pair)

Composite Test Rings (200 each)

Important Start-up/Set-up Instructions

(Follow these instructions prior to using the system)

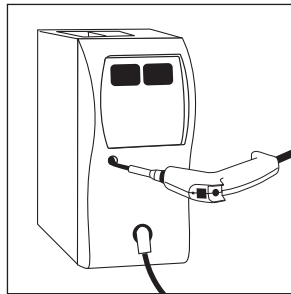
1. Attach the AC Power Cord to the power inlet on the Sapphire Plus light source and plug into AC outlet.



2. Install the Curing Light Guide by inserting the proximal end of the handpiece into the front panel receptacle until it stops. Make sure the device is firmly inserted all the way into the receptacle before turning the power ON. When the power switch (located on the back panel) is ON (I) position, display on the front panel will light up which means that system power is available. If the device is not installed correctly the system display will show “no HP” meaning No Hand Piece is detected otherwise it should display “Ch HP” meaning choose handpiece, which prompts the user to select mode (cure or bleach).

Once mode is selected, the Sapphire® Plus is now ready for use. It is required that users read through the user’s manual and understand the warnings and precautions prior to use. Also become familiar with all system features before use.

3. Check the light output with built-in light meter before every use. See the Light Meter (Radiometer) Section for details. Hold the handpiece as shown in the illustration. Record the values and maintain a log book with the dates and values. **DO NOT USE THE SAPPHIRE FOR CURING OR SINGLE TOOTH WHITENING IF THE LIGHT OUTPUT IS GREATER THAN 3000 mW/cm2.** Call DenMat and return the instrument for repair.



The tip should be centered inside of the aperture. Positioning the tip differently may result in reduced light intensity values.

4. Do not saturate the controller keypad area with disinfectant or other liquids. Wipe the keypad surface with a damp towel and dry completely.
5. If the lamp access plate on the bottom of the system is removed to check the lamp, make sure that it is replaced correctly. The corners of the plate must fit into the outline of the cutout and not rest on top of the edges of the surrounding metal. When installed properly, all surfaces areas are even with each other. If the access plate is misaligned, the lamp will not activate. If the access plate is misaligned the system will show “**Locd**” meaning system is locked and the lamp will not activate.

WARNING: Leave at least 3 inches spacing in the back for adequate ventilation. Heat buildup shortens the lamp life and even contributes to the risk of lamp explosion (see associated warnings regarding the lamp in Warnings and Precautions section).

WARNING: Three-conductor grounding plug with international IEC connector provided. The hospital grade power cord is available for separate purchase for replacement or if a different plug configuration is needed for international customers. Do not replace the power cord without ensuring that the new power cord is Hospital grade, 18 AWG (min), 300 Vac, 10A, 105°C.

NOTE: Make sure the light guide is pushed all the way in until it stops. Also, it is important to check that the lamp access plate is on correctly if it has been removed.



Dangerous Voltage



Attention: consult accompanying documents



Attention: may be hot



Protection Class BF, Insulation Class 1



Alternating Current



Fuse



Hazard, High-Intensity Light (applies when Curing/Whitening Handpiece is attached)



DO NOT use in the presence of flammable substances



Users must read Instruction Manual

Device Description and Intended Use

The Sapphire Plus Light system consists of a xenon plasma arc light source (lamp), power supply and a light guide with a pistol-type handpiece with user interface controls.

The Sapphire Plus Light system is a source of illumination for curing dental restorative materials and is a source of illumination for tooth whitening. Broad spectrum visible light emissions are filtered to provide peak performance for initiating rapid polymerization of photo-initiated dental restoratives or for tooth whitening. There are separate handpieces for curing/whitening that effectively utilize the visible light emissions for their indicated uses.

Once the light guide is firmly plugged into the Sapphire Light Source Unit’s Light Guide Port, the xenon arc lamp’s emissions can be accessed by the curing/whitening. When either the light guide is inserted, the Sapphire Plus’ microprocessor recognizes that they have been inserted, and that the xenon arc lamp can be used when needed.

Control panels for curing/bleaching are present. The user interfaces offer a wide range of timing increments for curing or bleaching. Bright display windows and LEDs provide visual status indications and clear audio signals are present to further ensure setting’s confirmation.

- **The light source is Class I:** The DenMat Holdings, LLC light source relies upon the connection to the protective earth conductor of the installation to prevent shock hazards.
- **The light source is Type BF:** The DenMat Holdings, LLC light source’s applied part is floating from earth.
- **Classification of the light source against ingress of liquids:** Ordinary Equipment (IPX0) – This DenMat Holdings, LLC light source provides no protection against the ingress of water.
- **Classification against Flammable Vapors with Air:** This DenMat Holdings, LLC light source is not suitable for use in the presence of a Flammable Anaesthetic Mixture with Air, Oxygen or Nitrous Oxide.

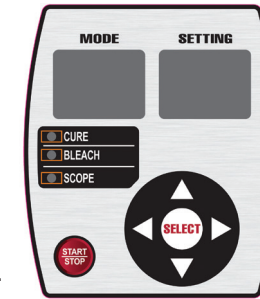
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Controls and Functions

1. **Sapphire® Plus Light Source**
2. **Sapphire Plus Control Panel:** Includes control wheel and select button, mode indicator, display windows, and start/stop button.
3. **Sapphire Plus Display Windows:** Digital display of the pre-set time, program mode, and light meter.
4. **Fiber Optic Light Guide:** Flexible optical device for delivery of light. Make sure the light guide is pushed all the way in until it stops.
5. **Sapphire Plus Curing Handpiece:**
 - A. Timer select button
 - B. Timer display
 - C. Activator button (Each handpiece has an activator button to activate the lamp.)
6. **Removable Autoclavable Tip:** Optical device for exact placement of light.
7. **Lamp Access Plate:** Access area on the bottom of the light source where the lamp is removed and replaced.
8. **Cooling Fan:** Provides cooling to the light source.
9. **Power Module:** Accepts AC power cord.
10. **Fuse Holders:** Contains the main fuses. (see fuse replacement section)
11. **Power Switch:** Turns power ON (I) and OFF (O).

Control Panel

START/STOP starts/stops lamp in CURE, BLEACH and SCOPE modes.



UP/DOWN arrows on CONTROL WHEEL increase and decrease time and output.

LEFT/RIGHT arrows on CONTROL WHEEL toggle between modes.

SELECT accepts mode and setting.

Accessories

Eyewear

WARNING: The protective eyewear provided with the Sapphire Plus must be worn by the operator, assistants, and patient when the system is in use. Additional eyewear is available through DenMat Holdings, LLC. See the back cover for ordering information.

PROTECTIVE EYEWEAR



Light Guide and Tips

The Light Guide provided with the Sapphire Plus provides an optical path for transmitting light energy from the source to the tips. Both the Light Guide and removable tip are available through DenMat Holdings, LLC as spares or replacement parts. See the back cover for ordering information.

WARNING:

RISK OF BURN: Extreme care must be used with use of the 2 mm and 4 mm Ceri-Taper™ Tacking Tips since the smaller tips focus all of the lamp energy output into a smaller point of light. As an example, the heat generation of the 2 mm tip is greater than 20 times the heat generation potential of the 9 mm tip!

REMOVABLE TIPS



Set-up and Operation Instructions

Compatibility of Existing Sapphire® and Sapphire Plus Lights and Devices

The labeling on the curing handpiece and Sapphire light source will indicate whether these are different than the new Sapphire Plus. The curing handpiece and Sapphire Light source may be labeled Sapphire, Rembrandt® Sapphire, or Sapphire Supreme.

The curing handpieces for the new Sapphire Plus light have been designed to work with existing Sapphire lights (reverse compatible). At the same time, curing handpieces for existing Sapphire lights can be used with the new Sapphire Plus light (forward compatible).

Using Existing Sapphire Curing Handpieces

When using existing curing devices in the Sapphire Plus, it is necessary to manually select the correct mode of operation.

When the Sapphire Plus light is powered up without a device installed in the light guide receptacle on the front of the light source, the error message “No HP” (no handpiece) will appear on the display.

When existing curing handpieces are installed in the light source, the display windows will change from “No HP” to a flashing “Ch HP” (choose handpiece). This means that a handpiece has been recognized and the operator is being prompted to select the correct user mode. Press the LEFT arrow key to advance directly to the SCOPE MODE or press the RIGHT arrow key to step through the BLEACH, SCOPE and CURING MODES and press the SELECT button to enter that mode. Warning: Scope Mode is no longer used. Do not stay in scope mode.

Follow all other instructions for operation of that mode.

Press SELECT to stay in the CURE mode and the LEFT or RIGHT arrow keys to alternate between the two curing timers C1 and C2.

Using the new Sapphire Plus Curing Handpieces

The curing handpiece for the new Sapphire Plus light have been designed to work with existing Sapphire lights (reverse compatible).

Follow all operating instructions for the selected handpiece.

Install Power Cord, Install Handpiece, and Power Up

Install the AC power cord into the power inlet on the back of the Sapphire Plus light source and into a grounded AC socket.

Insert the proximal end of the fiber optic light guide on the curing / bleaching handpieces into the light guide receptacle on the front of the Sapphire Plus light source.

Turn the power switch on the back of the system to the ON (I) position. Press the SELECT button to enter the Curing mode (CURE) or use the LEFT or RIGHT arrow keys to choose the BLEACH modes and press SELECT to enter that mode.

Warning: Double check that the system is in the right mode as indicated by the green indicator light.

The Sapphire Plus is ready for use. It is necessary to read and understand all usage and safety precautions before use of this system.

Light Meter (Radiometer)

Use the Sapphire Plus light meter to validate the power density (light intensity or mW/cm²) output of the curing handpiece and lesion detection handpiece prior to each use. The light meter window is located below the system control panel.

CAUTION: DO NOT USE 2 mm OR 4 mm TIPS ON THE LIGHT METER WINDOW (the Radiometer)

When the curing tip is placed on the light meter window and the lamp is activated, the system automatically detects the light and changes to the RADIOMETER mode. The output reading of power density is shown on the display windows. To get an accurate reading, the curing tip must be centered directly in the light meter window. Set the timer to 5 seconds and remove the tip from the light meter window as soon as you have a measurement.



Proper Light Meter Readings

- Curing: If light is below 300 mW/cm², do not use for curing. High light intensity (over 1500 mW/cm²) allows fast curing. Use curing test rings provided to test the material being cured.
- DO NOT USE THE SAPPHIRE FOR CURING OR SINGLE TOOTH BLEACHING IF THE LIGHT OUTPUT IS GREAT THEN 3000 mW/cm². Call DenMat and return the instrument for repair if the output is too high or too low.

Curing Mode

Timers and Control Panel Operation

There are two operator-adjustable curing timers available: C1 and C2. Each timer can be set from 1 to 10 seconds. It is recommended that multiple 5-second exposures should be used for resins that need a little more time.

WARNING: Single exposures longer than 5 seconds must be limited to use with the 12 mm curing tip. They can only be used, with careful monitoring of the heat build up inside the patients mouth. Use air flow to remove heat and help reduce heat buildup.

Whenever the curing handpiece is inserted, and cure mode selected, the system defaults to the first of two curing timers. The factory preset time for both of these is 5 seconds. The indicator light next to CURE on the control panel will turn on. The display windows will show “C1” in the MODE window and “05” in the SETTING window.

The exposure time setting can be increased or decreased by using the UP and DOWN arrow keys on the CONTROL WHEEL. The exposure time setting can be increased or decreased by using the UP and DOWN arrow keys on the CONTROL WHEEL. Each time the UP key is pressed, the time will increase one second; each time the DOWN key is pressed, the time will decrease one second. The time displayed in the SETTING window will display the time as it changes. Each of the two curing timers can be adjusted from 1 to 10 seconds using this method.

When the timer setting is adjusted, it will stay at that setting until the next time it is changed, even when the system power is turned off. This allows the operator to use favorite settings without having to reset before each usage.



Curing Mode (continued)

To change from the C1 to the C2 timer, press the LEFT and RIGHT arrow keys on the CONTROL WHEEL. The display windows show “C2” in the MODE window and “05” in the SETTING window.

The ACTIVATOR button on the curing handpiece will activate and deactivate the lamp. The TIMER SELECT button on the curing handpiece will alternate between the C1 and C2 timers.

ATTENTION: DO NOT HOLD DOWN THE START/STOP OR ACTIVATOR BUTTON.

PRESS AND RELEASE.

Fast Start (Note: See the Warnings and Precautions in this section and at the beginning of the User’s Manual before curing)

When the curing handpiece is installed, pressing the ACTIVATOR button on the handpiece or START/STOP button on the front panel will immediately activate the lamp and start the countdown timer. The timer setting will be either the factory-default 5 seconds or the last setting, from 1 to 10 seconds, when the power was turned off. When the CURE mode is selected, it is necessary to power down or unplug the light guide to reset the system and change to BLEACH mode.

Recommended Use of Both Timers

When placing LUMINEERS® set timer C1 for 2 seconds and timer C2 for 5 seconds. Use C1 for spot curing LUMINEERS with the 2 mm tacking tip, and use C2 for final curing with the 9 mm tip. Use the TIMER SELECT button to quickly alternate between the C1 and C2 timers. Spot curing with the 2 mm tacking tip makes clean-up of margins a breeze and greatly reduces finishing time.

Curing Instructions

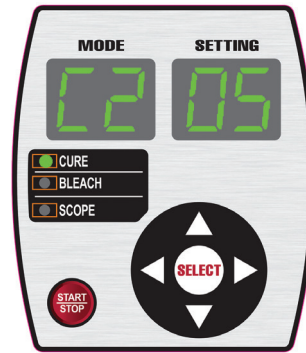
NOTE: Clean the tip prior to use for maximum light output.

PRECAUTION: Inspect the pistol handle, light cable and any curing tips which will be used. Ensure they are in good working order. Check to make sure there are no burrs or sharp edges or features, which could cut a patient or the user of the device.

ATTENTION: Do not touch the curved tip of the light guide handle to the restorative material. Hold the tip approximately 2 mm above the material to be cured! Direct the light onto the restorative material and tooth, avoiding the gingiva. See warning below.

WARNING: Do not direct the light on to unprotected gingiva or skin. Even a portion of the beam directed on unprotected gingiva or skin can cause a rapid rise in temperature, while the reflective surface of teeth is less prone to this effect, patient tissue must be monitored closely during exposure to the light. Use the correct curing/bleaching tip to ensure the light is focused on the tooth. The intense light can quickly blister gums or unprotected skin. Use extreme caution. Device must be used only by trained dental professional. Council patient to immediately notify you if they experience discomfort associated with a temperature rise or heat. It is the user’s responsibility to monitor temperature rise and the effect of the light on the teeth and gingival. Apply the light for only as long as needed to achieve required cure. Do not overexpose. Small tips focus all of the light energy onto a small area and can rapidly burn skin or gum tissue.

Test all restorative materials for the time required for complete curing prior to use. The curing test rings provided with the Sapphire are 2 mm deep x 5 mm interior diameter. Fill the ring with the restorative to be used. Set timer C1 or C2 to 5 seconds. Position the curved tip of the handpiece approximately 2 mm from the composite and



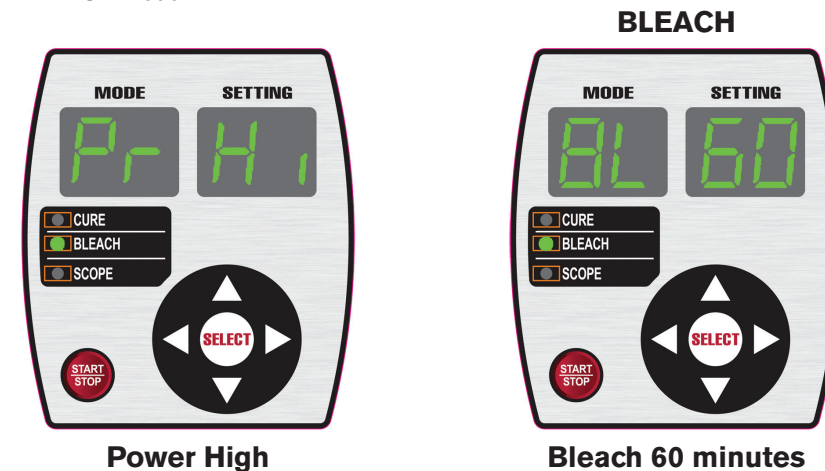
start the system. After the timing cycle is completed and the light turns off, test the bottom surface for hardness using a dental probe. If the material is not completely cured, restart the system again for another 5-second exposure. Test, and repeat again, if necessary. This will give you an indication of the optimum timing increment for the specific restorative to be used. Select a new timer increment which is close to the total time it took to cure the material. Repeat the test and verify that complete curing has occurred. If curing time is longer than 5 seconds, it is recommended that you repeat an additional 5-second exposure. It is important that you maintain a log of composite materials, shades, and associated curing times. This log can also be used to monitor system performance.

See Warnings and Precautions above with regard to curing for longer than 5 seconds.

If the cavity preparation is deep, an incremental filling technique is recommended and each increment should be cured following the manufacturer’s guidelines or your own experience with the restorative being used.

Bleach (Whitening) Mode

After the system power is switched ON (I), use the RIGHT arrow key to advance to the BLEACH mode. Or, if in the CURE mode, disconnect the light guide to reset the system. Use the RIGHT arrow key to advance to the BLEACH mode.



The indicator light next to BLEACH on the control panel will turn on. The display windows will show “Pr Hi” (power high). Use the DOWN arrow key to adjust power down in 5% increments.

Use the RIGHT arrow key to change to the bleach timer. The default timer is 60 minutes. The timer can be adjusted by using the UP and DOWN arrow keys on the CONTROL WHEEL.

To adjust the power output, press the DOWN arrow key on the CONTROL WHEEL to reduce the power and the UP arrow key on the CONTROL WHEEL to increase power.

WARNING: High power is ONLY used with the Whitening Crystal.

Note: Single Tooth whitening can also be done. Do this in the Curing Mode, using 5 seconds per tooth or less. Also ONLY use a 12 mm tip following all Indicated Warnings and Precautions.

WARNING: Do not perform single tooth whitening in bleaching mode, since the power setting could be too high and since the timers are designed for bleaching for longer periods associated with using the Whitening Crystal. Do not use tip sizes less than 12 mm for single tooth whitening.

WARNING: Do not direct the light on to unprotected gingiva or skin. Bleaching/Curing light will cause rapid rise in temperature, if the beam or a portion of the beam is directed on unprotected gingiva or skin. The reflective surface of teeth is less prone to this effect, but patient tissue should be monitored closely during exposure to the light. Only perform bleaching using the whitening crystal (Note: Single tooth bleaching is done in the curing mode as explained elsewhere). Excess light on unprotected gingiva or skin can blister gingiva or skin. Device must be used only by trained dental professional. Apply the light for only as long is needed to achieve required bleaching, with appropriate interim checks of the condition of the mouth.

Bleaching is only to be done along with chemical agents and treatment described in the “Whitening Section” of this user’s guide.

Start the lamp by pressing the ACTIVATOR button on the handpiece or the START/STOP button on the control panel. Stop the lamp by pressing the ACTIVATOR button or START/STOP again.

Whitening Instructions

LumiSmile White™ in-office whitening is designed to comfortably and quickly whiten patients’ teeth. The combination of LumiSmile White desensitizing enhancer and LumiSmile White whitening gel reduces chairtime required for effective whitening compared to traditional chairside bleaching treatments. This kit contains enough material to whiten both the upper and lower arches of one patient.

The LumiSmile White in-office whitening kit is for in-office use only.

Store at or below 75°. Do Not freeze.



WARNINGS:

- Product contains both strong oxidizing and alkaline agents and can cause chemical burns. Wear protective gloves and eyewear during preparation and application.
- Avoid contacting soft gingival tissue with both the desensitizing enhancer and whitening gel. Using the Paint-On Dental Dam included in the kit will shield gingival tissue from these materials. Vacuum LumiSmile White whitening gel off teeth as instructed before rinsing with water to prevent splattering. Should gel come in contact with soft tissues, rinse thoroughly to dilute.
- Material is not for injection.
- Keep out of the reach of children.

INSTRUCTIONS FOR USE:

1. Prophylax teeth to remove calculus and extrinsic stains before beginning the whitening treatment.
2. Insert cheek retractors. Have the patient bite down and rest tongue on a tongue block.
3. Take “before” photographs and record tooth color using a shade guide arranged in bleaching order.
4. Air-dry the gingival tissue and teeth.
5. Using the dispensing tip, apply Paint-On Dental Dam to the gingiva to isolate gums around the selected teeth. Overlap the dental dam onto the gingival tissue of adjacent teeth (about 0.5 mm) and light-cure for 1–2 seconds per tip width with a Sapphire® Plus Plasma Arc Curing (PAC) light.
6. Once the Paint-On Dental Dam is cured, apply Lip Moisturizer provided in the kit to the lips and mucosa, applying well beyond the vermillion border.
7. Prepare the auto-mix syringe.
 - Align the wedge-shaped key on edge of the static mixer housing with the opening in the syringe flange.
 - Push the static mixing tip onto the syringe and turn 90° clockwise until it stops.
8. Dispense a portion of the LumiSmile White whitening gel into separate dappen dish. Use the brush applicator to apply a 1–1.5 mm layer onto the labial surface of the teeth.
9. Install a sanitized Sapphire Whitening Crystal in place of the curing tip on the end of the Sapphire Plus PAC light pistol.
10. Position the Sapphire Whitening Crystal close to and directly in front of the teeth, using a combination of the articulating arm and chair adjustments. Center the Sapphire Whitening Crystal 1/4 to 1/2 inch from the teeth within the cheek retractor with the outer edges touching (if possible).
11. Press the Optional button on the Sapphire Plus PAC light keypad, then press 2 to select bleaching mode. The letters bL (bleach) will appear in the Program window, the number 60 will appear in the seconds window and 60 minutes will appear on the pistol handle.
12. Press the Start or pistol activator button to start the bleaching process. The number 60 (minutes) appears in the Program window and seconds begin to count down in the Seconds window.
13. When the Sapphire light beeps, fifteen (15) minutes have elapsed. Pause the light. Suction off whitening gel. Check on the comfort of the patient and reapply LumiSmile White whitening gel.
14. Unpause Sapphire curing light. After the second beep, 30 min have elapsed.



STEP 3



STEP 5



STEP 8



STEP 10



STEP 12

15. Move the Sapphire Whitening Crystal away from the teeth. Leave the Paint-On Dental Dam in place and vacuum gel from the teeth. Wipe with gauze and rinse the teeth while suctioning. Avoid splatter. Some patients with heavy discoloration or areas of unseen hypocalcification may need another 15 to 30-minute session to achieve desired whitening results. Evaluate the results with the patient, if possible.



STEP 16



STEP 18



STEP 19

- Note:** In some cases you may have attained acceptable whitening in the first 30-minute session. If so, a second session is not indicated.
- Note:** In some cases, it may be necessary to peel away the Paint-On Dental Dam to make a shade determination. If the Paint-On Dental Dam is removed and another 15 to 30-minute application is indicated, remember to reapply the Paint-On Dental Dam to protect the gingival tissue.
16. If another 15 to 30-minute session is desired, reapply the whitening gel following instructions, beginning at Step 7.
 17. At the end of the second session, vacuum gel from the teeth, wipe away with gauze and rinse the teeth while suctioning. Avoid splatter.
 18. Use a shade guide arranged in bleaching order to compare the color of the whitened teeth to the original shade recorded in Step 2 and take "after" photographs.
 19. If patient is experiencing sensitivity, apply desensitizer gel for 5-30 minutes, as needed. Remove the tip from the end of the LumiSmile White desensitizing enhancer recappable syringe and dispense a portion of the LumiSmile White desensitizing enhancer into a dappen dish. Apply in a very thin (about 0.2 mm) layer on the labial surface of the teeth using the brush applicator provided in the kit and allow to sit for one minute. Wipe off any excess. Firmly recap the LumiSmile White desensitizing enhancer syringe. Send home remaining if needed.

BLEACHING WITHOUT THE SAPHIRE® Plus PAC LIGHT

Whitening will also occur, to a lesser extent, if a Sapphire Plus PAC light is not used. Follow instructions above, disregarding use of the Sapphire whitening Crystal; maintain gel on teeth as indicated, for the periods described. However, for maximum results, use of the Sapphire PAC light with whitening Crystal is recommended.

SUPPLEMENTAL PRODUCTS


ITEM NUMBER

LumiSmile White Take-Home whitening Kit 16% Mint.	WHT1016
LumiSmile White Take-Home whitening Kit 22% Mint.	WHT1022
LumiSmile White Take-Home whitening Kit 32% Mint.	WHT1032
LumiSmile White Take-Home whitening Kit 16% Mint Refill.	WHT1116
LumiSmile White Take-Home whitening Kit 22% Mint Refill.	WHT1122
LumiSmile White Take-Home whitening Kit 32% Mint Refill.	WHT1132

MSDS SHEETS ARE AVAILABLE AT WWW.DENMAT.COM

To maintain desired shade, supply the patient with LumiSmile White™ Take-Home whitening kit for reapplication and touch-ups every few months. Order now to receive a special offer of 25% off LumiSmile White professional Take-Home whitening:

Take-Home Kit: Promo Code 94314U
 Take-Home Refill Kit: Promo Code 94316U



Sanitizing and Sterilizing

Sanitizing the Whitening Crystal

Clean with a mild, non-abrasive, liquid soap and thoroughly dry all surfaces. Sanitize with solutions containing glutaraldehyde, low concentrations of hydrogen peroxide, 70% isopropyl alcohol (70% IPA) or other disinfectants containing mostly inert ingredients.

Sterilizing the Curing Tip

Clean the tip regularly with composite solvent. The removable tip must be sterilized using standard autoclave procedures for stainless steel instruments (135° C). Use a sterilization bag and leave sealed for future use. Failure to sterilize tips between patients increases the risk of patient-to-patient infection.

CAUTION: DO NOT AUTOCLAVE THE LIGHT GUIDE!

Sanitizing The Light Guide and Handle

The light guide cannot be autoclaved. It should be sanitized by using a non-abrasive disinfectant. Do not use glutaraldehyde-type disinfectants.

Cleaning The Sapphire Plus System

WARNING: Unplug the power cord prior to cleaning with any liquid. Allow the system to cool prior to cleaning.

- Avoid spilling any liquid on the system. Do not use flammable liquids to clean the main system or light guide. If the internal electronics are exposed to any liquid, disconnect the power. Do not attempt to start the system. Contact the factory for instructions at 1-800-445-0345.
- Clean the main system using only mild soap and water solution as needed. Do not saturate the control panel with liquid. Wipe with a damp towel and dry completely.

Replacement Parts

Additional tips, shields, and curing rings, light guides and lamp modules are available from DenMat Holdings, LLC. See back cover for ordering information.

Service

Minor problems can be quickly identified and resolved. These are usually related to the electrical power connection or light guide connection. All other malfunctions must be diagnosed and repaired by DenMat Holdings, LLC. Contact DenMat Holdings, LLC for technical support at 1-800-445-0345.

WARNING: THE SUPPLIED ORANGE SAFETY GLASSES MUST BE WORN DURING USE OR TESTING.

Troubleshooting

Problem

The control panel and handpiece display does not light up. Buttons do not respond.

Corrective action

Check the AC electrical outlet, power cord, and power input on the light to verify that all connections are secure and that AC power is on at the outlet. Verify that the power switch is in the ON (I) position.

Problem

The control panel display lights up but the handpiece display does not light. Lamp does not start when the ACTIVATOR button on the handpiece is pressed.

Corrective action

Being careful not to look directly at the distal end of the light guide, press the START/STOP button on the front panel. If the lamp does not come on, move to the next step. If the lamp comes on, recheck the light guide connections. Disconnect the light guide and firmly reinstall, making sure that it is plugged in all the way. Rotate the light guide 1/4 to 1/2 turn in the light guide receptacle. Look for the display to light up on the handpiece. If the display on the handpiece responds, try starting the light again with the ACTIVATOR button.

Problem

The control panel display lights up and the CONTROL WHEEL and TIMER SELECT button work, but the START/STOP button and ACTIVATOR button do not start the lamp.

Corrective action

Contact DenMat Holdings, LLC for technical support at 1-800-445-0345.

Problem

Light output is low or curing of the composite is slow.

Corrective action

Verify the light guide is plugged all the way into the receptacle on the front of the unit. Check the tip for contamination, scratches, or breaks. Clean the tip with composite solvent. Check the light guide for damage. Follow instructions for checking and replacing the lamp.

If corrective action does not resolve the problem, contact DenMat Holdings, LLC for technical support at 1-800-445-0345. This includes possible lamp replacement or return of the system for repair.

Lamp Replacement Instructions

WARNING: LAMPS ARE FILLED TO VERY HIGH PRESSURES, OFTEN GREATER THAN 200 PSI AT ROOM TEMPERATURE. EYE PROTECTION MUST BE WORN. EXTREME CARE MUST ALWAYS BE EXERCISED WHEN HANDLING LAMPS. EXPLOSION HAZARDS ARE POSSIBLE (MOST HAPPEN DURING OPERATION, WHEN THE PRESSURE IS HIGHER). INTERNAL LAMP PRESSURES CAN DOUBLE WHEN THE LIGHT IS IN USE AND GREATLY EXCEED THAT IF IMPROPERLY COOLED. ONLY A QUALIFIED SERVICE TECHNICIAN MAY REPLACE THE SYSTEM LAMP. PROTECTIVE EYEWEAR MUST BE WORN. NEVER POINT THE WINDOW OF THE LAMP TO UNPROTECTED TISSUE.

Symptoms indicating need for replacement are:

1. Low intensity on system light meter.
2. Lamp fails while in use or does not turn on.

To Remove the Old Lamp

1. Turn unit off and unplug the power cord from its power source.
2. Wait for the unit and the lamp to cool.

WARNING: Lamp internal pressure is much higher when hot. Improper cooling increases risk of explosion.

3. Unscrew thumbscrews to remove the lamp access plate.
4. Grasp lamp and slide towards you to remove from light source. WARNING: Do not drop - Lamp can explode!
5. Unplug the lamp from the 2-pin lamp socket.

To Insert New Lamp

1. Orient the lamp facing forward in the lamp guides on the chassis.
2. Push toward the top of the unit until the lamp slides securely onto the lamp pins.
3. Replace the lamp access plate and tighten thumbscrews.

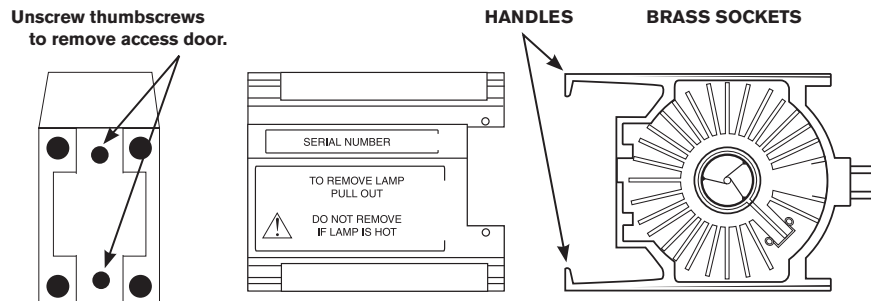
NOTE: Make sure the access plate fits correctly in the cutout provided. All corners should be even with the surrounding surfaces. If the access plate is misaligned, the unit may not receive AC power.

To Dispose of Old Lamp (Steps 1 and 2 must be performed by qualified service technicians) CeraLux lamps contain no hazardous materials such as mercury or rare earth elements. Lamps may be disposed of safely once the internal pressure of xenon is released.

To release internal pressure, do the following:

1. Wear safety glasses.
2. Firmly grasp the lamp and cut or twist the pinch off seal at the rear of the lamp. The gas will be heard escaping.
3. Afterwards, the lamp may be disposed in normal trash.

If unsure about the instructions, DO NOT PROCEED! Contact DenMat Holdings, LLC at 1-800-445-0345. DenMat can also give instructions regarding shipping the lamp back to DenMat and will dispose of the lamp properly.



Fuse Replacement

WARNING: ONLY A QUALIFIED SERVICE TECHNICIAN MAY REPLACE SYSTEM FUSES.

1. If the Sapphire® Plus source fails to operate after power is applied, disconnect the power cord from AC wall outlet before checking the fuse(s). Switch the power switch to the OFF (O) position.
2. Check for blown fuses by removing the fuse covers using a flat blade screw driver (medium size) or equivalent.
WARNING: If the unit powers off like the fuse is blown, but inspection of the fuse demonstrates that the fuse is not blown, then it is not safe to continue trying to operate the equipment. Close up the unit. Do not replace power cord. Do not plug in the unit into the mains. Do not power on the unit. Contact DenMat and return the unit for repair per Step 7 below.
3. Replace the blown fuse(s) with the same size and rating. Fuses are 6 amp AGC-6 1/4" x 1 1/4" Fast Acting.
4. Replace fuse cover.
5. Reconnect the power cord.
6. Switch the power switch to the ON (I) position.
7. If the unit fails to operate properly again, contact DenMat Holdings, LLC for repair at 1-800-445-0345.

Transportation

When transporting the Sapphire Plus, remove the power cord and the light guide from the Sapphire Plus light source. Hold the handle or carry it with both hands, one hand underneath the unit to insure safety.

To prevent damage to the Sapphire Plus during transportation, it is highly recommended that the unit be wrapped with bubble wrap and placed in a shipping box or similar packing materials.

Storage

Store the Sapphire Plus and accessories in a clean area and maintain the room temperature as follows:

Operating Environment:

Ambient Temperature 6° C to 38° C (43° F to 100° F)
Relative Humidity 10-90% (non-condensing)
Atmospheric Pressure 700hPa to 1060 hPa

Transportation & Storage Environment (Non-operating):

Ambient Temperature -34° C to 52° C (-30° F to 125° F)
Relative Humidity 10-90%
Atmospheric Pressure 700hPa to 1060 hPa

- DO NOT** bend the AC cord severely, apply excessive force, pull, twist, or squeeze the power cable.
- DO NOT** bend the light guide excessively, apply excessive force, pull, twist, or squeeze the light guide.
- DO NOT** subject the Sapphire Plus to excess impact during transportation; this may cause the unit to malfunction.

AVOID placing the Sapphire Plus in direct sunlight or high temperature.

System Warranty

When used under normal operating conditions as described in this manual, the Sapphire® Plus system (main system, light guide, and curing tip) is warranted to be free of defects in workmanship and materials for one (1) year from the date of original shipment, and the power supply and lamp module are warranted to be free of defects in workmanship and materials for three (3) years from the date of original shipment.

Within the warranty period, if service is required, the system must be returned to DenMat Holdings, LLC for diagnostics and repair. Contact the factory to receive Return Authorization prior to shipping. The Return Authorization will include a pick-up notice (Call Tag) for a common carrier to return the merchandise to DenMat Holdings, LLC. Freight charges for returns within the warranty period will be paid by DenMat Holdings, LLC pending the results of evaluation of cause of the failure or damage. Freight charges for returns outside of the warranty period will be paid by the customer. The outside shipping container and any accompanying documents must be clearly marked **“Repair Return.”** Use only the original shipping container or other adequate shipping materials to protect the system in transit. All returns will be evaluated for the cause and extent of failure or damage by DenMat Holdings, LLC Service Representatives. Subject to the results of this evaluation, DenMat Holdings, LLC will authorize warranty repair or will contact the customer with a price quotation for the cost of repairs for failures and damages occurring as a result of misuse, improper operation, or for merchandise outside of the warranty period.

This is a limited warranty and the liability of DenMat Holdings, LLC is to repair or replace the system. Repairs may be made with new or refurbished parts at the manufacturer’s discretion. DenMat Holdings, LLC has no liability to refund any part of the purchase price and no liability for consequential damages, loss of profits, and damages to person or injury by reasons of any defects in said system from any cause whatsoever.

Any buyer who purchases said system acknowledges their familiarity with the terms, conditions, and provisions of this limited warranty and purchases said system agreeing to such terms, conditions, and provisions.

Buyer purchases the Sapphire Plus system from DenMat Holdings, LLC on the terms, conditions, and provisions of this limited warranty and waives all other rights and claims against DenMat Holdings, LLC for any damages or remedies exceeding said limited warranty.

DenMat Holdings, LLC
 1017 West Central Avenue
 Lompoc, CA 93436 USA
 Toll Free 1-800-445-0345
 Tel. 1-805-922-8491
 www.denmat.com

Call your DenMat Holdings, LLC Technical Sales Representative to learn how to increase profits with your Sapphire Plus.

Whitening

LumiSmile White #WHT0025

Whiten patients’ teeth comfortably and efficiently when combined with Sapphire Plus and the whitening crystal.

Restorative Materials

Virtuoso® Flowable Custom Kit #030381800

A low-viscosity, easy-flow restorative material with excellent physical properties.

Virtuoso® Universal Introductory Kit #030381950

A nanohybrid for posterior and anterior restorations.

Ultra-Bond® Plus #032599750

Optimal viscosity for cementation of all porcelain restorations in a convenient, auto-mixing syringe system.

Ultra-Bond® Clear #UB2000

A light-cure resin cement formulated for bonding Lumineers®, as well as other ceramic or composite veneers.

Core Paste® XP Syringe #030654110

The recognized standard in core build-up materials in a fast, auto-mixing syringe that can be easily syringed directly into canals.

Infinity® Syringeable Value Kit #039680100

Self-adhesive, dual-cure resin cement with fluoride for placement of gold and PFM crown/bridge restorations.

Replacement Parts

Description	Item Number
Sapphire Lamp	043951176
Standard Curing Tip 9 mm	033958519
Standard Curing Tip 12 mm	033958503
Ceri-Taper 2 mm Tacking Tip	033958506
Ceri-Taper 4 mm Tacking Tip	033958501
Sapphire Light Guide	033958553
Curing Test Rings (bag of 200)	043952114
Protective Eyeglasses (1 pair)	043921901
Protective Light Shield.....	043957515
Power Cord, International (OUS).....	add
Power Cord, USA.....	add

CALL 1-800-445-0345 TO ORDER



