Dentsply Sirona

SmartLite® Pro

Modular LED Curing Light

Lampe LED à photopolymériser modulaire
Lampada fotopolimerizzatrice LED modulare
Modulare LED-Polymerisationslampe
Lámpara LED de polimerización modular
Luz LED modular de polimerização
Polymerisatielamp met modulaire led's
Modulär LED-härdningslampa
Modulær LED hærdelampe
Modulær LED-herdelampe
Modulaarinen LED-valokovetin
Modułowa lampa polimeryzacyjna LED
Modulārā LED polimerizācijas lampa
Modulinė LED polimerizacijos lempa
Modulaarne LED-kõvastuslamp
Modulární polymerační LED lampa
Modulárna LED polymerizačná lampa
Moduláris LED polimerizációs lámpa
Lampa modulară de polimerizare cu LED
Modularna LED lampa za polimerizaciju
Modularna LED lampa za polimerizaciju
Αρθρωτή συσκευή πολυμερισμού LED

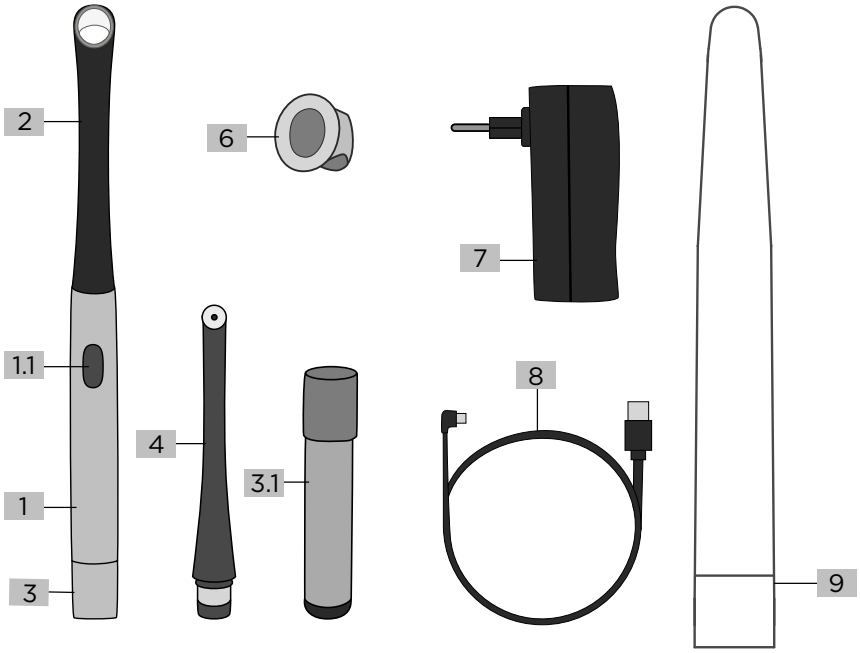
EN

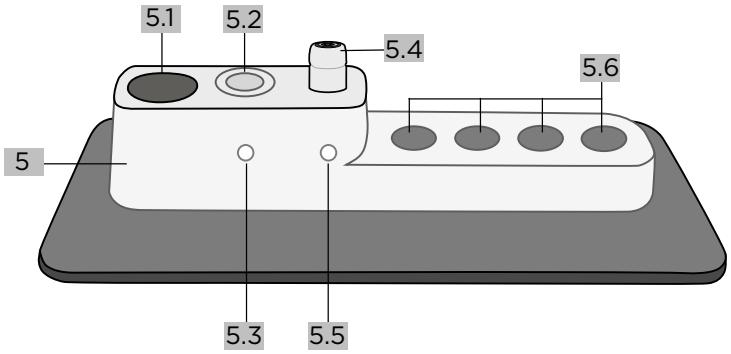
Dentsply Sirona

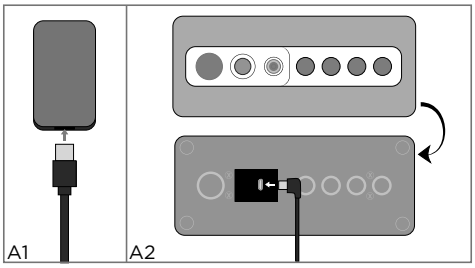
SmartLite®Pro

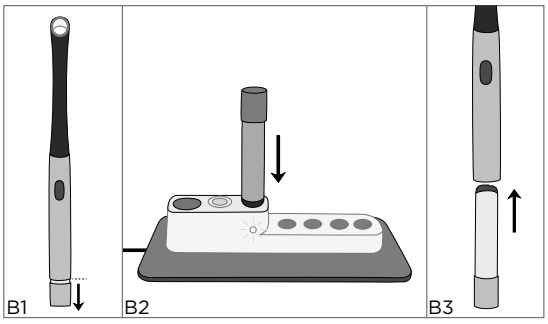
Modular LED Curing Light

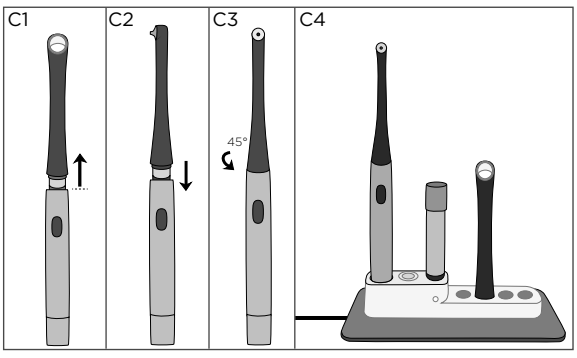
1. Handpiece
1.1 ON/OFF key
2. Cure Tip
3. Battery (installed)
3.1 Battery
4. Transillumination Tip (Illuminate)
5. Charging Base
5.1 Complete Light Holder
5.2 Radiometer
5.3 Radiometer Indicator Light (Red or Green)
5.4 Battery Charging Port
5.5 Battery Indicator Light (Orange or Green)
5.6 Tip Holders
6. Shield
7. Power Connector with Plug Adapter
8. Power Cord (USB)
9. SmartLite Pro Sleeve

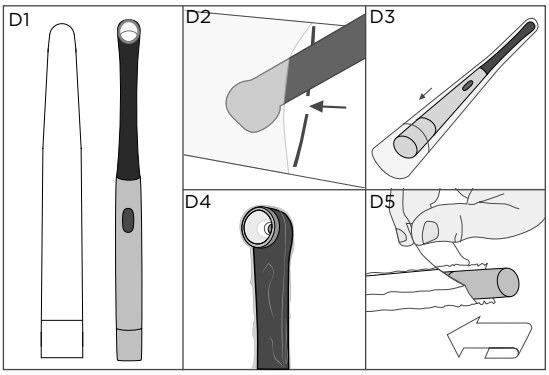


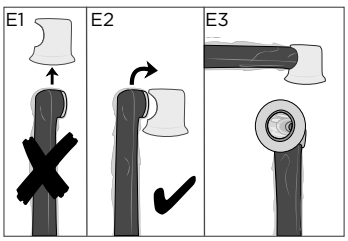


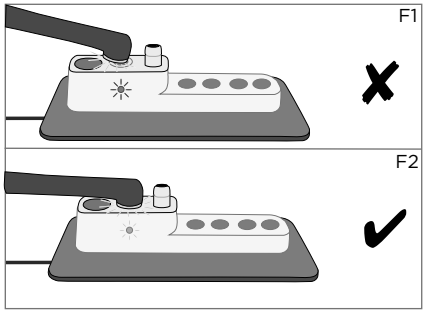












Dentsply Sirona

SmartLite®Pro

Modular LED Curing Light

CAUTION: For dental use only.
USA RX Only.

CONTENT

1. PRODUCT DESCRIPTION

The SmartLite Pro curing light is a cordless pen-style, LED light polymerization and illumination device for use by dental professionals in dental offices or dental laboratories.

SmartLite Pro curing light is characterized by:
- Small size and lightweight ergonomic design.
- Compact cordless design with convenient handling features and exchangeable battery pack.
- Individually adjustable LED tips, rotatable by 360°.
- LED tip design providing excellent intra-oral access.
- Polymerization area (optic effective cross-sectional area) of 10 mm in diameter.
- Up to 10 seconds curing time per activation with audible signal at start and end of cycle.
- Advanced heat management system limiting LED tip temperature.
- Exchangeable tips for:
  - curing of CQ initiated materials
  - curing of materials with initiators absorbing in the violet range
  - intraoral illumination and dental transillumination

1.1 Indications

- For light activated polymerization of dental materials such as composites, luting cements, and sealants using visible light.
- For Intraoral illumination used upon initial examination of the dental patient and dental transillumination to help locate crown fractures, posterior and anterior caries, and for use as an auxiliary light source for endodontic procedures.

1.2 Contraindications

The Smartlite Pro curing light is contraindicated for use in patients prone to photobiological reactions (including patients with solar urticaria or erythropoietic protoporphyria) or those currently undergoing treatment with photosensitizing pharmaceuticals.

1.3 Delivery Forms

Some delivery forms may not be available in all countries.

PRODUCT CONTENTS LIST (Note: See catalogue for detailed Intro Kit contents)
- 1x Handpiece 1
- 1x Cure Tip (blue light) 2
- 1x Transillumination Tip (only in Introductory Kit) 4
- 2x Batteries 3.1
- 1x Charging Base 5
- 1x Accessories Box containing:
  Power Connector; AU, EU, US, UK Plug Adapters; Power Cord (USB)
  1x DFU
  1x SmartLite Pro Sleeves refill
  3x SmartLite Pro Shields
  1x i•Cure
- 1x Curing Guidelines/Material Curing Card

1.4 Compatible Materials

SmartLite Pro curing light is designed to cure conventional CQ-initiated 450-480nm wavelength dental polymer- based restorative and luting materials with the standard Cure tip. The PolyCure tip is designed to cure materials initiated with CQ and/or other initiators absorbing violet light, 405-480nm wavelength. See polymer-based restorative material manufacturer's complete directions for use for specific product compatibility and curing recommendations.

2. SAFETY NOTES

Be aware of the following general safety notes and the special safety notes in other chapters of these Instructions for Use.

CAUTION

Safety alert symbol.
This is the safety alert symbol. It is used to alert you to potential personal injury hazards. Obey all safety messages that follow this symbol to avoid possible injury.

2.1 Warnings

Never modify the SmartLite Pro curing light or any of its equipment. Any modification may compromise safety and effectiveness.

2.1.1 SmartLite Pro handpiece

WARNING: This product can expose you to chemicals including Di-isononylphthalate (DINP), which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

- Always make sure the SmartLite Pro eye protection shields are securely fixed to SmartLite Pro curing tip to avoid accidental aspiration (press the SmartLite Pro eye protection shield firmly into correct position) E2
- Always make sure light aperture is not covered by the SmartLite Pro eye protection shields E3
- Do not use the device as a tissue retractor, as this may damage the connection between LED tip and handpiece.
- Do not use a damaged device, e.g. if among other things, the glass cover of the LED tip is scratched, broken or missing.
- The SmartLite Pro eye protection shields can be reprocessed at least 60 times. However, these accessories will wear over time. Exchange defect shield against spare shields included in the package or available as refill (see also [6.1 Accessories]).
- Only authorized technicians should repair the handpiece or battery pack.
- Persons fitted with cardiac pacemakers, defibrillators and other active implanted medical devices, have been cautioned that some types of electronic equipment might interfere with the operation of the device. Although no instance of interference has ever been reported to Dentsply Sirona, we recommend that the handpiece and cables be kept 6 to 9 inches (15 to 23cm) away from any device and their leads during use.
- There are a variety of pacemakers and other medically implanted devices on the market. Clinicians should contact the device manufacturer or the patient's physician for specific recommendations. This unit complies with IEC 60601 Medical Device Standards.

2.1.2 Charging base 5

WARNING: This product can expose you to chemicals including Bisphenol-A (BPA), which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

- Low voltages are present inside the charging base (5 V DC). Use only under dry conditions. Do not use if the charging base or handpiece is wet. Avoid short circuit between contact pads on the charging base. Only authorized technicians should repair the charging base.
- Do not use for voltages different from the range indicated on the charging base and power adapter.
- *Note:* Unplug power connector 7 from power source before disconnecting power cord 8 from the charging base. A2
- Always make sure the charging base is placed offside the dental unit and only touched with clean/disinfected gloves to prevent from exposure to spatter or spray of body fluids
- Always make sure handpiece, tips, and battery pack is completely reprocessed and thoroughly dry before inserting it into the charging base or attaching a light tip to the body.

2.1.3 Battery pack 3.1

- Prevent battery from short circuit during use and storage.
- Keep electrical contacts clean and dry.
- Do not remove battery pack from hand piece during operation.

2.1.4 Interchangeable LED tips

- Do not use the Cure 2 or the PolyCure curing tip for intraoral illumination or dental transillumination. Excessive heat may develop, causing burns to mucosa or pulpal irritation.
- Select the proper curing tip for the material. The PolyCure tip is designed for use with multiple initiated products. Undercuring of material may lead to post-operative sensitivity and/or premature restoration failure. Follow curing recommendations in Step-by-step instructions.
- The Transillumination tip 4 is intended to be used for visualization as an aid in locating fractures or caries, not for definitive diagnosis alone. Always confirm suspicious visual findings by suitable traditional means (e.g., manual examination, radiography) to establish the diagnosis.

2.1.5 Transport

- Intact devices can be transported by land freight or air freight in the original packaging. The applicable requirements must be met (see table below).
- Defective devices can also be transported by air freight or land freight in the original packaging. If the battery is defective, the device must not be transported by air freight under any circumstances.
- Leaking liquid can be an indicator of a defective battery.

Standards and regulations that apply to the transport of SmartLite Pro
- For international shipping of lithium-ion batteries, refer to the International Air Transport Association (IATA) guidelines, located at http://www.iata.org/lithiumbatteries.
- For shipping of lithium-ion batteries within the United States, refer to the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration (PHMSA) site at http://www.phmsa.dot.gov/hazmat/ guidance.

	Air Freight	Land Freight
Intact device or defective device with intact battery.	• UN 3481 Lithium batteries in equipment. • IATA Packing instruction 967 Part II. • Special regulations issued by airlines and national regulations must be complied with.	• UN 3481 Lithium batteries in equipment. • ADR Special provisions 188 f) and g).
Device with defective battery.	Not possible.	• International, multilateral agreements M 228 and M 259. • ADR SV 661 (international, road). • Regulations issued by GRS (German Joint Battery Takeback System Foundation) for the transport of waste lithium batteries (FRG, road).

2.2 Precautions

This product is intended to be used only as specifically outlined in these Instructions for Use.

Any use of this product inconsistent with these Instructions for Use is at the discretion and sole responsibility of the dental practitioner.
- Anyone with a history of retinopathy should consult their eye specialist before operating this unit. Use the SmartLite Pro curing light extremely carefully and comply with all the necessary safety precautions (including wearing suitable, light filtering safety glasses).
- Anyone who has had a cataract operation may be especially sensitive to light and should be advised against undergoing treatment with the SmartLite Pro curing light unless adequate safety precautions are taken such as wearing suitable, light filtering safety glasses.

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- Do not use a SmartLite Pro curing light which has not been properly reprocessed. Protect the SmartLite Pro curing light from gross contamination by applying the single use, FDA-cleared SmartLite Pro barrier sleeve D. SmartLite Pro barrier sleeves are intended for single use only. Discard after use D5. Do not reuse sleeves in other patients in order to prevent cross-contamination.
- Never aim the light directly at unprotected soft tissues, as this may cause injury or irritation. Do not aim the light at eyes. Light reflected from the tooth surface may also injure eyes. Use the SmartLite Pro eye protection shields supplied with the unit or suitable, light filtering safety glasses[1].
- Limit the action of the light to the area being treated.
- All dental curing lights cause a certain degree of heat development. Extended operation in areas near the pulp or soft tissues may result in severe damage. In these circumstances, do not cure for more than 10 seconds at a time without taking precautions such as air cooling.
- During heavy use (multiple curing cycles with 30s or less dwell between cycles), it is possible for the probe tip, which is an applied part, to reach up to 45.5° C. There should be no adverse effects resulting from short-term contact with intact skin or mucosa.
- Use only DentsplySirona supplied power supply, power cord, charging base and battery. Use of any accessories other than specified in this Directions for Use may result in damage to the SmartLite Pro curing light and its components as well as unpredictable performance
- Do not use adjacent to or stacked on other equipment. If adjacent or stacked use is necessary, closely watch SmartLite Pro and its components to verify normal operation in this configuration.
- Sterilizing the SmartLite Pro curing light, components and accessories will cause component damage and may cause bodily injury. The eye protection shields may be autoclaved *(see section 4)*.
- It is the responsibility of the Healthcare Professional to determine the appropriate uses of this product and to understand:
  - The health of each patient
  - The dental procedures being undertaken
  - Applicable industry and governmental agency recommendations for infection control in dental healthcare settings
  - Requirements and regulations for safe practice of dentistry
  - These Instructions for Use in their entirety
- Failure to follow recommendations for environmental operating conditions (see section 6.3) could result in injury to patients or users
- Inspect equipment before each use for worn, loose or damaged parts.
- There are no user serviceable parts except the O-ring attached to the coupling end of the light tips. Opening any of the components may result in unsafe operation and will void the warranty
- According to IEC60601-1, this device must not be used in the presence of a flammable anesthetic gas mixed with air, oxygen or nitrous oxide. (*Note:* nitrous oxide by itself is not a flammable anesthetic gas).
- User should not touch the patient and accessible charging base contacts or USB contact simultaneously.
- Wear suitable protective eyewear, mask, clothing and gloves. Protective eyewear is recommended for patients.
- Devices marked "single use" on the labeling are intended for single use only. Discard after use. Do not reuse in other patients in order to prevent cross contamination.
- As a precautionary measure the SmartLite Pro curing light may be protected from gross debris, but not all contamination, by applying a protective barrier sleeve D. Reprocess reusable components after each use according to instructions.
- Do not spray disinfectant or other fluid directly onto the light, tips, battery, charging base, power supply or cord. The user should spray solution onto a cloth or use a wipe to disinfect items per instructions in Section 4.
- Prevent liquids from entering the curing light body (handpiece), battery back, and charging base.
- Ensure the battery contacts are fully dry before charging batteries B2 or attaching batteries into the curing light body B3 (handpiece) to prevent corrosion. Similarly, ensure that the contacts on the light tips are fully dry before attaching to the light body.
- Do not place the system on or next to a radiator or other heat source. Excessive heat may damage the system's electronics.

2.3 Adverse Reactions

- Prolonged unfiltered exposure to the light source may cause damage to the eye. (See Warnings).
- Prolonged contact with soft tissue may cause injury or irritation to the tissue. (See Warnings).
- Medical conditions such as solar urticaria, erythropoietic protoporphyria or cataract surgery may be aggravated by exposure to emitted light. (See Contraindications, Precautions).

2.4 Storage Conditions

Inadequate storage conditions may shorten the shelf life and may lead to malfunction of the product.

- Store at temperatures between -5°C/35°C (23°F/95°F).
- Use the product at room temperature.
- Protect from moisture.
- Store at relative humidity range <75% (non-condensing).

3. STEP-BY-STEP INSTRUCTIONS

SmartLite Pro curing light– Operation at a glance

ON/OFF key 1.1

- **"Cure" and "PolyCure" tip 2:** Starts or disrupts the 10-second curing cycle.
- **"Illuminate" (Transillumination) Tip 4:** Pressing the ON/OFF key will change in a rotating manner from"low –anterior" to "high-posterior" to OFF mode.

Indicator lights

Light under ON/OFF Key 1.1

- **Slowly flashing orange** SmartLite Pro battery has low power and must be exchanged soon
- **Fast flashing orange** SmartLite Pro battery is empty and must be exchanged to continue to operate
- **Solid orange** SmartLite Pro unit is in an overheating protection state and can't be operated until light turns off.

Light adjacent charging port 5.5 (NOTE: no light with battery on top indicates missing contact)

- **Solid orange** SmartLite Pro curing light battery is charging
- **Solid green** SmartLite Pro curing light battery is fully charged

Light adjacent radiometer 5.3

- **Solid red** SmartLite Pro curing light output is below 1000 mW/cm² and not adequate (e.g. wrong positioning F1, contaminated, or scratched lens)
- **Solid green** indicates irradiance of at least 1000 mW/cm²

Audible signals

- **One short beep:** battery or probe tip insertion into handpiece.
- **One beep:**
  Transillumination Tip: start of cycle, change of power level, interrupt or end of cycle
  Cure/PolyCure Tip: start of cycle, interrupt or end of cycle
- **Two beeps:** warning (i.e. no tip attached)
- **Four beeps:** overheating protection

Vibratory signals

Transillumination Tip: no vibratory signals

- **One vibration:**
  Cure/PolyCure Tip: start of cycle, interruption of cycle, end of cycle
- **Two vibrations:**
  Cure/PolyCure Tip: warning (i.e. no tip attached)
- **Four vibrations:**
  Cure/PolyCure Tip: overheating protection

Signal Condition	Transillumination Tip			Cure / PolyCure Tip		
	Vibration	Beep	Signal LED	Vibration	Beep	Signal LED
Battery Insertion	-	1x	-	-	1x	-
Start Cycle	-	1x	-	1x	1x	-
Second power level	-	1x	-	NA	NA	NA
Stop cycle manually	-	1x	-	1x	1x	-
End of cycle	-	1x	-	1x	1x	-
Warnings (i.e. no head attached)	-	2x	-	2x	2x	-
Low battery	-	-	blinking	-	-	blinking
Empty battery	-	-	blinking fast	-	-	blinking fast
Overheating protection	-	4x	continuous	4x	4x	continuous

3.1 Installation and charging A&B

1. Insert battery pack into SmartLite Pro handpiece B3. SmartLite Pro battery pack is pre-charged however, it may be necessary to charge the battery before first use.
2. To recharge the battery:

- Connect the charging base to the Power Cord using the USB mini connector A2
- Make sure power socket used for power connector is accessible at all times in case of necessary emergency disconnection.
- Insert the battery onto the charging base B2. The battery light 5.5 will illuminate solid orange, indicating battery is recharging and will show constant green when fully charged.

Note, the SmartLite Pro comes with two batteries. It is recommended that the battery not being used is stored on the charging base so that it is fully charged when needed.

3.2 Operation – Curing

1. Select the appropriate LED curing tip for the material to be cured. Attach the tip to the handpiece by firmly pressing tip into handpiece opening while slightly rotating at the same moment.

CAUTION

To reduce the risk of Insufficient Curing – compromised restoration

- Always select the curing tip according to the wavelength of the initiator(s) in the material to be cured.
- Observe recommended curing time for the chosen tip and curing application.

2. Protect LED tip from gross debris by applying an FDA-cleared, single use SmartLite Pro barrier protection sleeve D. Make sure that the lens is not blocked by crinkles or seam of the sleeve D4.

CAUTION

To reduce the risk of Cross-contamination

- Ensure the disposable polyethylene FDA-cleared barrier protection sleeve has been correctly applied over the entirety of the LED tip and handpiece before beginning a procedure D3.
- The Polyethylene barrier Sleeve does not replace cleaning and disinfection of the dental instruments. Please clean and reprocess dental instruments after each patient as described in Section 4, Hygiene and Maintenance

3. Attach the SmartLite Pro eye protection shields supplied with the unit in combination with SmartLite Pro barrier protection sleeves. Hold the tip over

the opening of the shield and turn the tip against the shield by 90° into its final position E2. Always make sure SmartLite Pro eye protections shields are securely fixed to SmartLite Pro to avoid accidental aspiration (press SmartLite Pro eye protection shield firmly into correct position). Always make sure SmartLite Pro eye protection shields are properly mounted on SmartLite Pro without covering the light aperture E3.

4. Use suitable, light filtering safety glasses

To reduce the risk of High Intensity Light - Eye Damage
- Do not press activation button until properly positioned intraorally.
- Be sure everyone within the operating arena (patients, operators, assistants) is wearing appropriate protective filtering eyewear.
- Do not look directly at the light while it is activated.

5. Adjust the LED tip: The LED tip is rotatable by 360°, thus the position of light emission may be individually adjusted. The LED tip should be positioned as closely as possible to the restoration. Avoid shadowing (e.g. by metal matrix or parts of the cavity) by angulating the long axis accordingly. Fix correct position (e.g. with finger tip).
6. Polymerization
   Briefly press the ON/OFF key 1.1 to activate light.
   One Audible beep will be emitted. Handpiece will vibrate once.
7. SmartLite Pro is preset for 10 second cycles. To stop curing light before the end of the 10 second cycle, press ON/OFF key 1.1 at any time. To cure a restorative material that requires a curing time longer than 10 seconds, repeat activation by pressing the ON/OFF key 1.1 after the end of each 10-second curing cycle
8. Curing times for a range of Dentsply Sirona materials are outlined in the Curing Guide provided. When using other products, please refer to respective product's Instructions for Use and apply curing times specified for 1000 mW/cm^2. Double provided curing time when distance to surface of material to be cured is larger than 4 mm.
9. To utilize a different application during the same treatment visit, the probe tip must be changed. Remove light shield and barrier sleeve. Use moderate force to pull the probe tip from the handpiece C1. Place the desired probe tip on the handpiece C2 and press until the tip clicks into place while slightly rotating at the same moment C3. Reapply barrier, or apply a new barrier if damage is suspected. Reattach the light shield.
10. Clean, disinfect and prepare contaminated handpiece and used tip(s) for reuse according to section 4, Hygiene.

3.3 Operation – Illumination/Transillumination

1. Select the Transillumination (Illuminate) tip. Attach the tip to the handpiece by firmly pressing tip into handpiece opening C2 while slightly rotating at the same moment. C3
2. Protect Illumination/Transillumination tip from gross debris by applying single use SmartLite Pro barrier protection sleeve. After insertion turn the tip at least 180° to wrap sleeve around tip for easier handling. Make sure that the lens is not blocked by crinkles or seam of the sleeve.

To reduce the risk of Cross-contamination
- Ensure the disposable polyethylene FDA-cleared barrier protection sleeve has been correctly applied over the entirety of the LED tip and handpiece before beginning a procedure.
- The Polyethylene barrier Sleeve does not replace cleaning and disinfection of the dental instruments. Please clean and reprocess dental instruments after each patient as described in Section 4, Hygiene and Maintenance

To reduce the risk of High Intensity Light - Heat Damage
- Do not use curing tips for illumination or transillumination.
- Do not allow the tip to contact soft tissue for extended times

3. For visualizing anterior structures, briefly press the ON/OFF key 1.1 a single time, which will activate the lower output setting. To visualize posterior structures, briefly press the ON/OFF key 1.1 a second time, which will activate the higher output setting.
4. For transillumination, apply the tip to the cervical area of the tooth. Proximal defects are best visualized by placing the tip towards the interproximal. Rotating the tip slowly will provide multiple exposures of areas where caries is suspected. Cavitated areas typically appear as darkened shadows within the tooth structure. Posterior teeth may also be illuminated by applying the tip to the occlusal area so that vertical or horizontal cracks in enamel appear as dividing line between differently illuminated sections.
5. When complete, press the ON/OFF key 1.1 a third time, which will end the cycle.
6. To utilize a different application during the same treatment visit, the probe tip must be changed. Remove barrier sleeve. Use moderate force to pull the probe tip from the handpiece. Place the desired probe tip on the handpiece and press C2 until the tip clicks into place while slightly rotating at the same moment. C3 Reapply barrier, or apply a new barrier if damage is suspected. Attach the light shield when using one of the curing light tips.
7. Clean, disinfect and prepare contaminated handpiece and used tip(s) for reuse according to section 4, Hygiene and Maintenance.

4. HYGIENE

To reduce the risk of Cross-contamination.
Infection.
- Do not reuse single use products. Dispose of in accordance with local regulations.
- The barrier is designed for single use and must be disposed of after each use in accordance with local regulations. The barrier is not a replacement for cleaning, disinfection, and sterilization.
- Reprocess reusable products as described below.

4.1 SmartLite Pro handpiece

To reduce the risk of Electrical short-circuit or dangerous malfunction. Injury.
1. Safeguard handpiece against liquid penetration during cleaning and disinfection.

***NOTICE*: Wrong cleaning or disinfection method.**
Damage to SmartLite Pro curing light.

Instructions for Cleaning and Disinfecting SmartLite Pro Light Handpiece, Tips, Charging Base	
Warnings	• The SmartLite Pro Shield should be removed and cleaned / disinfected / sterilized as outlined below. The SmartLite Pro Light handpiece, tips and charging base are not sterilizable by autoclave. • The SmartLite Pro curing light cannot tolerate high-level disinfection procedures. Intermediate-level disinfection is appropriate for the handpiece, tips and charging base. • Do not autoclave in steam autoclave. • Do not clean/disinfect in automated washer/disinfector. • Do not immerse in liquid. • Do not clean or disinfect with chlorine bleach/sodium hypochlorite (corrosion of contacts) or Lysol® Brand I.C. ™ Disinfectant Spray (cracking of charging base). • Disconnect the power supply plug from the power outlet and charging base unit prior to cleaning/disinfection.
Limitations on reprocessing	• Repeated reprocessing has minimum effect on these instruments. End of life is normally determined by wear and damage due to use. • Cold liquid immersion disinfection/sterilization, chemical vapor sterilization, and dry heat sterilization methods have not been tested or validated for efficacy and are not recommended for use.
Initial treatment at the point of use	• Remove SmartLite Pro eye protection Shield. Reprocess as outlined below. • Remove protective barrier sleeve and discard according to local regulations. • Use a new, clean pair of examination gloves. • Do not disassemble tip from handpiece at point of use. • Wipe vigorously with disposable cloth / paper wipe in combination with an alcohol-based, tuberculocidal, quaternary ammonium solution with a label claim for cleaning e.g., VoloWipes® Disinfecting/Cleaning/Deodorizing Wipes • Remove all visible soil, ensuring fluid penetrates all crevices. Use fresh wipes to rub fluid into the crevices. Do not allow solution to penetrate the casing. Discard used wipes. Additional wipes may be used. • Do not remove battery pack from light handpiece. Do not attempt disassembly of charging base. • It is recommended that the device be reprocessed as soon as is reasonably practical following use. • Start reprocessing within 1 hour after use. • Charging base should be reprocessed as soon as reasonably practical after being exposed to spatter or spray of body fluids, or touched by contaminated hands or contaminated light handpiece.
Preparation before cleaning	Always disassemble Tip from handpiece before processing. Use moderate force to pull the probe tip from the handpiece.
Cleaning & Disinfection: Automated	Do not use automated washer/disinfectors for reprocessing SmartLite Pro light handpiece, tips or charging base. Component damage will occur.
Cleaning: Manual	The SmartLite Pro light handpiece, tips and charging base have to be manually cleaned. 1. Discard used gloves according to local regulations. 2. Disinfect hands with an appropriate bactericidal, virucidal, and fungicidal hand disinfectant solution according to local regulations. Use according to disinfectant solution manufacturer's Instructions for Use. 3. Use a new clean pair of examination gloves 4. Disassemble tip from handpiece. Use separate wipes for tip and handpiece. 5. Scrub handpiece, tips and charging base with an impregnated wipe or disposable towel soaked with an alcohol-based, tuberculocidal, quaternary ammonium solution with a label claim for cleaning (e.g. VoloWipes Disinfecting / Cleaning / Deodorizing Wipes) approved according to local regulations and use according to cleaning solution manufacturer's Instructions for Use until it is free of visible residues. 6. Special Note: use care when cleaning the mating surfaces of the probe tip and handpiece. Use only a moist impregnated towel. • For the probe tip: Vigorously scrub the area near the o-ring with a fresh wipe. Ensure fluid covers o-ring and surrounding crevices. When cleaning the mating surface, ensure that cleaning agent only contacts the sides that fit within the handpiece (with O-ring). Avoid applying cleaning agent to the electrical contacts on the bottom of the probe tip. • For the handpiece mating cavity: Use a fresh wipe to clean mating groove directly below the surface. Use care to ensure cleaning agent is applied only to the top of the cavity interior. Ensure only minimal cleaning agent enters the cavity that houses the electrical pins. Do not allow fluid to pool in the cavity around the contact pins. Immediately absorb excess fluid with a dry disposable towel. • For the battery and handpiece mating seam: Use a fresh wipe to clean mating groove. Remove all visible soil, ensuring fluid penetrates all crevices. Use fresh wipes to rub fluid into the crevices. Do not allow solution to penetrate the casing. Discard used wipes. Additional wipes may be used. 7. Remove cleaning solution residue with a damp cloth. Use tap water to dampen cloth 8. Allow the devices to air dry for at least 5 min.
Disinfection: Manual (Intermediate-Level)	1. After cleaning, wipe all device surfaces with a new single-use cloth in combination with an alcohol-based, tuberculocidal, quaternary ammonium solution e.g. VoloWipes™ Disinfecting / Cleaning / Deodorizing Wipes, 5 minute contact time, approved according to local regulations, and use according to disinfectant solution manufacturer`s Instruction for Use. Use a separate wipe for tip and handpiece. Ensure direct contact of device and disinfectant by pressing the wet wipes on the device after half of the required contact time. 2. Ensure that the device stays wet for the entire contact time specified by wrapping wipes around device. Use additional wipes as needed. 3. Pay special attention to seams, areas around buttons, window, and crevices.. 4. Use fresh wipes to disinfect the probe tip o-ring area, handpiece mating cavity, and battery/handpiece mating seam for the entire contact time. Use care to ensure cleaning agent is applied only to the top of the cavity interior. Ensure only minimal cleaning agent enters the cavity that houses the electrical pins. Immediately absorb excess fluid with a dry disposable towel. 5. Wipe the devices with a sterile, clean, lint-free cloth that is well dampened with deionized water for 30 seconds to remove all disinfecting agent. Pay special attention to all seems, especially around the probe tip/handpiece junction. Ensure cloth is damp with deionized water for the entire 30 seconds. Discard used cloth and repeat rinsing with a new, second dampened cloth for 30 seconds. Discard second cloth and rinse with a new, third dampened cloth for a final 30 seconds. 6. Wipe device with a fourth dry, sterile lint-free cloth to remove all fluid. 7. Allow the devices to air dry for at least 5 minutes

Packaging	No particular requirements.
Sterilization	Sterilization is not allowed. No methods have been validated. Do not subject components to Steam autoclaving or liquid chemical sterilant immersion. Component damage will occur.
Drying	Wipe the devices dry with a sterile, clean, lint-free cloth. Allow the components to fully air dry before storage.
Maintenance, Inspection and Testing	Visually inspect to ensure that all contamination has been removed. Visually inspect power supply and cord for damage. Components that are damaged, worn, or distorted such as the O-rings should be discarded and replaced. See maintenance section below for additional recommended maintenance and testing.
Storage	Store the SmartLite Pro light handpiece, tips and charging base at room temperature, away from moisture or excessive humidity.
Additional Information	Reassemble for Use as described above in step-by-step Instructions.
Manufacturer Contact	For areas outside the United States, contact your local Dentsply Sirona representative.

Instructions for Cleaning, Disinfecting and Sterilizing SmartLite Pro Light Shield	
Warnings	• These instructions are for use ONLY for the light eye protection Shield. The handpiece, tips and charging base should be disinfected according to the procedures in the "Instructions for Cleaning and Disinfecting SmartLite Pro Light Handpiece, Tips, Charging Base" section above. • The SmartLite Pro Shield should be removed and cleaned/disinfected/sterilized as outlined below. The SmartLite Pro Light handpiece, tips and charging base are not sterilizable by autoclave. • High level disinfection has not been validated as a terminal process for the light shield. • Steam autoclaving sterilization is appropriate and recommended for the light shield. • Do not allow the device to exceed 134°C.
Limitations on reprocessing	• Repeated reprocessing has minimum effect on these instruments. End of life is normally determined by wear and damage due to use. • Device can be reprocessed for at least 60 times. • Cold liquid immersion disinfection/sterilization, chemical vapor sterilization, and dry heat sterilization methods have not been tested or validated for efficacy and are not recommended for use.
Initial treatment at the point of use	• Use moderate force to pull the SmartLite Pro Light Shield from the handpiece. • Remove protective barrier and discard according to local regulations. • Use a new, clean pair of examination gloves. • Remove excess soil with disposable cloth / paper wipe in combination with a pH-neutral, phosphate-free cleaning solution (e.g.: Dr. Schumacher Instru Plus [3%]) • Reprocess SmartLite Pro Light Shield as outlined below. Reprocess handpiece, tips and charging base as outlined in the "Instructions for Cleaning and Disinfecting SmartLite Pro Light Handpiece, Charging Base" section above. • It is recommended that the device be reprocessed as soon as is reasonably practical following use. • Start reprocessing within 1 hour after use.
Preparation before cleaning	Always disassemble eye protection shield from handpiece before processing.
Cleaning and Disinfection: Automated	Use only properly maintained, calibrated, and approved washer-disinfector according to ISO 15883-1. Run washer-disinfection program with A0 value ≥ 3000 (e.g. 5 min at ≥ 90°C) using appropriate detergents. as indicated by the manufacturer in the operating instructions. Follow manufacturer's recommendation for use of detergent and neutralizer, e.g., neodisher® MediClean [0.5%] (alkaline detergent) and neodisher® Z [0.1%] (acid neutralization and cleaning detergent, observing concentrations and contact times. Proceed to Sterilization following Automated Cleaning and Disinfection.
Cleaning: Manual	As an alternative to automated cleaning and disinfection, the SmartLite Pro Shield can be manually cleaned. 1. Discard used gloves according to local regulations. 2. Disinfect hands with an appropriate bactericidal, virucidal, and fungicidal hand disinfectant solution according to local regulations. Use according to disinfectant solution manufacturer's Instructions for Use. 3. Use a new clean pair of examination gloves 4. Scrub with hot water and Immerse SmartLite Pro Shield in a pH-neutral, phosphate-free cleaning detergent solution (e.g.: Dr. Schumacher Instru Plus [3%]). Clean with a soft brush for at least 30 seconds until free of all visible contamination.. 5. Rinse under running potable water. 6. Dry with a lint-free single-use cloth.
Disinfection: Manual	• No appropriate manual terminal disinfection process has been validated. Device has been shown to be compatible with alcohol-based, tuberculocidal, quaternary ammonium solution e.g. VoloWipes™ Disinfecting/Cleaning/Deodorizing Wipes, 5 minute contact time, approved according to local regulations, and used according to disinfectant solution manufacturer's Instructions for Use. • Proceed to Sterilization following manual cleaning and any optional disinfection process.
Packaging	Paper / plastic steam sterilization pouches (e.g., AssurePlus® Sterilization Pouches) may be used, but are not required.
Sterilization*	After manual cleaning, and any optional disinfection or Automated Washer-Disinfector cycle, steam autoclaving is required. Prevacuum Steam Sterilization: • Full Cycle: 134˚C for 3 minutes 30 seconds. Follow manufacturer's instructions for loading and operation cycle.
Drying	Use the drying cycle of the autoclave, minimum 30 minutes. Allow the components to fully air dry before storage.
Maintenance, Inspection and Testing	• Immediately before use, visually inspect to ensure that all contamination has been removed. If the device is discolored, damaged, worn, or distorted it should be discarded. • No additional maintenance or lubrication is recommended.
Storage	Store the sterilized light shield at room temperature, away from moisture or excessive humidity. Instruments steam autoclaved bagged should remain bagged until ready for use. Prior to subsequent re-use, inspect the sterilization pouch and the shield. If the integrity of the sterilization pouch has been compromised, the shield must be reprocessed prior to use. Instruments steam autoclaved unwrapped should be used immediately. Light handpiece, tips and Charging Base should be cleaned, disinfected, dried and stored as outlined in the section above prior to storage.
Additional Information	Reassemble for Use as described above in step-by-step Instructions.
Manufacturer Contact	For areas outside the United States, contact your local Dentsply Sirona representative.

* This Prevacuum Steam Sterilization: Full Cycle: 134˚C for 3 minutes 30 seconds with drying time, minimum 30 minutes sterilization cycle, is not considered by the United States Food and Drug Administration (US FDA) to be a standard sterilization cycle. Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (time and temperature).

Incidental surface contact of the power supply and cord with water, soap or a water-based hospital-level disinfection solution will not damage the material of construction. Do not allow any solution to penetrate the casing.

The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

5. MAINTENANCE

5.1 Light output monitoring

1. Make sure that the LED aperture is clean and scratch-free; otherwise light output will be reduced and may be insufficient for proper curing of the material.
2. The light intensity of SmartLite Pro curing light should be checked frequently to ensure appropriate curing by using the radiometer **5.2** incorporated into the charging base.
3. Upon receipt of SmartLite Pro check the light intensity with the radiometer **5.2** on the charging base to ensure it meets the appropriate threshold for power (green light **5.3** means the output is equivalent to at least 1000 mW/cm², red light **5.3** means the output is below 1000 mW/cm²). Ensure that the light is centered over the radiometer window and held stationary in a horizontal position **F2** when confirming light output with the radiometer.
4. For subsequent monitoring retest the light intensity frequently.
5. If radiometer shows red light, **5.3** light efficiency can be verified using the i•Cure. Place i•Cure on a sheet of paper on a flat surface. Choose i•Cure segment according to step height required (please note that the step height should be twice the curing depth to be confirmed). Fill with composite. Hold SmartLite Pro in close proximity to the upper aperture and cure. If the material on the lower aperture has been cured (i.e. cannot be scraped off with a plastic spatula), the curing depth according to ISO 4049:2009 equals half the chosen step height (e.g. 4 mm step height = 2 mm depth of cure).
6. Do not continue to use SmartLite Pro if both light output is below reference intensity and i•Cure test has failed.

5.2 Battery **3.1**

- Batteries are equipped with low self-discharge technology resulting in a long operating life.
- Batteries are pre-charged and ready to use upon purchase, however, charging before the first use is recommended
- When the battery light shows solid orange **5.5** the battery is charging. Upon complete recharging, the battery light remains permanently green **5.5**. The battery needs approximately 2 hours to be fully recharged.
- When the ON/OFF key **1.1** light slowly flashes orange the battery needs to be recharged. At first occurrence approximately 10-20 curing cycles remain for completion of the treatment. Light output is not reduced during this period.
- If the battery pack needs to be replaced, simply pull the battery pack by pulling it from the main housing along its longitudinal axis. **B1**

5.3 General maintenance

- A thin coating of petroleum jelly may be applied to probe tip O-rings and charging base battery post as needed to facilitate insertion and removal.
- Inspect and replace worn or damaged O-rings as needed to maintain optimal performance (see Section 6).

6. REORDER INFORMATION, TECHNICAL DATA, WARRANTY TERMS

6.1 Accessories

Accessory	Reorder no.
SmartLite Pro Battery Refill 1x	644401
SmartLite Pro Sleeve Refill 100x	644402
SmartLite Pro Shield Refill 5x	644403
SmartLite Pro Power Connector Refill 1x	644404
SmartLite Pro Transillumination Tip Refill 1x	644405
SmartLite Pro PolyCure Tip Refill 1x	644406
SmartLite Pro Cure Tip refill 1x	644407
SmartLite Pro O-rings refill 3x	644408

6.2 Serial number

The handpiece, battery packs, charging base and tips have different serial numbers.

The serial number ([SN]) should be quoted in all correspondence which requires identification of the product. XXXXX = 00001 through 99999 as marked on the component

Serial number format SmartLite Pro handpiece and complete kit . . HXXXXX
Serial number format SmartLite Pro charging base:. CXXXXX
Serial number format SmartLite Pro Transillumination tip. . . . . TXXXXX
Serial number format SmartLite Pro Cure tip: . . . . . BXXXXX
Serial number format SmartLite Pro PolyCure tip: . . . . . PXXXXX

6.3 Technical Specifications

AC supply connection:	100V – 240V / - 50 - 60 Hz
Charging Base Power input:	5V, 1A
Operation:	Ambient temperature: Between 0 °C and +45 °C (32 °F and 113 °F) Relative humidity: Between 20% and 90%
Storage:	Ambient temperature: Between -5 °C and +35 °C (23 °F and 95 °F) Relative humidity: <75% (non-condensing)
Transport:	Ambient temperature: Between -10 °C and +50 °C (14 °F and 122 °F)
Battery performance:	• Battery is pre-charged however, charging is recommended prior to first use. • Time for battery recharge: Approximately 2 hours. • 3.2V, 600 mAh
Battery over current/ temperature protection:	Resettable fuse
Light emitting diode:	*Cure* and *PolyCure* tip: Four 3 W LEDs
Average light intensity:	*Cure* Tip: Approximate irradiance 1200 mW/cm^2 *PolyCure* Tip: Approximate irradiance 1200 mW/cm^2
Output peak wavelength range:	*Cure* Tip:Between 450 nm and 480 nm (intensity maximum peak around 465 nm) *PolyCure* Tip: Between 405 nm – 480 nm (intensity maximum peaks around 420 and 465 nm)
Effective curing diameter of curing tips:	10 mm
Transillumination Tip	Approximate power: 8-10 mW and 20-24 mW Light temperature: 4500K
Unit handpiece dimensions (with battery & curing tip):	Cure/PolyCure tip: Length: 10.5cm; Width: 1.5cm Transillumination tip: Length: 9.5cm; Width: 1.5cm
Unit weight:	Handpiece with Cure/Polycure tip and battery pack: 105 grams Handpiece with Transillumination tip and battery pack: 94 grams Charging base with power connector: 375 grams
Applied Parts	Probe tips, barrier sleeve

6.4 Classifications

Type of protection against electric shock	Class II
Degree of protection against electric shock	Type B Applied Part
Mode of operation for handpiece	Operating, off
Settings for Handpiece	1 (On/Off)
According to medical device directive:	I (Rule 12) (IEC 60601) UL 60601-1
Pollution Degree Classification	Pollution Degree 2
Overvoltage Category	Category II (connected to wall outlet)

6.5 Symbol Identification

Cure	Blue light curing tip
PolyCure	Multi-wavelength curing tip
Illuminate	Transillumination tip, full spectrum white light for inspection
	Class II Equipment
	Type B applied part Tip, barrier sleeve
CLASSIFIED C UL US E490506	MEDICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1CAN/CSA-C22.2 No. 601.1, ANSI/AAMI ES60601-1 (2005, 3rd ed.), CAN/CSA-C22.2 No. 60601-1 (2008),13VA
www.dentsplysirona.com www.dentsply.eu/ifu	Follow instructions for use
134°C	Sterilizable up to the temperature specified (eye protection shield only)
Single Use	Do not re-use
	Dispose of in accordance with the Waste Electrical and Electronic Equipment Directive 2012/19/EU of the European Parliament and the Council of the European Union
IPX4	Protection Class IPX4 – handpiece
SN	Serial Number
5V-1A	Power supply rating
	Date of Manufacture

6.6 Disposal of Unit

This device is provided with a lithium-ion phosphate battery. Device and battery must not be disposed of in normal domestic waste. For environmental reasons, dispose of device and battery according to local environmental guidelines or regulations.

6.7 Electromagnetic Compatibility Precaution

This information is required by the 4th edition of IEC 60601-1-2.

- The SmartLite® Pro Light needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- Portable and mobile RF communications equipment can affect the SmartLite® Pro Light.
- The use of accessories, transducers and cables other than those specified by Dentsply Sirona, may result in increased emissions or decreased immunity of the SmartLite® Pro Light.
- The SmartLite® Pro Light should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the SmartLite® Pro Light should be observed to verify normal operation in the configuration in which it will be used.
- Per IEC 60601-1-2, no additional environmental operating conditions are required for normal use

Guidance and manufacturer's declaration – electromagnetic emissions

The SmartLite® Pro Curing Light is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartLite® Pro Light should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The SmartLite® Pro Curing Light 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 CISPR11	Class B	The SmartLite® Pro Curing Light is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A - Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The SmartLite® Pro Curing Light is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartLite® Pro Curing Light 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, ± 4, ± 8, ± 15 kV air	± 8 kV contact ± 2, ± 4, ± 8, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5, + 1 kV line(s) to line(s) ± 0.5, ± 1, ± 2 kV Line(s) to earth	± 0.5, + 1 kV line(s) to line(s) ± 0.5, ± 1, ± 2 kV Line(s) to earth	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 % U_T for 0,5 cycle 0 % U_T for 1 cycle 70 % U_T for 25/30 cycles 0 % U_T for 250/300 cycles	0 % U_T for 0,5 cycle 0 % U_T for 1 cycle 70 % U_T for 25/30 cycles 0 % U_T for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SmartLite® Pro Curing Light requires continued operation during power mains interruptions, it is recommended that the SmartLite® Pro Curing Light be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The SmartLite® Pro Curing Light is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartLite® Pro Light should assure that it is used in such an environment.

IMMUNITY Test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the SmartLite® Pro Curing Light, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommended separation distance $d = [\frac{3,5}{3}]\sqrt{P}$ $d = [\frac{3,5}{3}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{3}]\sqrt{P}$ 800 MHz to 2,7 GHz
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m	Where ***P*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and ***d*** is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SmartLite® Pro Curing Light is used exceeds the applicable RF compliance level above, the SmartLite® Pro Curing Light should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SmartLite® Pro Modular LED Curing Light

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Complies with the following Directives/Standards:	
93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices amended by directive 2007/47/EC, annex 1
2002/95/EC	Restriction of the use of hazardous substances in electrical and electronic equipment
IEC 60601-1 ed. 3.1	2012 – Medical Electrical Equipment (General requirements for basic safety and essential performance)

IEC 60601-1-2	2005 – Medical electrical equipment - Part 1-2: General requirements for safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-2-57	2011 - Medical electrical equipment - Part 2-57: Particular requirements for basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic use
ISO 10650	2015 – Dentistry - Powered polymerization activators
EN 62471 IEC 62471	2008 – Photobiological Safety of Lamps and Lamp Systems 2006 – Photobiological Safety of Lamps and Lamp Systems
EN 980	2008 – Symbols for use in labeling of medical devices
EN 1041	2008 – Information supplied by the manufacturer of medical devices
EN 1639	2009 – Dentistry – Medical devices for dentistry - Instruments
EN ISO 10993-1	2009 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 17664	2017– Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices
IEC 80601-2-60	2012 – applies to the basic safety and essential performance of Dental Units, Dental Patient Chairs, Dental Handpieces and Dental Operating Lights.
IEC 62366	2015 – Application of usability engineering to medical devices

The SmartLite Pro curing light complies with:

UL 60601-1
CSA C22.2 No. 601.1
E113604

6.8 Warranty terms

Dentsply Sirona grants a 2-year warranty on all components of the SmartLite Pro Curing Light except the battery. The battery is covered by a 1-year warranty. The warranty commences on the date of purchase. Within the warranty period, Dentsply Sirona will eliminate free of charge any defects in the appliance resulting from faults in material or workmanship either by repairing or exchanging parts or exchanging the whole device at Dentsply Sirona's discretion.

Not covered by this warranty: Damage arising from improper use (operation with incorrect current/voltage, unsuitable power point, breakage, cleaning by other than the recommended methods), normal wear and defects which have a negligible effect on the value or operation of the appliance.

This warranty becomes void if repairs are undertaken by unauthorized persons.

This warranty extends to every country where this device is supplied by Dentsply Sirona or its appointed distributor and where no import restrictions or legal regulations hinder or prevent service being given under warranty.

Service under this warranty does not affect the expiration date of the warranty. The warranty on parts or entire devices which are exchanged ends when the warranty on this device expires.

In the event of a claim of this device, return the complete device (charging unit and the LED curing light) together with the invoice to your dealer or send it to your nearest Dentsply Sirona Service Center.

All other claims including those for damages resulting from this warranty are excluded unless our liability is legally mandatory.

6.9 Correspondence

1. The following numbers should be quoted in all correspondence:
   - Reorder number
   - Serial Number
2. Any serious incident in relation to the product should be reported to the manufacturer and the competent authority according to local regulations.

Manufactured for
Dentsply LLC
38 West Clarke Avenue
Milford, DE 19963 USA
Made in Switzerland
1-302-422-4511

www.dentsplysirona.com

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78467 Konstanz
Germany

 544400DFU (R 5-4-21)
109-DV5