radii plus

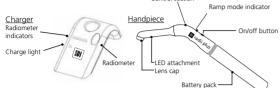
INSTRUCTIONS FOR USE

Thank you for purchasing the Radii Plus LED curing light. The Radii Plus is a powerful, cordless, lightweight curing light using an LED for the polymerization of composite restorative materials that contain the photo-initiator Camphorquinone. The Radii Plus produces a strong blue light in the wavelength range of 440 – 480 nm, the relevant range for Camphorquinone containing products. The Radii Plus features a 'NO RAMP' mode and 'RAMP' mode for convenient polymerization shrinkage minimization of composite materials. In addition to this, the LED attachments can be changed depending on the clinical application.

PRODUCT CONTENTS LIST



- Plug pack 100 Radii Plus barrier sleeves 3 Radii Plus lens caps Radii Plus light shields (5 Pack)



UNPACKING AND INITIAL CHARGING

UNPACKING AND INITIAL CHARGING
The Radii Plus has been carefully packed to withstand any damage during transit. Ensure all parts contained within the box match the product contents list above.
1) Remove all parts from the box.
2) Place the plug pack cable into the charger.
3) Fix the correct adapter head onto the plug pack.
4) Plug the plug pack into an available power outlet and turn power outlet on. The charger will conduct a brief LED test: the charge light LED should momentarily show red/green and the 5 blue radiometer LEDs should turn on/off.
5) Place the curing light handpiece into the charger. The handpiece can be rotated 360° in the charger. Depending on the length of time from manufacture to package opening, the charge remaining in the battery can vary. The charge light will show the blow three conditions.

Charge Light Color Battery condition discharged charging (OK to use) charged Flashing Green Groor

To ensure the highest level of performance, allow the Radii Plus to fully charge prior to first use. On average, it will take approximately 1-3 hours to initially charge the Radii Plus.

OPERATION

• Turning unit on and off Simply pick up the curing light handpiece, press the on/off button once to activate and de-activate the light. Audible beeps facilitate accurate time measurement of curing. Replace the Radii Plus back in the charger when not in use.

• NO RAMP mode and RAMP mode. The Radii Plus has two curing modes, NO RAMP and RAMP mode. NO RAMP mode will output 100% intensity immediately after pressing the on/off button whereas RAMP mode will output a reduced intensity for the first 5 seconds before irradiating at 100% intensity.

• Switching between the NO RAMP mode and RAMP mode. The Radii Plus has been set at the factory to the NO RAMP mode. To switch between the NO RAMP mode and RAMP mode, when the Radii Plus is off, hold down the or/off button for 3 seconds. Two audible beeps will be heard. The unit will now be programmed for RAMP mode. To switch back to the NO RAMP mode, hold down the or/off button for 3 seconds, a single audible beep will be heard indicating the unit has switched back to NO RAMP mode. NOTE: In RAMP mode the visible light starts slightly dimmer and progressively gets stronger, as opposed to in NO RAMP mode, where the visible light is constant from the start.

<u>RAMP mode indicator:</u> This unit has been fitted with a blue indicator light above the on/off button. When in RAMP mode, the indicator light will show blue. The indicator light is off in the NO RAMP mode.

• Audible beeps for NO RAMP and RAMP modes: Depending on the mode set (NO RAMP or RAMP), the beeping cycle will differ Below is a table explaining the audible beeps for each mode.

Audible beeps	Time between beeps (seconds)		Total elapsed time (seconds)	
CURE MODE	NO RAMP	RAMP	NO RAMP	RAMP
1 short beep	10 sec	15 sec	10 sec	15 sec
2 short beeps	10 sec	10 sec	20 sec	25 sec
3 short beeps	10 sec	10 sec	30 sec	35 sec
4 short beeps	10 sec	10 sec	40 sec	45 sec
5 short beeps	10 sec	10 sec	50 sec	55 sec
1 long beep	10 sec	10 sec	60 sec	65 sec

At the end of 60 seconds (or 65 seconds in case of "RAMP" mode) one long beep will be heard before the blue LED is automatically switched off. NOTE: The above cycle is based on the Standard LED attachment supplied in this kit. Other access types of LED attachments from SDI will have different cycles. Refer to instruction sheets associated with those products for beeping cycle.

• Rotating and changing the LED attachment The LED attachment, can be rotated 360° to ensure accurate and detailed polimerization in any area of the mouth. WARNING: Do not rotate the LED attachment at the LED end, instead turn at the end closer to the control section as shown below:



• Lens Cap The Radii Plus has been supplied with a lens cap fitted. The lens cap should be inspected prior to each use for scratches, cracks or foreign matter that may reduce the effectiveness of the LED light source. Generally lens caps should be replaced every 2 weeks. To remove the lens cap carefully unscrew the old lens cap counter-clockwise and fit the new lens cap by tightening clockwise.

Built in Radiometer
 The Radii Plus's built-in radiometer provides a simple test to check the
 functionality of the unit. With the Radii Plus on, carefully position the lens
 cap on the built-in radiometer. 4 or 5 lights should illuminate indicating a
 fully functional unit. If only 1,2 or 3 lights illuminate, it could be due
 to the following reasons:
 1) There could be some material on the lens cap such as composite: - the
 lens cap should be replaced.
 2) The lens cap could be damaged or cracked: - it should be replaced.
 3) The battery could be extremely low - the unit should be recharged.
 4) In a severe case the light could be malfunctioning: - the unit should be serviced.

Note: Portable radiometers can give inaccurate and inconsistent results. These results can vary by as much as 300 mW/cm $^\circ$ or more.

Disposable barrier sleeves Transparent, disposable barrier sleeves are supplied to protect the handpiece and prevent cross contamination. Testing showed no significant difference in spectral and energy output when operating with or without a barrier sleeve in place.

Slide the barrier sleeve over the end of the handpiece before placing the orange light shield on the end of the handpiece. It is essential to use disposable barrier sleeves to prevent any liquids getting on the handpiece. Evidence of liquids entering handpiece causing damage due to not using barrier sleeves will void warranty.

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• Automatic shut off function using the standard LED attachment Should the Radii Plus standard LED attachment become too hot due to excessive use (after about 4 minutes of continuous irradiation), the unit will automatically shut off and be un-usable for about 1 minute until it cools down. If using a different LED attachment, please refer to the instruction sheet for that attachment's automatic shut-off sequence as it may vary.

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<u>Changing the LED Attachment</u>
The Radii Plus allows you to change the LED attachment depending on the curing
situation. To change the LED attachment, pull off the LED attachment carefully by
placing fingers as shown below. Please refer to LED attachment instructions for us
for operation guidelines.







• <u>Changing the battery pack</u> Carefully unscrew the battery pack counter-clockwise to remove and replace. A single beep will be heard when the battery pack is successfully connected.

• <u>Cleaning the Radii Plus:</u> The ideal way to protect patients from cross-infection is to utilise Radii Plus barrier sleeves. Barrier sleeves are also essential to keep the Radii Plus clean. When cleaning the Radii Plus handpiece, ensure lens cap, battery pack, control section and LED attachment are connected as one unit.

- LIQUID CONTACT WITH TERMINALS OF HANDPIECE AND CHARGER WILL CAUSE DAMAGE VOIDING WARRANTY.
- LIQUID CONTACT WITH LED WILL CAUSE DAMAGE VOIDING WARRANTY.
- LIQUIDS MUST NOT ENTER ANY PART OF THE HANDPIECE OR CHARGER
- DO NOT SPRAY LIQUIDS DIRECTLY ONTO, OR APPLY COPIOUS AMOUNTS OF LIQUIDS TO THE RADII PLUS.

DO NOT AUTOCLAVE THE RADII PLUS.

General Surface Cleaning
General surface Cleaning can be conducted with anti-microbial
surface disinfectant such as Glutaraldehyde, Chlorhexidine
gluconate, and 70% Isopropyl alcohol. When applying the
disinfectant to any component of the device, spray the disinfectant
agent onto a piece of cloth and wipe over the external areas to be
cleaned.

• <u>Curing Times</u> Curing times will differ for different formulations of composite restorative materials. Follow the manufacturers instructions for recommended curing times. Always bench test new materials before use in-vivo.

• <u>Disposal of battery pack</u> As a means of protecting the environment, the Radii Plus battery pack is fitted with a Lithium Ion battery pack. Dispose of battery pack in accordance with local legal regulations

TROUBLE SHOOTING Problem	Causes	Solution
Charge light flashes red	Possible battery fault	Replace battery
 Handpiece blue LED flashes then goes off 	Battery charged too low	Re-charge battery
 audible beep heard but no light irradiates 	LED attachment is not correctly inserted	Correctly insert LED attachment (see below)



No lights appear on the charger when the hand piece is placed on the charger.

- Check terminals on the battery are clean and free of debris.
 Check power is getting to charger, turn power outlet on . The charge light LED should momentarily show red/green and the 5 blue radiometer LEDs should turn on/off.
 Check the power outlet is turned on, if so use a different power outlet.
 Check the plug pack is correctly connected to the charger.

 - the charger. 5. Check that the hand piece is placed into the
 - charger correctly.
 6. If the problem still exists after checking 1, 2, 3 and 4 above the charger may be faulty. Return the unit to the supplier for service.

When returning faulty units please make sure that all parts are returned together in the original packaging.

SAFETY AND PRECAUTIONS The safe operation of this unit depends on strictly following the operating instructions in this manual. The Manufacturer accepts no liability for any damage resulting from the use of this unit for any other purpose than the polimerization of dental composite materials.

- The equipment can not be exposed or immersed in water or wet locations. The equipment does not have protection against liquid penetration. - Equipment not suitable for use in the presence of flammable anesthetic mixtures with air oxygen or nitrous oxide.

CAUTIONI Irradiation of the eyes bears an inherent health risk. Hence, the light must not be directed towards the eyes. Exposure must be restricted to the area of the oral cavity in which clinical treatment is intended. Suitable blue-light filtering safety goggles should be used. The Radii Plus emits a high intensity light and intensive light exposure of soft tissues (gingiya, oral mucosa and skin) should be avoided as this exposure may cause damage or irritation. The emitted light should be placed directly above the material to be cured. If applicable cover soft tissue areas.

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 Do not use the Radii Plus in patients or by users with:
 heart pacemaker implants who have been advised to be cautious in regards to their exposure to small electrical devices.
 a history of photo biological reactions (including individuals with urticaria solaris or erythropoietic protoporphyria) or who are currently on photo-sensitizing medication (including 8-methoxypsoralen or dimethylchlorotetracycline).
 a history of cataract surgery. These people may be particularly sensitive to the exposure to light and should be discouraged from Radii Plus treatment unless adequate safety measures, such as the use of protective gogles to remove blue light, are undertaken.
 a history of retinal disease. These people should seek advice from their ophthalmologist prior to operating the unit. In operating the Radii Plus unit, this group of individuals must take extreme care and comply with all safety precautions (including the use of suitable light-filtering safety goggles).

WARRANTY PERIOD SDI Limited, the Manufacturer, extends a five (5) year warranty against defects in materials or workmanship to the original purchaser of this product, except the battery which has a two (2) year warranty. The Manufacturer agrees to correct any defects which develop within the warranty period, either by repair or replacement, at its option. This warranty is valid providing factory inspection indicates that any such defect developed during normal and proper use subject to the conditions halow

WARRANTY CONDITIONS - PLEASE READ CAREFULLY

- Please fill out the warranty card included in kit and send promptly back to SDI with proof of purchase. Failure to do so may void your
- warranty. Alternatively goto <u>http://www.sdi.com.au/warranty</u> to register your warranty. a) Claims for damage in shipment should be filed promptly with the transportation

a) Claims for damage in shipment should be filed promptly with the transportation company. b) All shipments claimed defective can only be returned to the Manufacturer with the written consent of the Manufacturer. All returned products must be accompanied by a full description of discrepancy or malfunction. c) Only SDI authorized service personnel are allowed to carry out repairs to the Radii Plus. Manufacturer shall be released from all obligations under this warranty if repairs or modifications are made by persons other than Manufacturer's own or authorized service personnel. d) Use only SDI parts exclusively to replace defective components. The product warranty does not cover any damage resulting from the use of third-party replacements parts. e) Manufacturer shall be released from all obligations under this warranty in the event of improper installation; damage from liquids and autoclaving. th Manufacturer shall in no event be liable for any consequential damages arising

in the event of improper installation; damage due to casualty; or obvious misuse including but not limited to damage from liquids and autoclaving. f) Manufacturer shall in no event be liable for any consequential damages arising from the misuse of the product. g) Only the above stated warranty shall be applicable, and all other warranties, expressed or implied, are hereby excluded.

All correspondence concerning the product should specify the model and serial

3 hours, 20 minutes 22mm diameter x 243mm long

176g /6.2 ounces 2 x 4.2V Lithium Ion – 1400 mAh

70mm high x 45mm wide x 50mm long 80g / 2.82 ounces

mm wide x 40mm high x 130mm long

Re-order Code 5600054

5600061

5600063 5600064 5600065

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USA & Canada 1 800 228 5166 www.sdi.com.au EC REP SDI Dental Limited Block 8, St Johns Court Swords Road, Santry Dublin 9, Ireland Tel +353 1 886 9577

Class II Equipment

264V - 50/60 Hz

90 – 264 12V DC 750 mA

255mm

REPLACEMENT PARTS AND ACCESSORIES Replacement parts and accessories which can be installed without special training or equipment, can also be obtained from your authorized SDI dealer.

60 – 180 minutes 10°C - 40°C

84g / 3 ounces

weight: battery:

Plug Pack - input voltage: - output voltage: - output current: - dimensions:

weight:

dimensions: weight

- Europe LED Radiometer

Charger - time to charge battery: - operating temperature: - total height with handpiece inserted:

According to classification IEC 60601-1

Radii Plus replacement lens caps (25 Pack) Radii Plus barrier sleeves (1000 pack) Radii Plus light shield (5 Pack) Radii Plus Single Tooth Bleaching LED attachment Radii Plus Single Tooth Bleaching LED attachment Radii Plus Standard LED attachment Radii Plus Standard LED attachment Radii Plus Control Section Radii Plus Charger (includes plug pack) - Australia/New Zealand - United Kingdom - North and South America / Asia - Europe

Ambient temperature: 0'C - 40°C (32'F - 104'F) Relative humidity: 10% - 85% Atmospheric pressure: 0.5 atm - 1.0 atm (500 hPa to 1060 hPa)

Transport and storage environment:

CAUTION

instructions)

(refer to accompanying

Type B Applied Part

Last Revised: 10 - 2012

 TECHNICAL DATA

 Equipment powered internally.

 Handpiece (battery, control section and standard LED attachment)

 wavelength range:

 440 nm - 480 nm

 peak wavelength range:

 A40 nm - 480 nm

 peak wavelength range:

 AMP mode elapsed time

 to ful intensity:
 5 seconds

 light intensity:

 duration of continuous use

 NO RAMP mode:
 60 seconds

 RAMP mode:
 65 seconds

 total continuous run time
 with fully charged battery:

 dimensions:
 22mm diameter x 243mr

 weight:
 175g /6.2 ounces

Table 201 - Guidance and MANUFACTURER'S declaration - ELECTROMAGNETIC EMISSIONS - for all equipment and systems

Guidance and manufacturer's declaration - electromagnetic emissions The Radii Plus is intended for use in the electromagnetic environment specified below. The customer or the user of the Radii Plus should assure that it is used in such an environment.			
RF emissions CISPR 11	Group 1	The Radii Plus uses RF energy only for its internal function. There- fore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class B	The Radii Plus is suitable for use in all establishments, including domestic establishments. The Radii Plus is powered by 2 x 4.2V DC Lithium ion batteries thus Harmonic emission and Voltage	
Harmonic emissions IEC 61000-3-2	Not applicable	fluctuation/flicker emissions are not applicable.	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable		

Table 202 - Guidance and MANUFACTURER'S declaration - Electromagnetic IMMUNITY - for all equipment and systems

Guidance and manufacturer's declaration - electromagnetic immunity			
The Radii Plus is intended for use in the electromagnetic environment specified below. The customer or the user of the Radii Plus 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	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 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%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environ- ment

Table 204 - Guidance and MANUFACTURER'S declaration - Electromagnetic IMMUNITY - for all equipment and systems that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration - electromagnetic immunity The Radii Plus is intended for use in the electromagnetic environment specified below. The customer or the user of the Radii Plus should assure that it is used in such an environment.			
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the TENS PRO 900, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3.5}{P_1}]\sqrt{P}$ $d = [\frac{3.5}{P_1}]\sqrt{P}$ = 00 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ = 00 MHz to 2.5 GHz Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in metres (m). Field strengths from fixed RF transmitter, 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.

Recommended separation distances between nortable and mobile RF communications equipment and the Radii Plus

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 **Radii Plus** is used exceeds the applicable RF compliance level above, the **Radii Plus** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or re-locating the **Radii Plus**.

Table 206 - Recommended separation distances between portable and mobile RF communications equipment and the equipment and systems - for equipment and systems that are not LIFE-SUPPORTING

	e between portable and mobile RF communications equipment (transmitte	he customer or the user of the Radii Plus can help prevent electromagnetic ers) and the Radii Plus as recommended below, according to the maximum	
Rated maximum output power of trans- mitter W	Separation distance according to frequency of transmitter m		
	80 MHz 10 800 MHz	800 MHz a 2,5 GHz	
	$d = [\frac{3.5}{E_1}]\sqrt{P}$	$d' = [\frac{7}{E_1}]\sqrt{P}$	
0,01	0.12	0.23	
0.1	0.38	0.73	
1	1.2	2.3	
10	3.8	7.3	
100	12	23	

transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.