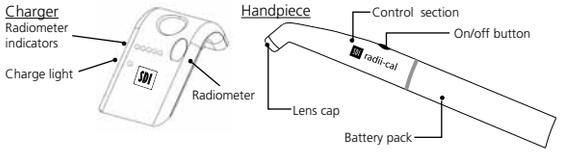
radii-cal

ENGLISH

INSTRUCTIONS FOR USE

Thank you for purchasing the Radii-cal LED curing light. The Radii-cal 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-cal produces a strong blue light in the wavelength range of 440 – 480 nm, the relevant range for Camphorquinone containing products.

PRODUCT CONTENTS LIST
- Handpiece
- Charger
- Plug pack
- 100 barrier sleeves
- 3 lens caps
- Light shields (5 Pack)



UNPACKING AND INITIAL CHARGING
The Radii-cal 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) 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.
4) 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 below three conditions.

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

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

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-cal back in the charger when not in use.

• Audible beeps
An audible beep will be heard after the first 15 seconds (5 second ramp, 10 seconds full cure) two audible beeps after a further 10 seconds then three audible beeps after an additional 10 seconds etc. The full cycle will continue as follows;

Audible beeps	Time between beeps (seconds)	Total elapsed time (seconds)
1 short beep	15 sec	15 sec
2 short beeps	10 sec	25 sec
3 short beeps	10 sec	35 sec
4 short beeps	10 sec	45 sec
5 short beeps	10 sec	55 sec
1 long beep	10 sec	65 sec

At the end of 65 seconds one long beep will be heard before the blue LED is automatically switched off.

• Lens Cap
The Radii-cal 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-cal's built-in radiometer provides a simple test to check the functionality of the unit. With the Radii-cal 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/cm² 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 causeing damage due to not using barrier sleeves will void warranty.

• Automatic shut off function
Should the Radii-cal LED 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.

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

• Cleaning the Radii-cal:
The ideal way to protect patients from cross-infection is to utilise Radii-cal barrier sleeves. Barrier sleeves are also essential to keep the Radii-cal clean. When cleaning the Radii-cal handpiece, ensure control section, lens cap and battery pack 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-CAL.**
- **DO NOT AUTOCLAVE THE RADII-CAL.**

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.

• Curing Times
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.

• Disposal of battery pack
As a means of protecting the environment, the Radii-cal 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
• No lights appear on the charger when the hand piece is placed on the charger.	**1.** Check terminals on the battery are clean and free of debris. **2.** 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. **3.** Check the power outlet is turned on, if so use a different power outlet. **4.** Check the plug pack is correctly connected to 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.
- Not appropriate to use the equipment in flammable mixtures.

CAUTION! 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-cal emits a high intensity light and intensive light exposure of soft tissues (gingiva, 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.

Do not use the Radii-cal 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-cal treatment unless adequate safety measures, such as the use of protective goggles 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 -cal 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 Ltd., the Manufacturer, extends a two year warranty against defects in materials or workmanship to the original purchaser of this product.
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 below.

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 http://www.sdi.com.au/warranty to register your warranty.**

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-cal. 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 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 number.

TECHNICAL DATA
Equipment powered internally.
Handpiece (battery, control section and standard LED attachment)
- wavelength range: 440 nm – 480 nm
- peak wavelength range: 460 nm
- RAMP to full intensity: 5 seconds
- light intensity: 1200 mW/cm² (peak)
- duration of continuous use 60 seconds
- total continuous run time with fully charged battery: 3 hours, 20 minutes
- dimensions: 22mm diameter x 243mm long
- weight: 144g /5.1 ounces
- battery: 2 x 4.2V Lithium Ion – 1400 mAh
- battery powered internally.

Plug Pack
- input voltage: 90 – 264V – 50/60 Hz
- output voltage: 12V DC
- output current: 750 mA
- dimensions: 70mm high x 45mm wide x 50mm long
- weight: 80g / 2.82 ounces

Charger
- time to charge battery: 60 – 180 minutes
- operating temperature: 10°C - 40°C
- total height with handpiece inserted: 255mm
- dimensions: 70mm wide x 40mm high x 130mm long
- weight 84g / 3 ounces

According to classification IEC 60601-1

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.

	Re-order Code
Replacement lens caps (25 Pack)	5600054
Barrier sleeves (1000 pack)	5600055
Light shield (5 Pack)	5600056
Radii-cal Control Section	5600106
Radii-cal Battery	5600105
Radii-cal Charger (includes plug pack)	
- Australia/New Zealand	5600110
- United Kingdom	5600111
- North and South America / Asia	5600112
- Europe	5600113
- China	5600114
LED Radiometer	5600028

Date of issue of last revision : 07 - 2012
Transport and storage environment:
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)

CAUTION (refer to accompanying instructions)

Class II Equipment

Type B Applied Part

Made in Australia by SDI Limited
Bayswater, Victoria 3153
Australia 1 800 337 003
Austria 00800 022 55 734
Brazil 0800 770 1735
France 00800 022 55 734
Germany 0800 100 5759
Ireland 01 886 9577
Italy 800 780625
New Zealand 0800 734 034
Spain 00800 022 55 734
United Kingdom 00800 022 55 734

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

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

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-Cal** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Radii-Cal** should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
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 $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz 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 **Radii-Cal** is used exceeds the applicable RF compliance level above, the **Radii-Cal** 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-Cal**.			

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

Recommended separation distances between portable and mobile RF communications equipment and the Radii-Cal		
The **Radii-Cal** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **Radii-Cal** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Radii-Cal** as recommended below, according to the maximum output power of the communications equipment.		
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m	
	80 MHz 10 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	**800 MHz a 2,5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
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
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		