User Manual

Mini LED™

EQUIPMENT ACTEON

This document is an English translation of the original French version.
Reference J02540 version V5 and drawing number NG13FR010E

Contents

Foreword

The SATELEC® medical device that you are about to install and use in your practice is a medical device designed for professional use. It is therefore a key tool with which you will provide treatment within the context of your work.

To ensure optimum safety for yourself and your patients, comfort in your daily practice and to benefit fully from your medical device's technology, please read the documentation provided carefully.

Please refer to the instructions for the entire range of SATELEC® Mini LED for information about the following:

- documentation format;
- documentation archiving period;
- warnings concerning user and patient populations;
- treatment area;
- medical device usage interactions, contraindications and prohibitions;
- electromagnetic compatibility;
- disposal and recycling of the medical device;
- manufacturer responsibility.

Please refer to the cleaning, disinfection and sterilisation instructions for accessories and to the cleaning, disinfection and sterilisation instructions for Mini LEDs for information about the following:

- preparation of parts for sterilisation;
- detailed manual and automated instructions;
- information concerning conditioning for sterilisation;
- recommendations for the inspection of parts.

1 Documentation

This document contains the following information:

- indications for use;
- medical device description;
- medical device installation;
- medical device use;
- preparation prior to cleaning and disinfecting the medical device;
- monitoring and general maintenance of the medical device;
- maintenance to be performed by the user.

1.1 Associated documentation

This document must be used in association with the following documents:

Document title	References
Cleaning, disinfection and sterilisation instructions for the SATELEC® Mini LED optical guide	J02941
Cleaning and disinfection instructions for the SATELEC® Mini LED rigid protection shield	J05541
General instructions relating to the SATELEC® complete range of table curing lamps	J02921
Consulting electronic user instructions	J00000
Mini LED™ User Manual	J02541

2 Required information

2.1 Indication for use

This medical device is designed to cure photosensitive reconstruction and bonding materials used in dentistry. The target clinical uses relate to conservative and restorative dentistry.

This medical device is used with an optical guide and a rigid protection shield.

2.2 Operating principle

Designed to light-cure dental materials, the Mini LED is fitted with electroluminescent diodes (LED) that emit a visible blue light in a spectrum of wavelengths between 440 nm - 460 nm. A removable optical guide is attached to the end of the medical device. The optical guide concentrates and directs the light produced to the clinical site.

The wavelength of the light source corresponds to that of the photo-initiators used in dental curing materials.

2.3 Date of first inclusion of EC marking

2007

2.4 Latest document update

01/2015

2.5 Repairing or modifying the medical device

Contact the supplier of your device. Using the services of an unapproved repairer could render your device dangerous for you and your patients.

Do not repair or modify the device without seeking the prior permission of SATELEC®.

If the device is modified or repaired, specific checks and tests must be carried out to ensure that the medical device is still safe to use.

In the event of doubt, contact an approved dealer or the SATELEC® customer service team:

www.acteongroup.com

satelec@acteongroup.com

> SATELEC® at the request of technical personnel working for the network of dealers approved by SATELEC®, provides all information required to repair the faulty parts on which they may perform repairs.

2.6 Warranty

The user must not disassemble the base, the battery or the handpiece as this will invalidate the medical device's warranty.

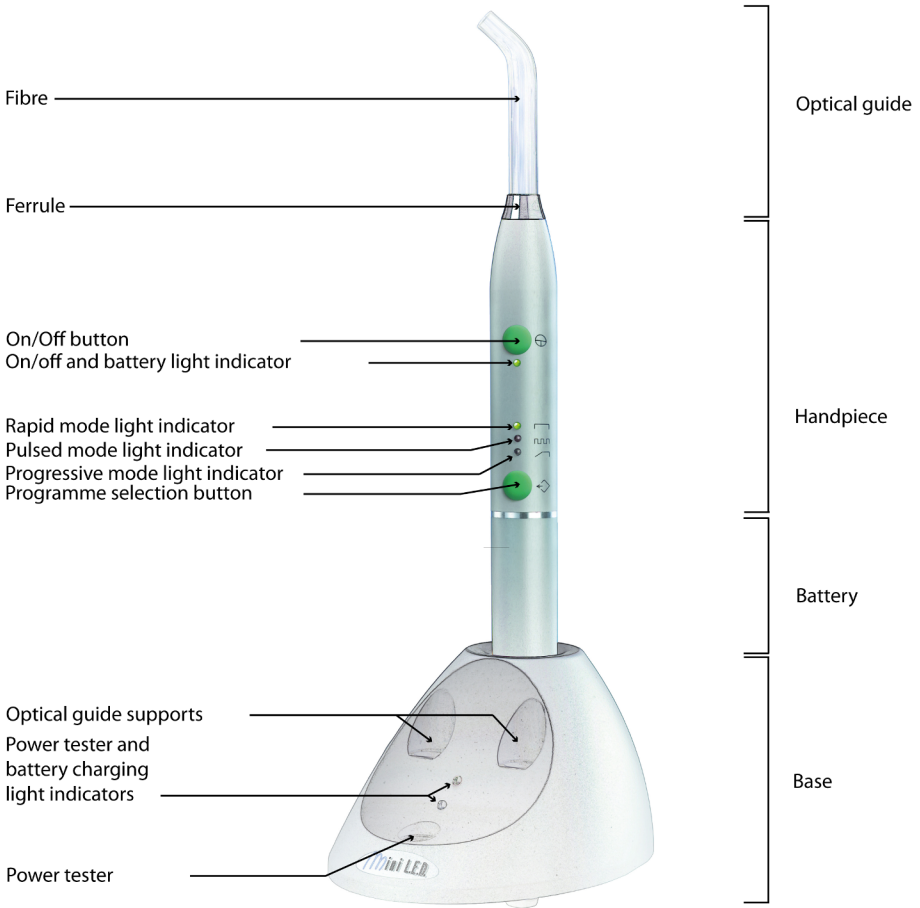
2.7 Accessory usage conditions

The optical guide must be cleaned and sterilised being being used. The rigid protection shield must be cleaned before being used.

3 Removal from packaging, installation, connections

3.1 Removing the medical device from its packaging

When you receive your medical device, check for any damage that may have occurred during transportation.
If you have received this medical device by mistake, please contact the supplier to arrange for it to be collected.
If you have any questions or requirements, contact your supplier.



The Mini LED™ includes the following items:

- a 7.5 mm-diameter multi-fibre optical guide with its ferrule;
- depending on the option, a 7.5 mm-diameter, amber-coloured multi-fibre optical guide with its ferrule;
- a Mini LED handpiece;
- two protection plugs for the handpiece;
- a charging base with an integrated power tester;
- a Lithium-ion battery;
- a rigid protection shield;
- a mains adapter.

3.2 Installing the medical device

Adjust the position of your medical device to correspond to your angle of vision and the characteristics of your workstation, e.g. lighting or distance between the user and the medical device. Ensure that your medical device is readily accessible.

> Do not install your medical device near or on another device.

Install the charging base of your Mini LED on a flat surface with a slope of less than 5°.

3.3 Connecting the medical device to the electrical network

Check that the mains voltage is compatible with that indicated on the medical device or its mains adapter. Next, connect the mains adapter to the wall socket in compliance with the standards in force in the country of use.

A different voltage would cause damage to the medical device and could injure the patient and/or user. Any variation in the electrical network voltage or electromagnetic field that is non-compliant with the limits in force, could interfere with the medical device's operation.

Medical devices equipped with a protective earth must be connected to a supply network equipped with a protective earth.

> Do not plug the medical device into an extension lead and do not put the mains cord in a cable cover or cable tray.

3.4 Installing the mains adapter

> The mains adapter and its cord are only designed to charge the Mini LED.

Check that the cord does not hinder the movement or free circulation of anyone whilst the Mini LED is charging. Make sure that it is not possible to wheel over or walk on the cord. Plug the mains adapter plug into the Mini LED.

4 Medical device description

4.1 First use

The Mini LED uses a Lithium-Ion battery. To guarantee optimum use, this battery must be fully charged before use but must never be flat. To prepare your Mini LED, follow the steps below:

- clean the rigid protection shield with an alcohol wipe;
- clean the handpiece with an alcohol wipe;
- plug the charging base into the mains;
- check that the green indicator light on the base lights up twice and listen out for a beep sound;
- install the battery on the handpiece;
- place the Mini LED on its charging base;
- the Mini LED is correctly installed when two beeps are heard and the green indicator light on the base starts flashing;
- leave the Mini LED to fully charge;
- the Mini LED is charged when the green indicator light on the base stops flashing and remains on permanently;
- remove the protection plug from the handpiece nozzle;
- insert the sterilised optical guide into the handpiece nozzle;
- you will hear a click when the optical guide is correctly inserted;
- install the rigid protection shield;
- wear safety goggles and protective gloves;
- provide your patient with safety goggles.

4.2 Using the Mini LED

The Mini LED is normally placed on its base. To use it, remove it from its base.

Prior to the day of use, check that you have enough sterilised optical guides and check the power output as indicated in the chapter *Checking the lamp power level page 19*.

> The patient and the practitioner must wear class II safety goggles when the Mini LED is in operation.

- Remove the Mini LED from the base;
- Press the on/off button.
- Install the rigid protection shield;
- Programme the Mini LED to select the required mode;
- Position the end of the optical guide as close as possible to the surface of the material to be cured;

> Do not allow the optical guide to touch the material to be cured.

- Press the on/off button to trigger the selected mode. A beep sound confirms cycle initiation;
- A second beep sound confirms cycle completion.

You can stop the cure cycle at any time by pressing the on/off button.

After three minutes of inactivity, the Mini LED switches to standby.

Depending on the cure material used, repeat the cure cycle as required.

4.3 Mini LED™

The Mini LED can only be used with the following accessories:

- 7.5 mm opalescent optical guide [F02648]
- 7.5 mm amber-coloured optical guide [F02620]
- Mini LED titanium battery [F02520]
- Mini LED handpiece [F02530]
- Protection plug [F57347]
- Rigid protection shield [F02555]
- Charging base and mains adapter [F02544]

The protection plug is designed to prevent any products from infiltrating the handpiece that may damage its electronics, the connector or the LEDs. The protection plug must be installed when the handpiece is being cleaned. Another transparent plastic protection plug protects the battery connectors.

4.4 Connecting and disconnecting accessories during use

> Never release the battery when the Mini LED is being used. When handling the mains adapter and the battery disconnected from the handpiece, avoid all contact with the patient or any other party.

> Do not disconnect the optical guide or the rigid protection shield when using your Mini LED.

4.5 Light indicator

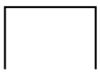
The light indicators are designed to signal the device's status.

The handpiece has four light indicators in total.

On/off light indicator

Colour	Mode
Green	Normal mode
Red	The battery is flat
Flashing red	Thermal cut-out activated

Three operating mode light indicators

Indicator	Pictogram	Colour	Mode
High		Green	Fast
Medium		Green	Pulsed
Low		Green	Progressive

The charging base has two light indicators.

Charging base light indicators

Colour	Meaning
Flashing green - upper indicator	Charging
Green - upper indicator	Charge carried out and finished
Red - lower indicator	Power measured at less than 930 mW/cm^2 and insufficient for required operation
Green - lower indicator	Power measured equal to or greater than 1100 mW/cm^2

4.6 Buttons

The Mini LED has two buttons.

 located near the optical guide used to switch the Mini LED on and off.

 used to select the required operating mode.

4.7 Base

The Mini LED charging base comprises a power tester. This is used to test correct operation of the Mini LED.

4.8 Mains Adapter

The mains adapter is part of the medical device and helps to ensure its electrical safety. It must be installed near the medical device and must be readily accessible.

The mains cord connects the mains adapter to the medical device

> Only use the mains adapter supplied with your medical device.

4.9 Operating modes

Rapid mode activates maximum power of the Mini LED for ten seconds.

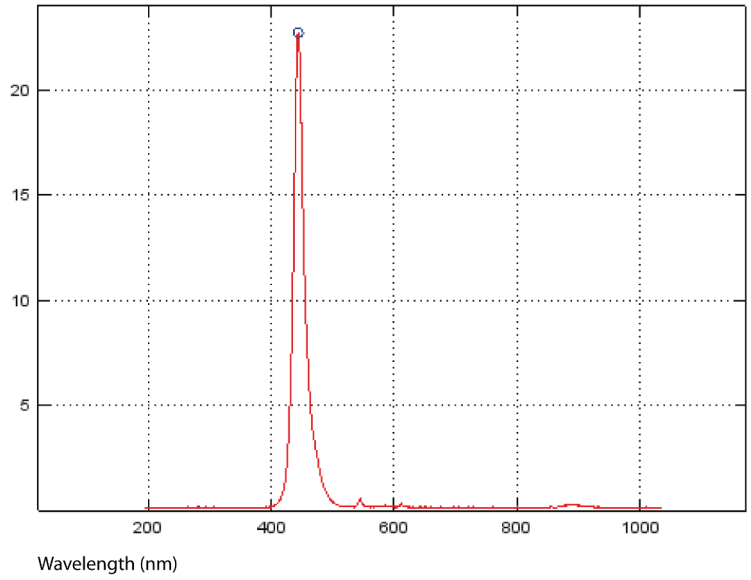
Pulsed mode activates maximum power of the Mini LED in ten successive bursts lasting one second, each separated by 250 ms.

Progressive mode initiates a gradual rise in power lasting ten seconds followed by ten seconds at full power.

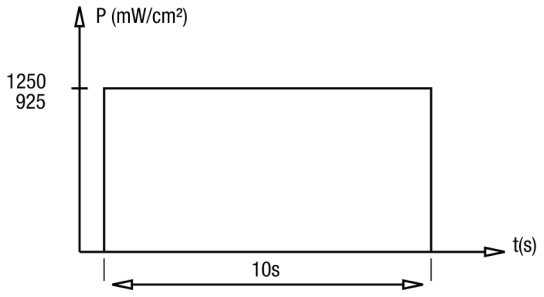
4.9.1 Wave peak

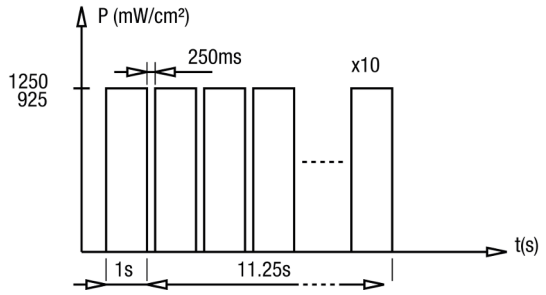
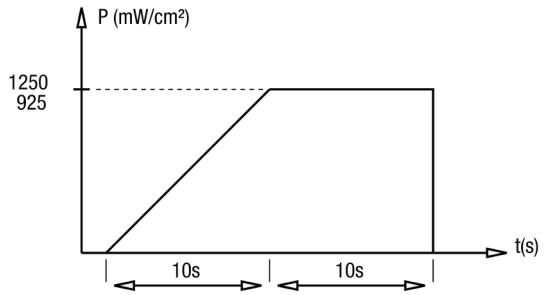
The waveform and its peak are identical in all three operating modes.

	Opalescent optical guide	Amber-coloured optical guide
Wave peak	447.5 nm	447.4 nm
Maximum irradiance at 2 mm	1900 mW / cm^2	1300 mW / cm^2
Mean spectral irradiance in relation to the nominal value and over time	1250 mW / cm^2	925 mW / cm^2



4.9.2 Waveform in each mode

	Waveform (nominal value, irradiance, duration)	Average irradiance over time
Rapid mode		1250 mW / cm^2 925 mW / cm^2

	Waveform (nominal value, irradiance, duration)	Average irradiance over time
Pulsed mode		1020 mW / cm^2 754 mW / cm^2
Progressive mode		937 mW / cm^2 693 mW / cm^2

4.10 Switching off the medical device

Press the ON/OFF button to stop a cure cycle.

The Mini LED switches off after three minutes of inactivity. Press the button to restart.

4.11 Disconnecting the medical device

Before a long absence or when not in use, the medical device must be cleaned, its battery must be removed and the charging base must be disconnected from the mains power.

5 Cleaning, disinfecting and sterilising

The instructions relating to cleaning, disinfection and sterilisation protocols for the medical device and accessories provided by SATELEC® have been approved for each medical device and accessory. The applicable guides are listed in the chapter *Associated documentation page 5*.

They can be downloaded at the following address: www.satelec.com/documents.

Download

Instructions For Use

In all cases, the local regulations in force relating to the cleaning, disinfection and sterilisation instructions for accessories take precedence over the information provided by SATELEC®.

5.1 Cleaning and disinfecting the Mini LED

The Mini LED must be OFF during cleaning and disinfecting procedures. It must also be disconnected from its electricity supply.

Avoid using cleaning and disinfection products that contain flammable agents. Otherwise, ensure that the product has completely evaporated or that there is no fuel left on the medical device and its accessories before switching it on.

> Do not use an abrasive product to clean the medical device.

> Never apply sprays directly to the medical device to clean it. Always spray the product onto a wipe, then clean the medical device.

> Use alcohol disinfectant wipes.

- Unplug the power cord from the base.
- Remove the rigid protection shield.
- Remove the optical guide.
- Block the Mini LED handpiece nozzle with a protection plug.
- Clean the body of the Mini LED handpiece with an alcohol wipe.
- Clean the Mini LED base with an alcohol wipe.
- Clean the rigid protection shield as indicated in the instructions in the chapter *Associated documentation page 5*
- Clean and sterilise the optical guide as indicated in the instructions in the chapter *Associated documentation page 5*

5.2 Cleaning, disinfecting and sterilising accessories

The Mini LED accessories include:

- a charging base;
- an optical guide;
- a rigid protection shield.

Refer to the cleaning, disinfection and sterilisation instructions for accessories listed in the chapter *Associated documentation page 5*.

6 Monitoring and general maintenance of the medical device

Before and after use, check the medical device and its accessories entirely for any problems. This is necessary to detect any isolation fault or damage. If necessary, replace damaged parts.

Check the cleanliness of the handpiece nozzle. It must be clean, smooth and corrosion-free. The optical guide must fit easily and firmly inside it.

Check the handpiece electrical connectors. These must be clean, smooth and corrosion-free. The battery must be able to be screwed in easily.

7 Maintenance

The only preventive maintenance the medical device requires is:

- monitoring of accessories;
- everyday cleaning, disinfection and sterilisation;
- cleaning.

7.1 Checking the lamp power level

It is important to regularly check that the lamp is working correctly. To do this, follow the steps below:

- Check that the optical guide is intact and has no composite residues.
- Set the lamp to Rapid mode.
- Insert the optical guide into the power tester.
- Switch on the Mini LED.
- The power tester may give the following results:

Colour	Result
Green	The lamp is working correctly and has a power output equal to or more than 1000 mW per cm2
Red	The lamp is not working correctly. Please read the chapter *Identifying incorrect operation page 19*

7.2 Identifying incorrect operation

In the event of incorrect operation, refer to the tables below to quickly identify and repair the non-complex parts of the medical device.

If the incorrect operation is not described in the tables below, please contact your supplier or the Customer Service Team at SATELEC®.

Do not use the medical device if it appears to be damaged or faulty. Isolate the medical device and make sure that it cannot be used.

7.2.1 Not working

Symptoms: The Mini LED does not switch on and does not emit blue light.

Possible causes	Solutions
The on/off button is set to off	Press the on/off button to switch on the Mini LED
The battery is flat	Charge the battery
The charging base is incorrectly connected to the mains power preventing the battery from charging normally	• Disconnect the charging base; • Check that the socket is not faulty; • Connect the charging base; • Check that the charging light comes on; • Wait for the battery to fully charge.
The battery switched itself to safety mode	Install another battery
The internal temperature of the Mini LED has reached the maximum permitted level	Allow the Mini LED to cool before using it again
The battery charging light is red. The battery was not fully charged before being switched on	Remove the partly charged battery and install a fully charged battery

7.3 The power of the Mini LED is not as expected

Possible causes	Solutions
Cure composite residue remains on the optical guide	• Remove the residue. • Check that the surface of the optical guide is intact. • Change the optical guide if necessary.

Possible causes	Solutions
The optical guide is damaged or is not clean	Clean the optical guide using the multi-purpose syringe air function
The power of the Mini LED has changed	Check the power using a purpose-designed tester

7.4 Other malfunctions

If the Mini LED™ is not working for any other reason, contact the SATELEC® Customer Services Team.
If you need to return your Mini LED, please ensure the optical guide and battery are packaged to prevent any impact damage during transportation.

8 Technical specifications of the medical device

8.1 Identification

Manufacturer	SATELEC®
Name of the medical device	Mini LED™

8.2 Mains Adapter

Manufacturer	Friwo
Supply voltage	100 - 240 VAC
Power supply frequency	50 Hz / 60 Hz
Drawn current	250 mA
Output voltage	12 V
Output current	800 mA
Width	58 mm
Height	66 mm
Depth	35.5 mm without the plug
Weight	151 g
Ingress protection rating	IP 40

8.3 Optical Guide

Weight	23 g
Length	94 mm
Distal end diameter	7.5 mm
Active diameter	6.8 mm
Optical cross-section	0.36 cm^2

8.4 Mini LED handpiece

Length	112 mm
Maximum outer diameter	23 mm
Weight	72 g
Ingress protection rating	IPX0
Distance with user	0 cm - 70 cm
Number of LED lights	4
Wavelength range	440 nm - 460 nm
Mean wavelength	450 nm
Irradiance with opalescent optical guide	1125 mW / cm^2 - 2400 mW / cm^2
Irradiance with amber-coloured optical guide	785 mW / cm^2 - 1680 mW / cm^2
Operating mode	Continuous

Safety	Thermal
Type	B

8.5 Technical specifications of the battery

Capacity	2500 mA / hr
Output voltage	3.7 V - 4.2 V
Type	Lithium-ion
Maximum diameter	23 mm
Length	99 mm
Weight	74 g

8.6 Charging base

Supply voltage	12 V DC
Protection	3 A / 125 V AC fuse

8.7 Environmental characteristics

Operating temperature	+10°C to +30°C
Storage temperature	0°C to +50°C
Operating humidity	30 % to 70 %
Atmospheric storage pressure	500 hPa to 1060 hPa
Atmospheric operating pressure	800 hPa to 1060 hPa
Maximum operating altitude	Equal to or less than 2000 metres

8.8 Environmental restrictions

Usage premises	Designed for use in all medical establishments, the medical device cannot be used outside.
Use in gas-filled atmosphere	The Mini LED is not designed to be used in an AP or APG gas-filled atmosphere.
Immersion	The Mini LED must not be immersed.

8.9 Main performance characteristics

Wavelength between 440 and 460 nm.

Irradiance of 1125 mW / cm2 to 2400 mW / cm2, calculated based on the active diameter of 6.8 mm with the opalescent optical guide.

Irradiance of 785 mw / cm^2 - 1680 mW / cm^2, calculated based on the active diameter of 6.8 mm with the amber-coloured optical guide.

9 Regulations and standards

9.1 Official Texts

This medical device complies with the essential requirements of European Directive 93/42/EEC. It was designed and manufactured in accordance with an EN ISO 13485-certified quality assurance system.

9.2 Medical class of the device

Class of medical device: I according to 93/42/EEC directive

9.3 Symbols

Symbols	Meaning
	Refer to the accompanying documentation
	Consult the User Manual
	The accompanying documentation is available in electronic format
	Do not use the medical device if the patient or practitioner are fitted with an implantable device
	Always wear safety goggles
	Always wear protective gloves
	Sterilisation at 134°C in an autoclave
	Sterilisation at 132°C in an autoclave
	Washer-disinfector for thermal disinfection

Symbols	Meaning
	Ultrasonic bath
	EC marking
	Do not dispose of as household waste
YYYY 	Year of manufacture
IPX1	**IP**: ingress protection ratings procured by a range **X**: no ingress of protection rating claim against the penetration of solids 1: protects against the vertical falls of drops of water
Rx only	Under the United States Federal Law, this medical device must only be sold by or under the orders of a qualified doctor.
	On/off button
	Programme selection button

9.4 Manufacturer identification

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9.6 Disposal and recycling

As an Electrical and Electronic item of Equipment, the medical device must be disposed of via a specialist collection, removal, recycling or destruction channel. This applies in particular to the European market, in reference to Directive 2002/96/EC dated 27/01/2003.

When your medical device has reached the end of its service life, contact your nearest dental equipment dealer, or ACTEON GROUP head office or one of the company branches to find out how to proceed. The relevant contact details are given in the chapter *Branch addresses page 25*.

Do not dispose of as household waste

The indication below applies to France only.

In compliance with the provisions of the French Environment Code relating to the disposal of electronic and electrical equipment waste or DEEE (Decree no. 2012-617 dated 2 May 2012), our Company fulfils its obligations to reclaim and dispose of its electrical and electronic equipment through the means established by the approved organisation Recydent (NOR approval: DEVP1229534A).

As a producer, our Company is listed in the National Register of Producers kept by the ADEME (French Environment and Energy Management Agency). Professionals buying our products directly from the distribution chain are responsible for passing on this information about our established recycling methods to the end user.

In addition, the buyer agrees to take back our brand's devices at the end of their service life and to transfer them to one of the collection centres set up by Recydent for recycling (see list of collection centres on the site `Recydent.fr`).

If necessary, Recydent can come and collect these devices from you free of charge once the quantity of devices has reached a certain level in the pallets-containers with which you are provided to store this waste.

10 Index

U

11 Glossary

A

Active diameter

area of the effective optical cross-section of the LED light beam at the optical guide tip

F

Ferrule

metal ring placed on the end of the optical guide. Makes it easier to insert the optical guide into the handpiece nozzle and prevents the optical guide from rotating. Also known as a collar

Flexible protection shield

available in 5.5 mm-diameter and 7.5 mm-diameter sizes. In contact with the patient, it must be sterilised after each use. Suitable for autoclaving. Previously called the cup

I

Irradiance

term used in radiometry to quantify the power of an electromagnetic radiation per unit area. It is expressed in watts per square metre. Often confused with the power of a light source

L

LED

electroluminescent diode, more commonly known as Led (light-emitting diode), designates an optoelectronic component that allows the emission of monochromatic light.

O

Optical guide

light conductor fitted to the handpiece nozzle and transmitting light to the cure site. Is cleaned and is suitable for autoclaving

P

Protection plug

two plastic plugs used to protect the handpiece connectors and electronics during cleaning. One fits on the nozzle and the other fits onto the handpiece's electrical connectors

R

Rigid protection shield

removable oval shield forming an integral part of the handpiece once in place. Is cleaned with wipes. Not suitable for autoclaving

W

Wavelength peak

maximum amplitude of a wavelength spectrum

CE

Ref: J02541 • V5 • 07 • 01/2015 • NG13EN010E

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