User Manual

MINILED STANDARD

acteon

This document is an English translation of the original French version.
Drawing number NG13FR010K and version V11

Contents

1 Documentation

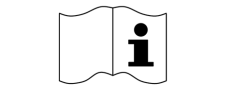
This document contains the following information:

- Indications for use
- Medical device description
- Installation of the medical device
- Medical device use
- Preparation for cleaning and disinfection of the medical device
- Monitoring and general maintenance of the medical device
- Maintenance to be performed by the user
- Patient, practitioner and environment safety
- Installing your medical device in optimum conditions
- Identifying the manufacturer or the latter's representatives if necessary

1.1 Latest document update

01/2024

1.2 Electronic documentation



The user instructions for your device are available in electronic format on the specified website and not in printed format. If the website is unavailable, try again later. You can also request a free printed copy of the user instructions within seven days via our website, by telephone or in writing.

The electronic user instructions are available in PDF format (Portable Document Format). You will need to have a PDF file reader installed to read the electronic user instructions. It is important for you to have read and understood the content of the user instructions relating to the use of your device and its accessories.

> Never use your device without first reading the user instructions.

The device user instructions can be consulted at `www.satelec.com/documents`

When you receive your device, you are asked to print and/or to download all documents or sections of documents that you may need to refer to in the event of an emergency, if you are unable to connect to the internet or if your electronic display tool is not working (computer, tablet, etc.). We recommend that you visit the website regularly to consult and to download the latest version of your device's user instructions. Users are asked to keep documentation close at hand for reference when necessary.

All paper or electronic documentation relating to your medical device must be kept for the device’s entire service life.

Keep the original documentation for your medical device and its accessories for future reference. When loaning out or selling the medical device, the documentation must be provided with it.

> The Quick Start and Quick Clean documents are summaries created for your approval. The only binding instructions are the user manuals and regulatory documentation associated with the medical device.

2 Identifications

2.1 Identification of the medical device

Manufacturer	SATELEC, a company of ACTEON® Group
Name of the medical device	MINILED STANDARD

2.2 Date of first CE marking

2007

2.3 Manufacturer identification

SATELEC
A Company of ACTEON® Group
17, avenue Gustave Eiffel
ZI du Phare
33700 MERIGNAC
France

CE

2.3.1 Manufacturer responsibility

The manufacturer shall under no circumstances be liable in the following cases:

- Non-compliance with manufacturer recommendations
- Maintenance or repair procedures performed by people who are unauthorised by the manufacturer.
- Use on an electrical fixture that is not compliant with regulations in force.
- Use of the device for purposes other than those specified in this manual.
- The use of accessories or handpieces other than those supplied by SATELEC, a company of ACTEON® Group.
- Non-compliance with the instructions contained in this document.

> Note: the manufacturer reserves the right to modify the medical device and any documentation without notice.

3 Instructions

3.1 Intended purpose of the medical device

Dental Curing Light

3.2 Medical indications

This medical device is designed to cure photosensitive composites and bonding composites 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.

3.3 User population

This medical device must only be used by dental health practitioners, fit and certified to perform their professional duties.
The user is not the patient.
The user must wear gloves.
The user must not be prone to any of the following:

- visual impairments: any vision problems must be corrected by glasses or lenses.
- arm disability that may prevent the user from holding a handpiece;
- hearing difficulties that could prevent the user hearing audible alarms depending on medical devices;
- difficulty memorizing or concentrating that could affect the setting of sequences or the performance of treatment protocols.

Users must know and comply with the rules of dental practice in compliance with knowledge acquired in the field and the key medical hygiene principles including cleaning, disinfection and sterilisation of medical devices.
The medical device can be used by any adult dental practitioner of any weight, age, height, gender or nationality.

3.3.1 Federal Law

> The indication below applies to the United States of America only.

The United States Federal Law restricts the use of this medical device in its territory to qualified, fit and certified health professionals (either directly or under their supervision).

3.4 Patient population

This medical device is designed to be used with the following patient populations:

- children;
- Teenagers,
- Adults,
- Old Age Pensioners.

This medical device can be used on any patient of any weight (except children), age, height, gender or nationality.

3.4.1 Patient population restriction

This medical device must not be used on the following patient populations:

- infants
- pregnant or breastfeeding women due to restrictions associated with the possible use of medical solutions such as anaesthetics;
- patients with medical issues,
- Patients allergic to some of the medical device components,
- patients with a clinical site not suitable for treatment,

The patient must be calm, relaxed, still, ideally lying flat on a dental chair.
The user is the only person who can decide whether or not to treat his/her patients.
Do not use the MINILED on patients currently afflicted by or with a past history of the following conditions:

- photo-biological reactions, including solar urticaria or erythropoietic Protoporphyria;
- treatment with photosensitizing medicines, including Methoxsalen and Chlorotetracycline.

Practitioners and patients who have suffered from retina or lens problems or who have had an operation on their eyes, in particular to treat cataracts, must consult their ophthalmologist before using the MINILED. Even with your ophthalmologist's approval, proceed with caution. The intensity of the light could cause accidents.

3.5 Parts of the body or types of tissues treated

Treatment must only be performed on the patient's oral environment.

3.6 Applied parts

Part in indirect contact with the patient	Optical guide

4 Clinical benefit and performance

4.1 Operating principle

Designed to light-cure dental composites, the MINILED is fitted with electroluminescent diodes (LED) that emit a visible blue light in a spectrum of wavelengths between 440 nm - 460 nm.
The wavelength of the light source corresponds to that of the photo-initiators used in dental curing composites.
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.

4.2 Performances

The medical device can be used to perform the following procedures:

- Curing of dental materials such as composites, adhesives and other photo-curable materials

4.3 Clinical benefits

- Restoration of the dental anatomy
- Treating dental problems

4.4 Essential performance

The manufacturer has determined that the medical device did not manage essential performances.

5 Prerequisites before use

5.1 Environmental restrictions

Usage premises	Usable in all medical premises. The medical device must not be used in an operating theatre or outdoors.
Use in gas-filled atmosphere	The medical device is not designed for use in a type AP or APG gas-filled atmosphere or in the presence of anaesthetic gases.
Immersion	The handpiece must not be immersed.

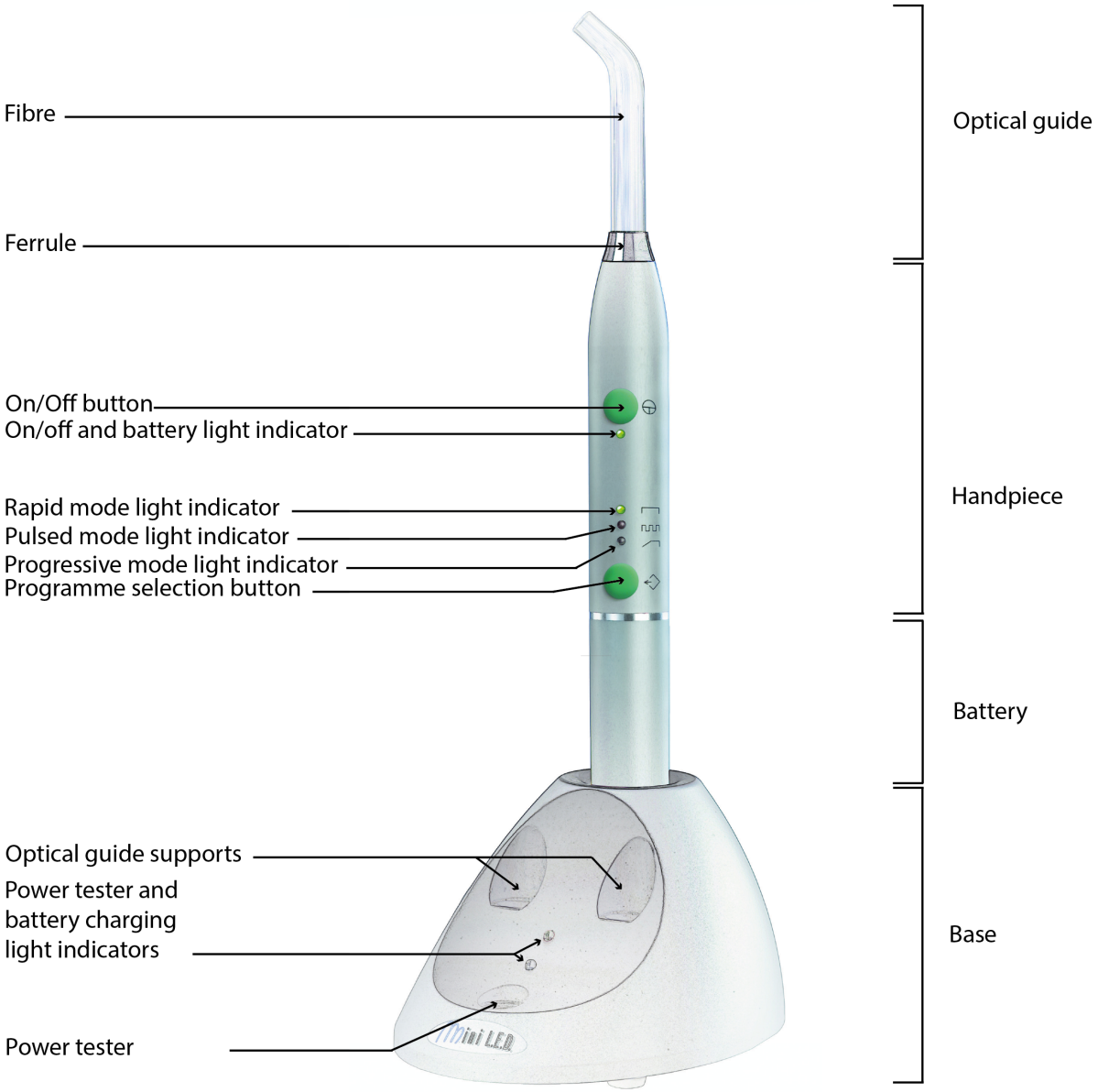
5.2 Specific user training

No specific training other than initial professional training is required to use this medical device.
The practitioner is responsible for performing clinical treatments and for dangers that may arise due to a lack of skill and/or training.

5.3 Unpacking the medical device

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 returned.
If you have any questions or requirements, contact your supplier.
Keep the original packaging of the medical device and use it to return the device for servicing, maintenance or repair.

5.4 Medical device description



The MINILED STANDARD can only be used with 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 handpiece MINILED
- a protection plug for the handpiece
- a charging base with an integrated power tester
- a Lithium-ion battery
- a rigid protection shield
- a mains adapter

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.

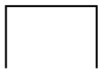
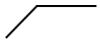
5.4.1 Light indicator

The light indicators are designed to signal the device's status.
The handpiece has four light indicators in total.

On/off and battery 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 MINILED charging base comprises a power tester. This is used to test correct operation of the MINILED.

The charging base has two light indicators.

Colour	Meaning
Flashing green - upper indicator	Charging
Green - upper indicator	Charge fully completed
Red - lower indicator	Power measured at less than 605 mW/cm^2 and insufficient for required operation
Off - lower indicator	Power measured is insufficient for required operation
Green - lower indicator	Power measured equal to or greater than 785 mW/cm^2

5.4.2 Buttons

The MINILED has two buttons.

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

used to select the required operating mode.

5.4.3 Operating mode

Rapid mode activates maximum power of the MINILED for ten seconds.

Pulsed mode activates maximum power of the MINILED in ten successive bursts lasting 1 second at 250 ms intervals.

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

5.5 Installing the medical device

Place the medical device in the position that is suitable for your activity.
Check that the cords do not hinder the movement or free circulation of anyone.
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. The disconnecting devices - the switch and the power plug - must be easy to locate and access.
Do not install your medical device near or on another device.

5.6 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.

A different voltage would cause damage to the medical device and could injure the patient and the 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.

5.7 Moving the medical device

> The indication below only applies to the member countries of the European Union.

After its initial installation, the medical device is not designed to be moved. The medical device must be fixed to ensure that it cannot be removed or moved without the use of a tool.

5.8 Mains adapter

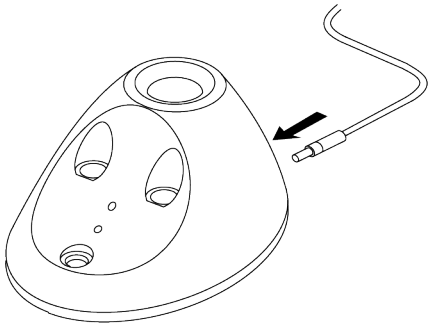
The medical device is designed to be connected to a separate power source that is considered to be an integral part of the medical device. The device's power supply plug serves as the disconnect device and contributes to its electrical safety. The power supply plug must be connected in close proximity to the device and be easily accessible.

> Do not touch the accessible charging base and battery connections.

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

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

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



- 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.

5.9 Charge the battery

The MINILED operates with a Lithium-Ion battery. To guarantee optimum use, this battery must be fully charged before use but must never be flat.

1. Remove the insulating ring located between the battery and the MINILED and screw the battery onto the handpiece.
2. Place the MINILED on its charging base.

   > The MINILED is correctly installed when two beeps are heard and the green indicator light on the base starts flashing.

3. Leave the MINILED to fully charge.

   > The MINILED is charged when the green indicator light on the base stops flashing and remains on permanently.

5.10 Precautions for use

The active part, the handpiece is held by the practitioner throughout the treatment.
As a highly skilled medical expert, the practitioner can immediately detect any problems at the treatment area and react accordingly.
It is advisable to have a spare medical device or an alternative means with which to perform the medical treatment in the event of device failure.

Throughout the duration of the procedure, the practitioner and the patient must wear class 2 safety goggles designed for use with medical devices emitting radiation with a wavelength of less than 500 nm.

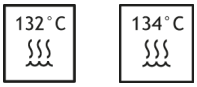
> Light rays emitted by the MINILED can be harmful and must never be aimed directly at the eyes even if the practitioner and the patient are wearing class 2 safety goggles.

Over exposure of the pulp and soft tissues to light rays may result in heat generation and may harm the patient. To prevent any feeling of heat, carry out the cure cycles with a rest time of 30 seconds between each 10-second cure cycle.
Do not use accessories that are damaged or that have unrecognisable markings, corrosion or sharp or cutting surfaces.

6 User Instruction

6.1 Operating conditions of combined medical devices

The optical guide must be cleaned and sterilised prior to use. The rigid protection shield must be cleaned and disinfected prior to use.



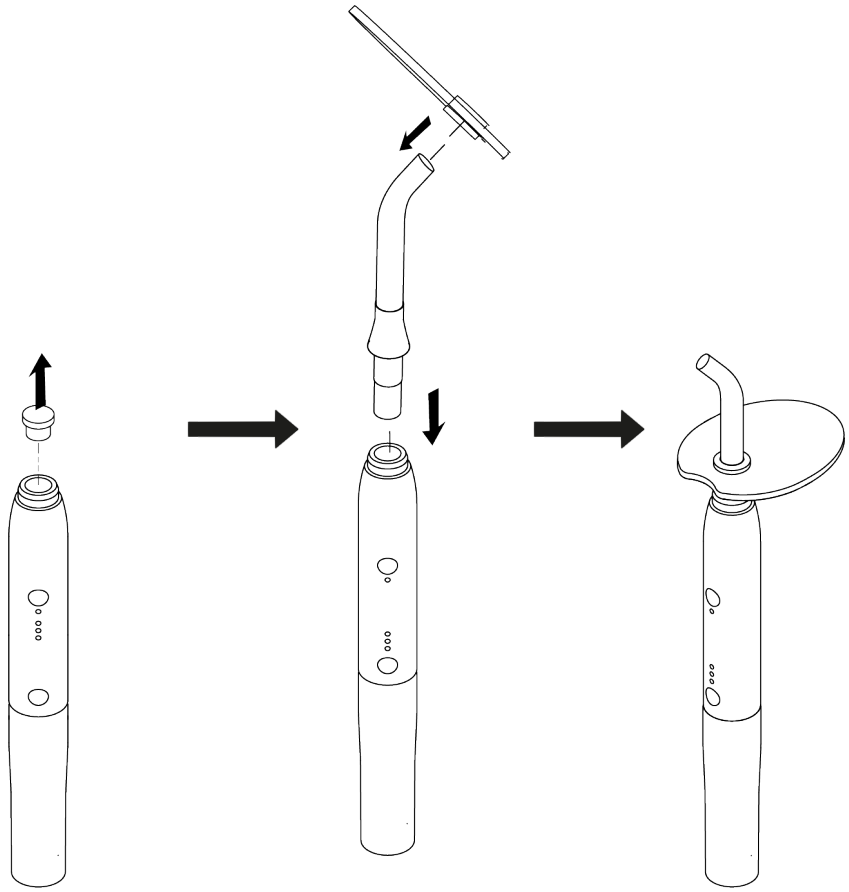
Refer to the cleaning, disinfection and sterilisation protocols for accessories listed in the chapter *Disinfection and sterilising page 14*.

6.2 Preparation for use

To prepare your MINILED, follow the steps below:

1. Disconnect the MINILED from its charging base.
2. Clean and disinfect the handpiece with an alcohol wipe.
3. Remove the protection plug from the handpiece nosepiece.
4. Install the optical guide and the rigid protection shield.

   | You will hear a click when the optical guide is correctly inserted.
5. Provide your patient with safety goggles.



Your MINILED is now ready to use.

6.3 Using the medical device

Never point the medical device directly at the eyes even when it is not in use.

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

> Before each use, check that the light intensity is compliant using a purpose-designed testing means or by making a test on a small piece of light-curing composite, or, depending on the configuration, the power tester built into the charging base.

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

- Remove the MINILED from the base;
- Press the on/off button.
- Install the rigid protection shield;
- Programme the MINILED 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 MINILED switches to standby.
Depending on the cure material used, repeat the cure cycle as required.

6.4 Switching off the medical device

Press the ON/OFF button to stop a cure cycle.
After three minutes of inactivity, the MINILED switches to standby and the on/off light indicator goes off.

6.5 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.

7 Disinfection and sterilising

The cleaning, disinfection and sterilisation instructions provided by SATELEC, a company of Acteon group, have been approved for each type of medical device and for the accessories.
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, a company of Acteon group.

7.1 Warnings

Do not clean the medical device with steel wool or abrasive cleaning products.
Do not use solutions containing iodine or with a high chlorine content.
The pH of the detergents and disinfectants must be between 7 and 11.
It is the responsibility of the end user to ensure that all equipment used to recondition SATELEC, a company of ACTEON® Group products is properly installed, validated, maintained and calibrated.
When possible, use a washer-disinfector. Prevent the overloading of wash baskets during ultrasonic cleaning or in a washer-disinfector.

> Throughout the procedure, wipe away blood and debris to prevent it from drying on the surfaces.

> After the procedure, soiled devices must be covered with a damp cloth to prevent residue from drying. Soiled devices must also be separated from non-contaminated devices to avoid contamination of personnel or surroundings.

7.1.1 Cleaning cycle limits

Repeated packaging cycles involving manual washing have little effect on the MINILED accessories. End of service life is normally determined by wear and damage due to use.

7.1.2 Containment and transportation

Soiled items must be transported separately from non-contaminated items to avoid any contamination.

7.2 Clean and disinfect the body of the MINILED

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

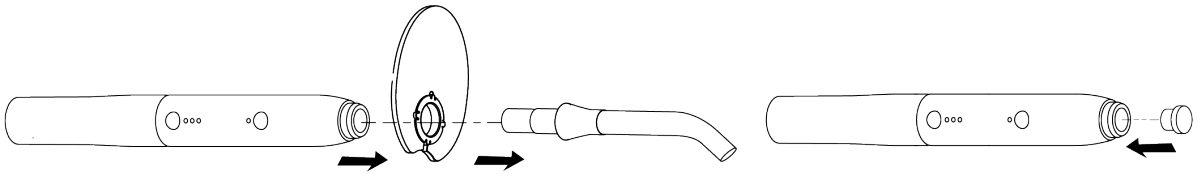
> Before cleaning the handpiece, insert the protection plug in the location of the optical guide provided to prevent any liquid from entering the handpiece.

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 handpiece nosepiece with a protection plug
- Clean the body of the MINILED handpiece with an alcohol wipe.
- Clean the MINILED base with an alcohol wipe.
- Pre-disinfect and clean the rigid protection shield as indicated below.
- Pre-disinfect, clean and sterilise the optical guide, as indicated below.

7.3 Pre-disinfection and cleaning for accessories – manual method

7.3.1 Flexible protection shield and optical guide

> Equipment: soft brush, soft lint-free swab, lint-free cloth, alkaline cleaner, dipping tank.

Minimum duration of step	Cleaning instructions
1 minute	Rinse the soiled device under cold running water. Use a soft-bristled brush, a swab or a lint-free cloth to remove most of the contamination.
10 minutes	Immerse the medical device in a freshly prepared alkaline cleaning solution for at least ten minutes. Adhere to the manufacturer's exposure time, concentration, water quality and temperature recommendations.
1 minute	Rinse the device under cold running water.
1 minute 30 seconds	Clean and disinfect the medical device for a least one minute using an alkaline cleaning solution. Remove surface contamination using a soft brush or a swab. Wash the medical device in water to prevent contaminants from spreading into the air.
1 minute	Rinse the medical device in deionised or purified water.
	Visually inspect the medical device. Repeat this procedure until the medical device is visibly clean. Perform a final rinse of the device using distilled or purified water. Dry using a soft lint-free cloth or medical grade clean compressed air

7.3.2 rigid protection shield

Equipment: soft brush, soft lint-free swab, lint-free cloth, alkaline cleaner, dipping tank.

Minimum duration of step	Cleaning instructions
1 minute	Rinse the soiled device under cold running water. Use a soft-bristled brush, a swab or a lint-free cloth to remove most of the contamination.
2 minutes	Immerse the medical device in a freshly prepared alkaline cleaning solution for at least two minutes. Adhere to the manufacturer's exposure time, concentration, water quality and temperature recommendations.
1 minute	Rinse the device under cold running water.
1 minute	Clean and disinfect the medical device for a least one minute using an alkaline cleaning solution. Remove surface contamination using a soft brush or a swab. Wash the medical device in water to prevent contaminants from spreading into the air.
1 minute	Rinse the medical device in deionised or purified water.
	Visually inspect the medical device. Repeat this procedure until the medical device is visibly clean. Perform a final rinse of the device using distilled or purified water. Dry using a soft lint-free cloth or medical grade clean compressed air

7.4 Pre-disinfection and cleaning – Automated method

7.4.1 Flexible protection shield and optical guide

Equipment: soft brush, soft lint-free swab, lint-free cloth, alkaline cleaner, dipping tank.

Minimum duration of step	Cleaning instructions
1 minute	Rinse the soiled device under cold running water. Use a soft-bristled brush, a swab or a lint-free cloth to remove most of the contamination.
2 minutes	Immerse the medical device in a freshly prepared alkaline cleaning solution for at least two minutes. Adhere to the manufacturer's exposure time, concentration, water quality and temperature recommendations.
1 minute	Rinse the device under cold running water.

Minimum duration of step	Cleaning instructions
1 minute 30 seconds	Clean and disinfect the medical device for a least one minute using an alkaline cleaning solution. Remove surface contamination using a soft brush or a swab. Wash the medical device in water to prevent contaminants from spreading into the air.
1 minute	Rinse the medical device in deionised or purified water.
	Visually inspect the medical device. Repeat this procedure until the medical device is visibly clean. Perform a final rinse of the device using distilled or purified water. Dry using a soft lint-free cloth or medical grade clean compressed air

7.4.2 Cleaning of washer-disinfector accessories

Step	Minimum duration	Cleaning instructions
Pre-washing	2 minutes	Cold tap water
Washing	10 minutes	Warm tap water, hotter than 40°C. Use an alkaline cleaning solution
Neutralisation	2 minutes	Warm tap water, hotter than 40°C, with neutraliser if necessary.
Rinsing	2 minutes	Distilled or purified water, hotter than 40°C
Drying	40 minutes	At a temperature of 90°C.

7.4.3 Thermal disinfection

Thermal disinfection at 90°C for at least five minutes.

7.5 Sterilising of accessories

The sterilisation stage only applies to the optical guide and the flexible protection shield. The rigid protection shield cannot be sterilised.

Unless otherwise specified, non-sterile products can be resterilised using validated steam sterilisation methods (ISO 17665 or national standards). SATELEC, a company of ACTEON® Group recommends the following:

Sterilisation exposure time	Sterilisation exposure temperature	Drying time
4 minutes	132°C	15 minutes minimum and 20 minutes
18 minutes	134°C	15 minutes minimum and 20 minutes
4 minutes	134°C	15 minutes minimum and 20 minutes
3 minutes	134°C	15 minutes minimum and 20 minutes

Saturated steam sterilisation with pre-vacuum

The drying times vary from 15 to 60 minutes according to the following criteria:

- the type of packaging material, such as a sterile barrier system or rigid reusable containers;
- steam quality;
- total mass;
- steriliser performance;
- usual practices for the geographical area;
- varying cool-down times.

The manufacturer accepts no responsibility for sterilisation procedures performed by the end user or the customer that are not performed according to the manufacturer's recommendations.

7.5.1 Inspection

Before being packaged, sterilised MINILED accessories must be examined to ensure they are perfectly clean and to ensure they are not damaged. Damaged devices must be disposed of.

7.5.2 Packaging

Use suitable packaging. ACTEON® recommends packaging that is compliant with ISO standard 11607. Prevent any contact between accessories and other objects that could damage their surface or the packaging.

7.5.3 Storage

Storage conditions are printed on the packaging label. Packaged products should be stored in a clean, dry environment, protected from direct sunlight, pests, humidity and extreme temperatures. Use products in the order in which they are received First in, First out, taking into account the expiry date indicated on the label.

8 Maintenance

8.1 Monitoring and routine maintenance

Before and after use, check the medical device and its accessories entirely for any problems. This is necessary to detect any electrical isolation fault or damage. If necessary, replace damaged parts.
Check the cleanliness of the handpiece nosepiece. 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.
The only preventive maintenance the medical device requires is:

- The monitoring of accessories and the medical device itself
- Routine cleaning, disinfection and sterilisation

8.1.1 Check the power

It is important to regularly check that the lamp is working correctly.
This can be done using a purpose-designed tester.
To do this, proceed as follows:

1. Check that the optical guide is intact and has no curing composite residues.
2. Set the lamp to Rapid mode.
3. Insert the optical guide into the power tester.
4. Switch on the MINILED.

The power tester may yield the following results:

Colour	Result
Green	The lamp is working correctly and has a power output equal to or more than 785 mW/cm^2
Red	The lamp is not working correctly. Please read the chapter *page 18*

8.2 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, a company of ACTEON® Group.
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.

8.2.1 Not working

Symptoms: The MINILED 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 MINILED
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	Replace the battery
The internal temperature of the MINILED has reached the maximum permitted level	Allow the MINILED 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

8.2.2 Charging base not working

Possible causes	Solutions
The wall socket is defective	Contact your electrician.
The mains adapter is defective	Send the MINILED to ACTEON®'s Customer Services team.

Possible causes	Solutions
The light indicators and/or beep sounds are defective	Send the MINILED to ACTEON®'s Customer Services team.
There is a contact fault at the jack connector	Send the MINILED to ACTEON®'s Customer Services team.
The fuse is defective	Send the MINILED to ACTEON®'s Customer Services team.

8.2.3 Optical guide

Possible causes	Solutions
Cure composite residue remains on the optical guide	1. Remove the residue. 2. Check that the surface of the optical guide is intact. 3. Change the optical guide if necessary.
The optical guide is damaged or is not clean	Clean the optical guide with an alcohol wipe. Clean the optical guide using the multi-purpose syringe air function. Change the optical guide if necessary.
The power of the MINILED has changed	Check the power using the power tester on the charging base.

8.2.4 The power is not as expected

Symptoms: The composite does not cure.

Possible causes	Solutions
The composite is too old or has been poorly preserved	Use a new composite
The MINILED does not produce enough power	Check the power. Please read the chapter *Check the power page 18*
The end of the optical guide is too far from the cure site	Place the end of the optical guide at 2 mm from the cure site

8.2.5 Malfunction of the power tester

Possible causes	Solutions
Defective light indicator	Send the MINILED to ACTEON®'s Customer Services team.
The optical guide is defective, damaged or dirty	Clean the optical guide using the multi-purpose syringe air function and/or return the MINILED to ACTEON®'s Customer Service team
The reflector is defective or dirty	Clean the reflector using the multi-purpose syringe air function and/or return the MINILED to ACTEON®'s Customer Service team
The power tester window is defective or dirty	Clean the power tester window and/or return the MINILED to ACTEON®'s Customer Service team

8.2.6 Other malfunctions

If the MINILED STANDARD is not working for any other reason, contact the ACTEON® Customer Services Team.
If you need to return your MINILED, please ensure the optical guide and battery are suitably packed to prevent any impact damage during transportation.

8.3 Warranty

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

8.4 Performance loss

Before and after use, check all of the medical device for any problems.
It is advisable to have a spare medical device or an alternative means with which to perform the medical treatment in the event of device failure.

8.5 Service life

Systematically replace an optical guide that is damaged due to accidental impact. Do not use the MINILED if it or the optical guide are damaged or faulty.
The control elements are sensitive to pressure and to wear that may be caused by excessive pressure.

9 Interactions, contraindications, prohibitions

This includes information relating to the interactions, contraindications and prohibited operations known by the manufacturer on the date on which this document was written.

9.1 Contraindications

The medical device presents potential risks due to the emission of electromagnetic fields. Interference may occur when the system is used on patients with implantable medical devices, such as a pacemakers, cochlear implants, deep brain stimulators or vagus nerve stimulators.

It may in particular cause malfunction of all types of active implanted device:

- before using this medical device, check whether patients and practitioners are fitted with a device of this type (active or inactive);
- explain the situation;
- weigh up the benefits versus the risks and contact your patient's cardiologist or another qualified health professional prior to starting treatment;
- keep this system away from implantable devices;
- apply suitable emergency measures and act fast if the patient shows signs of being unwell.

> Symptoms such as an increased heart beat, irregular pulse or dizziness may indicate a malfunction of a pacemaker or an implantable defibrillator.

The medical device is not designed to withstand electrical defibrillation shocks.

The MINILED is powered by a built-in battery. Take the following precautions to protect your own safety:

- Do not remove, open or tear any parts of the MINILED.
- Do not expose the MINILED to sunlight, heat or fire.
- Never short-circuit your MINILED.
- Do not store your MINILED in a box or a drawer, where it could be short-circuited by other metal objects.
- If the battery of the MINILED leaks, avoid contact between the fluid and the skin or eyes. In the event of contact, rinse thoroughly and refer to a doctor.
- Regularly wipe the power supply connector with a soft and dry cloth.
- After lengthy storage, charge and discharge the MINILED several times in order to achieve maximum performance.

9.2 Prohibited uses

Never point the medical device directly at the eyes even when it is not in use.

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

Only use the medical device for the purpose for which it has been designed.

- Do not immerse or use outdoors.
- Do not place the medical device next to a source of heat or in direct sunlight.
- Do not expose the medical device to water spray or mist.
- Do not use the medical device in an AP or APG gas-filled atmosphere.

The medical device is not designed to operate near a source of ionising radiation.

The medical device may not be stored or used outside the temperature, atmospheric pressure and humidity ranges recommended in the User Manual supplied with your medical device.

9.2.1 Connecting and disconnecting accessories during use

> Never release the battery when the MINILED is in use. When handling the mains adapter and the battery disconnected from the handpiece, avoid all contact between these parts and the patient or any other party.

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

9.3 Using accessories not supplied by the manufacturer

The MINILED is designed to be used with SATELEC, a company of ACTEON® Group accessories. The use of optical guides, protection shields or mains adapters made by other manufacturers will damage the MINILED.

9.4 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, a company of ACTEON® Group.

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, a company of ACTEON® Group Customer Service team:

Tel: +33,800,702,014

sav@acteongroup.com

> SATELEC, a company of ACTEON® Group, at the request of technical personnel working for the network of approved dealers, will provide any information required to repair defective parts on which they may perform repairs.

10 Undesirable side effects

Using the device does not cause side effects for the patient in the normal operating conditions recommended by the manufacturer.
The normal usage conditions are as follows:

- storage;
- installation;
- use;
- maintenance;
- disposal.

10.1 Severe incident

Any severe incident must be reported to the manufacturer and the competent authority of the member state where the user and/or the patient is based.

Manufacter contact in the event of a severe incident:
Email: quality.satelec@acteongroup.com
Telephone number: +33 5 56 34 06 07

11 Disposal and recycling

As an item of Electrical and Electronic 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, with reference to Directive no. 2012/19/EC of July 2012.

When your medical device has reached the end of its service life, contact your nearest dental equipment dealer, or the ACTEON® 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 35*.

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 WEEE (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 Récylum, NOR approval: DEVP1427651A.

As a manufacturer, 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 Récylum for recycling (see list of collection centres on the site `http://www.recylum.com/`.

If necessary, Récylum 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.

An accessory that has reached the end of its service life must be disposed of in infectious clinical waste containers.

12 Technical specifications of the medical device

12.1 Applicable standards and regulations

This equipment is designed and developed in compliance with the Electrical Safety standard IEC60601-1 in force.
This medical device complies with the general security and performance requirements of the 2017/745/EU regulation.

12.1.1 Medical class of the device

Class of medical device: I according to the 2017/745/EU regulation.

12.2 Main performance characteristics

Wavelength between 440 and 460 nm.
Irradiance of 1125 mW/cm^2 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.

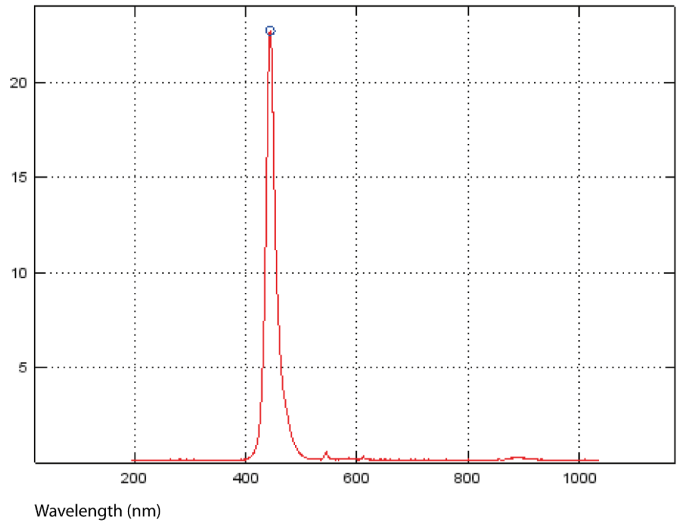
12.3 Environmental characteristics

Ambient operating temperature	+10°C to +30°C
Operating RH	30% to 75%
Atmospheric operating pressure	Between 800 hPa and 1060 hPa
Maximum operating altitude	Equal to or less than 2000 metres
Storage temperature	0°C to +50°C
Storage RH	10% to 95%, including condensation
Atmospheric storage pressure	Between 500 hPa and 1060 hPa

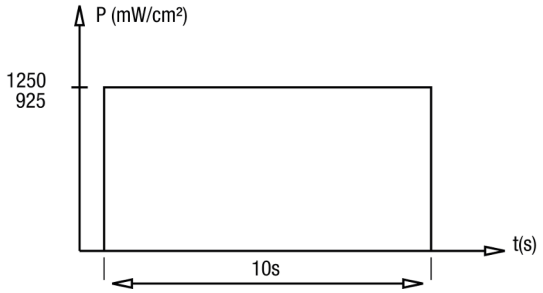
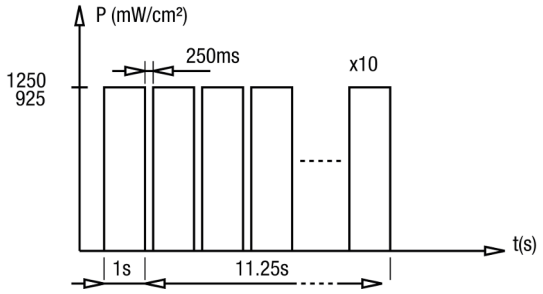
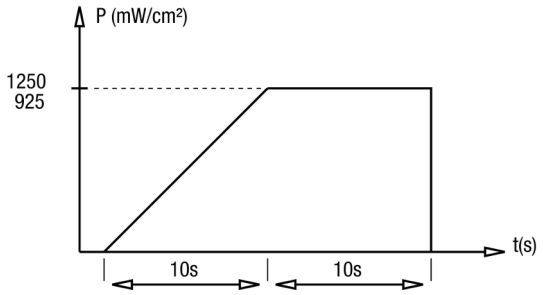
12.4 Wave peak

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

	Opalescent optical guide	Amber-coloured optical guide
Wave peak	447.5 nm	447.5 nm
Maximum irradiance at 2 mm	1,900 mW / cm^2	1300 mW / cm^2
Mean spectral irradiance in relation to the nominal value and over time	1,250 mW / cm^2	925 mW / cm^2



12.5 Wave form

	Waveform (nominal value, irradiance, duration)	Average irradiance over time
Rapid mode		1250 mW / cm^2 925 mW / cm^2
Pulsed mode		1020 mW / cm^2 754 mW / cm^2
Progressive mode		937 mW / cm^2 693 mW / cm^2

12.6 Cure depth

Cure depth in mm with a distance of 2 mm between the optical guide and the cure composite

Curing composite	Rapid mode	Pulsed mode	Progressive mode
Z100 MP, 3M	3 mm/2.5 mm	2 mm/2.5 mm	3 mm/2.5 mm
Tetric EvoCeram, Ivoclar Vivadent	2 mm/1.5 mm	1.5 mm/1.5 mm	2 mm/2 mm
Charisma, Heraeus - Kulzer	2 mm/2 mm	2 mm/1.5 mm	2.5 mm/2 mm

12.7 Mains Adapter

Model 1

Manufacturer	Friwo
Model	FW8000M/12
Supply voltage	100 - 240 VAC ±10%
Power supply frequency	50 / 60 Hz
Drawn current	300 - 150 mA
Output voltage	12 V DC
Output current	1,000 mA
Power output	12 W
Electrical rating	II

Model 2

Manufacturer	XP Power
Model	ACM12US12
Supply voltage	90 - 264 VAC
Power supply frequency	47 / 63 Hz
Drawn current	500 mA at 230 VAC
Output voltage	12 V (DC)
Output current	1,000 mA
Power output	12 W
Electrical rating	II

12.8 Optical guide

Weight	23 g
Length	94 mm
Diameter at the end of the distal	7.5 mm
Diameter active	6.8 mm
Optical cross-section	0.36 cm^2

12.9 Handpiece

Distance with user	0 cm - 70 cm
Length	110 mm
Diametermaximum outer	23 mm
Weight	73 g
Number of LED lights	4
Wavelength range	440 nm - 460 nm
Centre 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
Ingress protection rating	IPX0

12.10 Battery

Type	Lithium-ion
Capacity	2500 mA / hr
Output voltage	3.7 V - 4.2 V
Diameter maximum	22 to 23 mm
Length	88 mm
Weight	75 g

12.11 Base

Supply voltage	12 V DC
Protection	3 A / 125 V AC fuse
Ingress protection rating	IPX0

13 Electromagnetic compatibility

> All the information below is based on the requirements of standards to which the manufacturers of electrical medical devices must adhere (as stated in standard IEC60601-1-2).

The medical device complies with the electromagnetic compatibility standards in force. However, the user must make sure that any electromagnetic interference does not create an additional risk, such as those created by radiofrequency transmitters, or other electronic devices.

This chapter contains the information required for you to install and use your medical device in optimum conditions in terms of electromagnetic compatibility.

The different medical device cords must be kept away from each other.

Some types of mobile telecommunication devices such as mobile phones may interfere with the medical device. The separation distances recommended in this chapter must be complied with.

The medical device must not be used near another device or placed on top of it. If this cannot be avoided, correct operation of the device in operating conditions must be checked prior to use.

The use of accessories other than those specified or sold by SATELEC, a company of ACTEON® Group as replacement parts, may increase the transmission or reduce the immunity of the medical device.

13.1 Cable length

Cables and accessories	Maximum length	Test type	In compliance with:
Cables/Cords	< 3 m	RF emission	CISPR 11, Class B
		Harmonic current emission	IEC61000-3-2
		Voltage fluctuation and flickers	IEC61000-3-3
		Electrostatic discharge immunity	IEC61000-4-2
		Radiated immunity – Electromagnetic fields	IEC61000-4-3
		Electrical fast transient/burst immunity	IEC61000-4-4
		Surge immunity	IEC61000-4-5
		Immunity to conducted disturbances, induced by radiofrequency fields	IEC61000-4-6
		Radiated immunity - Magnetic fields	IEC61000-4-8
		Voltage dips, short interruptions and voltage variation immunity	IEC 61000-4-11

13.2 Recommended separation distances

The medical device is designed to be used in an electromagnetic environment in which interferences caused by radiofrequency radiation are controlled.

Do not use handheld radiofrequency communication devices within 30 cm (12 inches) of any part of the medical device, including its cables.

Aerial cables and external aerials of handheld radiofrequency communication devices must not be positioned or used within 30 cm (12 inches) of any part of the medical device.

If the minimum distance is not adhered to when using handheld radiofrequency communication devices, this may impact the performance of the medical device.

13.3 Electromagnetic emissions

The medical device is designed for use in the electromagnetic environment described in the table below. The user and/or installer must ensure that the medical device is used in the environment described below.

Emission test	Conformity	Electromagnetic environment - comments
Electromagnetic radiation disturbance, radiated emissions (CISPR 11)	Group 1	The medical device uses radiofrequency energy for its internal operation. Consequently, its radiofrequency emissions are very low and are not likely to create any interference with other nearby equipment.
Radiofrequency emission (CISPR 11)	Class B	The medical device is suitable for use in a home-based health care setting or in a professional health care setting.
Harmonic current emission (IEC61000-3-2)	Class A	
Voltage fluctuation and flickers (IEC61000-3-3)	Compliant	

The following medical devices are categorised as Class B radio-frequency equipment according to CISPR 11:

- MINILED STANDARD

13.4 Magnetic and electromagnetic immunity

The medical device is designed for use in the magnetic and electromagnetic environment described in the table below. The user and/or installer must ensure conformity of the electromagnetic environment.

Immunity test	Test level in accordance with IEC60601	Conformity level	Electromagnetic environment / comments
Electrostatic discharge (ESD) (IEC61000-4-2)	± 8 kV on contact ± 15 kV in the air	± 8 kV on contact ± 15 kV in the air	The medical device is suitable for use in a home-based health care setting or in a professional health care setting.
Electrical fast transient/burst immunity (IEC61000-4-4)	± 2 kV for electricity supply lines ± 1 kV for signal ports Valid for medical devices with signal ports	± 2 kV for electricity supply lines ± 1 kV for signal ports	The medical device is suitable for use in a home-based health care setting or in a professional health care setting.
Surge (IEC61000-4-5)	±0.5 kV, ±1 kV between phases ±0.5 kV, ±1 kV, ±2 kV between phase and earth Valid for earthed medical devices	±0.5 kV, ±1 kV between phases ±0.5 kV, ±1 kV, ±2 kV between phase and earth	The medical device is suitable for use in a home-based health care setting or in a professional health care setting.
Magnetic field at the assigned industrial frequency (IEC61000-4-8)	30A/m	30A/m	The magnetic field intensity must be equal to the level found in a home-based health care setting and in a professional health care establishment setting.

Immunity test	Test level in accordance with IEC60601	Conformity level	Electromagnetic environment / comments
Voltage dip (IEC 61000-4-11)	0% UT for 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle and 70% UT for 25 cycles at 50 Hz for 30 cycles at 60 Hz Single phase at 0°	0% UT for 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle and 70% UT for 25 cycles at 50 Hz for 30 cycles at 60 Hz Single phase at 0°	The quality of the network supply must be equal to that of a home-based health care setting and a professional health care establishment setting. If the use of the system requires continuous operation during mains power outages, it is advisable to supply the medical device using a separate current source (UPS, etc.).
Voltage interruptions (IEC61000-4-11)	0% UT for 250 cycles at 50 Hz for 300 cycles at 60 Hz	0% UT for 250 cycles at 50 Hz for 300 cycles at 60 Hz	The quality of the network supply must be equal to that of a home-based health care setting and a professional health care establishment setting. If the use of the system requires continuous operation during mains power outages, it is advisable to supply the medical devices using a separate current source (UPS, etc.).

13.5 Electromagnetic immunity, handheld radiofrequency equipment

The medical device is designed for use in the magnetic and electromagnetic environment described in the table below. The user and/or installer must ensure conformity of the electromagnetic environment.

Immunity test	Test level	Conformity level	Electromagnetic environment - comments
Do not use handheld radiofrequency communication devices within 30 cm (12 inches) of any part of the medical device, including its cables. Aerial cables and external aerials of handheld radiofrequency communication devices must not be positioned or used within 30 cm (12 inches) of any part of the medical device. If the minimum distance is not adhered to when using handheld radiofrequency communication devices, this may impact the performance of the medical device.			
Radiated, radiofrequency, electromagnetic fields (IEC61000-4-3)	10 V/m 80 MHz to 2.7 GHz 80% MA at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80% MA at 1 kHz	The medical device is suitable for use in a home-based health care setting or in a professional health care setting.

Immunity test	Test level	Conformity level	Electromagnetic environment - comments
Proximity fields transmitted by wireless radiofrequency communication devices (IEC 61000-4-3, temporary method)	9 V/m 710 MHz, 745 MHz, 780 MHz, 5 240 MHz, 5 550 MHz, 5 785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930MHz, 1 720 MHz, 1 845 MHz, 1 970 MHz, 2 450 MHz	9 V/m 710 MHz, 745 MHz, 780 MHz, 5 240 MHz, 5 550 MHz, 5 785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930MHz, 1 720 MHz, 1 845 MHz, 1 970 MHz, 2 450 MHz	The medical device is suitable for use in a home-based health care setting or in a professional health care setting.
Conducted disturbances, induced by radiofrequency fields (IEC61000-4-6)	3 V/m 0.15 MHz to 80 MHz 6 V in ISM band and bands between 0.15 MHz and 80 MHz, amateur radio bands included 80% MA at 1 kHz	3 V/m 0.15 MHz to 80 MHz 6 V in ISM band and bands between 0.15 MHz and 80 MHz, amateur radio bands included 80% MA at 1 kHz	The medical device is suitable for use in a home-based health care setting or in a professional health care setting.

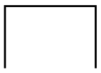
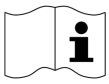
These specifications may not be applicable in all situations. The electromagnetic propagation is affected by the absorption and reflection of structures, objects and people.

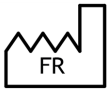
The electromagnetic field intensity of fixed radiofrequency transmitters, such as base stations for portable phones (mobiles / wireless), mobile radios, radio amateurs, AM/FM radio transmissions and TV transmissions cannot be determined accurately by the theory.

To assess the electromagnetic environment caused by fixed radiofrequency transmitters, an electromagnetic environment measurement must be taken. If the measured intensity of the radiofrequency field in the product's immediate use environment exceeds the radiofrequency conformity level specified above, it is necessary to test product performance to check this complies with specifications. If abnormal performance is observed, additional measures may be necessary, such as changing the direction of or moving the product.

In the 150 kHz to 80 MHz frequency range, the electromagnetic fields must be less than 3 V/m.

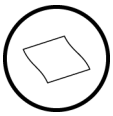
14 Symbols

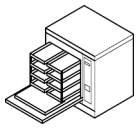
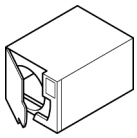
Symbol	Meaning
	On/off button
	Rapid mode: maximum power of the MINILED for ten seconds
	Pulsed mode: maximum power of the MINILED in ten successive bursts lasting one second at 250 ms intervals.
	Slow mode: initiates a gradual rise in power lasting ten seconds followed by ten seconds at full power
	Programme selection button
	Always wear safety goggles
	Always wear protective gloves
	Refer to the supporting documentation
 www.satelec.com/documents	Consult the electronic instructions for use
	Pressure limit
	Temperature limit
	Humidity limit
 Packaging Unit	Packaging unit

Symbol	Meaning
	Fragile, handle with care
	Store in a dry place
	Warning
	Biohazard
	Sterilisation at 134°C in an autoclave
	Sterilisation at 132°C in an autoclave
	Washer-disinfector
	Type B part in contact
	Direct current
	Direct current supply connector
	CE marking
YYYY 	Year of manufacture
	Made in France
	Manufacturer SATELEC A Company of ACTEON® Group 17, avenue Gustave Eiffel ZI du Phare 33700 MERIGNAC France

Symbol	Meaning
	Do not dispose of as household waste
	Recycle your lamps and professional electrical equipment with Récylum
Rx Only	Under the United States Federal Law, this medical device must only be sold by or under the orders of a qualified doctor.
IP40	**IP**: ingress protection ratings procured by a range **4**: ingress protection rating against the penetration of solids of a diameter greater than 1 mm **0**: no protection against the penetration of liquids
	Serial Number
	Medical Device
	Unique Device Identifier

14.1 Quick Start and Quick Clean symbols

	Use a dipping tank for cleaning
	Use a soft brush for cleaning
	Use a lint-free cloth for cleaning
	Use a swab for cleaning
	Use deionised or osmosis-purified water for cleaning
	Use an alcohol disinfectant wipe for pre-disinfection and cleaning.

	Clean under running water
	Use a washer-disinfector for cleaning and disinfection
	Use a pre-vacuum air autoclave for sterilisation

15 Branch addresses

AUSTRALIA/NEW ZEALAND
ACTEON AUSTRALIA/NEW ZEALAND
Suite 119, 30-40 Harcourt Parade
Rosebery NSW 2018
Australia
Tel. +612 9669 477 307
Fax. +612/96692204
info.au@acteongroup.com

BRAZIL
MICRO IMAGEM INDUSTRIA COMERCIO IMPORTAÇÃO E EXPORTAÇÃO LTDA
CNPJ: 14.041.012/0001-79
Alameda Vênus, 233
Distrito Industrial
Indaiatuba – SP – CEP 13347-659
Brazil
Tel. +55 19 3936 809

CHINA
ACTEON CHINA
Office 1615, 13Floor No. 2, North East Third Ring Road, Chaoyang District, Beijing 100027, P. R. CHINA.
Tel. +86 10 646 570 11
beijing@cn.acteongroup.com

GERMANY
Acteon Germany GmbH
Klaus Bungert Straße 5, D-40468 Düsseldorf
GERMANY
T: +49 211 16 98 00-0
F: +49 211 16 98 00-48
www.acteongroup.com/de-de

INDIA
ACTEON INDIA
1202, PLOT NO. D-9
GOPAL HEIGHTS, NETAJI SUBASH PLACE
PITAMPURA, DELHI - 110034 - INDIA
Gujarat - India
Tel. +91 11 47 018 291 / 47 058 291 / 45 618 291
Fax. +91 79 2328 7480
info.in@acteongroup.com

ITALIA
ACTEON ITALIA
Via Roma 45
21057 OLGIATE OLONA (VARESE)
ITALY
Tel. +39 0331 376 760
Fax. +39 0331 376 763
info.it@acteongroup.com

RUSSIA
ACTEON RUSSIA
Gilyarovskogo str, 6b1, off 212
129090 MOSCOW
RUSSIA
Mob. +7 926 233 1695
Tel. +7 495 150 1323
info.ru@acteongroup.com

SPAIN
ACTEON MEDICO-DENTAL IBERICA, S.A.U.
Avda Principal n°11 H
Poligono Industrial Can Clapers
08181 SENTMENAT (BARCELONA) - SPAIN
Tel. +34 93,715 45 20
Fax. +34 93 715 32 29
info.es@acteongroup.com

TAIWAN
ACTEON TAIWAN
11F., No.1, Songzhi Rd.
Xinyi Dist., Taipei City 11047
TAIWAN (R.O.C.)
+ 886 2 8729 2103
info.tw@acteongroup.com

THAILAND
ACTEON (THAILAND) LTD
23/45 Sorachai Building 16th floor - Sukumvit 63 Road, Klongton Nua - Wattana, BANGKOK 10110 - THAILAND
Tel. +66 2 714 3295
Fax. +66 2 714 3296
info.th@acteongroup.com

TURKEY
ACTEON TURKEY
Barbaros Mah. Dereboyu Cad.
Akzambak Sokak Uphill Towers
B Blok K14 D84 Atasehir
ISTANBUL 34746 - TURKEY
Mob. +90 532 481 20 57
Tel. +90 216 688 88 68
talha.gonca@acteongroup.com

U.K.
ACTEON UK
Phoenix Park– Eaton Socon, St Neots
CAMBS PE19 8EP - UK
Tel. +44 1480 477 307
Fax. +44 1480 477 381
info.uk@acteongroup.com

LATIN AMERICA
ACTEON LATINA AMERICA
Bogotà - COLOMBIA
Mobile: +57 312 377 8209
info.latam@acteongroup.com

MIDDLE EAST
ACTEON MIDDLE EAST
247 Wasfi Al Tal str.
401 AMMAN - JORDAN
Tel. +962 6 553 4401
Fax. +962 6 553 7833
info.me@acteongroup.com

U.S.A. & Canada
ACTEON North America
124 Gaither Drive, Suite 140
Mount Laurel, NJ 08054 - USA
Tel. +1 856 222 9988
Fax. +1 856 222 4726
info.us@acteongroup.com

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SATELEC ■ A company of ACTEON Group
17, avenue Gustave Eiffel ■ ZI du Phare ■ 33700 MERIGNAC ■ FRANCE
Tel. +33 (0) 556 340 607 ■ Fax. +33 (0) 556 349 292 ■ info@acteongroup.com