

# silverlight



Manual of use and maintenance

## Summary

00.0	Introduction	4
00.1	Foreword	4
00.2	Description of the apparatus	4
00.3	Intended use	4
00.4	Safety requirements	5
01.0	Identification data	6
01.1	Identification data	6
01.2	Identification plate of the recharging unit	6
01.3	Identification plate of the silverlight handpiece	7
02.0	Testing	7
02.1	Testing of the equipment	7
03.0	Delivery	7
03.1	Delivery of the device	7
03.2	List of material included in the standard supply	8
04.0	Installation	9
04.1	Safety requirements at the time of installation	9
04.2	Description of the controls and signaling lamps	9
04.3	Connecting the device	11
05.0	Battery	11
05.1	New battery - first charging	11
05.2	Battery low signal	11
05.3	Battery dead signal	12
05.4	Battery failed signal	12
05.5	Battery problems	12
05.6	Safety requirements relating to the battery	12
06.0	Use	13
06.1	Connecting the accessories	13
06.2	Safety requirements during use	14
06.3	Instructions for use	14
06.4	Measuring the light intensity	15
06.5	Safety protection	16
06.6	Yellow battery LED on the recharging unit illuminated	16
07.0	Cleaning, disinfection, sterilization	16
07.1	Cleaning and disinfection of the casing of the recharging unit	16
07.2	Cleaning and disinfecting the Silverlight handpiece	16
07.3	Sterilization procedure	17
07.4	Cleaning, disinfection and sterilization of the optical fiber	17
07.5	Cleaning, disinfection and sterilization of the optical protection	18
08.0	Disposal procedures and precautions	18
09.0	Symbols	19
10.0	Problem-solving	20
11.0	Technical specifications	21
11.1	Electromagnetic compatibility EN 60601-1-2	22
12.0	LED Information concerning the radiation emitted	26
13.0	Limited Warranty	27
13.1	Customer service - RETURNS	28


## 00.1 Foreword

**Before proceeding with the installation, use, maintenance or any other activities on the equipment please read this manual carefully.**

Always keep this manual within easy reach.

**Important:** To avoid causing personal injuries or damage to property, read all the points concerning "Safety requirements" contained in this manual with particular attention.

Depending on the level of risk involved, safety requirements are classed under the following indications:

 **DANGER (always referred to personal injury)**

 **WARNING (referred to possible damage to property)**

The purpose of this manual is to ensure that operators are aware of the safety requirements, of the installation procedures and of the instructions for correct use and maintenance of the apparatus.

The user is not authorized to tamper with the equipment under any circumstances.

If any problems are encountered, please contact a GC America Customer Service.

Any attempts on the part of the user or any unauthorized personnel to tamper with or alter the apparatus will invalidate the warranty and release the manufacturer, Mectron S.p.A and the importer distributor, GC America Inc, from any liability in respect of any harm or damage to persons or property.

The information and illustrations contained in this manual are updated to the date of publication indicated on the last page.

The manufacturer Mectron S.p.A. is committed to continuous updating of products, which may entail changes to components of the equipment.

If there are any discrepancies between the descriptions contained in this manual and your equipment, please contact your dealer or the GC America Inc. Customer Service for explanations.

Using this manual for purposes other than those relating to the installation, use and maintenance of the equipment is strictly prohibited.

## 00.2 Description of the apparatus

The Silverlight is an apparatus for polymerizing photo-hardening composites. It uses a source of light consisting of a very high-efficiency monochromatic LED (wavelength comprised between 440 and 480 nm).

The light emitted by the LED is directed to the treatment area by means a fiber optic.

The equipment consists of a charging unit and a handpiece powered by a rechargeable lithium-ion battery.

The Silverlight can be used to operate in either of two emission modes:

- Constant intensity of emission - **FAST** (cycle lasting 10 seconds);
- Gradual intensity of emission - **SLOW RISE** (cycle lasting 20 seconds).

## 00.3 Intended use

The Silverlight device is a dental curing light unit intended for use in the oral cavity for the polymerization of photo-hardening dental materials that are activated in the 440 – 480 nm. wavelength range.

### **IMPORTANT:**

Although most dental composite materials are activated within this wavelength range, in case of uncertainty consult the manufacturer's composite specifications

## 00.4 Safety requirements

The manufacturer Mectron S.p.A. and the importer/distributor, GC America Inc, will not accept any liability for direct or incidental personal injury or damage to property in the following cases:

- 1 If the equipment is used for purposes other than that for which it is intended.
- 2 If the equipment is not used in accordance with all the instructions and requirements described in this manual.
- 3 If the wiring system in the room where the equipment is used does not comply with the applicable standards and appropriate requirements.
- 4 If any assembly operations, extensions, settings, alterations or repairs have been carried out by personnel not authorized by GC America Inc. or its affiliates.
- 5 If the environmental conditions in which the device is kept and stored do not comply with the requirements indicated in the chapter on technical specifications.

### **DANGER: Qualified and specialized personnel.**

The equipment should be used only by specialized personnel having the appropriate training. The equipment does not produce any side effects if it is correctly used.

### **DANGER: Intended use.**

Use the equipment solely for the purpose for which it is intended (see point "00.3"). Failure to comply with this requirement could lead to serious harm to the patient and/or to the operator and/or damage to/failure of the equipment.

### **DANGER: Contraindications.**

Do not use this equipment on patients fitted with pace-makers or any other implantable electronic devices. This requirement applies equally to the operator.

### **DANGER: Point the beam of light directly at the material to be polymerized.**

Do not use the beam of light on the gums or other soft tissues (if necessary these parts should be suitably shielded). The effect of the light should be limited to that part of the oral cavity to be clinically treated.

### **DANGER: Never point the beam of light towards the eyes.**

The effect of the light should be limited to that part of the oral cavity to be clinically treated.

### **DANGER: Contraindications.**

Do not use this equipment for patients who have a case history of positive reaction to stimulation by light e.g. urticaria solaris and/or porphyria, etc. or who are receiving treatment with photosensitizing drugs. In all cases of possible risk consult a specialized physician.

### **DANGER: Contraindications.**

Adopt strict safety measures for patients who have undergone cataract surgery and who are therefore particularly sensitive to light (e.g. protective goggles able to filter out blue light should be worn).

### **DANGER: Contraindications.**

Patients who have a case history of diseases of the retina should consult their optician beforehand and be specifically authorized to receive treatment with the Silverlight.

### **DANGER: Cleaning, disinfection and sterilization of new or repaired products.**

Before treatment, all new or repaired products should be cleaned and disinfected and, if suitable for this treatment, autoclave sterilized following the instructions provided under point "07.0" strictly.

**⚠ DANGER: Infection control.**

In order to ensure maximum safety for both the patient and the operator, clean, disinfect and sterilize the fiber optic and the optical protection before each treatment. Follow the instructions provided under point "07.0" closely.

**⚠ DANGER: Use only original Mectron S.p.A. accessories and spare parts.**

**⚠ DANGER: Checking the condition of the device before treatment.**

Before each treatment always check that the equipment is in proper working order and that the accessories are efficient.

Do not carry out the treatment if any problems are encountered in operating the apparatus.

If the problem concerns the equipment, contact an authorized technical service center.

**⚠ DANGER: Do not install the equipment anywhere there is a risk of explosions.**

The equipment cannot function in places where there is an inflammable atmosphere (anesthetic mixtures, oxygen, etc.).

**⚠ DANGER: Do not use the recharging unit to recharge other types of batteries or other equipment with rechargeable batteries.**

**⚠ WARNING: Recharge the battery only with the Silverlight recharging unit.**

**Do not attempt to recharge the battery using a generic battery charger.**

**This entails a risk of explosion and fire.**

## 01.0 Identification data

### 01.1 Identification data

An exact description of the model including the serial number of the equipment will make it easier for GC America Inc. Customer Service to provide rapid and effective answers.

Always provide the above information whenever you contact GC America Inc. Customer Service.

### 01.2 Identification plate of the recharging unit

Each recharging unit has an identification plate (Fig. 1) on which the technical specifications and the serial number are indicated. The identification plate is fixed to the underside of the equipment. The remaining data are contained in this manual (see point "11.0").

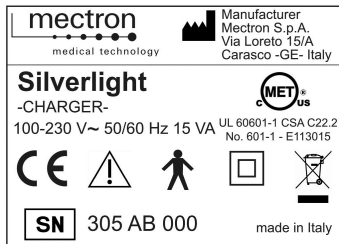
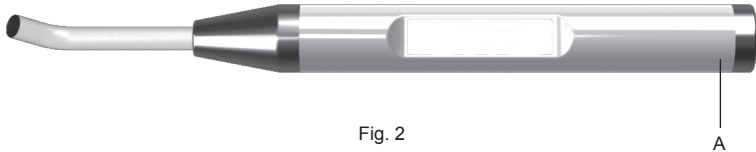


Fig. 1

### 01.3 Identification plate of the silverlight handpiece

The Silverlight handpiece serial number is engraved on the shell near the back steel ring nut (Fig.2 - Ref.A).



## 02.0 Testing

### 02.1 Testing of the equipment

All equipment, including all components, is thoroughly checked and tested by the manufacturer Mectron. During the testing procedure the components are subjected to a number of operational work cycles. This procedure ensures proper functioning and reliability of all components.

## 03.0 Delivery

### 03.1 Delivery of the device

The equipment contains electronic components that may be damaged by impacts even inside the packaging.

Special care must therefore be taken during both transport and storage.

In order to avoid crushing, do not place cartons on top of one another.

All material shipped by GC America Inc. is checked at the time of shipment.

The equipment is delivered properly protected and packaged.

If the shipping packaging is damaged or the protective material shows signs of stress, immediately notify the carrier.

Keep the shipping material for carrier inspections.

### 03.2 List of material included in the standard supply

- A Silverlight recharging unit (Fig.3 - Ref.A).
- B Silverlight handpiece with rechargeable lithium-ion battery (Fig.3 - Ref.B).
- C Fiber optic (Fig.3 - Ref.C).
- D Optical protection (Fig.3 - Ref.D).
- E Power supply cable for the recharging unit (Fig.3 - Ref.E).

This equipment may vary at the time of promotional campaigns.



Fig. 3

### 04.1 Safety requirements at the time of installation

**⚠ DANGER:** The wiring system of the premises where the apparatus is installed and used must comply with the applicable standards and the relevant electrical safety requirements.

**⚠ DANGER:** Do not install the apparatus in places where there is a risk of explosion. The apparatus may not be used in areas where there are inflammable atmospheres (anesthetic mixtures, oxygen, etc.).

**⚠ DANGER:** Install the apparatus in a place where it will be protected from blows and from accidental sprays of water or other liquids.

**⚠ DANGER:** Do not install the apparatus above or in the vicinity of sources of heat. Make sure there is sufficient air circulating around the apparatus.

**⚠ DANGER:** Do not short circuit the electric contacts of the recharging unit with metal objects (Fig.5 - Ref.B) and do not touch them with your hands while the apparatus is switched on.

**⚠ WARNING:** The apparatus is transportable, however it must be handled with care when moved.

**⚠ WARNING:** Do not expose the apparatus to direct sunlight or sources of UV light.

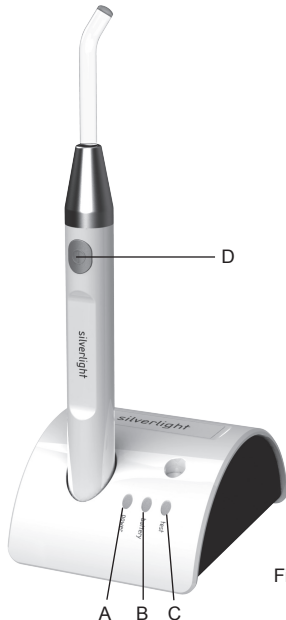


Fig. 4

### 04.2 Description of the controls and signaling lamps

Description of the controls (Fig. 4):

- |               |   |
|---------------|---|
| <b>Ref. A</b> | Green power LED.  |
| Function:     | This indicates that the recharging unit is powered up.  |
| <b>Ref. B</b> | Battery LED.  |
| Function:     | <b>Green:</b> Indicates that the battery of the Silverlight is being charged.<br><b>Yellow:</b> Indicates that the battery of the Silverlight has failed. |
| <b>Ref. C</b> | Test LED.   |
| Function:     | <b>Green:</b> Indicates that the light intensity is suitable for effective therapy.<br><b>Yellow:</b> Indicates that the light intensity is insufficient. |
| <b>Ref. D</b> | Push-button for activating and cutting off the emission of light.   |
| Function:     | This starts or stops a polymerization cycle.  |

Description of signaling for the recharging unit:

**(Table 1):**

Green Power LED	Battery LED		Position of Silverlight in the recharging unit	Function
	Green	Yellow		
ON	OFF	OFF	Not in place	Recharging unit powered
ON	ON	OFF	In place	Battery being recharged
ON	OFF	OFF	In place	Recharging completed. Battery charged.
ON	OFF	ON	In place	Battery failed.
ON	OFF	ON	Not in place	Electric contacts of the recharging unit short-circuited.

**⚠ WARNING: Do not tamper with the recharging unit electrical contacts.**

The recharging unit recognizes the battery state. If after some exposure cycles the battery is not flat enough when the handpiece is placed on the recharging unit, the green battery LED does not switch on. This is normal.

Description of the acoustic signals of the handpiece:

**(Table 2)**

Function	Push-button control	Acoustic signal
FAST polymerisation	Brief pressure of push button	<b>1 beep</b> on starting exposure <b>1 beep</b> on completing exposure (10 seconds)
SLOW RISE polymerisation	Pressure of push button for at least 2 seconds	<b>1 beep</b> when starting and <b>1 beep</b> after 2 seconds <b>1 beep</b> after 10 seconds of exposure <b>1 beep</b> on completing exposure (20 seconds)
Interruption of exposure cycle	Pressure of push button during exposure	<b>1 beep</b>
Battery low signal. The residual charge is sufficient for 6 cycles.		<b>2 beeps</b> on completing the exposure cycle
Battery dead signal	Pressure of push button for FAST or SLOW RISE polymerisation	<b>2 beeps</b> - No light emission
Thermal protection signal		<b>3 beeps</b> during the exposure cycle

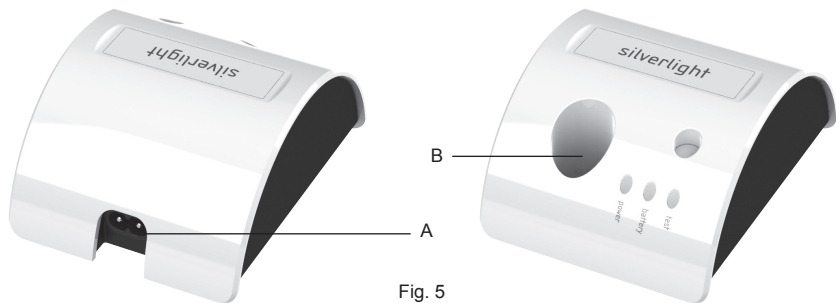


Fig. 5

### 04.3 Connecting the device

In order to render the apparatus operational it is necessary to proceed as follows:

1. Place the recharging unit on a flat surface.
2. Plug the power cable (Fig.3 - Ref.E) into the connector on the rear of the apparatus (Fig.5 - Ref.A) and then into the power outlet. The green power LED should light up (Fig.4 - Ref.A).

**⚠ WARNING:** Make sure that the voltage and frequency of the power-supply line match the values indicated on the identification label under the recharging unit.

**⚠ DANGER:** Check the condition of the power cable regularly. If it is found to be damaged, replace it with an original Mectron S.p.A. spare part.

## 05.0 Battery

The Silverlight is powered by a rechargeable lithium-ion battery already contained inside the handpiece, with no memory effect.

The Silverlight is equipped with microprocessors that check the battery continuously and maintain the optimum battery charging parameters.

The handpiece may therefore be placed back into the recharging unit at the end of each treatment and left there, regardless of the charge of the battery.

### 05.1 New battery - first charging

**NOTE:** The battery of the Silverlight is supplied in a partly charged condition.

To charge the battery completely:

1. Insert the handpiece into its housing in the recharging unit (Fig.5 - Ref.B). The green battery LED will light up (Fig.4 - Ref.B).
2. The recharging phase has been completed when the green battery LED extinguishes.

### 05.2 Battery low signal

When the charge of the battery becomes low after frequent use of the Silverlight, the microprocessor will allow 6 more exposures to be carried out (FAST or SLOW RISE) without any need to recharge the battery. A battery low state is signaled at the end of each of these six cycles by means of two beeps.

Once the six cycles have been completed, the handpiece enters a battery dead state (see point "05.3"). Place the Silverlight back into the recharging unit.

### 05.3 Battery dead signal

The battery of the Silverlight is dead if no light is emitted when the push-button is pressed and at the same time an acoustic signal is heard (two beeps).

To recharge the battery:

1. Place the handpiece in its housing in the recharging unit (Fig.5 - Ref.B). The green battery LED will light up (Fig.4 - Ref.B).
2. When the green battery LED extinguishes the recharging phase has been completed.

### 05.4 Battery failed signal

If the yellow battery LED (check) on the recharging unit lights up, this indicates that the battery has failed (Fig.4 - Ref.C).

NOTE: This failure condition disables operation of the recharging unit. To restore proper working conditions proceed as follows:

1. Remove the handpiece from the recharging unit.
2. Cut off the power supply to the recharging unit for a few seconds (disconnect the power cable). All the LEDs will extinguish.
3. Reconnect the cable of the recharging unit. The green power LED will light up.

### 05.5 Battery problems

To replace a failed battery, contact GC America Inc. Customer Service. Do not attempt to open, remove, change, replace, or in any other way adjust the battery. These or similar actions will void the Warranty (see Section 12.0). Call GC America Inc Customer Service for any battery issue that is not resolved by Problem Solving Tips (see Section 10.0).

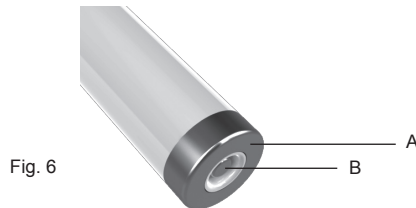


Fig. 6

### 05.6 Safety requirements relating to the battery

The battery can cause damage to property and/or personal injuries such as burns if conducting materials such as jewelry, keys or beaded necklaces come into contact with the exposed terminals.

The conducting material could close an electrical circuit (short circuit) and become very hot.

Make a habit of handling the device with care, particularly if it is placed inside a pocket, bag or other container in which there are metal objects.

**⚠ DANGER: Do not short-circuit the electric contacts of the handpiece with metal objects or liquids (Fig. 6 - Ref. A Ref. B).**

**⚠ DANGER: Keep the battery out of the reach of children.**

**⚠ WARNING: Use only original Mectron S.p.A batteries.**  
Contact GC America Inc Customer Service for battery problems.

**⚠ WARNING:** Recharge the battery only with the Silverlight recharging unit. Do not attempt to recharge the battery using a generic battery charger. This entails a risk of explosion and fire.

**⚠ WARNING:** The battery should be recycled or disposed of in the appropriate manner according to national rules and regulations. The battery should not be thrown away with normal waste. The user will be liable for any damages caused by improper disposal of the battery.

**⚠ WARNING:** Do not use the battery for purposes other than those for which it is intended.

**⚠ WARNING:** Do not open, pierce or crush the battery. It contains toxic substances.

**⚠ WARNING:** Do not burn, incinerate or expose the battery to a high temperature. There is a risk of explosion.

**⚠ WARNING:** Do not short-circuit the battery terminals. This could cause burns and fire.

## 06.0 Use

### 06.1 Connecting the accessories

**⚠ DANGER:** Check the condition of the device before the treatment. Before each treatment, always make sure that the apparatus is working properly and check the efficiency of the accessories. If any improper functioning is noted, do not proceed with the treatment. If the problem concerns the apparatus contact an authorized technical assistance center.

**⚠ DANGER: Infection control.** To ensure maximum safety both of the patient and of the operator, clean, disinfect and sterilize the fiber optic and the optical protection before each treatment. Follow the instructions given under point "07.0" very carefully.

In order to use the Silverlight, the following accessories have to be connected:

1. Fit the fiber optic into the handpiece. Do this by hand, rotating it slightly in a clockwise direction until it reaches the end of travel.
2. Fit the optical protection onto the fiber optic by hand. **Fig. 7**



Fig. 7

## 06.2 Safety requirements during use

**⚠ DANGER:** Never point the beam of light in the direction of the eyes.

**⚠ DANGER:** Before each cycle of exposure make sure that the fiber optic is fitted correctly and fully into the handpiece.

**⚠ DANGER:** Before each cycle of exposure always make sure that the optical protection has been fitted onto the end of the fiber optic Fig.7.

**⚠ DANGER:** Point the beam of light directly onto the material to be polymerized.  
Do not subject the gum or other soft tissues to the beam of light (shield these parts suitably if necessary). The effect of the light should be limited to the oral cavity and in particular to the sector requiring clinical treatment.

**⚠ DANGER:** Do not short-circuit the electric contacts of the handpiece with metal objects or liquids (Fig. 6 - Ref. A Ref. B).

**⚠ DANGER:** During the first few seconds of exposure avoid contact of the fiber optic with the material to be polymerized.

Deposits of composite material adhering to and polymerized to the surface of the tip of the fiber optic lower the amount of light transmitted and will therefore prejudice subsequent polymerization operations.

**⚠ WARNING:** If the fiber optic is damaged or not efficient, this will reduce the intensity of the light being emitted considerably.

In such cases it should therefore be replaced.

## 06.3 Instructions for use

The silverlight can be used in two different modes:

- **FAST:** exposure time of 10 seconds at the maximum light intensity.
- **SLOW RISE:** exposure time 20 seconds with a gradual increase of the light intensity during the first three seconds up to the maximum intensity.

### Selecting the FAST exposure mode.

- To start the FAST exposure cycle press the push button on the handpiece briefly (Fig.4 - Ref.D). An acoustic signal will be heard (1 beep).
- After 10 seconds an acoustic signal will be heard (one beep). The FAST cycle has been completed.

### Selecting the SLOW RISE exposure mode.

- To start the SLOW RISE exposure cycle hold the push button on the handpiece down for two seconds (Fig.4 - Ref.D). At the start an acoustic signal will be heard and after two seconds another acoustic signal to confirm the SLOW RISE cycle beginning.
- After 10 seconds an acoustic signal will be heard (one beep).
- After 20 seconds an acoustic signal will be heard (one beep). The SLOW RISE cycle has been completed.

After the end of the treatment, place the Silverlight handpiece back into the recharging unit (Fig.5 - Ref.B).

### NOTE: Interrupting the cycle.

Both in the FAST and in the SLOW RISE mode, the exposure cycle can be broken off at any time by pressing the push button on the handpiece (Fig.4 - Ref.D).

**NOTE: Additional exposure cycles.**

At the end of any exposure cycle, it is possible to carry out one or more additional cycles by pressing the push button on the handpiece again each time (Fig.4 - Ref.D).

For a quick guide to the signaling, see Tables 1 and 2.

## 06.4 Measuring the light intensity

To determine whether the light intensity is sufficient:

- 1 Place the fiber optic (Fig.8 - Ref.A) flat on the surface of the light-intensity sensor without pressing it (Fig.8 - Ref.B);
- 2 Press the button (Fig.8 - Ref.C) to switch on the lamp.

The test LED (Fig.7 - Ref.D) will indicate the working luminous flux measured:

- **Green** = luminous flux suitable for effective treatment
- **Yellow** = luminous flux insufficient.

**⚠ WARNING:** If the working luminous flux is not sufficient, do not proceed with the treatment on the patient and carry out the following checks:

- 1 Make sure that the fiber optic is correctly inserted onto the handpiece
- 2 Check whether the fiber optic is dirty. Clean the fiber optic (see point 7.4 - Cleaning, disinfecting and sterilizing the fiber optic)
- 3 Check whether the fiber optic is damaged and, if appropriate, replace it with a new one.

If these measures do not lead to improved performance, place the device out of commission (by disconnecting it from the mains) and make sure that it cannot be started by unauthorized persons. Contact GC America Inc Customer Service.

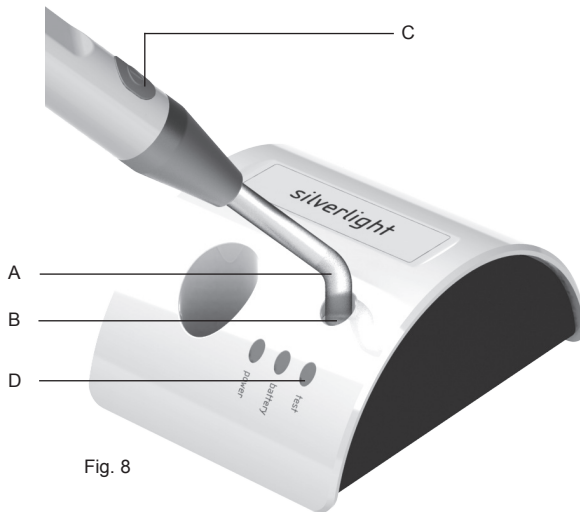


Fig. 8

## 06.5 Safety protection

In the event of extreme heavy duty use, with long and repeated exposure cycles, a thermal protection device is triggered automatically.

An acoustic signal (three beeps) will be heard.

This protection device will temporarily prevent use of the lamp for a few minutes.

## 06.6 Yellow battery LED on the recharging unit illuminated

The yellow battery LED (check) on the recharging unit indicates the following:


1. Battery failed (see point 05.4).
2. Contacts on the recharging unit short-circuited.

In the second case, to restore correct functioning of the charging unit:


1. Disconnect the charging unit from the power supply. All LEDs extinguished
2. Eliminate the cause of the short circuit
3. Re-connect the charging unit to the power supply - green power LED on.

# 07.0 Cleaning, disinfection, sterilization


## 07.1 Cleaning and disinfection of the casing of the recharging unit

 **DANGER: Switch off the recharging unit.**

Before carrying out any cleaning and disinfection, disconnect the recharging unit from the main power supply.

 **DANGER: The casing of the recharging unit is not protected against the entry of liquids.**

 **DANGER: Do not spray liquids directly onto its surface or onto the electrical contacts of the recharging unit.**

 **DANGER: The recharging unit must not be sterilized.**

Proceed as follows after each treatment:

- 1 Remove the handpiece from the recharging unit.
- 2 Clean and disinfect the surface of the casing using a cloth moistened with a solution of mild detergent/disinfectant having a neutral pH (pH = 7).  
Follow carefully the instructions provided by the manufacturer of the disinfectant solution.  
Allow the disinfectant solution to air dry before reconnecting the recharging unit to the power supply.  
Above all, make sure that the electric contacts are completely dry.

**NOTE:** Water-based disinfectants with a neutral pH are strongly recommended. Some alcohol-based disinfectant solutions may be harmful and cause damage to plastic materials.

## 07.2 Cleaning and disinfecting the Silverlight handpiece

 **DANGER: The handpiece is not protected against the penetration of liquids.**

 **DANGER: Do not spray liquids directly onto its surface or onto the electric contacts.**

**⚠ DANGER: Do not short-circuit the electric contacts of the handpiece with metal objects or liquids.**

**⚠ DANGER: The handpiece should not be sterilized.**

Proceed as follows after each treatment:

- 1 Remove the fiber optic and optical protection from the handpiece.
- 2 Clean and disinfect the surface of the handpiece using a cloth moistened with a solution of mild detergent/disinfectant having a neutral pH (pH = 7). Follow carefully the instructions provided by the manufacturer of the disinfectant solution.  
Allow the disinfectant solution to air dry on the handpiece before placing it back in the recharging unit.  
Above all, make sure that the electric contacts are completely dry.

**NOTE:** Water-based disinfectants with a neutral pH are strongly recommended. Some alcohol-based disinfectant solutions may be harmful and cause damage to plastic materials.

### 07.3 Sterilization procedure

**⚠ WARNING: Carry out sterilization only in a steam autoclave.**

Do not use any other sterilization procedures (dry heat, radiation, ethylene oxide, gas, low-temperature plasma, etc.).

**⚠ DANGER: The handpiece and recharging unit must not be sterilized.**

**⚠ DANGER: Infection control - Sterilizable parts.**

To avoid infection caused by bacteria or viruses, always clean the following components after each treatment:

1. Fiber optic;
2. Optical protection.

Sterilization of the above components have been validated by independent laboratory, using a pre-vacuum steam autoclaving.

Recommend minimum sterilization parameters that provide a  $10^{-6}$  Sterility Assurance Level (SAL):

- Three times pre-vacuum cycle
- Minimum sterilization temperature: 132°C (interval 0 °C; + 3 °C)
- Sterilization time: 4 minute
- Drying Time: 10 min

Do not exceed 135°C


### 07.4 Cleaning, disinfection and sterilization of the optical fiber

**⚠ WARNING: Do not use sharp-edged objects to clean the fiber optic.**

Carry out the following operations:

1. Eliminate any residues of polymerized composites from the surface of the fiber optic with alcohol.
2. Disinfect the surface using a cloth moistened with a solution of mild detergent/disinfectant having a neutral pH (pH = 7).
3. Dry.
4. Seal the fiber optic in a disposable bag on its own.
5. Autoclave sterilize the fiber optic.

## 07.5 Cleaning, disinfection and sterilization of the optical protection

 **WARNING: Do not use sharp-edged objects to clean the optical protection.**

Proceed as follows:

1. Clean and disinfect the surface using a cloth moistened with a solution of mild detergent/disinfectant having a neutral pH (pH = 7).
2. Dry.
3. Seal the optical protection in a disposable bag on its own.
4. Autoclave sterilize the optical protection

## 08.0 Disposal procedures and precautions


 **WARNING: This device contains a LITHIUM-ION battery.**

The battery must be disposed of and treated as waste requiring separate collection.

This equipment must be disposed of and treated as waste requiring separate collection

Dispose of unserviceable batteries and curing light according to national rules and regulations.

Batteries must not be incinerated

 **DANGER: Hospital waste.**

Treat the following items as hospital waste:

- Fiber optic, when worn or broken
- Optical protection, when worn or broken

## 09.0 Symbols



WARNING, See instructions for use



Type "B" applied part in conformity with technical norm EN 60601-1



Class II apparatus



Alternate Current



Serial number



Manufacturer



Device manufactured in conformity with directive 93/42/EEC including technical norms EN 60601-1 and EN 60601-1-2.



MET Trademark

UL 60601-1 CSA C22.2  
No. 601-1 - E113015

Conformity to norms UL - CSA



The device and its accessories must not be disposed of or treated as solid urban waste



Danger symbol  
LED radiation

## 10.0 Problem-solving

If the device appears not to be working correctly, read the instructions again and then check the following table.

PROBLEM	POSSIBLE CAUSE	SOLUTION
The recharging unit does not switch on (none of the LEDs will light up).	The power cable is not connected correctly.	Connect the cable both to the recharging unit and to the wall socket.
	The power cable is faulty.	Replace the power cable.
	The recharging unit is out of order.	Contact GC America Inc. Customer Service
The yellow battery LED (check) of the recharging unit is ON.	The contacts of the recharging unit have been short-circuited.	See point "06.6".
The yellow battery LED (check) of the recharging unit is ON.	Battery failed.	Contact GC America Inc. Customer Service. See point "05.4" and "05.5".
There is no beam of light when the push button of the Silverlight is pressed and an acoustic signal is heard (two beeps).	Battery dead.	Recharge the battery. See point "05.3".
An acoustic signal is heard at the end of the exposure cycle (two beeps).	Battery low.	Recharge the battery. See point "05.2".
An acoustic signal (three beeps) is heard during the exposure cycle and at the end of the cycle Silverlight will not enable any further treatment to be carried out.	The thermal protection has been activated.	It will be possible to use the device only after it has cooled down.
The polymerisation is insufficient.	The surface of the tip of the fiber optic is soiled.	See point "07.4".
The green battery LED does not light up when the handpiece is placed back on the charging unit.	Recharging complete. Battery charged.	See point 04.2 - Table 1.

## 11.0 Technical specifications

This apparatus complies with Directive 93/42/EEC: Class I

<b>Class according to EN 60601-1:</b>	II Type B IP 20 (Recharging unit) IP 20 (Silverlight)
<b>Charging station:</b>	SILVERLIGHT -CHARGER-
<b>Charging station power supply requirements:</b>	100-230 V~ 50/60 Hz 15 VA
<b>Power supply of Silverlight handpiece:</b>	Rechargeable Lithium-ion battery Rated voltage: 3.7V Rate capacity: 1100 mAh
<b>Handpiece for intermittent operation:</b>	120° ON 40° OFF Max 3 times running
<b>Source of light:</b>	High-luminosity LED with optics. Class 2 M (IEC 60825-1) LEDs. Dominant wavelength: 440 - 465 nm Average life: 1,800,000 cycles, 20 seconds each.
<b>Fiber optic included in the supply:</b>	Diameter 8 mm. Composition: Drawn coherent fibers melted in transparent quartz. Sterilizable by steam autoclave. Minimum sterilization parameters: Three times pre-vacuum cycle at 132°C for 4 minutes. Drying time. 10 minutes. (max. temp. 135°C - max. 500 cycles)
<b>Exposure:</b>	<b>FAST:</b> Exposure time 10 seconds Acoustic signals indicating start and end of exposure. <b>SLOW RISE:</b> Exposure time 20 seconds Acoustic signal at the start, after 10 seconds and at the end of the 20 seconds. The cycles can be stopped or repeated at any time
<b>Time required to recharge a dead battery:</b>	About two hours.
<b>Operating conditions:</b>	From +10°C to +40°C Relative humidity from 30% to 75%
<b>Transport and storage conditions:</b>	From -10°C to +70°C Relative humidity from 10% to 90% Air pressure P: 500 hPa/1060 hPa
<b>Weights and dimensions:</b>	Recharging unit: Weight 555 g 96 x 120 x 58 mm Silverlight handpiece: Weight 105 g L 198 mm Max. Ø 22.5 mm.

## 11.1 Electromagnetic compatibility EN 60601-1-2

**⚠ DANGER:** The device requires specific EMC precautions and must be installed and started up in accordance with the EMC information given in this paragraph.

**⚠ DANGER:** Portable and mobile radio communication appliances may affect the correct functioning of the device.

<b>Guidance and manufacturer's declaration - Electromagnetic emissions</b>		
The Silverlight is intended for use in the electromagnetic environment specified below. The customer or the user of the Silverlight should assure that it is used in such an environment.		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment - Guidance</b>
RF emissions CISPR 11	Group 1	The Silverlight 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 Silverlight is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

**Guidance and manufacturer's declaration - Electromagnetic immunity**


The Silverlight is intended for use in the electromagnetic environment specified below.  
The customer or the user of the Silverlight should assure that it is used in such an environment.

<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - Guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	The device continues to work regularly and in safety.	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines  ±1 kV for input/output lines	The device continues to work regularly and in safety.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	The device continues to work regularly and in safety.	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % $U_T$ (>95 % dip in $U_T$ ) for 0,5 cycle  40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycle  70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycle  <5 % $U_T$ (>95 % dip in $U_T$ ) for 5 s	The device can vary from the required levels of immunity with a duration of <5% / > 95% / 5s as long as the device remains in safety, no malfunctions have been detected and can be restored to pre-test status with the intervention of the operator.	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	The device continues to work regularly and in safety.	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

**Guidance and manufacturer's declaration - Electromagnetic immunity**

The Silverlight is intended for use in the electromagnetic environment specified below.  
The customer or the user of the Silverlight should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance
<p><b>Conducted RF</b> IEC 61000-4-6</p> <p><b>Radiated RF</b> IEC 61000-4-3</p>	<p><b>3 Veff</b> <b>150 kHz to 80 MHz</b></p> <p><b>3 V/m</b> <b>80 MHz to 2,5 GHz</b></p>	<p>The device continues to work regularly and in safety.</p>	<p><b>Portable and mobile RF communications equipment should be used no closer to any part of the disposal including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</b></p> <p><b>Recommended separation distance</b> <math>d = 1,2 \sqrt{P}</math></p> <p><math>d = 1,2 \sqrt{P}</math> 80 MHz to 800 MHz <math>d = 2,3 \sqrt{P}</math> 800 MHz to 2,5 GHz</p> <p>where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range<sup>b</sup>. Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

**Notes:**

- (1) At 80 MHz and 800 MHz, the higher frequency range applies.
- (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 Silverlight is used exceeds the applicable RF compliance level above, the Silverlight should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Silverlight.
  - b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Recommended separation distances between portable and mobile RF communications equipment and the Silverlight**

The Silverlight is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Silverlight can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Silverlight 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"		
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3 \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	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.
- (2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## 12.0 LED Information concerning the radiation emitted

This device uses high-luminosity LEDs, Class 2M (IEC 60825-1).

**⚠ DANGER: Diverging beams**

Do not observe the emission of light from the LED using optical instruments such as monacles, magnifying glasses or microscopes from a distance of less than 100 mm as this could cause a risk of damage to your eyes.

**⚠ DANGER: Collimated beams**

Do not observe the emission of light from the LED using optical instruments designed for use at a distance, such as telescopes or binoculars, since this could cause a risk of damage to your eyes.

Labels are provided on the packaging of the device, as indicated in Fig. 9.

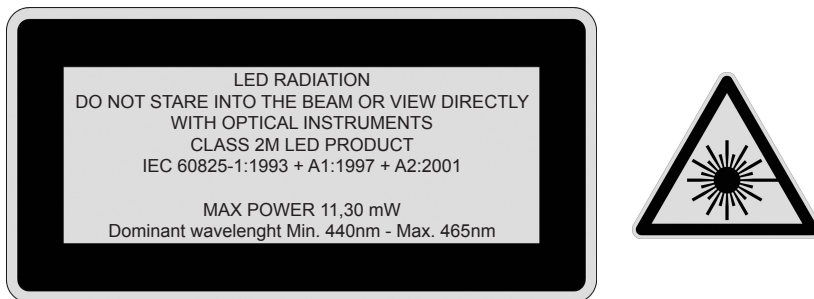


Fig. 9

## 13.0 Limited Warranty

For all Silverlight products unless otherwise specified.

Any non-approved usage of the Silverlight device and accessories will void the warranty.

Any usage of non-Silverlight parts, components/accessories or procedures will void the warranty.

The manufacturer, Mectron S.p.A., warrants to the first original purchaser (customer) that their products have been tested, inspected and shipped in proper working order.

All Silverlight products are covered by warranty for a period of one year from the date of purchase.

Products are warranted to be free from defects in material and workmanship.

This limited warranty does not apply to any unit/accessory which has been subject to abnormal wear and tear, misuse, abuse, neglect, improper installation or operation or that has been altered, adjusted or tampered with by any person other than GC America Inc. authorized personnel.

The warranty is valid only if GC America Inc. is notified within thirty (30) days following discovery of a defect.

For returning procedure make reference to the paragraph "CUSTOMER SERVICE – RETURNS"

Returns must be authorized by GC America Inc.

GC America Inc. cannot accept responsibility for returns which have not been authorized.

Contact GC America Inc. Customer Service at 800-323-7063 for return authorization.

GC America Inc. will investigate and shall correct any defect covered by warranty by providing a replacement of the product.

If upon examination by GC America Inc.'s service personnel it is determined that the malfunction is caused by abnormal wear and tear or by damage caused by misuse, abuse, tamper with, or by failure to perform normal and routine maintenance as set out in the instructions for use and maintenance booklet provided with the unit, warranty provisions will not apply.

GC America Inc will not replace or repair any product or part of the product after the warranty period (one year from date of purchase) has expired.

## 13.1 Customer service - RETURNS

Returning products for any reason, must be authorized by GC America Inc. Customer Service and the following information must be provided:

- Product name
- Serial number/lot number (if applicable)
- Reason of return and detailed description of the problem.
- Original Invoice Number
- Date of purchase

The above information must be always included in the package of the returning products under warranty. GC America will not replace product, product parts, or product accessories that are out of warranty period (one year from date of purchase).

### RETURNED GOODS.

Contact GC America Inc Customer Service for instructions on how to return product.

### WARNING: Packaging

Pack the equipment in its original packaging to ensure it is not damaged during shipment.

### DANGER

All the products must be cleaned and sterilized before returning.

GC America Inc. will not accept and process potentially bio-contaminated products which do not meet this requirement.

Contaminated products will be immediately returned to you for decontamination and sterilization.

This warranty gives you specific legal rights and you may have other rights which vary by state and municipality.

The foregoing limited warranty is in lieu of all other warranties, expressed or implied, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

Except claims for personal injury, in no case shall the company be liable for any special, incidental or consequential damages based upon breach of warranty or any other legal theory.

Some jurisdictions do not allow limits on warranties, or on remedies, and, in such jurisdictions, the limit in this and the preceding paragraphs may not apply.

The information given in this manual is not binding and can be modified without prior notice.














Distributed in the U.S. by:  
GC America Inc.  
3737 West 127th St., Alsip, IL 60803  
Phone: 800-323-7063  
Fax. 800-GCFAXME

Caution: US Federal Law restricts this device to sale by or on the order of a dentist



 manufacturer:  
Mectron S.p.A.  
Via Loreto 15/A  
16042 Carasco (Ge) Italy