stomdevice

mectron

medical technology

EN

starlight ortho



Manuale d'uso e manutenzione
Manual of use and maintenance
Gebrauchs- und Wartungshandbuch
Notice d'utilisation et d'entretien
Manual de uso y mantenimiento

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00.0 Introduction

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 equipment.
The user is not authorised to tamper with the equipment under any circumstances.
If any problems are encountered, please contact a Mectron Service Centre.
Any attempts on the part of the user or any unauthorised personnel to tamper with or alter the equipment will invalidate the warranty and release the Manufacturers from any liability in respect of any harm or damage to persons or property.
The information and illustrations contained in this manual are updated as of the date of publication indicated on the last page.
MECTRON are committed to continuous up-dating of their 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 MECTRON After-Sale 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 equipment

The Starlight ortho is an equipment for polymerising photo-hardening composites. The light source used is a very high-efficiency monochromatic LED with a dominant wavelength between 440 nm and 465 nm.
Unlike traditional halogen lamps, therefore, all the light being emitted by the Starlight ortho is used to activate the camphorquinone photoinitiator. This means that it is possible to achieve excellent polymerisation performance levels using decidedly less power and without emitting heat.
Furthermore, the light emitted by the diode is focused on the optical fibre by means of an optical elements, the shape of which was designed specifically for this purpose.
The equipment consists of a charging unit and a handpiece powered by a rechargeable lithium-ion battery.
The Starlight ortho enables to operate in two polymerization times:
- 5 seconds Polymerization cycle;
- 10 seconds Polymerization cycle.

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00.3 Intended use

Polymerisation of photo-hardening dental materials with a photoinitiator that can be activated in the wavelength band comprised between 440 and 480 nm with a narrow peak at 460 nm.
Although most composite materials are activated within this wavelength range, in case of uncertainty consult the specifications of the composite material.
This equipment may be used only in a dentist's surgery or out-patient's department where there are no inflammable gases (anaesthetic mixtures, oxygen, etc.).

00.4 Safety requirements

Mectron 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 authorised by Mectron.
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.

⚠ **WARNING:** No alterations to this device are permitted.

⚠ **WARNING:** The wiring system of the premises on which this device is used must comply with the applicable standards and requirements.

⚠ **DANGER: Qualified and specialised personnel.**
The equipment should be used only by specialised 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 polymerised.**
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 photosensitising drugs. In all cases of possible risk consult a specialised physician.

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⚠ **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).

⚠ **DANGER: Contraindications.**
Patients who have a case history of diseases of the retina should consult their optician beforehand and be specifically authorised to receive treatment with the Starlight ortho.

⚠ **DANGER: Cleaning, disinfection and sterilisation of new or repaired products.**
Before treatment, all new or repaired products should be cleaned and disinfected and, if suitable for this treatment, autoclave sterilised 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 sterilise the optical fibre and the optical protection before each treatment. Follow the instructions provided under point “07.0” closely.

⚠ **DANGER: Use only original Mectron 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 equipment. If the problems concern the equipment contact an authorised technical service centre.

⚠ **DANGER: Do not instal the equipment anywhere where there is a risk of explosions.**
The equipment cannot function in places where there is an inflammable atmosphere (anaesthetic mixtures, oxygen, etc.).

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

⚠ **WARNING: Recharge the battery only with the Mectron charging unit (Fig.3 - Ref.A). Do not attempt to recharge the battery using a generic battery charger. This entails a risk of explosion and fire.**

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01.1 Identification data

An exact description of the model including the serial number of the equipment will make it easier for our After-Sale Service to respond quickly and efficiently to your queries.
Always provide the above information whenever you contact a Mectron Service Centre.

01.2 Identification plate of the charging unit

Each charging 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 Starlight ortho handpiece

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



Fig. 2

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02.0 Testing

02.1 Testing of the equipment

All equipment manufactured by MECTRON is thoroughly checked and tested, including all components.
During the testing procedure the components are subjected to a number of work cycles.
The tests highlight any malfunctioning due to faulty components.
This procedure ensures proper functioning and reliability of all components.

03.0 Delivery

03.1 Delivery of the equipment

The equipment contains electronic components that may be damaged by impacts even inside the packaging. Special care must therefore be taken for both transport and storage.
All material shipped by MECTRON is checked at the time of shipment.
The equipment is delivered properly protected and packaged.
At the time of receipt of the equipment check it for possible transport damage. If any damage is found, make a complaint to the carrier.

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03.2 List of material included in the standard supply

1 Starlight ortho charging unit (Fig.3 - Ref.A).
1 Starlight ortho handpiece with rechargeable lithium-ion battery (Fig.3 - Ref.B).
1 Optical fibre (Fig.3 - Ref.C).
1 Optical protection (Fig.3 - Ref.D).
1 Power supply cable for the charging unit (Fig.3 - Ref.E).

This equipment may vary at the time of promotional campaigns.



Fig. 3

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04.1 Safety requirements at the time of installation

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

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

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

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

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

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

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



Fig. 4

04.2 Description of the controls and signalling lamps

Description of the controls (Fig. 4):

Ref. A - Green **power** LED.
Function: This indicates that the charging unit is powered up.

Ref. B - **battery** LED.
Function **Green:** Indicates that the battery of the Starlight ortho is being charged.
Yellow: Indicates that the battery of the Starlight ortho has failed.

Ref. C - **test** LED.
Function **Green:** Indicates that the light intensity is suitable for effective therapy.
Yellow: Indicates that the light intensity is insufficient.

Ref. D - Push-button for activating and cutting off the emission of light.
Function: This starts or stops a polymerisation cycle.

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Description of signalling of the charging unit **(Table 1)**:

Green Power LED	Battery LED Green	Battery LED Yellow	Position of Starlight ortho in the charging unit	Function
ON	OFF	OFF	Not in place	Charging 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 charging unit short-circuited.

⚠ **WARNING: Do not tamper with the charging unit electrical contacts.**
The charging unit recognizes the battery state. If after some exposure cycles the battery is not flat enough, when the handpiece is placed on the charging unit, the green battery LED doesn't switch on. This is normal.

Description of the acoustic signals of the handpiece **(Table 2)**:

Function	Push-button control	Acoustic signal
Exposure time 5 sec.	Brief pressure of push button	**1 beep** on starting exposure **1 beep** on completing exposure (5 seconds)
Exposure time 10 sec.	Pressure of push button for at least 2 seconds	**1 beep** when starting and **1 beep** after 2 seconds **1 beep** after 5 seconds of exposure **1 beep** on completing exposure (10 seconds)
Interruption of exposure cycle	Pressure of push button during exposure	**1 beep**
Battery low signal. The residual charge is sufficient for 6 cycles.		**2 beeps** on completing the exposure cycle
Battery dead signal	Pressure of push button for 5 sec. or 10 sec. exposure	**2 beeps** - No light emission
Thermal protection signal		**3 beeps** during the exposure cycle and functioning interruption

04.3 Connecting the equipment

In order to make the equipment operational it is necessary to proceed as follows:
1 Place the charging unit on a flat surface.
2 Plug the power cable (Fig.3 - Ref.E) into the connector on the rear of the equipment (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 charging unit.

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

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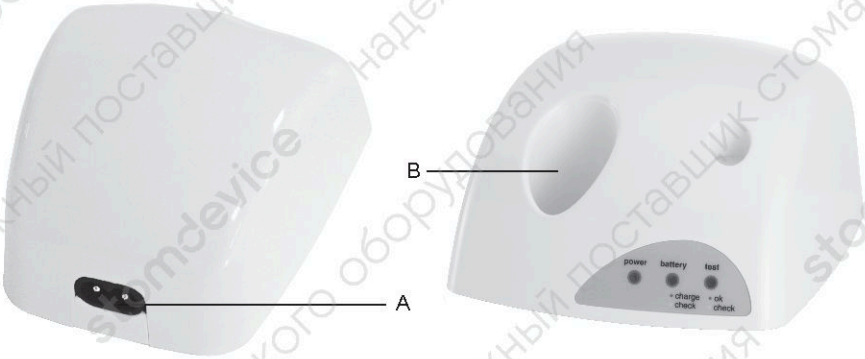


Fig. 5

05.0 Battery

The Starlight ortho is powered by a rechargeable lithium-ion battery already contained inside the handpiece, with no memory effect.
The Starlight ortho is equipped with two microprocessors that check the battery continuously and maintain the optimum battery charging parameters. The handpiece may therefore be placed back into the charging 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 Starlight ortho is supplied in a partly charged condition.

To charge the battery completely:
1 Insert the handpiece into its housing in the charging unit (Fig.5 - Ref.B). The green battery LED will light up (Fig.4 - Ref.B).
2 The charging 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 Starlight ortho, the microprocessor will allow 6 more exposures to be carried out (5 sec. or 10 sec.) without any need to recharge the battery.
A battery low state is signalled at the end of each of these 6 cycles by means of 2 beeps.
Once the 6 cycles have been completed, the handpiece enters a battery dead state (see point “05.3”).
Place the Starlight ortho back into the charging unit.

05.3 Battery dead signal

The battery of the Starlight ortho is dead if no light is emitted when the push-button is pressed and at the same time an acoustic signal is heard (2 beeps). Recharge the battery:
1 Place the handpiece in its housing in the charging 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.

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05.4 Battery failed signal

If the yellow battery LED (check) on the charging unit lights up, this indicates that the battery has failed (Fig.4 - Ref.C).
NOTE: This failure condition disables operation of the charging unit. To restore proper working conditions proceed as follows:

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

05.5 Replacing the battery

To replace a failed battery, contact Mectron Customer Service.

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 jewellery, 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 batteries.
To replace a failed battery, contact Mectron Customer Service.

⚠ WARNING: Recharge the battery only with the Mectron charging unit (Fig.3 - Ref.A). 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 in accordance with the law. 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 the battery or expose it to a high temperature. There is a risk of explosion.

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

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06.1 Connecting the accessories

⚠ **DANGER: Check the condition of the device before the treatment.**
Before each treatment, always make sure that the equipment 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 equipment contact an authorised technical assistance centre.

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

In order to use the Starlight ortho, the following accessories have to be connected:
1 Manually insert the optic fibre onto the handpiece, applying gentle pressure. If necessary, rotate until it clicks into place.
2 Fit the optical protection onto the optical fibre by hand.



Fig. 6

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 optical fibre 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 optical fibre.**

⚠ **DANGER: Point the beam of light directly onto the material to be polymerised.**
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).**

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⚠ **WARNING: During the first few seconds of exposure avoid contact of the optical fibre with the material to be polymerised.**
Deposits of composite material adhering to and polymerised to the surface of the tip of the optical fibre lower the amount of light transmitted and will therefore prejudice subsequent polymerisation operations.

⚠ **WARNING: If the optical fibre 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 Starlight ortho can operate in two different exposure times:
- Exposure time 5 seconds.
- Exposure time 10 seconds.

Selecting the exposure of 5 sec.
- To start the 5 sec. exposure cycle press the push button on the handpiece briefly (Fig.4 - Ref.D). An acoustic signal will be heard (1 beep).
- After 5 seconds an acoustic signal will be heard (1 beep). The cycle has been completed.

Selecting the exposure of 10 sec.
- To start the 10 sec. exposure cycle hold the push button on the handpiece down for 2 seconds (Fig.4 - Ref.D). At the start an acoustic signal will be heard and after 2 seconds another acoustic signal to confirm the 10 sec. cycle beginning.
- After 5 seconds an acoustic signal will be heard (1 beep).
- After 10 seconds an acoustic signal will be heard (1 beep). The cycle has been completed.

Once the treatment is completed, place the Starlight ortho handpiece back into the charging unit (Fig.5 - Ref.B).

NOTE: Interrupting the cycle.
The exposure cycle can be interrupted 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 signalling, see Tables 1 and 2.

06.4 Measuring the light intensity

To determine whether the light intensity is sufficient:
1 Place the optical fibre (Fig.7 - Ref.A) flat on the surface of the light-intensity sensor without pressing it (Fig.7 - Ref.B);
2 Press the button (Fig.7 - 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.

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Fig. 7

⚠ **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 optical fibre is correctly inserted onto the handpiece;
2 Check whether the optical fibre is dirty. Clean the optical fibre (see point 7.4 - Cleaning, disinfecting and sterilising the optical fibre);
3 Check whether the optical fibre 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 unauthorised persons. Any repair work on the device should be carried out by an authorised Mectron service centre.

06.5 Safety protection

In the event of extremely heady duty use, with long and repeated exposure cycles, a thermal protection device is triggered automatically. An acoustic signal (3 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 charging unit lighted

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

1 Battery failed (see point 05.4).
2 Contacts on the charging 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.

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07.0 Cleaning, disinfection, sterilisation

07.1 Cleaning and disinfection of the casing of the charging unit

⚠ **DANGER: Switch off the charging unit.**
Before carrying out any cleaning and disinfection, disconnect the charging unit from the mains power supply.

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

⚠ **DANGER: The charging unit should not be sterilised.**

⚠ **DANGER: During the clearing procedures do not tamper the electric contacts of the charging unit (Fig.5 - Rif.B).**

⚠ **DANGER: Do not spray liquids directly onto its surface and onto the electrical contacts of the charging unit.** Proceed as follows after each treatment:

1 Remove the handpiece from the charging unit;
2 Clean the surface of the charging unit with a clean, soft cloth with low fibre-release, moistened with a detergent solution (pH 6-9) and, if need be, disinfect with a non-aggressive disinfectant solution with neutral pH (pH 7), following the instructions provided by the manufacturer of the solution;
3 Dry the charging unit with a clean, nonabrasive cloth with low fibre-release before reconnecting the charging 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 Starlight ortho handpiece

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

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

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

⚠ **DANGER: Do not spray liquids directly onto the cone, the surface and onto the electric contacts of the hadpiece.** Proceed as follows after each treatment:

1 Remove the optical fibre and optical protection from the handpiece;
2 Clean the surface of the handpiece with a clean, soft cloth with low fibre-release, moistened with a detergent solution (pH 6-9) and, if need be, disinfect with a non-aggressive disinfectant solution with neutral pH (pH 7), following the instructions provided by the manufacturer of the solution;
3 Dry the handpiece with a clean, nonabrasive cloth with low fibre-release before using the handpiece again and before placing it back in the charging 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.

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07.3 Sterilisation procedure

⚠ **WARNING: Carry out sterilisation only in a steam autoclave at a maximum temperature of 135° for 20 minutes.**
Do not use any other sterilisation procedures (dry heat, radiation, ethylene oxide, gas, low-temperature plasma, etc.).

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

⚠ **DANGER: Infection control - Sterilisable parts.**
To avoid infection caused by bacteria or viruses, always clean the following components after each treatment:
1 Optical fibre;
2 Optical protection.
These components are made of materials able to withstand a maximum temperature of 135 °C for a maximum of 20 minutes.
The steam autoclave sterilisation processes (SAL 10^{-6}) must be carried out using the parameters given below:
- 3 times pre-vacuum.
- Sterilisation temperature 132 °C (interval 0 °C ÷ +3 °C).
- Sterilisation time 4 minutes.
- Minimum drying time 10 minutes.

All the stages of sterilisation must be carried out by the operator in accordance with EN ISO 17665-1:2006, EN 556-1:2001 and ANSI/AAMI ST:46:2002.

NOTE: Do not used oxygenated water to disinfect. Only use neutral pH disinfectants. Always rinse with sterile water.

⚠ **DANGER:** Once clearing operations have been completed, before sterilisation check all objects under a suitable light source. Pay particular attention to parts that may hide residue dirt (threading, cavities, channelling). If necessary, repeat the cleaning cycle.

07.4 Cleaning, disinfection e sterilisation of the optical fibre

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

Carry out the following operations:
1 Eliminate any residues of polymerised composites from the surface of the optical fibre 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 optical fibre in a disposable bag on its own.
5 Autoclave sterilise the optical fibre.

07.5 Cleaning, disinfection and sterilisation 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 sterilise the optical protection.

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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;
- At the end of the life-cycle of this equipment, the purchaser is entitled to return the equipment to the dealer supplying new equipment. Instructions for disposal are available from Mectron S.p.A.;
- Failure to comply with the foregoing points may entail punishment in accordance with Directive about *waste of electrical and electronic equipment WEEE*.

⚠ **DANGER: Hospital waste.**

Treat the following items as hospital waste:

- Optical fibre, when worn or broken
- Optical protection, when worn or broken

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09.0 Symbols



WARNING, See instructions for use



Consult operating instructions



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



Class II apparatus



Alternate Current



Can be sterilised in autoclave up to a maximum temperature of 135 °C



Serial number



Catalogue number



Manufacturer



Temperature limitation - transport and storage conditions



Humidity limitation - transport and storage conditions



Atmospheric pressure limitation - transport and storage conditions



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



Danger symbol
LED radiation



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

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10.0 Problem-solving

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

PROBLEM	POSSIBLE CAUSE	SOLUTION
The charging 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 charging unit and to the wall socket.
	The power cable is faulty.	Replace the power cable.
	The charging unit is out of order.	Contact an authorised MECTRON technical assistance centre.
The yellow battery LED (check) of the charging unit is ON.	The contacts of the charging unit have been short-circuited.	See point “06.6”.
The yellow battery LED (check) of the charging unit is ON.	Battery failed.	Contact Mectron Customer Service. See point “05.4” and “05.5”.
There is no beam of light when the push button of the Starlight ortho is pressed and an acoustic signal is heard (2 beeps).	Battery dead.	Recharge the battery. See point “05.3”.
An acoustic signal is heard ad the end of the exposure cycle (2 beeps).	Battery low.	Recharge the battery. See point “05.2”.
An acoustic signal (3 beeps) is heard during the exposure cycle and at the end of the cycle Starlight ortho will not enable any further treatment to be carried out.	The thermal protection has been activated.	It will be possible to use the equipment only after it has cooled down.
The polymerisation is insufficient.	The surface of the tip of the optical fibre is soiled.	See point “07.5”.
The green battery LED does not light up when the handpiece is placed back on the charging unit.	Battery not sufficiently low.	See point 04.2 - Table 1.

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11.0 Technical specifications

This equipment complies with Directive 93/42/EEC:	Class I
Class according to EN 60601-1:	II Applied part type B (Optical fibre) IP 20 (Charging unit) IP 20 (Starlight ortho)
Charging station:	Model Starlight ortho -CHARGER-
Charging station power supply requirements:	100-230 V~ 50/60 Hz 15 VA
Power supply of Starlight ortho handpiece:	Lithium-ion battery Rated voltage : 3.7V Rate capacity: 1100 mAh
Handpiece for intermittent operation:	120" ON 40" OFF Max 3 times running
Source of light:	High-luminosity LED with optics. Class 2 M (IEC 60825-1) LEDs. Dominant wavelength: 440 - 465 nm LED light emission: > 1.400 mW/cm^2 Average life: 3,600,000 cycles, 10 seconds each.
Optical fibre included in the supply:	Diameter 8 mm. Composition: Drawn coherent fibres surfused with quartz. Autoclave sterilisable (max. temp. 135 °C for 20 minutes - max. 500 cycles).
Esposure:	Exposure time 5 seconds - Acoustic signals indicating start and end of exposure. Exposure time 10 seconds - Acoustic signal at the start, after 5 seconds and at the end of the 10 seconds. The cycles can be stopped or repeated at any time.
Time required to recharge a dead battery:	About 2 hours.
Operating conditions:	from 10 °C to 35 °C Relative Humidity from 45% to 85% Air pressure P: 800 hPa/1060 hPa
Transport and storage conditions:	from -20 °C to 40 °C Relative Humidity from 45% to 85% Air pressure P: 500 hPa/1060 hPa
Weights and dimensions:	Charging unit: Weight 555 g 96 x 120 x 58 mm Starlight ortho handpiece: Weight 105 g L 190 mm Max. Ø 23 mm

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11.1 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 monocles, 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. 8.

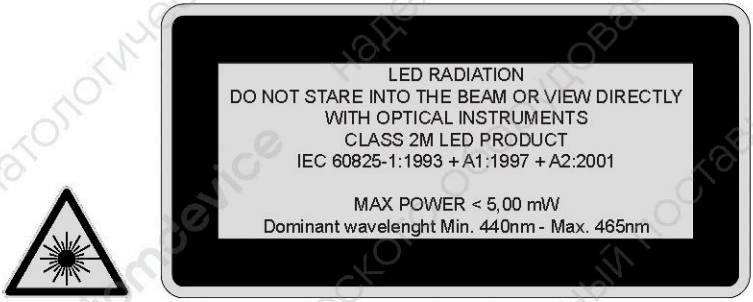


Fig. 8

11.2 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.

Guidance and manufacturer's declaration - Electromagnetic emissions		
The Starlight ortho is intended for use in the electromagnetic environment specified below. The customer or the user of the Starlight ortho should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - Guidance**
RF emissions CISPR 11	Group 1	The Starlight ortho 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 Starlight ortho 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	

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Guidance and manufacturer's declaration - Electromagnetic immunity			
The Starlight ortho is intended for use in the electromagnetic environment specified below. The customer or the user of the Starlight ortho should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	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.			

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Guidance and manufacturer's declaration - Electromagnetic immunity			
The Starlight ortho is intended for use in the electromagnetic environment specified below. The customer or the user of the Starlight ortho should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Veff 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	The device continues to work regularly and in safety.	*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.* **Recommended separation distance** $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ *80 MHz to 800 MHz* $d = 2,3\sqrt{P}$ *800 MHz to 2,5 GHz* where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

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

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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Recommended separation distances between portable and mobile RF communications equipment and the Starlight ortho

The Starlight ortho is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Starlight ortho can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Starlight ortho 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.

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12.0 Warranty

Before being placed on the market, all Mectron equipment undergoes a thorough final check to ensure that it is are in proper working order.
Mectron warrant their products, purchased brand-new from authorised Mectron dealers or importers, free from material or manufacturing defects for a period of 3 (THREE) years from the date of purchase.
Throughout the warranty period, Mectron undertake to repair (or, at their sole discretion, to replace) free of charge any parts that, in their opinion, are faulty.
Complete replacement of Mectron products is excluded.
Mectron cannot accept any liability for direct or incidental damage or personal injury in the following cases:

- If the equipment is used for purposes other than that for which it is intended.
- If the equipment is not used in accordance with all the instructions and requirements described in this manual.
- If the wiring system in the room where the equipment is used does not comply with the applicable standards and appropriate requirements.
- If the wiring system in the room where the equipment is used does not comply with the applicable standards and appropriate requirements.
- If any assembly operations, extensions, settings, alterations or repairs have been carried out by personnel not authorised by Mectron.
- 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.

Accidental damages due to transport, incorrect use or carelessness or to connection to power supplies other than as envisaged and damage to the signalling lamps, handpieces and all accessories are excluded from the warranty.
The warranty will no longer apply if the equipment has been tampered with or repaired by unauthorised personnel.

WARNING

The warranty is valid only if the warranty slip enclosed with the product has been completed in full and returned to us or, if appropriate, to your Mectron dealer or importer within 20 (TWENTY) DAYS from the date of purchase, as proven by the consignment note/invoice issued by the dealer/ importer.
In order to benefit from the warranty service, the customer must return the equipment to be repaired to the Mectron dealer/importer from which it was purchased, at his own expense.
The equipment should be returned suitably packed (possibly in its original packing material), accompanied by all the accessories and by the following information:

a) Owner's details, including his telephone number.
b) Details of the dealer/importer.
c) Photocopy of the consignment note/purchase invoice of the equipment issued to the owner and indicating, in addition to the date, also the name of the equipment and its serial number.
d) A description of the problem.

Transport and any damages caused during transport are not covered by the warranty.
In the event of failures due to accidents or improper use, or if the warranty has lapsed, repairs to Mectron products will be charged on the basis of the actual cost of the materials and labour required for such repairs.

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mectron

medical technology

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starlight ortho V.EN
Rev. 00 Del 31-03-2015

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