stomdevice

mectron

medical technology

English



starlight s sler®

Manual of use and maintenance

CE

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00.0 Introduction

00.1 Foreword

Please read this manual carefully before proceeding to install, use, maintain or carry out any other activities on the equipment.
Always keep this manual close at hand.

Important: To avoid any injury to people or damage to property, please take particular note of all the 'Safety requirements' paragraphs included in this manual.
Depending on the level of risk involved, the safety requirements are classified as follows:
⚠ **DANGER (always related to personal injury)**
⚠ **WARNING (relating to possible damage to property)**

This purpose of this manual is to ensure that operators are aware of the safety requirements, installation procedures, and instructions for correct use and maintenance of the apparatus.
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 apparatus will invalidate the warranty and release the Manufacturer from any liability with regards to any injury or damage to people or property.
The information and illustrations contained in this manual are updated as of the date of publication indicated on page 20.
MECTRON are committed to continuous updating of our 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 retailer or MECTRON after-sales service for clarification.
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 device

The 'starlight s SLER' has been designed to polymerise photo-hardening compounds.
The light source used is a very high-efficiency monochromatic LED with a dominant wavelength between 440 nm and 465 nm.
As such, differently to traditional halogen lamps, all the light emitted by the 'starlight s SLER' is useful to activating the camphorquinone photo initiator. This allows for excellent polymerisation results at significantly lower powers and without heat emission.

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00.3 SLER® technology

SLER® (Soft Light Energy Release) technology is a recent proposal in the field of dentistry, for the photo-polymerisation of compound materials. It uses a new method of polymerisation, with a gradual decrease in power during the final phase of material radiation, to allow for thermal control of the treatment process.
The SLER® effect on the photo-polymerisation process has been evaluated by means of extensimetric contraction tests assisted by thermal measurements, whilst the effect on mechanical properties has been evaluated by means of standardised mechanical penetration tests.
The results suggest that this new photo-polymerisation process improves the mechanical resistance of compound materials polymerised with high light intensity. Furthermore, this new photo-polymerisation method provides an important aid in the clinical field for the control of problems linked to the contraction of composite materials during high power polymerisation.

00.4 Intended use

Polymerisation of photo-hardening dental materials with photo-initiator that can be activated in the wavelength band ranging between 440 - 480 nm.
Although most compounds are activated within this wavelength range, if in doubt, please refer to the compound's technical data or contact the manufacturer.
The equipment may only be used in a dentist's surgery or out-patient department where there are no inflammable gases (anaesthetic mixtures, oxygen, etc.).

00.5 Safety requirements

Mectron will not accept any liability for direct or indirect 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 the instructions and requirements described in this manual.
3 If the wiring systems 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 section on technical data.

⚠ **DANGER: Qualified and specialised personnel.**
This equipment may only be used by specialised, suitably trained staff. If correctly used, this equipment does not give rise to side effects.

⚠ **DANGER: Intended use.**
Only use the equipment for the purposes for which it has been designed (see paragraph '00.3'). Failure to comply with this requirement may lead to serious injury to the patient or operator, and damage/failure of the equipment.

⚠ **DANGER: Contraindications.**
Do not use the equipment on patients fitted with pace-makers or other implantable electronic devices. This requirement also applies to the operator.

⚠ **DANGER: Direct the beam of light directly onto the material to be polymerised**
Do not subject the gums or other soft tissues to the beam of light (shield these parts if necessary). The effect of the light should be limited to the oral cavity, and the sector to be clinically treated.

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⚠ **DANGER: Never direct the light beam towards the eyes.**
The effect of the light should be limited to the oral cavity, and the sector to be clinically treated.

⚠ **DANGER: Contraindications.**
Do not use the equipment on patients with a positive case history to light stimulations, for example in photodermatitis and/or in porphyria, etc., or who are undergoing treatment involving photo-sensitising drugs. Wherever there may be a risk, consult the specialist physician.

⚠ **DANGER: Contraindications.**
Take severe safety measures when treating patients subjected to cataract surgery, and who are therefore particularly sensitive to light (e.g. protective goggles to filter blue light).

⚠ **DANGER: Contraindications.**
Patients whose case history shows pathologies of the retina must first consult an ophthalmologist for authorisation to treatment with the 'starlight s SLER'.

⚠ **DANGER: Cleaning, disinfection and sterilisation of new or repaired products.**
Before treatment, all new or repaired products must be cleaned, disinfected and, if safe for steriliser use, sterilised. This must be done in complete compliance with the instructions given in chapter '05.0'.

⚠ **DANGER: Infection control.**
For maximum patient and operator safety, clean, disinfect and sterilise the optic fibre and optical protection before each treatment. Always comply with the instructions given in chapter '05.0' in full.

⚠ **DANGER: Only use original Mectron accessories and spare parts.**

⚠ **DANGER: Check 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 device. If problems concern the equipment, contact an authorised technical service centre.

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

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01.1 Identification data

An exact description of the model and appliance serial number will make it easier for our after-sales service to respond to your queries quickly and efficiently.
Always provide this information whenever you contact a Mectron service centre.

01.2 Identification plate for the 'starlight s SLER' handpiece

The serial number of the 'starlight s SLER' handpiece is engraved into the rear part as shown in Fig. 1 - Ref. E.



Fig. 1

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02.0 Testing

02.1 Equipment testing

All components of all equipment manufactured by MECTRON is thoroughly checked and tested.
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 Appliance delivery

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.
To avoid crushing, do not place boxes on top of each other.
All material shipped by MECTRON is checked at the time of shipment.
The equipment is delivered properly protected and packaged.
Upon receipt of the equipment, please check for any possible damages suffered during transport. If any damage is noted, please file a complaint with the courier.

03.2 List of materials supplied as standard

1 'starlight s SLER' handpiece (Fig. 1 - Ref. A).
1 Optic fibre (Fig. 1 - Ref. B).
1 Optical protection (Fig. 1 - Ref. D).

The material included in the supply may vary in the event of promotional campaigns.

04.0 Use



Fig. 2

04.1 Description of commands and warnings

Commands description (Fig. 2):

Ref. A - 'Start' button
Function Starts or stops a polymerisation cycle

Ref. B - 'Mode' button
Function Allows you to set the emission function desired
SLER SLER+ SOFT

Ref. C - Series of three LED indicators
Function Indicates the function set

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Sets 'starlight s SLER' functions **(Table 1)**:

'Mode' command button Function choice	Signal	Type of light emitted	Exposure time
SLER polymerisation	Left LED on	Maximum power emitted with SLER function at cycle end 10 secs.	10 secs. 20 secs.
SLER+ polymerisation	Central LED on	Increased emission during first two seconds. Maximum emission power with SLER function at cycle end	11 secs. 21 secs.
SOFT polymerisation	Right LED on	Emission 70% of maximum power for whole cycle	10 secs. 20 secs.

04.2 Connecting the accessories

⚠ **DANGER: Check 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 device. If problems concern the equipment, contact an authorised technical service centre.

⚠ **DANGER: Infection control.**
For maximum patient and operator safety, clean, disinfect and sterilise the optic fibre and optical protection before each treatment. Always comply with the instructions given in chapter '05.0' in full.

In order to use the 'starlight s SLER', you will need to connect the following accessories:
1 Manually insert the optic fibre onto the handpiece, applying gentle pressure. If necessary, rotate until it clicks into place.
2 Manually insert the optical protection onto the optic fibre.
3 Correctly insert the 'starlight s SLER' onto the cord, checking that the electrical contacts of both parts are completely dry. Dry with an air syringe if necessary.

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04.3 Safety requirements during use

⚠ **DANGER: Never direct the light beam towards the eyes.**

⚠ **DANGER: Before each exposure cycle, check that the optic fibre is correctly inserted fully into the handpiece.**

⚠ **DANGER: Before each exposure cycle, always check that the optical protection is in place at the tip of the optic fibre.**

⚠ **DANGER: Direct the beam of light directly onto the material to be polymerised.**
Do not subject the gums or other soft tissues to the beam of light (shield these parts if necessary).
The effect of the light should be limited to the oral cavity, and the sector to be clinically treated.

⚠ **WARNING: Avoid bringing the optic fibre into contact with the material to be polymerised during the first few seconds of exposure.**
Any compound deposits remaining adhered and polymerised on the tip surface of the optic fibre will decrease light transmission, thereby affecting subsequent polymerisations.

⚠ **WARNING: Replace any damaged or inefficient optic fibre, as this will significantly reduce light intensity.**

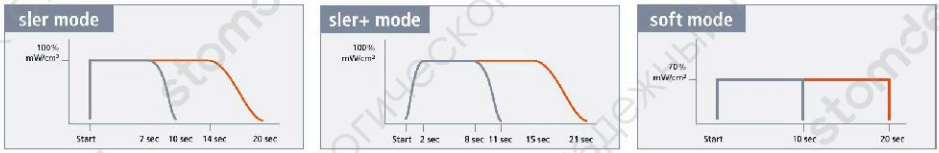


Fig. 3

04.4 Instructions for use

The 'starlight s SLER' allows for the use of 3 types of light emission (Fig. 3):
- **SLER:** light emission at maximum intensity with SLER function at cycle end;
- **SLER+:** increased emission of light intensity during the first 2 seconds up to maximum value and SLER function at cycle end;
- **SOFT:** emission 70% of maximum power for whole cycle.

Selecting 10/11-second exposure.
- Briefly press and release the 'start' button on the handpiece (Fig. 2 - Ref. A) to begin the exposure cycle. An acoustic warning will sound (1 beep).
- After 10/11 seconds, an acoustic warning will sound (1 beep). The cycle is complete.

Selecting 20/21-second exposure.
- Press and hold the 'start' button on the handpiece (Fig. 2 - Ref. A) for 2 seconds to begin the exposure cycle. An acoustic warning will sound as the cycle starts and, after 2 seconds, another warning will sound to confirm the start of the 20/21-second cycle.
- After 10 seconds, an acoustic warning will sound (1 beep).
- After 20/21 seconds, an acoustic warning will sound (1 beep). The cycle is complete.

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NOTE: Cycle interruption.
In all modes, the exposure cycle can be interrupted at any time by pressing the 'start' button on the handpiece (Fig. 2 - Ref. A).

NOTE: Subsequent exposures.
At the end of each exposure, further subsequent cycles can be carried out by pressing the 'start' button on the handpiece (Fig. 2 - Ref. A), each time.

04.5 Safety protection

In the event of particularly onerous use, with long and repeated exposure times, thermal protection intervenes automatically. An acoustic warning will sound (3 beep). The intervention of the protection temporarily inhibits use of the lamp for a few minutes.
Replace the equipment and wait 10 minutes before re-using.

05.0 Cleaning, disinfecting and sterilising

05.1 Cleaning and disinfecting the 'starlight s SLER' handpiece

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

⚠ **DANGER: Do not spray liquids directly onto the surface or electrical contacts.**

⚠ **DANGER: The handpiece cannot be sterilised.**

After each treatment, carry out the following operations:
1 Remove the optic fibre and optical protection of the handpiece.
2 Clean and disinfect the handpiece surface using a cloth dampened with a non-aggressive, pH-neutral (pH7) detergent/disinfectant solution. Carefully follow the instructions given by the manufacturer of the disinfectant solution. Allow the disinfectant solution to air dry prior to using the handpiece. Above all, ensure that electrical contacts are properly dry.

NOTE: Water-based disinfectant solutions with a neutral pH are highly recommended. Some alcohol-based disinfectants may harm or damage plastic materials.

05.2 Sterilisation procedures

⚠ **WARNING: Only use a steam autoclave for sterilisation. A maximum temperature of 135°C for 20 minutes, may be used.**
Do not use any other type of sterilisation procedure (dry heat, radiation, ethylene oxide, gas, low-temperature plasma, etc.).

⚠ **DANGER: The handpiece cannot be sterilised.**

⚠ **DANGER: Infection control - Sterilisable parts.**
To avoid bacterial or viral infection, always clean, disinfect and sterilise the following components after each treatment:
1 Optic fibre;
2 Optical protection.

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These components are made from 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 UNI EN ISO 17665-1:2007 and UNI EN 556-1:2002 standards.

05.3 Cleaning, disinfecting and sterilising the optic fibre

⚠ **WARNING: Do not use sharp instruments to clean the optic fibre.**

Carry out the following operations:
1 Use alcohol to remove any residues of polymerised compounds from the optic fibre surface.
2 Disinfect the surface using a cloth dampened with a non-aggressive, pH-neutral (pH7) detergent/disinfectant solution.
3 Dry.
4 Seal the optic fibre individually in a disposable bag.
5 Sterilise the optic fibre in a steam autoclave.

05.4 Cleaning, disinfecting and sterilising the optical protection

⚠ **WARNING: Do not use sharp instruments to clean the optical protection.**

Carry out the following operations:
1 Clean and disinfect the surface using a cloth dampened with a non-aggressive, pH-neutral (pH7) detergent/disinfectant solution.
2 Dry.
3 Seal the optical protection individually in a disposable bag.
4 Sterilise the optical protection in a steam autoclave.

06.0 Disposal procedures and precautions

- This appliance 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 above points may incur penalties in accordance with Directive 2002/06/EC.

⚠ **DANGER: Hospital waste.**
Treat the following items as hospital waste:
- Optic fibre, when worn or broken
- Optical protection, when worn or broken

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07.0 Symbols


Warning: read the instructions for use


Class II device


Type 'BF' applied part


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


Manufacturer


Apparatus complies with directive EC 93/42 EEC
EN 60601-1 and EN 60601-1-2 inclusive

08.0 Troubleshooting

08.1 Quick troubleshooting guide

If the device does not seem to be working properly, read the instructions again and then check the following table.

PROBLEM	POSSIBLE CAUSE	SOLUTION
During the exposure cycle, an acoustic signal sounds (3 beeps) and at the end of the cycle, the 'starlight s SLER' will not allow you to perform any further treatment.	Thermal protection intervention.	You will only be able to re-activate the device after it has cooled. Wait approximately 10 minutes before re-using the device.
When the 'start' button is pressed, an acoustic warning sounds (4 beeps) and the device does not emit light.	The temperature control circuit reports a failure.	Contact a Mectron service centre.
When the 'start' button is pressed, the mode selection LED flashes. The device does not emit light, or the intensity of the light emitted is unsuitable.	The control circuit reports an LED failure.	Contact a Mectron service centre.
Polymerisation is insufficient.	The tip surface of the optic fibre is dirty.	See paragraph '05.3'.

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08.2 Diagnostic system and possible solutions

The device is equipped with a diagnostic circuit that allows for the identification of function problems.

4 beeps	**The temperature control circuit reports a failure.** The devices does not emit light. - Contact a Mectron service centre.
3 beeps	**The control circuit reports reaching maximum LED temperature.** The devices does not emit light. - Replace the equipment and wait 10 minutes before re-using.
Mode selection LED flashing.	**The control circuit reports an LED failure.** The device does not emit light, or the intensity of the light emitted is unsuitable. - Contact a Mectron service centre

08.3 Method for sending the device and accessories for repair

Should it become necessary to send the device, optic fibre or accessories to an authorised Mectron service centre, please comply with the following rules of good conduct:

1 Clean the device, optic fibre and accessories in accordance with the instructions given in the chapter '05.0 Cleaning, disinfection and sterilising';
2 Sterilise the sterilisable parts in accordance with the instructions given in the chapter '05.0 Cleaning, disinfection and sterilising':
   - Optic fibre;
   - Optical protection.
3 Leave the parts sterilised in the bag certifying completed sterilisation;
4 If the device is still under warranty, attach a photocopy of the purchase document;
5 Where possible, send in original packaging or otherwise appropriately packaged, to avoid damage during transport.

The above requests (points 1 and 2) are in compliance with current requirements concerning the protection of health and safety in the workplace, as per Italian legislative decrees 626/94 and 81/08 and subsequent amendments.
Should you fail to comply with these requests (points 1 and 2), Mectron reserves the right to charge cleaning and sterilising costs back to you, or to refuse the goods delivered for repair in unsuitable conditions.

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09.0 Technical data

Device complies with Dir. 93/42/EEC:	Class I.
Class according to EN 60601-1:	II BF type IP 20 (Device)
Handpiece for intermittent operation:	120” ON 40” OFF.
Voltage supply:	24 V AC ± 10 % 50/60 Hz. 33 V DC ± 10 % supply double insulation
Max. power absorbed:	9 W.
Fuse:	315 mA T (Not included in Mectron supply)
Light source:	High-luminosity LED with optics. Dominant wavelength: 440 - 465 nm Average life media: 1,800,000 cycles of 20 seconds each.
Optic fibre supplied:	Diameter 8 mm. Composition: Drawn coherent fibres surface in transparent quartz. Steriliser sterilisable (T.max 135 °C for 20 minutes - max. 500 cycles).
Exposure:	**SLER:** Exposure time 10/20-seconds SLER function at cycle end **SLER+:** Exposure time 11/21-seconds Gradual increase during first 2 seconds SLER function at cycle end **SOFT:** Exposure time 10/20-seconds Light emission at 70% of maximum power. Possibility of cycle interruption or repetition at all times.
Environmental use conditions:	from 10 °C to 40 °C Relative humidity from 30% to 75%
Transport and storage conditions:	from -10°C to 70 °C Relative humidity from 10% to 90% Air pressure P: 500hPa/1060hPa
Weight and dimensions:	‘starlight s SLER’ handpiece: 122 g L 141 mm Ø max 25 mm

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09.1 Electromagnetic compatibility EN 60601-1-2

⚠ **DANGER: Contraindications. Interference by other equipment.**
An electrosurgical knife of other electrosurgical devices near the device, may interfere with its correct functioning.

⚠ **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 s SLER' is intended for use in the electromagnetic environment specified below. The customer or user of the 'starlight s SLER' should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - Guidance**
RF emissions CISPR 11	Group 1	The 'starlight s SLER' only uses RF energy for internal function. Therefore, its FR emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class B	The 'starlight s SLER' 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 s SLER' is intended for use in the electromagnetic environment specified below. The customer or user of the 'starlight s SLER' should ensure that it is used in such an environment.			
Immunity test	**Test level IEC 60601**	**Compliance level**	**Electromagnetic environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	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	±1 kV differential mode ±2 kV common mode	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 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	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	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a commercial or hospital environment.
N.B.: U_T is the AC mains voltage prior to application of the test level.			

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Guidance and manufacturer's declaration - Electromagnetic immunity			
The 'starlight s SLER' is intended for use in the electromagnetic environment specified below. The customer or user of the 'starlight s SLER' should ensure that it is used in such an environment.			
Immunity test	**Test level IEC 60601**	**Compliance level**	**Electromagnetic environment - Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the device including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Veff from 150 kHz to 80 MHz	3 Veff	$d = 1,2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m from 80 MHz to 2,5 GHz	3 V/m	$d = 1,2 \sqrt{P}$ da 80 MHz a 800 MHz $d = 2,3 \sqrt{P}$ da 800 MHz a 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], may be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

N.B.:

(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 any reasonable 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 s SLER' is used exceeds the applicable RF compliance level given above, the 'starlight s SLER' 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 s SLER'.

b Over the frequency range from 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 s SLER'

The 'starlight s SLER' is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the 'starlight s SLER' can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile FR communications equipment (transmitters) and the 'starlight s SLER' as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter 'W'	Separation distance according to the frequency of transmitter 'm'		
	from 150 kHz to 80 MHz $d = 1,2\sqrt{P}$	from 80 MHz to 800 MHz $d = 1,2\sqrt{P}$	from 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 calculated 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.
N.B.:
(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.

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10.0 Warranty

Before marketing, all MECTRON equipment undergoes a thorough final check to ensure that it is in proper working order.
MECTRON guarantees its products, purchased new from a MECTRON dealer or importer, as free from manufacturing or material flaws for a period of 3 (THREE) YEARS, as from 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 will not accept any liability for direct or indirect personal injury or damage to property 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 the instructions and requirements described in this manual.
- If the wiring systems 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 section on technical data.

The warranty excludes accidental damages due to transport, incorrect use or carelessness, or to connection to power supplies other than those envisaged, and damage to the warning lights, handpieces and all accessories.
The warranty will no longer apply if the apparatus has been tampered with or repaired by unauthorised personnel.

WARNING

The warranty is only valid 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 apparatus to be repaired to the MECTRON dealer/importer from whom it was purchased, At his own expense.
The apparatus should be returned suitably packed (if possible, in its original packing), together with all the accessories and a sheet or card bearing the following information:

a) Owner's details, including telephone number.
b) Details of the dealer/importer.
c) Photocopy of the consignment note/purchase invoice of the apparatus issued to the owner and indicating, in addition to the date, the name of the apparatus 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.

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

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stomdevice

mectron

medical technology

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