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 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 Manufacturers from any liability in respect of any harm or damage to persons or property.

The information and illustrations contained in this manual are up-dated to the date of publication indicated on page 16. 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 apparatus

The Starlight s is an apparatus 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 s 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 Starlight s 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

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 or contact the manufacturer.

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.

⚠️ 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.

⚠️ 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 authorised to receive treatment with the Starlight s.

⚠ 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 “05.0” 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 “05.0” 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 apparatus. 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.).
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 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 Starlight s handpiece

The Starlight s handpiece serial number is engraved on its connector (Fig.1 - Ref.E).
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 apparatus

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

03.2 List of material included in the standard supply

1 Starlight s handpiece (Fig.1 - Ref.A).
1 Optical fibre (Fig.1 - Ref.B).
1 Optical protection (Fig.1 - Ref.D).
1 Starlight s cord 180 cm long (Fig.1 - Rif.F).

This equipment may vary at the time of promotional campaigns.
04.0 Installation

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 (anaesthetic 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 that there is sufficient air circulating around the apparatus.

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

⚠️ **DANGER:** The voltage of the line used to power the appliance must be compatible with the rating plate data.

⚠️ **WARNING:** If long leads are required, use wires with a suitable cross section not inferior to 0.5 mm².

04.2 Connecting the appliance

The appliance has no particular installation requirements. We advise following the connection diagram in Figure 2, where the power supply is 24Vac ±10% or 33 Vdc ±10%, controlled by the contact on the quiver, protecting the line with a fuse.

![Connection Diagram]

Supply voltage
24 Vac ± 10% 50/60 Hz
or 33 Vdc ± 10%

 Fuse  
 T 315 mA

Quiver

Terminal board

Black

Red

White

Tearing-resistant line

Starlight s cord

Fuse carrier, fuse, quiver and terminal board are not included in the Mectron supply.

Fig. 2
05.0 Disposal procedures and precautions

- 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 2002/96/EC;

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

06.0 Symbols

N.B.: Please read carefully the instructions for use

Class II apparatus

Type “BF” applied part”

Manufacturer

This device and its accessories shouldn’t be disposed or treated as solid urban waste

Apparatus in accordance with EC Directive 93/42 EEC
Including EN 60601-1 and EN 60601-1-2.
Notified body: CERMET

07.0 Problem-solving

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

<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>POSSIBLE CAUSE</th>
<th>SOLUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>An acoustic signal (3 beeps) is heard during the exposure cycle and at the end of the cycle Starlight s will not enable any further treatment to be carried out.</td>
<td>The thermal protection has been activated.</td>
<td>It will be possible to use the apparatus only after it has cooled down.</td>
</tr>
<tr>
<td>The polymerisation is insufficient.</td>
<td>The surface of the tip of the optical fibre is soiled.</td>
<td>See point “05.3”</td>
</tr>
</tbody>
</table>
08.0 Technical specifications

this apparatus complies with Directive 93/42/EEC:
Class IIa

Class according to EN 60601-1:
II
Type BF
IP 20 (Device)

Handpiece for intermittent operation: 120” ON 40” OFF.

Supply voltage:
24 Vac ± 10 % 50/60 Hz.
33 Vdc ± 10 %

Max. absorbed power: 9 W.

Fuse: 315 mA T (Not included in the Mectron supply)

Source of light:
High-luminosity LED with optics.
Dominant wavelength: 440 - 465 nm
Average life media: 1,800,000 cycles of 20 seconds each.

Optical fibre included in the supply: Diameter 8 mm.
Composition: Drawn coherent fibres surfused in transparent quartz.
Autoclave sterilisable (max. temp. 135 °C for 20 minutes - max. 500 cycles).

Exposure:
Fast: Exposure time 10 seconds
- Acoustic signals indicating start and end of exposure
Slow rise: 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.

Operating 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: 500 hPa/1060 hPa

Weights and dimensions:
Starlight s handpiece: Weight 65 g
L 148 mm Ø max 22 mm
08.1 Electromagnetic compatibility EN 60601-1-2

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group 1</td>
<td>The STARLIGHT S 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.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class B</td>
<td>The STARLIGHT S 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.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations / flicker</td>
<td>Complies</td>
<td></td>
</tr>
<tr>
<td>emissions</td>
<td>IEC 61000-3-3</td>
<td></td>
</tr>
</tbody>
</table>
The STARLIGHT S is intended for use in the electromagnetic environment specified below. The customer or the user of the STARLIGHT S should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>±6 kV contact ±8 kV air</td>
<td>±6 kV contact ±8 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.</td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge</td>
<td>±1 kV differential mode ±2 kV common mode</td>
<td>±1 kV differential mode ±2 kV common mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines</td>
<td>&lt;5 % (U_r) (&gt;95 % dip in (U_r)) for 0,5 cycle 40 % (U_r) (60 % dip in (U_r)) for 5 cycle 70 % (U_r) (30 % dip in (U_r)) for 25 cycle</td>
<td>&lt;5 % (U_r) (&gt;95 % dip in (U_r)) for 0,5 cycle 40 % (U_r) (60 % dip in (U_r)) for 5 cycle 70 % (U_r) (30 % dip in (U_r)) for 25 cycle</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

NOTE: \(U_r\) is the a.c. mains voltage prior to application of the test level.
Guidance and manufacturer’s declaration - Electromagnetic immunity

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

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>IEC 61000-4-6</td>
<td>3 Veff 150 kHz to 80 MHz</td>
<td>3 Vrms</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>IEC 61000-4-3</td>
<td>3 V/m 80 MHz to 2,5 GHz</td>
<td>3 V/m</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Recommended separation distance $d = 1,2 \sqrt{P}$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$d = 2,3 \sqrt{P}$ 800 MHz to 2,5 GHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 S is used exceeds the applicable RF compliance level above, the STARLIGHT S 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.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
The STARLIGHT S is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the STARLIGHT SO can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the STARLIGHT S as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter “W”</th>
<th>Separation distance according to frequency of transmitter “m”</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td></td>
<td>$d = 1,2 \sqrt{P}$</td>
</tr>
<tr>
<td>0,01</td>
<td>0,12</td>
</tr>
<tr>
<td>0,1</td>
<td>0,38</td>
</tr>
<tr>
<td>1</td>
<td>1,2</td>
</tr>
<tr>
<td>10</td>
<td>3,8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

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.
Before being placed on the market, all MECTRON equipment undergoes a thorough final check to ensure that it is 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 apparatus 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 apparatus to be repaired to the MECTRON dealer/importer from which it was purchased, at his own expense.
The apparatus 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 apparatus issued to the owner and indicating, in addition to the date, also 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.