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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 20.

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 head. 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.

\triangle 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.

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).

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: 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

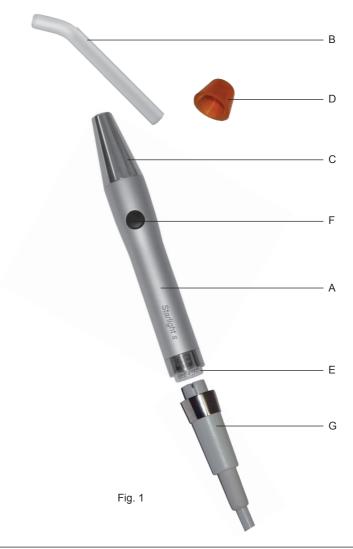
01.1 Identification data

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).



02.1 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).

This equipment may vary at the time of promotional campaigns.

04.1 Description of the controls and signalling lamps

Description of the controls (Fig. 1):

Ref. F - Push-button for activating and cutting off the emission of light.

Function: This starts or stops a polymerisation cycle.

Description of the acoustic signals of the handpiece (Table 1):

Function	Push-button control	Acoustic signal	
Fast polymerisation	Brief pressure of push button	1 beep on starting exposure 1 beep on completing exposure (10 seconds)	
Slow Rise polymerisation	Pressure of push button for at least 2 seconds.	1 beep when starting and 1 beep after 2 seconds 1 beep after 10 seconds of exposure 1 beep on completing exposure (20 seconds)	
Interruption of exposure cycle Pressure of push button during exposure 1		1 beep	
Thermal protection signal		3 beep during the exposure cycle.	

04.2 Connecting the accessories

⚠ DANGER: Check the condition of the device before the treatment.

Before each treatment, always make sure that the apparatus is working properly and check the efficiency of the accessories. If any improper functioning is noted, do not proceed with the treatment. If the problem concerns the apparatus contact an authorised technical assistance centre.

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 "05.0" very carefully.

In order to use the Starlight's, the following accessories have to be connected:

- 1 Fit the optical fibre into the handpiece. Do this by hand, rotating it slightly in a clockwise direction until it reaches the end of travel.
- 2 Fit the optical protection onto the optical fibre by hand.
- 3 Connect properly the starlight's handpiece to the cord and make sure that the electrical contacts of both are thoroughly dry. If necessary dry them with the syringe.

04.3 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.

 \triangle 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.

04.4 Instructions for use

The Starlight's can be used in two different modes:

- Fast: exposure time of 10 seconds at the maximum light intensity.
- Slow rise: exposure time 20 seconds with a gradual increase of the light intensity during the first 3 seconds up to the maximum intensity.

Selecting the Fast exposure mode.

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

Selecting the Slow Rise exposure mode.

- To start the Slow Rise exposure cycle hold the push button on the handpiece down for 2 seconds (Fig.1 Ref.F). At the start an acoustic signal will be heard and after 2 seconds another acoustic signal to confirm the Slow Rise cycle beginning.
- After 10 seconds an acoustic signal will be heard (1 beep).
- After 20 seconds an acoustic signal will be heard (1 beep). The Slow Rise cycle has been completed.

NOTE: Interrupting the cycle.

Both in the Fast and in the Slow Rise mode, the exposure cycle can be broken off at any time by pressing the push button on the handpiece (Fig.1 - Ref.F).

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.1 - Ref.F).

For a quick guide to the signalling, see Tables 1.

04.5 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.

05.0 Cleaning, disinfection, sterilisation

05.1 Cleaning and disinfecting the starlight's handpiece

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

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

⚠ DANGER: The handpiece should not be sterilised.

Proceed as follows after each treatment:

- 1 Remove the optical fibre and optical protection from the handpiece.
- 2 Clean and disinfect the surface of the handpiece using a cloth moistened with a solution of mild detergent/disinfectant having a neutral pH (pH = 7). Follow carefully the instructions provided by the manufacturer of the disinfectant solution. Allow the disinfectant solution to dry in air before using the handpiece again. 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.

05.2 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.

The above components are made of materials that will withstand a maximum temperature of $135\ ^{\circ}\text{C}$ for maximum of 20 minutes.

The autoclave sterilisation process must be carried out using either of the following parameters:

- Cycle at 121°C for 16 minutes;
- Cycle at 134°C for 4 minutes.

All the stages of sterilisation must be carried out by the operator in accordance with EN ISO 17665-1:2006 and EN 556-1:2001 standards.

05.3 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.

05.4 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.

06.0 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

07.0 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

08.0 Problem-solving

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

PROBLEM	POSSIBLE CAUSE	SOLUTION	
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.	The thermal protection has been activated.	It will be possible to use the apparatus only after it has cooled down.	
The polymerisation is insufficient.	The surface of the tip of the optical fibre is soiled.	See point "05.3"	

09.0 Technical specifications

this apparatus complies with Directive 93/42/EEC:

Class IIa.

Class according to EN 60601-1:

Type BF

IP 20 (Device)

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

Supply voltage: According to the instructions given by the dental

unit manufacturer.

Max. absorbed power: According to the instructions given by the dental

unit manufacturer.

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).

Esposure: 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

I 148 mm Ø max 22 mm

09.1 Electromagnetic compatibility EN 60601-1-2

Guidance and manufacturer's declaration - Electromagnetic emissions				
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.				
Emissions test	Compliance	Electromagnetic environment - Guidance		
RF emissions CISPR 11	Group 1	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.		
RF emissions CISPR 11	Class B	The STARLIGHT S is suitable for use in all establishments, including domestic establishments and those directly connected		
Harmonic emissions IEC 61000-3-2	Class A	to the public low-voltage power supply network that supplies buildings used for domestic purposes.		
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies			

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.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic envi- ronment - 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 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	<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	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 typical commercial or hospital environment.

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.

Immunity test	IEC 60601 test level	Complian- ce level	Electromagnetic environment - Guidance	
			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.	
Conducted RF IEC 61000-4-6	3 Veff 150 kHz to 80 MHz	3 Vrms	Recommended separation distance $d = 1, 2 \sqrt{P}$	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	d = 1,2 √P 80 MHz to 800 MHz d = 2,3 √P 800 MHz to 2,5 GHz	
			where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in metres (m). 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 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.

Recommended separation distances between portable and mobile RF communications equipment and the STARLIGHT S

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.

Rated maximum	Separation distance according to frequency of transmitter "m"			
output power of transmitter "W"	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.

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 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.





Rivenditore - Reseller - Wiederverkäufer - Revendeur - Revendedor





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