mectron
medical technology

USE AND MAINTENANCE MANUAL

EN

PLANMECA
Lumion™ Plus

CE

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Disclaimer
Considering that technical contents continuously evolve and become more specific, even due to the fast developments in methodology, in design and manufacture of its products, MECTRON does not guarantees the completeness of the contents in this document and consequently cannot assume any responsibility for any error or damages of any kind arising out of or in any way connected to the information issued on the product and on the use of the same.

It is understood that it is the responsibility of the user to control the updates that Mectron S.p.A. will make available in a special section of its website.

Where required, Mectron S.p.A. undertakes to release paper copy of the updates.

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1 INTRODUCTION

Carefully read this manual before proceeding with installation operations, use, maintenance or other intervention operations on the device.
Always keep this manual at hand.

Important: To avoid damages to persons or things, read with particular attention all the paragraphs “Safety Requirements” present in the manual.

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According to the degree of severity the safety requirements are classified with the following indications:

⚠ **WARNING:** Always referred to damage to persons

⚠ **CAUTION:** Referring to possible damages to things

The aim of this manual is to make the operators aware of the safety regulations, installation procedures, instructions for proper use and maintenance of the device and its accessories.
Use of this manual for aims other than those strictly linked to the installation, use and maintenance of the device is prohibited.
The information and illustrations in this manual were updated on the edition date shown on the last page.
MECTRON is engaged in continuously updating its products with possible changes to the components of the device.
In case you encounter discrepancies between the descriptions found in this manual and the device in your possession you can:

- check for any available updates in the s*ection MANUALS of MECTRON website*[1];
- ask clarifications to Your Dealer;
- contact MECTRON After Sales Service.

1 manuals.mectron.com

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1.1 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.
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 device may be used only in a dentist's surgery or out-patient's department where there are no inflammable gases (anaesthetic mixtures, oxygen, etc.).

1.2 Description of the Device

PLANMECA Lumion™ Plus is an device 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 PLANMECA Lumion™ Plus is used to activate the camphorquinone photoinitiator.

1.2.1 Patient Group Directions

This medical device is designed to be used with the following patient population:

- Children;
- Adolescents;
- Adults;
- Elderly.

This medical device can be used on any patient (if applicable) of any age, weight, height, gender and nationality.

1.2.2 Patient Selection Criteria

The use of the device is not recommended in the following cases:

1. Patients with active implantable medical devices (for example: hearing aids and/or other electromagnetic prostheses) without the prior authorization of their doctor;
2. Patients with a history of light stimulation, for example in photoexposure dermatitis and/or porphyrias, etc. or who are being treated with photosensitizing drugs. In all cases of possible risk, consult a specialist doctor;
3. Patients whose medical history shows pathologies of the retina must first consult the ophthalmologist to receive authorization for treatment with the MECTRON curing light.

⚠ **WARNING:** Adopt strict safety measures for patients who have undergone cataract surgery and are therefore particularly sensitive to light (for example, safety glasses that filter out blue light).

All models of curing lights are intended for professional use only. Therefore, the user is the only person able to decide if and how to treat their patients.

⚠ **WARNING: Contraindications.** In all cases of potential risk, a specialist doctor must be consulted.

1.2.3 Indications for Use

The use of the device is indicated for all the intended patients (see *Chapter 1.2.1 on page 2*) for whom a polymerization treatment of light-curing dental materials is prescribed, by the treating physician, within the intended use of the device (see *Chapter 1.1 on page 2*).

1.2.4 Users

The device must be used only by specialised and properly trained personnel, such as the dentist and/or assistant, adults of any weight, age, height, gender and nationality, able-bodied. No specific training activities are required for the use of the device.

1.3 Disclaimer

The manufacturer MECTRON disclaims all responsibility, express or implied, and cannot be held responsible for direct or indirect personal injury and/or property damage, occurring as a result of incorrect procedures linked to the use of the device and its accessories.
The manufacturer MECTRON cannot be held responsible, expressly or by implication of any type of injury to persons and/or damage to things, carried out by the user of the product and its accessories and happened by way of example and not of limitation, in the following cases:

- Misuse or use during procedures other than those specified in the destination of use of the product;
- The environmental conditions for preservation and storage of the device are not complying with the requirements indicated in *Chapter 9 on page 17*;
- The device is not used in accordance with all the instructions and requirements described in this manual;
- The electrical system of the places where the device is used do not comply with the laws in force and the related regulations;
- Assembly operations, extensions, re-adjustments, upgrades and repairs of the device are carried out by personnel not authorized by MECTRON;
- Misuse, abuse, abnormal use, negligent use, intentional misconduct or use exceeding the limits of the device indicated and allowed and/or normal wear or deterioration, ill-treatment and/or incorrect interventions;
- Any attempt to tamper with or modification of the device under every circumstance;
- Breach of the requirements and the information contained in *Chapter 5 on page 11 of* this manual;
- Unauthorized repairs in accordance with the indications contained in *Chapter 10 on page 27* of this manual.

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1.4 Safety Requirements

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

⚠ **CAUTION:** The electrical system of the premises in which the device is installed and used must comply with the rules in force and the relevant requirements of electrical safety.

⚠ **WARNING: Qualified and specialised personnel.**
The device must be used exclusively by specialized personnel with proper medical culture; no training activities are foreseen for the use of the device. The use of the device does not cause side effects if it is used correctly.

⚠ **WARNING: Intended use.**
Use the device solely for the purpose for which it is intended (see *Chapter 1.1 on page 2*). 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 device.

⚠ **WARNING: Contraindications.**
Do not use the device on patients with Pacemakers or other implantable electronic devices. This regulation also applies to the operator.

⚠ **WARNING: Point the beam of light directly at the material to be polymerised.**
Do not point 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..

⚠ **WARNING: Never point the beam of light on the eyes.**
The effect of the light should be limited to that part of the oral cavity to be clinically treated.

⚠ **WARNING: Contraindications.**
Do not use this device 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.

⚠ **WARNING: 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).

⚠ **WARNING: 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 device.

⚠ **CAUTION: Photobiological safety of the curing lights and lamp systems IEC 62471.**
According to the Standard IEC 62471, the device results in risk class 2 (moderate risk) concerning a retinal risk from blue light or thermal retinal risk.
The following CAUTION indication is applied to the device package.

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Risk Group 2
CAUTION. Possibly hazardous optical radiation emitted from this product. Do not stare at operating lamp. May be harmful to the eye
Product tested against IEC62471

⚠ **WARNING: 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 in *Chapter 5 on page 11* strictly.

⚠ **WARNING: 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 in *Chapter 5 on page 11*.

⚠ **WARNING:** Use only original MECTRON accessories and spare parts.

⚠ **WARNING: Checking the condition of the device before treatment.**
Before each treatment always check that the device 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 the problems concern the device contact an authorised technical service centre.

⚠ **WARNING: Risk of explosions.**
The device cannot operate in environments where there are saturated atmospheres of flammable gases (anaesthetic mixtures, oxygen, etc.).

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

⚠ **CAUTION:** In case the final user, operating in their own medical room or surgery, in order to comply with mandatory requirements, must periodically inspect the device present in the surgery, the test procedures to apply to medical electrical equipment and medical electrical systems for the safety assessment must be carried out following the standard EN 62353 'Medical electrical equipment - Periodic inspections and tests to be carried out after repair of medical electrical equipment'. The interval for periodic checks, in the intended operating conditions and described in this "Use and Maintenance" manual, is one year or 2000 hours of use, depending on which of these two conditions occurs first.

⚠ **WARNING:** If an adverse event and/or serious incident attributable to the device occurs during correct and intended use, it is recommended to report it to the Competent Authority and to the manufacturer indicated on the product label.

2 IDENTIFICATION DATA

A correct description of the model and of the serial number of the device will allow the After Sales Service to provide fast and effective answers.
Always provide this information every time that you contact MECTRON After Sales Service.

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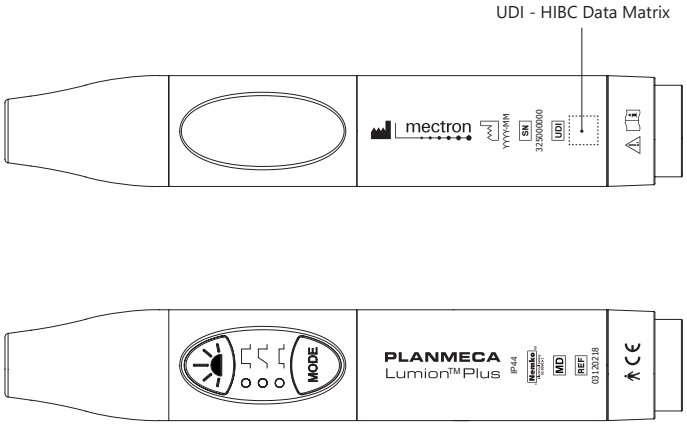
2.1 Identification Data of the Handpiece

On the handpiece are lasermarked the traceability data, UDI code included. (see figure below).

NOTE: The complete list of symbols and their description are shown in *Chapter 7 on page 14*.



3 DELIVERY

The packaging of the device cannot undergo strong impacts as contains electronic components, therefore the transport and the storage must be carried out with particular care.
All the material shipped by MECTRON is controlled at the time of dispatch.
The device is shipped appropriately protected and packaged.
Upon receipt of the device, check for any possible damage caused during transport and in case any damage and/or defects is found, complain to the transporter.
Keep the packaging in case there is a necessity to send any item to a MECTRON Authorized Service Centre and to store the device during long periods of inactivity.

3.1 List of Components

Refer to the following figure:

A. 1 PLANMECA Lumion™ Plus handpiece;

B. 1 Optical fibre;

C. 1 Optical protection.

These components can also be ordered separately.

NOTE: The components included in the package may vary in occasion of promotional campaigns.

4 USE

4.1 Connecting the Accessories

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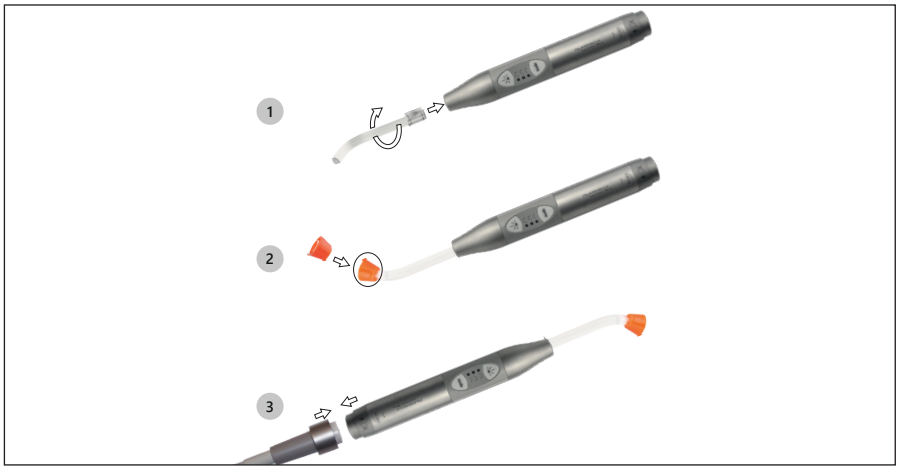
⚠ **WARNING: Check the condition of the device before the treatment.** Before each treatment, always make sure that the device is working properly and check the efficiency of the accessories. If any improper functioning is noted, do not proceed with the treatment. If the problem concerns the device contact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

⚠ **WARNING: Infections control.** For maximum safety of the patient and of the operator, before each treatment, clean, disinfect and sterilise the optical fibre and the optical protection. Carefully follow the instructions provided in *Chapter 5 on page 11*.

Before using the PLANMECA Lumion™ Plus proceed as follows (see figure below):

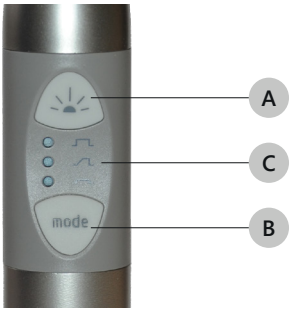
1. Manually insert the optic fibre onto the handpiece, applying gentle pressure. If necessary, rotate until it clicks into place;
2. Fit the optical protection onto the optical fibre by hand.
3. Correctly insert PLANMECA Lumion™ Plus onto the cord, checking that the electrical contacts of both parts are completely dry. Dry with an air syringe if necessary.



4.2 Descriptions of Commands and Signalling

For the descriptions of commands and signalling, refer to the figure and the following tables.

Ref.	Name	Description
A	**Start** button	Starts or stops a polymerisation cycle.
B	**Mode** button	Allows selecting the exposure type. By repeatedly pressing the button, in the order are selected: FAST, SLOW RISE, SOFT
C	Green Mode LED	Indicates the selected exposure. From left to right: FAST, SLOW RISE, SOFT



Selected function via Mode button	Signalling	Exposure Type	Exposure Time
FAST Polymerisation	Left LED ON	Maximum power emitted.	10 sec. 20 sec.
SLOW RISE Polymerisation	Middle LED ON	Increased emission during first two seconds. Maximum emission power	10 sec. 20 sec.
SOFT Polymerisation	Right LED ON	Emission 70% of maximum power for whole cycle	10 sec. 20 sec.

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4.3 Safety Requirements During Use

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

⚠ **WARNING: Before each cycle of exposure make sure that the optical fibre is correctly and fully fitted into the handpiece.**

⚠ **WARNING: Before each cycle of exposure always make sure that the optical protection has been fitted onto the end of the optical fibre.**

⚠ **WARNING: 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..

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

⚠ **CAUTION:** 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.

⚠ **WARNING:** During the intervention on the patient, do not perform any maintenance tasks on the system.

4.4 Instructions for Use

PLANMECA Lumion™ Plus allows performing 3 types of exposures:

- **FAST**: light emission at maximum intensity;
- **SLOW RISE**: increased emission of light intensity during the first 2 seconds up to maximum value;
- **SOFT**: emission 70% of maximum power for whole cycle.

NOTE: Refer to Chapter 4.2 on page 9 for the descriptions of commands.

Selecting the 10-seconds exposure:

1. Press the Start button on the handpiece for a short time. An acoustic signal will be emitted (1 beep).
2. After 10 seconds, an acoustic signal will be produced (1 beep). The cycle has been completed.

Selecting the 20-seconds exposure:

1. Keep pressed the on/off button on the handpiece for 2 seconds. An acoustic signal is emitted when the cycle starts and after 2 seconds.
2. After 10 seconds an acoustic signal will be emitted (1 beep).
3. After 20 seconds an acoustic signal will be emitted (1 beep). The cycle has been completed.

NOTE: Cycle interruption.
In all modes, the exposure cycle can be interrupted at any time by pressing the Start button on the handpiece .

NOTE: Additional exposures.
At the end of any exposure cycle, it is possible to carry out one or more additional cycles by pressing the Start button on the handpiece again each time.

4.5 Safety Protection

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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 emitted and the selected function LED flashes. This protection device will temporarily prevent use of the lamp for a few minutes. Place the device back in its housing and wait about 10 minutes before using it again.

5 CLEANING, DISINFECTION AND STERILISATION

5.1 Cleaning and Disinfecting the Handpiece

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

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

⚠ **WARNING:** Do not spray liquids directly onto its surface and onto the electrical contacts of the charging unit.

After each treatment, proceed as follows:

1. Remove the optical fibre and the optical protection from 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.

⚠ **CAUTION:** Water-based disinfectants with a neutral pH are strongly recommended. Some alcohol based disinfectant solutions may be harmful and cause damage to plastic materials. Do not use as disinfecting agents:

- Very alkaline products (pH > 9);
- Products containing sodium hypochlorite;
- Products containing hydrogen peroxide;
- Products containing abrasive substances;
- Acetone;
- Methylethylketone.

as they can discolour and/or damage the plastic materials.

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5.2 Sterilisation Procedure

⚠ **WARNING:** 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.

⚠ **CAUTION: Carry out sterilisation only in a steam autoclave at a maximum temperature of 135 ° (275 °F) for 20 minutes.** Do not use any other sterilisation procedures (dry heat, radiation, ethylene oxide, gas, low-temperature plasma, etc.).

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

⚠ **WARNING: Infections control - Sterilisable parts.** To avoid infection caused by bacteria or viruses, always clean the following components after each treatment:

- Optical fibre;
- Optical protection.

These components are made of materials able to withstand a maximum temperature of 135 °C (275 °F) for a maximum of 20 minutes.

The sterilization process, in a steam autoclave, guarantees SAL 10^{-6} by setting the parameters indicated below:

- Type of cycle: 3 times Pre-vacum (pressure min. 60 mBar (0.87 psi)).
- Minimum sterilisation temperature: 132 °C (270 °F) (interval 0 °C ÷ +3 °C (32 °F ÷ 37 °F)).
- Minimum sterilisation time: 4 minutes.
- Minimum drying time: 20 minutes.

All stages of sterilisation must be performed by the operator in compliance with the current revision standards: UNI EN ISO 17665-1, UNI EN ISO 556-1 and ANSI/AAMI ST:46.

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5.3 Cleaning, Disinfection e Sterilisation of the Optical Fibre

⚠ **CAUTION:** 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.

5.4 Cleaning, Disinfection e Sterilisation of the Optical Protection

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

Carry out the following operations:

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.

6 DISPOSAL PROCEDURES AND PRECAUTIONS

⚠ **CAUTION: This device contains a LITHIUM-ION battery.** The battery must be disposed of and treated as waste requiring separate collection;

- This device must be disposed of and treated as waste requiring separate collection;
- At the end of the life-cycle of this device, the purchaser is entitled to return the device 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 device WEEE.

⚠ **WARNING: 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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7 SYMBOLS

Symbol	Description	Symbol	Description
CE	Class I device compliant with Regulation (EU) 2017/745.	c Nemko US Electrical Safety ES 60601-1	Nemko brand Compliance with UL - CSA regulations
	Caution		Consult instructions for use or consult electronic instruction for use
	Manufacturer		Date of manufacture
UDI	Unique Device Identifier	HIBC	Health Industry Bar Code
SN	Serial Number	LOT	Batch Number
REF	Catalogue number	#	Model number
MD	Medical Device		Generic warning signal [a]
	Starts or stops a polymerisation cycle		Type B applied part
	Sterilizable up to a max. temperature of 135 °C (275 °F)		Non-sterile
	Direct current		Alternating current
	Temperature limit		Separate collection for waste of electrical and electronic equipment
	Humidity limitation		Atmospheric pressure limitation
	Keep dry		Fragile
IP 44	Protection degree provided by the casing (IEC/EN 60529)		

a) The symbol is represented by a yellow warning triangle and a black graphical symbol.

8 TROUBLESHOOTING

8.1 Quick Troubleshooting Guide

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

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Problem	Possible Cause	Solution
An acoustic signal (3 beeps) is produced during the exposure cycle and at the end of the cycle PLANMECA Lumion™ Plus will not allow any further treatment to be carried out. The selected function LED flashes.	The thermal protection has been activated.	It will be possible to use the device only after it has cooled down. See *Chapter 4.5 on page 11*. 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.
The polymerisation is insufficient.	The terminal surface of the tip of the optical fibre is soiled.	See *Chapter 5.3 on page 13*.

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8.2 Diagnostic System and Possible Solutions

The device is provided with a diagnostic circuit that allows identifying the main operating issues.

Signalling Type	Description	Solution
4 Beep	The temperature control circuit is failed. The device does not emit any light.	Contact a MECTRON service centre.
3 Beep	The control circuit indicates that the maximum LED temperature has been reached. The device does not emit any light.	Place the device back in its housing and wait about 10 minutes before using it again.
Mode LED flashing	The control circuit reports an LED failure. The device does not emit any light, or the intensity of the emitted light is very low.	Contact a MECTRON service centre.

8.3 How to Prepare the Device and the Accessories Before Sending them to Repair

In the event that there is a need to send the device, the optical fiber and accessories to an authorized MECTRON service center, we invite our kind customers to respect the good code of conduct reported in the following:

1. Clean the device, optic fibre and accessories according to the instructions reported in the Chapter 5 on page 11;
2. Sterilse the sterilisable parts according to the instructions reported in the Chapter 5 on page 11:
   - Optic fibre;
   - Optical protection.
3. Leave the sterilised parts in their sterilization pouches that certify the sterilization completion;
4. If the device is still under warranty, attach a copy of the purchase document;
5. Whenever possible, send all the parts in their original packaging or, alternatively, in proper packages, to avoid any damage during the transportation.

The above requirements (points 1 and 2) are in compliance with the current requirements concerning the protection of health and safety in the workplace, as per Italian legislative decrees 81/08 and subsequent amendments.
In the event that the customer does not comply with the requirements (points 1 and 2), MECTRON reserves the right to charge him/her for cleaning and sterilization costs or to reject the items for repair received in unsuitable conditions.

9 TECHNICAL SPECIFICATIONS

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Device compliant with Regulation (EU) 2017/745	Class I
Classification under the IEC 60601-1	The class definition is delegated to the manufacturer of the dental chair incorporating the device. Applied part type B (Optical Fibre)
Classification under the IEC 60529	IP 44 (Device)
Essential performances	According to IEC 80601-2-60 Standard, the device does not provide essential performances.
Handpiece for intermittent operation	60" ON 60" OFF - Max 3 consecutive cycles
Voltage	Power supply compliant to IEC 60601-1 with double insulation. 24 V~ 50/60 Hz or 32 V ⎓
Power Consumption	11 VA
Light source	High power LED with optic. Dominant wavelength: 440 - 465 nm LED in Class 2 (IEC 62471) retinal risk from blue light or thermal retinal risk.
Optical fibre	Diameter 8 mm (0.32 in). Composition: Drawn coherent fibres surfused with transparent quartz. Autoclave sterilisable (max. temp. 135 °C (275 °F) for 20 minutes - max. 500 cycles).
Exposures	**FAST**: Exposure time 10/20-seconds Acoustic signal at the beginning and at the end of an exposition cycle; in case of 20 seconds there will be also a signal after 10 seconds of exposition. **SLOW RISE**: Exposure time 10/20-seconds Gradual increase during the first 2 seconds. Acoustic signal at the beginning and at the end of an exposition cycle; in case of 20 seconds there will be also a signal after 10 seconds of exposition. **SOFT**: Exposure time 10/20-seconds Light emission at 70% of maximum power. Acoustic signal at the beginning and at the end of an exposition cycle; in case of 20 seconds there will be also a signal after 10 seconds of exposition. The cycles can be stopped or repeated at any time.

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Operating conditions	from 10 °C to 35 °C (from 50 °F to 95 °F) Relative Humidity from 30% to 75% Air pressure P: 800 hPa/1060 hPa (11.6 psi / 15.37 psi)
Transport and storage conditions	from -10 °C to 60 °C (from 14 °F to 140 °F) Relative Humidity from 10% to 90% Air pressure P: 500 hPa/1060 hPa (7.25 psi / 15.37 psi)
Altitude	less than or equal to 2000 meters (6562 ft)
Weights and dimensions	Handpiece: Weight 102 g (3.6 oz) L 141 mm (5.55 in) Ø max 23 mm (0.91 in)

9.1 Electromagnetic Compatibility IEC 60601-1-2

⚠ **WARNING: Contraindications. Interference with other equipment**
Even if compliant with standard IEC 60601-1-2, PLANMECA Lumion™ Plus may interfere with other devices in the vicinity. PLANMECA Lumion™ Plus must not be used near or stacked with other devices. However, if this is necessary, the correct operation of the device in that configuration, and of all equipment, must be checked and monitored before starting the intervention.

⚠ **WARNING: Contraindications. Interference from other equipment**
An electrosurgical scalpel or other electrosurgical units positioned near the PLANMECA Lumion™ Plus device may interfere with the correct operation of the device itself.

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

⚠ **WARNING:** The use of cables and accessories not supplied by MECTRON, may adversely affect the EMC performances.

9.2 Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The device is designed to operate in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore its RF emissions are very low and probably do not cause any interference with nearby electronic devices.
RF Emissions CISPR 11	Class B	The device 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	
Emissions of fluctuations voltage/flicker IEC 61000-3-3	Compliant	

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9.3 Accessible Parts of the Casing

The device is designed to operate in the electromagnetic environment specified below.
The customer or the user of the device should ensure that it is used in such environment.

Phenomenon	Basic EMC standard or test method	Immunity test levels	Electromagnetic Environment Guidance
Electrostatic discharge (ESD)	IEC 61000-4-2	±8 kV on contact ±2 kV, ±4 kV, ±8 kV, ±15 kV in air	The floor must be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity should be at least equal to 30%.
Radiated RF EM fields [a)]	IEC 61000-4-3	3 V/m [f)] 80 MHz - 2,7 GHz [b)] 80% AM a 1 kHz [c)]	Portable and mobile RF communication devices should not be used near any part of the product, including cables, except when they respect the recommended distances, calculated from the equation applicable at the frequency of the transmitter.
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See *Chapter 9.5 on page 25*	
RATED power frequency magnetic fields [d)]	IEC 61000-4-8	30 A/m 50 Hz o 60 Hz	The magnetic fields at the mains frequency should have levels characteristic of a typical location in a commercial or hospital environment.
Proximity magnetic fields	IEC 61000-4-39	See *Chapter 9.6 on page 26*	Potable and mobile RF communication devices shall be used with a separation distance of at least 0,15 m from the field sources.

a) The interface between the PATIENT physiological signal simulation, if used, and the PLANMECA Lumion™ Plus shall be located within 0,1 m of the vertical plane of the uniform field area in one orientation of the PLANMECA Lumion™ Plus.

b) PLANMECA Lumion™ Plus that intentionally receives RF electromagnetic energy for the purpose of its operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
This test assesses the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when anambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.

c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

d) Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.

e) Void.

f) Before modulation is applied.

9.4 Guidance and Manufacturer's Declaration - Electromagnetic Immunity

9.4.1 Power Connection A.C. Input

The device is designed to operate in the electromagnetic environment specified below.
The customer or the user of the device should ensure that it is used in such environment.

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Phenomenon	Basic EMC standard or test method	Immunity test levels	Electromagnetic Environment Guidance
Electrical fast transients / bursts [l) o)]	IEC 61000-4-4	±2 kV on contact 100 KHz repetition frequency	The quality of the network voltage should be that of a typical commercial or hospital environment.
Surges [b) j) o)] Line-to-line	IEC 61000-4-5	± 0.5 kV, ± 1 kV	The quality of the network voltage should be that of a typical commercial or hospital environment.
Surges [b) j) k) o)] Line-to-ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2kV	The quality of the network voltage should be that of a typical commercial or hospital environment.
Conducted disturbances induced by RF fields [c) d) o)]	IEC 61000-4-6	3 V [m)] 0.15 MHz - 80 MHz 6 V [m)] in the ISM bands between 0.15 MHz and 80 MHz [n)] 80 % AM at 1 KHz [e)]	Portable and mobile RF communication devices should not be used near any part of the product, including cables, except when they respect the recommended distances, calculated from the equation applicable at the frequency of the transmitter.
Voltage dips [f) p) r)]	IEC 61000-4-11	0% UT; 0,5 cycle [g)] At 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 ° and 315 ° [q)]	The quality of the network voltage should be that of a typical commercial or hospital environment.
		0 % UT; 1 cycle e 70 % UT; 25/30 cycle [h)] Single phase: at 0 °	
Voltage interruptions [f) i) o)]	IEC 61000-4-11	0% UT; 250/300 cycle [h)]	The quality of the network voltage should be that of a typical commercial or hospital environment.

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a) Void.

b) All PLANMECA Lumion™ Plus cables are attached during the test.

c) Calibration for current injection clamps shall be performed in a 150 Ω system.

d) If the frequency stepping skips over an ISM or amateur band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

f) ME EQUIPMENT and ME SYSTEMS with a d.c. power input intended for use with a.c.-to-d.c. converters shall be tested using a converter that meets the specifications of the MANUFACTURER of the ME EQUIPMENT or ME SYSTEMS. The IMMUNITY TEST LEVELS are applied to the a.c. power input of the converter.

g) Applicable only to PLANMECA Lumion™ Plus connected to single-phase a.c. mains.

h) E.g. 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.

i) ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase shall be interrupted once for 250/300 cycles at any angle and at all phases at the same time (if applicable). PLANMECA Lumion™ Plus5 with battery backup shall resume line power operation after the test. For ME EQUIPMENT and ME SYSTEMS with RATED input current not exceeding 16 A, all phases shall be interrupted simultaneously.

j) ME EQUIPMENT and ME SYSTEMS that does not have a surge protection device in the primary power circuit may be tested only at ± 2 kV line(s) to earth and ± 1 kV line(s) to line(s).

k) Not applicable to CLASS II PLANMECA Lumion™ Plus.

l) Direct coupling shall be used.

m) r.m.s. , before modulation is applied.

n) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

o) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase and ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase.

p) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase.

q) At some phase angles, applying this test to ME EQUIPMENT with transformer mains power input might cause an overcurrent protection device to open. This can occur due to magnetic flux saturation of the transformer core after the voltage dip. If this occurs, the ME EQUIPMENT shall provide BASIC SAFETY during and after the test.

r) For ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the power input voltage specified in Table 1 - "Power input voltages and frequencies during the tests" of the IEC 60601-1-2:2014/AMD1:2020.

9.4.2 Points of Contact with the Patient

The device is designed to operate in the electromagnetic environment specified below.
The customer or the user of the device should ensure that it is used in such environment.

Phenomenon	Basic EMC standard or test method	Immunity test levels	Electromagnetic Environment Guidance
Electrostatic discharges (ESD) [c]	IEC 61000-4-2	±8 kV on contact ±2 kV, ±4 kV, ±8 kV, ±15 kV in air	The floor must be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity should be at least equal to 30 %.
Conducted disturbances induced by RF fields [a]	IEC 61000-4-6	3 V [b] 0.15 MHz - 80 MHz 6 V [b] in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 KHz	Portable and mobile RF communication devices should not be used near any part of the product, including cables, except when they respect the recommended distances, calculated from the equation applicable at the frequency of the transmitter.

a) The following apply:
- All PATIENT-COUPLED cables shall be tested, either individually or bundled
- PATIENT-COUPLED cables shall be tested using a current clamp unless a current clamp is not suitable. In cases were a current clamp is not suitable, an EM clamp shall be used.
- No intentional decoupling device shall be used between the injection point and the PATIENT COUPLING POINT in any case.
- Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
- Tubes that are intentionally filled with conductive liquids and intended to be connected to a PATIENT shall be considered to be PATIENT-COUPLED cables.
- If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
- The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0, 15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18, 17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29, 7 MHz and 50,0 MHz to 54,0 MHz.

b) R.M.S., before modulation is applied.

c) Discharges shall be applied with no connection to an artificial hand and no connection to PATIENT simulation. PATIENT simulation may be connected after the test as needed in order to verify BASIC SAFETY and ESSENTIAL PERFORMANCE.

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9.4.3 Parts Accessible to the Input / Output Signals

The device is designed to operate in the electromagnetic environment specified below.
The customer or the user of the device should ensure that it is used in such environment.

Phenomenon	Basic EMC standard or test method	Immunity test levels	Electromagnetic Environment Guidance
Electrostatic discharges (ESD) [e]	IEC 61000-4-2	±8 kV on contact ±2 kV, ±4 kV, ±8 kV, ±15 kV in air	The floor must be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity should be at least equal to 30%.
Electrical fast transients / bursts [b] [f]	IEC 61000-4-4	±1 kV on contact 100 KHz repetition frequency	The quality of the network voltage should be that of a typical commercial or hospital environment.
Surges Line-to-ground [a]	IEC 61000-4-5	± 2kV	The quality of the network voltage should be that of a typical commercial or hospital environment.
Conducted disturbances induced by RF fields [d] [g] [j] [K]	IEC 61000-4-6	3 V [h] 0.15 MHz - 80 MHz 6 V [h] in the ISM bands between 0.15 MHz and 80 MHz [i] 80 % AM a 1 KHz [c]	Portable and mobile RF communication devices should not be used near any part of the product, including cables, except when they respect the recommended distances, calculated from the equation applicable at the frequency of the transmitter.

a) This test applies only to output lines intended to connect directly to outdoor cables.

b) SIP/SOPS whose maximum cable length is less than 3 m in length are excluded.

c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

d) Calibration for current injection clamps shall be performed in a 150 Ω system.

e) Connectors shall be tested per 8.3.2 and Table 4 of IEC 61000-4-2:2008. For insulated connector shells, perform air discharge testing to the connector shell and the pins using the rounded tip finger of the ESD generator, with the exception that the only connector pins that are tested are those that can be contacted or touched, under conditions of INTENDED USE, by the standard test finger shown in Figure 6 of the general standard, applied in a bent or straight position.

f) Capacitive coupling shall be used.

g) If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

h) R.M.S., before modulation os applied.

i) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0, 15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18, 17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29, 7 MHz and 50,0 MHz to 54,0 MHz.

j) See IEC 61000-4-6:2013, Annex B, for modified start frequency versus cable length and equipment size.

k) SIP/SOPS whose maximum cable length is less than 1 m are excluded.

9.5 Specifications of the tests for the Immunity of the Accessible Parts of the Casing to the Wireless RF Communications Device

The device is designed to operate in an electromagnetic environment in which radiated RF disturbances are under control. The customer or the user of the device can help prevent electromagnetic interference by ensuring a minimum distance between the mobile and portable RF (transmitters) communication devices and the device, as recommended, in relation to the maximum output power of radiocommunications equipment.

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Test Freq. (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Max power (W)	Distance (m)	Immunity test level (V/m)
385	380 - 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460 FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 Band LTE 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1, 3, 4, 25 UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 Band LTE 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50% duty cycle square wave signal.

c) As an alternative to FM modulation, the carrier may be pulse modulateci using a 50% duty cycle square wave signal at 18 Hz. While it does noi represent actual modulation, it would be worst case.

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the device may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

⚠ **WARNING:** Portable RF communication equipment (including peripheral devices as antenna cables and external antennas) must not be used closer than 30 cm to any part of the device, including the cables specified by the manufacturer. Otherwise, there may be a performance degradation of these devices.

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9.6 Immunity to Proximity Magnetic Fields in the Frequency Range 9 kHz to 13,56 MHz

The following Table reports the test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz.

Test Frequency	Modulation	Immunity test level (A/m)
30 kHz [a)]	CW	8
134,2 kHz	Pulse modulation [b)] 2,1 kHz	65 [c)]
13,56 MHz	Pulse modulation [b)] 50 kHz	7,5 [c)]

a) This test is applicable only to devices intended for use in the HOME HEALTHCARE ENVIRONMENT.

b) The carrier shall be modulated using a 50% duty cycle square wave signal.

c) r.m.s., before modulation is applied.

10 WARRANTY

Before being marketed, all MECTRON devices, are subjected to a thorough final check that verifies the full functionality.
MECTRON warrants its products, purchased new from a MECTRON dealer or importer, against defects in material and workmanship for a period of 2 (TWO) YEARS from the date of purchase. During the period of validity of the warranty, MECTRON undertakes to repair (or, at his free choice, replace) free of charge those parts of products that in their opinion prove being defective. Complete replacement of MECTRON products is excluded.
MECTRON disclaims any responsibility for direct or indirect damage to people or things, in the following cases:

- The device is not used according to the intended use for which it is provided;
- The device is not used in accordance with all the instructions and requirements described in this manual;
- The electrical system of the places where the device is used do not comply with the laws in force and the related regulations;
- Assembly operations, extensions, re-adjustments, modifications, replacements and repairs are carried out by personnel not authorized by MECTRON or in breach of what is provided in this manual also in regard to the origin of the authorised material;
- The environmental conditions for preservation and storage of the device are not complying with the requirements indicated in *Chapter 9 on page 17*;
- The installation or the transport of the device is not performed as specified in this manual or in other documentation provided by MECTRON, or in any case available on the website of the latter;
- The device or the component thereof is purchased from a subject not authorised by MECTRON;
- The device, including its subcomponents, parts or assemblies, are altered or modified with respect to what is provided in this manual.
- Accident, misuse, abuse, abnormal use, negligent use, misconduct or intentional use exceeding the limits recommended and allowed by the device or in the case of normal wear or deterioration of the same.
- If the defect or non-conformity are not been promptly and readily communicated in writing to MECTRON as specified in this manual.
- If the damage, costs or expenses are caused by events of force majeure.
- The connection of the device has been carried out at a voltage different from the one envisaged, including WARNING lights, knobs and all the accessories.

In any case, MECTRON case will not recognize indemnity or compensation for loss of use, inconvenience, loss of profits, loss of business, business opportunities lost, damage to reputation, and any incidental or consequential damages arising out of or relating to the device.

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The expected service life of the device is 5 years, minimum.
The service life/duration does not define a limit of use; the service life of the device defines the period of time, subsequent to installation and/or commissioning, during which the original performances or, in any case, adequate for the intended use are guaranteed, without any degradation occurring such as to compromise its functionality and reliability.
The service life is a minimum qualitative target of the design, therefore, it is not excluded that single parts or components guarantee performances and reliability higher than those declared by the manufacturer.
The service life is intended in compliance with the maintenance plans provided for in this manual, it does not include components normally subjected to "wear" and it is independent of the warranty period: the service life period does not establish any implicit or explicit extension of the warranty period.

CAUTION

The warranty starts from the date of purchase of the device, which evidence is given by the delivery note/purchase invoice issued by the Dealer / Importer or, in case of device with activation code, from the date of activation of the same.
In order to avail of the warranty service, the customer must return, at its own expense, the device to be repaired to the MECTRON Dealer / Importer from which they purchased the product.
The device must be returned together with the original packaging, accompanied by all the accessories and by a form containing:

- The data of the owner and telephone number;
- The data of the Dealer / Importer;
- Photocopy of the delivery note/purchase invoice of the device by the owner where are reported the date, the name of the device and the serial number;
- Description of the failure.

The transport and the damage caused by transport are not covered by the warranty.

mectron
medical technology

Mectron S.p.A.
Via Loreto 15/A
16042 Carasco (Ge) Italy
Tel. +39 0185 35361
Fax +39 0185 351374
www.mectron.com
mectron@mectron.com

Rivenditore - Reseller - Revendeur - Wiederverkäufer

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