mectron
medical technology

USE AND MAINTENANCE MANUAL

MANUALE D'USO E MANUTENZIONE

GEBRAUCHS- UND WARTUNGSANLEITUNG

MODE D'EMPLOI ET D'ENTRETIEN

MANUAL DE USO Y MANTENIMIENTO

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starlight uno

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USE AND MAINTENANCE MANUAL

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SUMMARY

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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 apparatus.
In case you encounter discrepancies between the descriptions found in this manual and the equipment 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 http://mectron.it/en/technical-support/users-manuals/

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

1.2 Description of the Device

starlight uno is an equipment for polymerising photo-hardening composites.
The light source used is a very high-efficiency monochromatic LED.
Unlike traditional halogen lamps, therefore, all the light being emitted by starlight uno is used to activate the camphorquinone photoinitiator.
The device consists of a charging unit with a brightness meter and a handpiece powered by a rechargeable lithium-ion battery that can be removed and replaced directly by the user.
starlight uno 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).

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: pacemakers, 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

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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 11 on page 25*;
- 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 equipment 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 7 on page 18 of* this manual;
- Unauthorized repairs in accordance with the indications contained in *Chapter 12 on page 34* 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 equipment 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 equipment.

⚠ **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 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.

⚠ **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 starlight uno.

ⓘ **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 indications are applied to the device package.

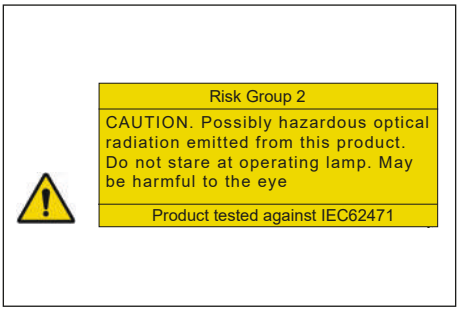

Figure 1 – Photobiological safety

⚠ **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 7 on page 18* strictly.

⚠ **WARNING: Infection control.**
For maximum safety of the patient and of the operator, before each treatment, clean and disinfect the charging unit and the handpiece, clean and sterilise the optical protection and replace the protective sheath. Carefully follow the instructions provided *Chapter 7 on page 18*.

⚠ **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 equipment is in proper working order and that the accessories are efficient. Do not carry out the treatment if any problems are encountered in operating the equipment. If the problems concern the equipment contact an authorised technical service centre.

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

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

ⓘ **CAUTION:** Recharge the battery only with the Mectron charging unit (*Figure 5 at page 8* - Ref. A). Do not attempt to recharge the battery using a generic battery charger. This entails a risk of explosion and fire.

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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 equipment 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.

2.1 Identification Label of the Charging Unit

Each charging unit is provided with an identification label (see Figure 2 at page 6) on which the main technical specifications and the lot number are reported. The identification label is placed to the underside of the equipment. The complete technical data are reported in *Chapter 11 on page 25*.

NOTE: The complete list of symbols is reported in Chapter 9 on page 23.

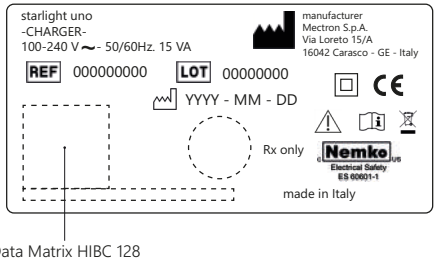

Figure 2 – Identification Label of the Charging Unit

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2.2 Identification Data of the Handpiece

On the handpiece are reported some symbols (see *Chapter 9 on page 23*) and the serial number (see Figure 3 at page 7).

NOTE: The complete list of symbols is reported in Chapter 9 on page 23.

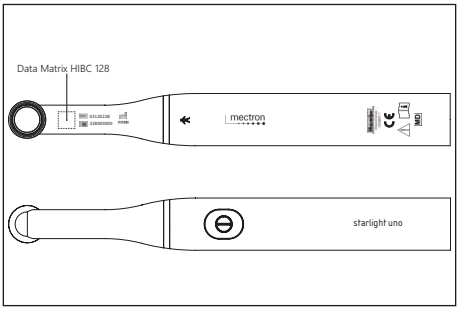

Figure 3 – Identification Data of the Handpiece

2.3 Identification Data of the Battery Module

On each battery module are reported the technical specifications and the batch number (see Figure 4 at page 7).

NOTE: The complete list of symbols is reported in Chapter 9 on page 23.

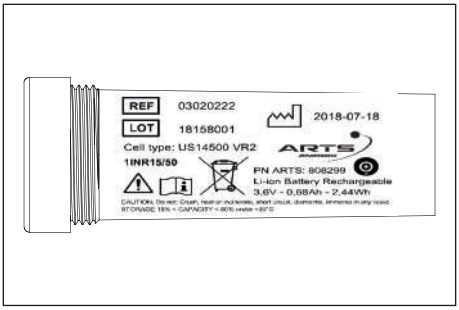

Figure 4 – Identification Data of the Battery Module

3 DELIVERY

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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 Figure 5 at page 8:

A. 1 starlight uno charging unit;
B. 1 starlight uno handpiece;
C. 1 Rechargeable lithium-ion battery module;
D. 1 Optical protection;
E. 50 Single use protective sheaths;
F. 1 Power supply cable for the charging unit.

These components can also be ordered separately.

NOTE: The content may vary during promotional campaigns.

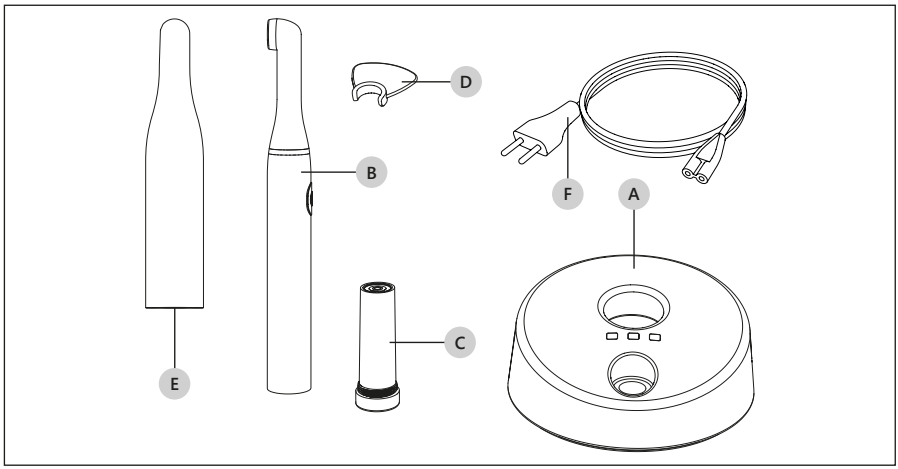

Figure 5 – List of Components

4 INSTALLATION

The device must be installed in a suitable place that is convenient for its use.

⚠ **WARNING:** The place where the device is installed must meet the requirements found in the *Chapter 4.1 on page 9*.

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4.1 Safety Requirements in the Installation Phase

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

⚠ **WARNING:** Install the device in a safe place protected from impact or accidental water or liquid spray.

⚠ **WARNING:** Do not install the device above or near sources of heat. Arrange during installation for a suitable circulation of air around the device.

⚠ **WARNING:** Do not introduce metal objects into the handpiece housing in the charging unit (Figure 6 at page 10 - Ref. B) when the device is on.

ⓘ **CAUTION:** The device can be transported but must be handled with care when moved.

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

ⓘ **CAUTION:** Place the device in such a way as to always have the power plug easily accessible as it is considered to be a disconnection device.

ⓘ **CAUTION:** The handpiece is intended for use within the patient environment whereas the charger unit is not intended for use within the patient environment.

NOTA: The patient environment is defined as an area 1.5 m from the patient (as per IEC 60601-1, third edition).

⚠ **WARNING:** The operator must not come simultaneously into contact with the elements outside the patient environment (charger units and switching power supply adapter) and the patient. Do not connect other external components to the medical system.

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4.2 Connecting the Accessories

In order to make the equipment operational it is necessary to proceed as follows:

1. Place the charging unit on a flat surface;
2. Plug the power cable (Figure 5 at page 8 - Ref. F) into the connector on the back side of the charging unit (Figure 6 at page 10 - Ref. A) and then into the power outlet. The green power LED should light up (Table 1 at page 11 - Ref. A).
3. Connect the battery module to the handpiece by tightening the nut of the battery module to the handpiece as shown in Figure 7 at page 10.

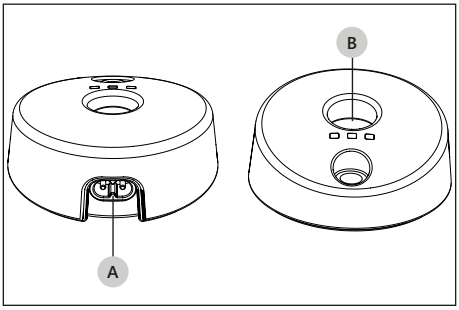

Figure 6 – Charging unit.

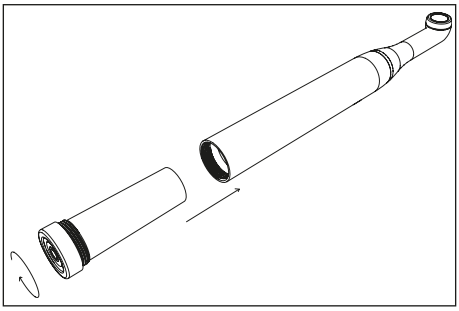

Figure 7 – Battery module insertion.

ⓘ **CAUTION:** Make sure that the voltage and frequency of the power-supply line match the values indicated on the identification label under the charging unit.

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

ⓘ **CAUTION:** Place the device in such a way as to always have the power plug easily accessible as it is considered to be a disconnection device.

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4.3 Descriptions of Commands and Signalling

For the descriptions of commands and signalling, refer to Table 1 at page 11.

Ref.	Name	Description
A	Power LED green	Indicates that the charging unit is powered up.
B	Battery LED green	Indicates that the battery is fully charged (charging completed).
	Battery LED yellow	Indicates that the battery is being charged.
C	Test LED green	Indicates that the light intensity is suitable for effective therapy.
	Test LED yellow	Indicates that the light intensity is insufficient.
D	on/off button	Starts or stops a polymerisation cycle.

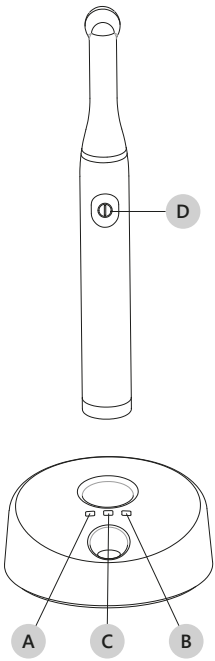

Table 1 – Descriptions of Commands and Signalling

Function	Action/Button	Acoustic signal	Light signal
FAST polymerisation	**on/off** button pressed for a short time	**1 beep** when the light emission starts. **1 beep** on completion of the 10 sec exposure.	Green LED steady on.
SLOW RISE polymerisation	**on/off** button pressed for at least 2 sec	**1 beep** when the light emission starts and 1 beep after 2 sec. **1 beep** after 10 sec. of exposure. **1 beep** on completion of the 20 sec exposure.	Yellow LED steady on.

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Function	Action/Button	Acoustic signal	Light signal
Interruption of exposure cycle	**on/off** button pressed for a short time during the exposure	**1 beep**	
Low battery indication. The remaining battery charge is sufficient for the execution of 6 cycles.		**2 beep** on completion of the exposure cycle.	
Battery discharged indication.	**on/off** button pressed for FAST or SLOW RISE polymerisation	**2 beep** - No light emission.	Green and Yellow LEDs flashing.
Thermal protection intervention indication		**3 beep** on completion of the FAST polymerisation cycle or halfway through the SLOW RISE polymerisation cycle and interruption of the cycle.	Green and Yellow LEDs flashing.

Table 2 – Description of the acoustic and light signals of the handpiece.

Power LED	Battery LED	Test LED	Position of the handpiece in the charging unit	Function
ON	OFF	OFF	Not inserted	Charging unit powered.
ON	Yellow ON	OFF	Inserted	Battery being recharged.
ON	Green ON	OFF	Inserted	Recharging completed. Battery charged.
ON	OFF	OFF	Not inserted	No light emission.

Power LED	Battery LED	Test LED	Position of the handpiece in the charging unit	Function
ON	OFF	Yellow ON	Not inserted	Low light emission.
ON	OFF	Green ON	Not inserted	Light emission suitable for an effective treatment.

Table 3 – Description of light signals on the charging unit.

5 BATTERY

starlight uno is powered by a rechargeable lithium-ion battery already contained inside the handpiece, with no memory effect.
starlight uno is equipped with two microprocessors that check the battery continuously and maintain the optimum battery charging parameters. The handpiece may therefore be placed back into the charging unit at the end of each treatment and left there, regardless of the charge of the battery.

5.1 New Battery - First Charging

NOTE: The battery of the starlight uno is provided partially charged.

To charge completely the battery:

1. Place the handpiece into its housing in the charging unit (Figure 6 at page 10 - Ref. B). The yellow battery LED will light up (Table 1 at page 11 - Ref. B).
2. The charging phase has been completed when the battery LED turns to green.

5.2 Low Battery Indication

When the charge of the battery becomes low, after frequent use of starlight uno, the microprocessor will allow 6 more exposures to be carried out (FAST or SLOW RISE) without any need to recharge the battery.
A battery low state is signalled at the end of each of these 6 cycles by means of 2 beeps.
Once the 6 cycles have been completed, the handpiece enters a battery discharged state (see *Chapter 5.3 on page 13*).
Place the starlight uno handpiece back into the charging unit.

5.3 Battery Discharged Indication

The battery of starlight uno is discharged if no light is emitted when pressing the on/off button and at the same time an acoustic signal is produced (2 beeps). Recharge the battery:

1. Place the handpiece into its housing in the charging unit (Figure 6 at page 10 - Ref. B). The yellow battery LED will light up (Table 1 at page 11- Ref. B).

2. The charging phase has been completed when the battery LED turns to green.

5.4 Battery Failure Indication

When the low battery handpiece is placed in the charging unit and the battery yellow LED on the charging unit Table 1 at page 11- Ref. B), this means that there is a fault with the battery.

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NOTE: This failure condition disables operation of the charging unit. To restore proper working conditions proceed as follows:

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

5.5 Battery Replacement

To replace the faulty battery, unscrew the battery module from the handpiece, remove it and insert a new one (Figure 7 at page 10).

5.6 Battery Safety Requirements

The battery can cause damage to property and/or personal injuries such as burns if conducting materials such as jewellery, keys or beaded necklaces come into contact with the exposed terminals.
The conducting material could close an electrical circuit (short circuit) and become very hot.
Make a habit of handling the device with care, particularly if it is placed inside a pocket, bag or other container in which there are metal objects.
In the case of contact of the terminals with metal objects and consequent short circuit, the lamp stops and it is necessary to reposition it on the battery charger to resume its operation.

⚠ **WARNING:** Do not insert metal objects into the handpiece housing, in the charging unit, when the device is on.

⚠ **WARNING:** Do not leave the battery within reach of children.

ⓘ **CAUTION:** Use only original Mectron batteries.

ⓘ **CAUTION:** Recharge the battery only with the Mectron charging unit (*Figure 5 at page 8* - Ref. A). Do not attempt to recharge the battery using a generic battery charger. This entails a risk of explosion and fire.

ⓘ **CAUTION:** The battery should be recycled or disposed of in the appropriate manner in accordance with the law. The battery should not be thrown away with normal waste. The user will be liable for any damages caused by improper disposal of the battery.

ⓘ **CAUTION:** Do not use the battery for purposes other than those for which it is intended.

ⓘ **CAUTION:** Do not open, pierce or crush the battery. It contains toxic substances.

ⓘ **CAUTION:** Do not burn the battery or expose it to a high temperature. There is a risk of explosion.

ⓘ **CAUTION:** Do not short-circuit the battery terminals. This could cause burns and fire.

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6 USE

6.1 Connecting the Accessories

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

⚠ **WARNING: Infections control.** For maximum safety of the patient and of the operator, before each treatment, clean and disinfect the charging unit and the handpiece, cleanse and sterilise the optical protection and replace the protective sheath. Carefully follow the instructions provided in *Chapter 7 on page 18*.

⚠ **WARNING:** The protective sheaths are single use. Each protective sheath must be used for one application only on a single patient.

Before using the starlight uno proceed as follows:

1. Ensure the battery module is correctly connected to the handpiece;
2. Insert the single use protective sheath onto the handpiece (Figure 8 at page 15 - Ref. A);
3. Fix the optical protection onto the handpiece (Figure 8 at page 15 - Ref. B).

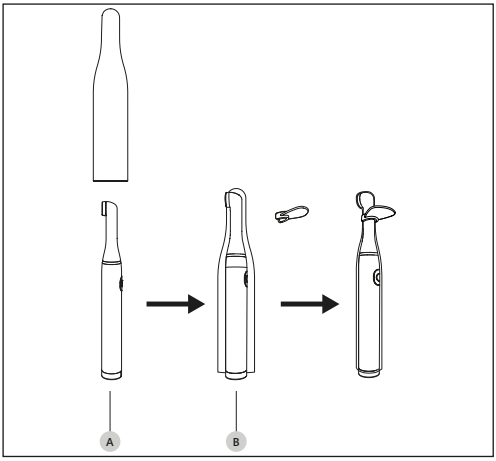

Figure 8 – Connecting the Accessories

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6.2 Safety Requirements During Use

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

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

⚠ **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..

⚠ **WARNING:** Do not insert metal objects into the handpiece housing in the charging unit when the device is on.

ⓘ **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.

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

6.3 Instructions for Use

starlight uno allows performing 2 types of exposures:

- **FAST**: exposure time of 10 seconds at the maximum light intensity.
- **SLOW RISE**: exposure time of 20 seconds with a gradual increase of the light intensity during the first 3 seconds up to the maximum intensity.

FAST exposure selection:

1. Press the on/off button on the handpiece (Table 1 at page 11 - Ref. D) for a short time. An acoustic signal will be emitted (1 beep) and the green LED on the handpiece will light on.
2. After 10 seconds an acoustic signal will be produced (1 beep) and the green LED on the handpiece will light off. The FAST cycle has been completed.

SLOW RISE exposure selection:

1. Keep pressed the on/off button on the handpiece (Table 1 at page 11 - Ref. D) for 2 seconds. An acoustic signal is emitted when the cycle starts and after 2 seconds. The yellow LED on the handpiece will light on.
2. After 10 seconds an acoustic signal will be emitted (1 beep).
3. After 20 seconds an acoustic signal will be emitted (1 beep) and the yellow LED on the handpiece will light off. The SLOW RISE cycle has been completed.

After the end of the treatment, remove the protective sheath used and place the starlight uno handpiece back into the charging unit (Figure 5 at page 8 - Ref. B).

NOTA: Cycle interruption.
Both in the FAST and in the SLOW RISE mode, the exposure cycle can be interrupted at any time by pressing the on/off button on the handpiece (Table 1 at page 11 - Ref. D).

NOTA: Additional exposures.
At the end of any exposure cycle, it is possible to carry out one or more additional cycles by pressing the on/off button on the handpiece again each time (Table 1 at page 11 - Ref. D).

For a quick guide to the signalling, see Table 2 at page 12 and Table 3 at page 13.

6.4 Light Intensity Measurement

To determine whether the light intensity is sufficient:

1. Place the tip (Figure 9 at page 17 - Ref. A) flat, on the surface of the light-intensity sensor without pressing it (Figure 9 at page 17 - Ref. B);
2. Press the on/off button (Figure 9 at page 17 - Ref. C) to switch on the lamp.

The test LED (Table 1 at page 11 - Ref. D) will indicate the measured light-intensity:

- Green = light-intensity suitable for effective treatment;
- Yellow = light-intensity insufficient.

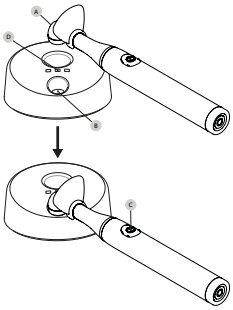

Figure 9 – Light Intensity Measurement

ⓘ **CAUTION:** If the working luminous flux is not sufficient, do not proceed with the treatment on the patient and carry out the following checks:

1. Check that the tip is not dirty.
2. Clean the tip (see *Chapter 7.1 on page 18*);

If these measures do not lead to improved performance, place the device out of service (by disconnecting it from the mains) and make sure that it cannot be started by unauthorised persons. Any repair work on the device should be carried out by an authorised Mectron service centre.

6.5 Safety Protection

In the event of extremely heavy 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. The yellow and green LEDs flash.

7 CLEANING, DISINFECTION AND STERILISATION

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The Table 4 at page 18 is purely indicative.
For the complete cleaning, disinfecting and sterilization procedures of the individual parts, refer to the paragraphs indicated in the Table 4 at page 18.

ⓘ **CAUTION:** All the phases indicated in the following table must be performed, avoiding using methods not referred to in that table.

⚠ **WARNING:** The protective sheaths are single use. Each protective sheath must be used for one application only on a single patient.

Phase	Chapter	Procedure	Handpiece	Charging unit	Optical protection
I	*Chapter 7.1 on page 18*	Manual cleaning with detergent solution and disinfecting agent	X	X	
II	*Chapter 7.2.1 on page 20*	Immersion into enzymatic detergent			X
III	*Chapter 7.2.2 on page 21*	Check cleaning			X
IV	*Chapter 7.2.3 on page 21*	Drying			X
V	*Chapter 7.2.4 on page 21*	Sterilisation			X

Table 4 – Cleaning, Disinfection and Sterilisation

7.1 Cleaning and Disinfection of the Handpiece and the Charging Unit

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

7.1.1 Preparation

- Remove the handpiece from the charging unit;
- Remove the optical protection from the handpiece;
- Remove the protective sheath from the handpiece.

7.1.2 Necessary Material

- Clean, soft cloths with low fiber-release;
- Detergent solution (pH 6-9);
- Demineralised water;
- Disinfectant agent (Glutaraldehyde, Ghlorhexidine gluconate or Isopropyl alcohol 70%).

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7.1.3 Cleaning Method

1. Clean the surface of the charging unit and the handpiece with a clean, soft and low fibre release cloth, dampened with a cleaning solution (pH 6-9) prepared according to the manufacturer's instructions;
2. Clean the surface of the charging unit and the handpiece with a clean, soft and low fibre release cloth, dampened with demineralised water to remove all residues of the cleaning solution;
3. Dry the surface of the charging unit and the handpiece with a clean, soft and low fibre release cloth;
4. If you intend to disinfect, spray the disinfecting agent onto a clean, soft and low fibre release cloth and clean the surface of the charging unit and of the handpiece.

ⓘ **CAUTION:** 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.

ⓘ **CAUTION:** Contact of liquid with the lamp terminals can cause damage and therefore voids the warranty.

ⓘ **CAUTION:** Contact of liquid with the LED causes damage and therefore voids the warranty.

ⓘ **CAUTION:** Do not spray liquid directly onto the surface of the charging unit and/or of the handpiece.

ⓘ **CAUTION:** The casing of the charging unit and/or the handpiece are not protected against the entry of liquids.

ⓘ **CAUTION:** The charging unit and the handpiece should not be sterilised.

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7.2 Cleaning and Sterilisation of the Optical Protection

7.2.1 Manual Cleaning

ⓘ **CAUTION:** The only part of the device that can be sterilised is the optical protection.

7.2.1.1 Necessary Material

- Clean, soft cloths with low fiber-release;
- Enzymatic detergent at pH 6-9;
- Water;
- Container for immersion in the enzymatic liquid;
- Brush with soft nylon bristles.

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

7.2.1.2 Cleaning Method

1. Prepare an enzymatic detergent solution with pH 6-9, as per the instructions of the manufacturer;

ⓘ **CAUTION:** Once used, dispose of the enzymatic detergent correctly, do not recycle it.

2. Place the optical protection horizontally in a clean container and add enzymatic detergent solution until the optical protection is covered completely;
3. Let the optical protection soak for 10 minutes at 40°C ±2°C;
4. During immersion in the enzymatic solution, delicately brush the surface of the optical protection using the brush with soft nylon bristles to eliminate all traces of visible dirt;
5. Delicately brush the surface of the optical protection under running water using the brush with soft nylon bristles.

ⓘ **CAUTION:** 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.

EN

7.2.2 Cleaning Control

Once the cleaning operations have been completed, visually inspect the optical protection under an adequate source of light, if necessary using a magnifying glass 2.5X, paying attention to the details that could conceal dirt residue (threading, cavities, grooves) and, if necessary, repeat the cleaning cycle if dirt is still visible. Finally, check the integrity of those parts and those elements that could have deteriorated during use.

7.2.3 Drying

Thoroughly dry all parts of the optical protection with a soft low fibre release cloth, possibly blowing with compressed air.

7.2.4 Sterilisation

ⓘ **CAUTION: Carry out sterilisation only in a steam autoclave.** Do not use any other sterilisation procedures (dry heat, radiation, ethylene oxide, gas, low-temperature plasma, etc.).

ⓘ **CAUTION:** The optical protections are made from materials able to withstand a maximum temperature of 135°C for a maximum period of 20 minutes.

⚠ **WARNING: Infections control - Sterilisable parts.** To avoid infection by bacteria or viruses, carefully remove any remaining organic dirt prior to sterilisation.

7.2.4.1 Sterilisation Method

Seal the optical protection individually in a disposable bag for sterilisation and proceed with the process of sterilisation in a steam autoclave.
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).
- Minimum sterilisation temperature: 132 °C (interval 0 °C ÷ +3 °C).
- 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.

8 DISPOSAL PROCEDURES AND PRECAUTIONS

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

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

⚠ **WARNING: Hospital waste.**
Treat the following items as hospital waste:

- Optical protection, when worn or broken;
- Protective sheath, at the end of each application.

9 SYMBOLS

Symbol	Description	Symbol	Description
CE	Device compliant with Regulation EU MDR 2017/745.	c Nemko US Electrical Safety ES 60601-1	Nemko Mark UL - CSA standards compliance
MD	Medical Device		CAUTION, See instructions for use.
	Consult instructions for use		Manufacturer
	Date of manufacture	SN	Serial number
LOT	Lot Number	REF	Product Number
	Do not reuse	NON STERILE	Non sterile
135°C	Can be sterilised in autoclave up to a maximum temperature of 135 °C		Type "B" applied part in conformity with technical norm IEC/EN 60601-1
	Class II equipment		Alternate current
	Starts or stops a polymerisation cycle		Identify the power LED (see Table 1 at page 11)
	Identify the battery LED (see Table 1 at page 11)		Identify the test LED (see Table 1 at page 11)
	The device and its accessories must not be disposed of or treated as solid urban waste		Temperature limitation - transport and storage conditions
%	Humidity limitation - transport and storage conditions		Atmospheric pressure limitation - transport and storage conditions
	General warning[a)]	LATEX	Not made with natural rubber latex

Table 5 – Symbols

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

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10 TROUBLESHOOTING

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If the equipment appears not to be working correctly, read the instructions again and then check the Table 6 at page 24.

Problem	Possible Cause	Solution
The charging unit does not switch on (none of the LEDs light up).	The power cable is not correctly connected.	Connect the cable both to the charging unit and to the wall socket.
	The power cable is faulty.	Replace the power cable.
	The charging unit is out of order.	Contact an authorised MECTRON technical assistance centre.
There is no light emission when the on/off button of the starlight uno is pressed and an acoustic signal is produced (2 beeps).	Battery discharged.	Recharge the battery. See *Chapter 5.3 on page 13.*
An acoustic signal is produced at the end of the exposure cycle (2 beeps).	Battery low.	Recharge the battery. See *Chapter 5.2 on page 13.*
An acoustic signal (3 beeps) is produced during the exposure cycle and at the end of the cycle starlight uno will not allow any further treatment to be carried out.	The thermal protection has been activated.	It will be possible to use the equipment only after it has cooled down. See *Chapter 6.5 on page 17.*
The polymerisation is insufficient.	The terminal surface of the tip is soiled.	See *Chapter 6.4 on page 17.*
An acoustic signal is produced (4 beeps) and there is no light emission.	Hardware failure.	Contact an authorised MECTRON technical assistance centre.

Table 6 – Troubleshooting

11 TECHNICAL SPECIFICATIONS

Device compliant with Regulation (EU) 2017/745	Class I
Classification under the IEC/EN 60601-1	II Applied part type B (Tip) IP 20 (Charging unit) IP 20 (Handpiece)
Essential performances	According to IEC 80601-2-60 Standard, the device does not provide essential performances.
Charging station	Model starlight uno - CHARGER ⚠ **WARNING:** The charger unit is not intended for use within the patient environment. **NOTE:** The patient environment is defined as an area 1.5 m from the patient (as per IEC 60601-1, third edition).
Charging station power supply	100-240 V~ 50/60 Hz 15 VA
Handpiece power supply	Rechargeable Lithium-ion battery. Manufacturer: Panasonic Model: UR-14500 Nominal Voltage: 3,6 V Nominal capacity (Typical): 840 mAh
Handpiece for intermittent operation	40" ON 60" OFF - Max 3 consecutive cycles
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.
Exposures	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.
Battery charging time when completely discharged	About 4 hours. Ch: CC-CV 200mA ±10% 4,20V ±1%
Operating conditions	from 10 °C to 35 °C Relative Humidity from 45% to 85% Air pressure P: 800 hPa/1060 hPa

EN

Transport and storage conditions	from -20 °C to 40 °C Relative Humidity from 45% to 85% Air pressure P: 500 hPa/1060 hPa
Altitude	less than or equal to 2000 meters
Weights and dimensions	Charging unit: Weight 108 g 93 x 93 x 40 mm[a)] Handpiece: Weight 77 g L 190 mm Max. Ø 21 mm

Table 7 – Technical Specifications

a) **l = width; L = length; H = height**

11.1 Electromagnetic Compatibility IEC/EN 60601-1-2

⚠ **WARNING:** Portable and mobile radio communication appliances may affect the correct functioning of the device.

⚠ **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.

11.1.1 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	

11.1.2 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.
RATED power frequency magnetic fields [d] [e]	IEC 61000-4-8	30 A/m [g] 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.

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

b) The device 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 an ambient 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) During the test, the device may be powered at any NOMINAL input voltage, but with the same frequency as the test signal.

f) Before modulation is applied.

g) This test level assumes a minimum distance between the device and sources of power frequency magnetic field of at least 15 cm. If the RISK ANALYSIS shows that the device will be used closer than 15 cm to sources of power frequency magnetic field, the IMMUNITY TEST LEVEL shall be adjusted as appropriate for the minimum expected distance.

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11.1.3 Guidance and Manufacturer's Declaration - Electromagnetic Immunity

11.1.3.1 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.

Phenomenon	Basic EMC standard or test method	Immunity test levels	Electromagnetic Environment Guidance
Electrical fast transients / bursts a) 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 a) 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 a) 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°	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) r)	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.

a) The test may be performed at any one power input voltage within the device RATED voltage range. If the device is tested at one power input voltage, it is not necessary to re-test at additional voltages.

b) All the device 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 the device 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). The device 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 the device .

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 minimum and maximum RATED input voltage. ME EQUIPMENT and ME SYSTEMS with a RATED input voltage range of less than 25 % of the highest RATED input voltage shall be tested at one RATED input voltage within the range.

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11.1.3.2 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.

11.1.3.3 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 [b] [d] [g]	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 is 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.

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11.1.4 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.

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 - 2750	Bluetooth WLAN 802.11 b/g/n RFID 2450 Band LTE 7	Pulse modulation [b] 217 Hz	2	0.3	28
5420	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, 50 % pulse modulation at 18 Hz may be used because while it does not 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.

12 WARRANTY

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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 3 (THREE) YEARS for the handpiece and 1 (ONE) YEAR for the battery module 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 equipment 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 11 on page 25*;
- 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.

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.

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