



Lumoral Junior – User manual

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This user manual is intended for the following Koite Health Ltd. device: Lumoral Junior, Version 2.
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Basic UDI-DI: 6429810197LumoralJunioB8

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1 Introduction

1.1 General information

This document is the user manual for both healthcare professionals and consumers using the Lumoral Junior device.

- Read this manual carefully before using the device and strictly follow all instructions.
- Lumoral Junior device is an antibacterial home- or clinic-use medical device for prevention of bacteria-caused diseases, such as caries and gingivitis. The Lumoral Junior device is used in conjunction with mechanical dental cleaning (brushing and flossing teeth).
- Lumoral Junior device is intended to be used only with Lumorinse mouthrinse. Each Lumorinse tablet contains 7 mg of the active substance indocyanine green. When dissolved in water, Lumorinse soluble tablet forms a mouthrinse. The mouthrinse is then swished in the mouth and it adheres to the plaque.
- Lumoral Junior device produces both near-infrared light and antibacterial blue light. The interaction of Lumorinse with Lumoral Junior device's near-infrared light produces a bactericidal effect on plaque. The effect is enhanced by the simultaneous antibacterial blue light.
- The Lumoral Junior device is intended for use by healthcare professionals or for personal use. For more information, please contact Koite Health by email at info@koitehealth.com.
- After opening the package, make sure that there are no external defects or damages to the device. If you suspect that something is faulty with your device, contact your dealer.
- Store the device out of the reach of children and pets. In pediatric use, the device can be used by only under the supervision of an adult.
- In case you encounter any serious incident related to the to the Lumoral or Lumorinse products, please report the incident to Koite Health safety@koitehealth.com and your local competent authority.

Please contact Koite Health or the reseller if you need assistance in setting up, using, or maintaining the Lumoral Junior device. Report any unexpected events related to the use of the device to the reseller or customer support at info@koitehealth.com.

1.2 About the Lumoral Junior device

Lumoral Junior device is an antibacterial treatment for the reduction of the amount of bacteria and inhibition of growth of bacteria on the teeth. It reduces formation of dental plaque and it can be used to prevent bacteria-caused oral diseases, such as caries and gingivitis. It can also be used to prevent oral mucositis due to chemotherapy or radiotherapy. Lumoral Junior device improves oral hygiene and it is used to complement mechanical dental cleaning (brushing teeth and flossing).

The device can be used at home or at any health care environment, including dental clinics, when the health care provider takes appropriate precautions to prevent bacterial contamination between patients.

Lumoral Junior is intended for children over three years old, or to any person to whom the device fits between and along the dental arches.

Lumoral Junior dual-light activator should be used together with light-activated dental plaque-adhering Lumorinse mouthrinse.

The device is intended for regular use. The recommended treatment protocol for prevention of caries is minimum twice-a-week use.

The Lumoral Junior Starter Kit package includes

- Lumoral Junior device
- Power bank (USB type C)
- Charging cord for the power bank
- 10 Lumorinse tablets
- Measuring cup
- User manual

Lumoral Junior device is intended to be powered by the external power unit as specified below:

- Capacity: 9000-15000(mAh)
- Port Type: Type C USB Port
- Output: 12V 1.5A
- Input: 5V 2.4A

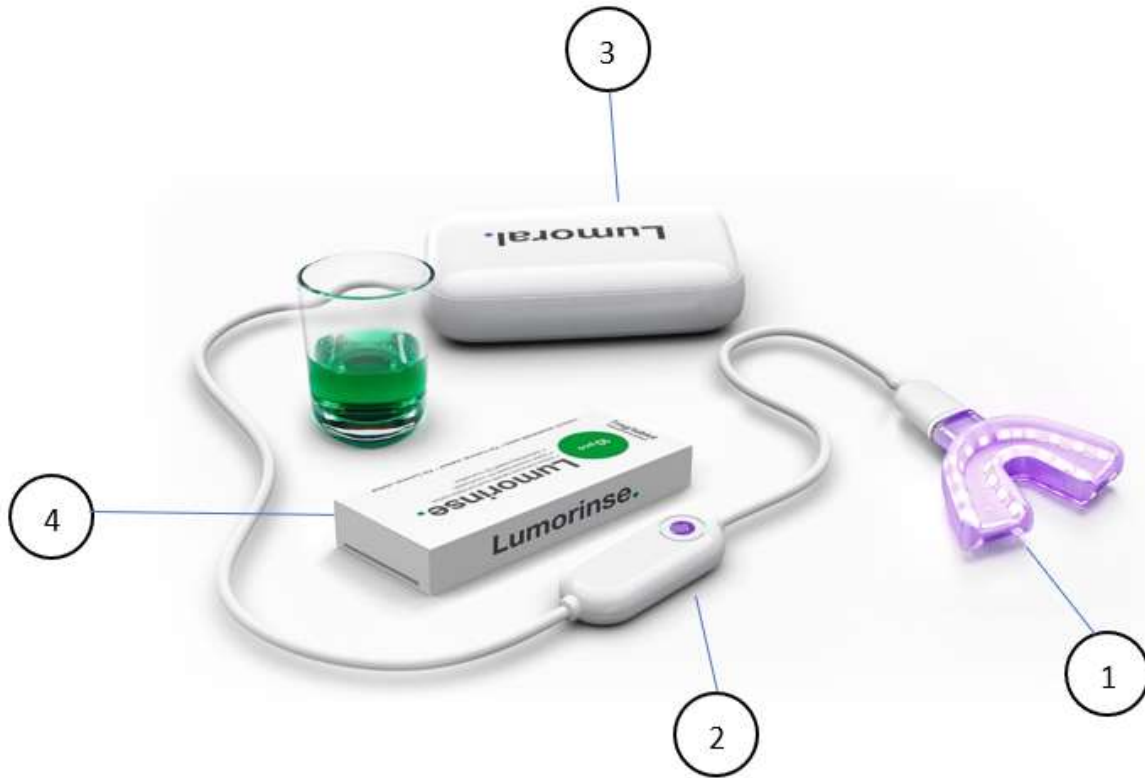


Figure 1. The mouthpiece (1) is joined with the control unit (ON/OFF button)(2) and the power unit (3). Lumorinse tablets (4). The glass (not included in the pack) contains a dose of Lumorinse dissolved in water.

The treatment is started by rinsing the mouth with the Lumorinse mouthrinse. Rinsing the mouth causes the Lumorinse active substance indocyanine green to adhere to dental plaque. The antibacterial effect is activated with the Lumoral Junior dual-light applicator.

The Lumoral Junior device, when used together with Lumorinse, kills cavity-causing *pathogenic oral bacteria* from dental plaque. The effect is targeted at the dental plaque. The targeted approach helps to keep the overall oral flora diverse in the mouth.

The Lumoral Junior device is safe to use, and there are no known side effects when the instructions for use are followed. The light emitted by the device is visible light and near-infrared light wavelengths. The device is compliant with the IEC 62471 Photobiological safety of lamps and lamp system.

The mechanism of action is initiated when the photosensitizer (Lumorinse) absorbs a photon and undergoes an energy transfer reaction. The absorbed energy is released in the form of singlet oxygen (photodynamic process) and localized heat generation (photothermal process). Dental pathogenic bacteria are especially vulnerable to photodynamic and photothermal effects.

The device will generate heat, which is a part of the treatment effect. The user will feel warmth in the teeth and gums during treatment. If the treatment is uncomfortable, the treatment can be performed in two parts with a break of one or two minutes in between.

2 Safety information

2.1 Warnings



This symbol indicates safety information about the hazards of handling and using the product.

The following precautions must be taken to reduce side effects when using the Lumoral Junior device.

- Use the device only according to the instructions provided in this user manual. The manufacturer is not responsible for any damage or consequences that may result from non-intended use or misuse of the device.
- Avoid looking directly into the light source of the device.
- Do not perform any repair or maintenance activity other than what is specified in this manual. All other repair and maintenance actions must be performed by the manufacturer or authorized service agent. For more information about maintenance and service, see section 5 of this manual (Device operation and maintenance).
- Do not modify or open the device, as the safety of the device cannot be guaranteed after such actions.
- Do not use the device near flammable materials, including flammable anaesthetics.
- Do not use the device in environments with strong magnetic fields or with high levels of electromagnetic interference.
- Do not use the device next to electromagnetically sensitive equipment.
- Do not immerse the control unit in any liquid. The control unit and the power bank contain sensitive electronic components that can be damaged by contact with liquids. The mouthpiece can be immersed in water.
- Do not connect any other power sources to the device than those specified in these instructions. We recommend using the power source that comes with the device.
- Ensure that use and storage are carried out under the conditions specified in Section 8 of this manual (Technical specifications).
- Ensure that the cables/cords and their protective parts are in perfect working condition before use.
- Lumorinse is safe to use and is not absorbed in the digestive tract. However, we recommend spitting it out after swishing in mouth and avoid swallowing it.
- For safety reasons, do not drop, short circuit, or use the power bank at high temperatures.
- If the power bank swells or changes shape, stop using it.
- Keep the power bank out of the reach of small children and pets.
- Failure to follow the instructions for the power bank may result in fire or possible injury.



Note! The device must be used only with Lumorinse products.



Note! Consult this instruction for use and the Lumorinse package markings concerning indication, contraindications and effects before using the Lumorinse product.

2.2 Restrictions for use and known side-effects

- Use of the device does not replace the need of daily mechanical dental cleaning or regular dentist and dental hygienist visits.
- The device should not be used in children below four years. Children should only use the device under adult supervision.
- If your healthcare professional has given you recommendation to use Lumoral Junior, follow your healthcare professional's instructions.
- Consult a health care professional before using the device in case you have
 - oral candidiasis (thrush)
 - medication that is known or suspected to be light-sensitive
 - bisphosphonate osteoporosis medication
 - chlorhexidine mouthwash in use
 - epilepsy
 - teeth that have been root canal treated or have large fillings. Such teeth are more vulnerable to heat than normal teeth.
 - untreated cracks, chips, or erosion that extends beyond the surface of the enamel potentially exposing the underlying dentin or pulp
- Users have reported temporary side-effects such as pain in teeth, tongue or tissue staining, discomfort due to heat sensation during the device use, increased saliva secretion during the device use, discomfort of non-optional fitting light applicator device, and oral mucosal irritation. Typically, these symptoms are mild and should go away once you stop using the device.
- If you feel excessive heat, you can split the 10 minutes use into two parts and let the device cool under cold water in between.
- If you experience pain or discomfort during the treatment, stop using the device. If the pain continues after the treatment, contact health care professional.

In case of suspected adverse events, report to safety@koitehealth.com

Depending on the shape of the dental arch, the mouthpiece might not fit optimally. It is important to note that the mouthpiece is applying light, and perfect fit is not required for the treatment to be effective. Do not bite the device.

3 Effects of use

The Lumoral Junior device is intended to be used in addition to regular daily dental hygiene: toothbrushing a minimum of 2 times a day with toothpaste and daily interdental cleaning (tooth flossing).

For optimal results, use Lumoral Junior as recommended by the dental professional. The treatment can be used daily up to three times a day. The minimum recommended use is twice a week, for 10 minutes at a time.

Lumoral Junior device, when used together with Lumorinse, kills cavity-causing bacteria effectively in the dental biofilm. The effect is selective; it is targeted at the dental plaque. The overall oral flora stays diverse.

Lumoral Junior device is safe to use, and there are no side effects when the instructions for appropriate use are followed. The light emitted by the device is visible light and near-infrared light wavelengths.

Following sensations may occur during use:

- Lumoral Junior device produces heat. The user will feel warmth in the teeth and gums during treatment.
- Device increases the blood circulation in the tissues locally. Heat and near-infrared light may enlarge the blood vessels (vasodilation), which may feel like a feeling of weight or pulsing in the gums.
- Increased saliva production may temporarily be experienced. Saliva has an important oral health-promoting function because it moisturizes, cleanses and protects the teeth, oral mucous membranes, gums and throat.

4 Instructions for use

4.1 Setting up and using the Lumoral Junior device

Follow these instructions (refer to the images above in Figure 1):

1. Unpack and inspect the device and accessories from the package.
2. Measure 30 ml of water into the measuring cup and pour it into a glass. 30 ml equals about 2 tablespoons of water.
3. Put one Lumorinse tablet (4) into the water. Let it dissolve for about 30 seconds or until fully dissolved.



Note! Wait until the tablet is dissolved.



Note! The active substance is photosensitive when dissolved in water. For the active ingredient to function properly, the mouthwash should be used immediately after dissolving the tablet in water.

4. Swish the mouthrinse for about 60 seconds, and then spit it out. Do not rinse your mouth with water.
5. Position the mouthpiece (1) gently in place between your upper and lower dental arch (teeth).
6. Attach the Type-C connector of the mouthpiece (1) to the power bank (3).



Note! If the power bank does not supply power to Lumoral Junior mouthpiece. Press twice with quick repeats the power bank button on the side of the power bank. The

power bank LEDs should then turn off. Then press the power bank side button again to turn LEDs on, and mouthpiece is operational.

7. Press the ON/OFF button on the cord (2) to start the device.



Note! Put the device to your mouth first.

8. Keep the mouthpiece in place for 10 minutes until the light goes off automatically.
9. The device can also be turned OFF by pressing the ON/OFF button (2) on the control unit.
10. Clean the device after use with warm water and mild dish washing detergent.
11. Brush your teeth for 2 minutes with toothpaste.
12. Store the device in a safe place so that it does not fall and so that the cords/cables are not damaged.



Note! Lumoral Junior mouthpiece must not be bitten. If the surface of the mouthpiece is damaged, the device cannot be used.



Note! The thermal effect is part of the antibacterial effect. Both the device itself and the photothermal reaction produce heat. The maximum operating temperature is 53°C. If you have concerns about the temperature being too high, contact Koite Health info@koitehealth.com or the reseller.



Note! Lumorinse releases part of the light activation energy as heat. Therefore, the treatment feels warm or hot in some cases when there is a high amount of dental plaque on the tooth surface. This is because dental plaque uptakes the Lumorinse inside in higher concentrations and causes local heat release. This is part of the treatment effect. If there is discomfort during treatment, we advise keeping a short break or brushing teeth before treatment to limit dental plaque quantity at the treatment area.

4.2 Device signalling

The Lumoral Junior device has five different states that are indicated by a signalling light in the control unit (Figure 1, item 2):

1. Turned OFF – The power button has no light on.
2. Operating – The power button light is on
3. Wrong power input – The light blinks 5 times
4. The temperature threshold is exceeded – The device shuts down, and the signal light blinks 10 times.
5. The device has not cooled down enough – The device will not turn on, and the signal light blinks 3 times.



Note! If the temperature threshold is exceeded repeatedly, please contact customer support at info@koitehealth.com.

4.3 Charging and handling the power bank

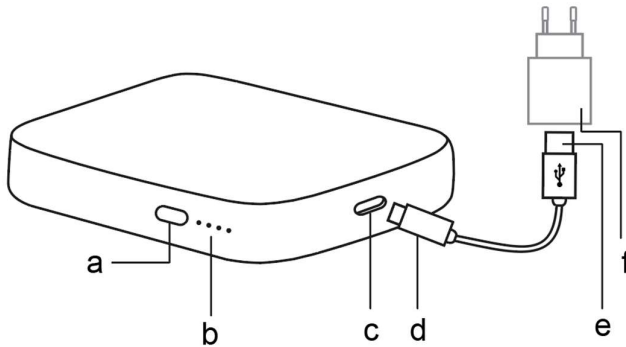


Figure 2. The power bank. The capacity indicator button (a), the capacity indicator LEDs (b) and the type C port (c). The charger cord with type-C connector (d) and USB type 2.0 connector (e). Example of a power adapter (f) (not included in the package).

Charging the power bank:

Connect the charging cable with the type-C USB connector to the power bank. Connect the type 2.0 USB connector to a suitable power adapter with a USB type 2.0 output. You can use, for example, the power adapter of your mobile phone charger.

To check the charge level of the power bank, press the indicator button once. A single light flashing indicates the need for charging. The capacity indicator LED lights show the approximate power bank capacity.

Do not press the power bank switch before connecting to the Lumoral Junior device.

When you press the indicator button, the power bank measures the charge status, cutting power from Lumoral Junior device. To stop measuring, press the indicator button twice. After reconnecting the cord, the device is ready for use again.

Capacity indicator LEDs	0 on	1 on	2 on	3 on	4 on
Capacity	Fully discharged	<25%	25-50%	50-75%	75-100%



Note! Do not use or connect the mouthpiece to the power bank while the power bank is charging.



Note! Do not connect the mouthpiece to any USB-C output which is powered directly from the electric grid.



Note! For safety reasons, do not drop the power supply, cause a short circuit in it, hit it with hard objects, disassemble it yourself or use it at high temperatures.



Note! If the power bank swells or changes shape, stop using it immediately.



Note! Keep the power bank out of the reach of children. The power bank is for adults only.



Note! Follow the instructions of this user manual. Failure to do so may result in fire or damage to the unit.

5 Device operation and maintenance

5.1 Device operation

After the Lumoral Junior mouthpiece has been connected to the power bank, the device operation can be started by pressing the power button. The device stays on for 10 minutes to complete the treatment protocol. The device automatically turns itself off.

5.2 Storing

Store the device in a location where it is not exposed to excessive dust. Dust accumulation can prevent the device from operating reliably. More detailed information about storage conditions can be found in section 8 (Technical specifications).

Protect the Lumorinse tablets from moisture, heat, light and freezing. The shelf life of the tablets is printed on the Lumorinse package.

5.3 Cleaning

See Figure 1. Turn off the power from the power bank (3) before cleaning the device. Remove the mouthpiece connector from the power bank. The mouthpiece (1) can be rinsed with water or wiped with a damp cloth. If detergent is needed, a mild dishwashing liquid is recommended.

The control unit (2) can be wiped with a damp cloth. The connector plug, control unit or power bank should not be immersed in water.

If necessary, disinfect with mild, non-corrosive substances. Strong acids, bleach, aromatic or chlorine-containing hydrocarbons, spirits, esters, ethers and ketones must not be used, as they can corrode the material.



Note! Do not rinse the control unit with water. If the connector plug is wet, let it dry before connecting it to the power bank.

5.4 Service

Do not service the device yourself except as described in this manual. If technical maintenance is required, please contact Koite Health customer support via email at info@koitehealth.com.

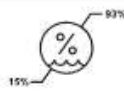
5.5 Calibration

The device has been initially calibrated at the time of manufacture. If this device is used according to the instructions of use, periodic calibration is not required. If at any time you question the accuracy and functionality of the device, please contact the distributor or manufacturer.

5.6 Disposal

The Koite Health Lumoral Junior device consists of metal, plastic and electronic components. The power bank is a lithium-ion battery. Do not throw away the device or power bank in the mixed household waste at the end of life. They should be disposed of according to the electrical and electronic equipment waste recycling legislation. Deliver the device for recycling to an official collection point for electronic devices. Check with the appropriate recycling organization for local disposal information.

6 Symbols used

General symbols					
Symbol	Explanation	Symbol	Explanation	Symbol	Explanation
	Consult instructions for use.		General warning sign.		Item is a medical device.
	Follow instructions for use.		Manufacturer.		Temperature limit (storage).
	Serial number.		Type BF device.		Humidity limitation (storage).
	Batch code.		Use-by date.		Keep dry.
	IP Classification. Protected against short periods of immersion in water.		Non-ionizing radiation.		Do not use if the package is damaged
	CE marking. The product is compliant with medical device regulation (EU) 2017/745 (MDR). Notified body number underneath.		FCC label. The electromagnetic interference is under limits approved by the US Federal Communications Commission.		Keep away from sunlight
	Do not dispose of the product with household waste. Deliver it to appropriate recycling point.		ROHS label: The device is compliant with Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU		Environmentally Friendly Use Period (EFUP) of batteries and devices. 5 indicates the number of years within which a battery or device is unlikely to have an environmental impact.
	The product is recyclable.				

7 Compliance with safety directives and standards

The Koite Health Lumoral Junior is a CE-marked class IIa medical device. It is compliant with the following directives and standards:

EU Regulation 2017/745 – Medical Devices Regulation

Directive 2011/65/EU – Restriction of Hazardous Substances (RoHS) Directive

Directive 2012/19/EU – Waste Electrical and Electronic Equipment (WEEE) Directive

European Committee for Standards - electrical – EN 60601-1:2006/AMD1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010, EN 60601-1-11:2015

8 Technical specifications

Operating conditions	
Operating temperature	+10 Celsius - +35 Celsius
Operating humidity	15 - 93 %
Storage conditions	
Storage temperature	+5 Celsius - +40 Celsius
Storage humidity	15 - 93 %
Operating system	
Suitable charging power	5V - 2A
Operating voltage	20 VDC
Operating power	8W
Safety class	I
Protection class	IP X7 (Mouthpiece)
Performance	
Operating wavelength range	400 – 850 nm
Output light intensity	100 mW/cm ²
Maximum on-time	11 min
Minimum off-time	5 min. or until device has cooled down to ambient temperature.

9 Electromagnetic emission declaration

Lumoral Junior is a medical device and is intended for use in the electromagnetic environment specified below. The end user of the device should ensure that it is used in such an environment. The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the unit.

Guidance and manufacturer's declaration - Electromagnetic emissions		
RF emissions CISPR 11	Group 1	The Lumoral Junior device uses radio frequency energy only for internal functions. Therefore, its RF emissions are very low and should not cause harmful interference to electronic devices in the vicinity of the device.
RF emissions CISPR 11	Class BF	The Koite Health Lumoral Junior device is suitable for use in all establishments, including domestic establishments and those directly connected to a public low-voltage power supply network that supplies buildings used for domestic purposes.

Recommended separation distances between portable and mobile RF communications equipment and the Lumoral Junior device

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 1.2 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W), according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration – electromagnetic immunity			
<i>The Lumoral Junior device is intended for use in the electromagnetic environment specified below.</i> <i>The end user of the device should ensure that it is used in such an environment.</i>			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHZ	10 V/m 80 MHz – 2,7 GHZ	Portable and mobile RF communications equipment should be used no closer to any part of the Lumoral Junior device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3 \sqrt{P} \text{ 800 MHz to 2,5 GHz}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey¹, should be less than the compliance level in each frequency range². Interference may occur in the vicinity of equipment marked with this symbol: 
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Electrical fast transient	± 2 kV, 100Hz repetition frequency		
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. ¹ Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasting and TV broadcasting cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Lumoral Junior device is used exceeds the applicable RF compliance level above, the Lumoral Junior device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Lumoral Junior device. ² Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

10 Warranty

This warranty is valid in the territory of the European Union. It does not limit the applicability of mandatory legislation in force in the European Union, such as the Consumer Protection Act, to the sale of the device.

Koite Health provides a twenty-four (24) month warranty against defects for the device. The warranty period is calculated from the date the first user of the device takes possession of the product, as shown on the purchase receipt.

Koite Health or an authorized dealer will repair a defective device or exchange the device for a new one at their discretion.

This warranty does not cover normal wear and tear of the device. In addition, Koite Health does not provide any warranty for the device if the device has been used in violation of this manual, has been used incorrectly or negligently, has been connected to another device, has been repaired or opened, or has otherwise been modified or incorrectly installed. The expected minimum service life of the device is 24 months (2 years).

If the user of the device wishes to make a warranty claim, the user must submit a legible purchase receipt of the device.

11 Product support

Koite Health Ltd
Karaportti 5
02610 Espoo
Finland

Email: info@koitehealth.com

Website: www.lumoral.com

An updated list of the most frequently asked questions may be found on our website at www.lumoral.com.

In case of any suspected adverse events, report to safety@koitehealth.com.

For more information and support for use, please email us at info@koitehealth.com.