

ManaRay

INSTRUCTIONS FOR USE

LED System



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Do not use this product before reading this manual. If you have any questions,
please call your physician or email ManaMed at support@manamed.com

To learn more about ManaMed, visit www.manamed.com



ManaRay Label Symbol Descriptions



The use of accessories, power supplies and cables other than those specified, with the exception of components sold by the manufacturer of the ManaRay as replacement parts, may result in increased emissions or decreased immunity of the ManaRay.



Designates Class II medical electrical equipment.



This unit is an electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in landfill. Consult local county requirements for proper disposal instructions.



This symbol designates the degree of protection against electrical shock from the wrap as being a Type BF Applied part.



IFU - Consult instructions for use.

IP20

Protected against solid objects larger than 12.5mm, such as fingers or large tools.
It offers no protection against water and must not be exposed to moisture or liquid environments.



MR Unsafe – Remove before entering MRI suite

Symbol Glossary

For an explanation of symbols, please refer to <https://www.manamed.com/glossary/symbol-glossary.pdf>

Technical Data

Device Box Components

ManaRay Device
ManaRay Charger
ManaRay Joint Specific Wrap

Power Supply

USB / DC 5V 500mA
Battery: 3.7V Lithium-ion

Specifications

Dimensions: 70 x 48 x 15.6 mm (approximately 2.76" x 1.89" x 0.61")
Weight: 0.07 kg (without battery), 0.09 kg (with battery)
LED Wavelengths: 660nm / 850nm / 940nm
Timing: 15 minutes
Expected service life: 1 year for the pad, 5 years for the control unit.
Battery life: Approximately 5 to 6 sessions per charge.

System Operating Environment:

Operating Conditions: 5–40°C,
15–93% humidity
Storage Conditions: -10 to +50°C,
0–90% humidity

Device Description

The ManaRay device is a wearable LED-based system with adjustable hook and loop straps designed to deliver red and near-infrared light therapy. It includes:

- A control unit with USB-C charging port and power indicator lights.
- A flexible LED pad with 60 + 60 LEDs emitting at 660nm, 850nm, and 940nm

The device is powered by a built-in 3.7V lithium-ion battery and is designed for short-duration therapy sessions.

Indications for Use

The ManaRay device is intended to emit energy in the near-infrared and visible red spectrum at wavelengths of 660 nm, 850 nm, and 940 nm to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and/or the temporary relaxation of muscle.

Contraindications

Do not use the ManaRay device:

- On or near the eyes.
- On open wounds or sunburned skin.
- On cancerous lesions.
- Over cardiac pacemakers or other implanted electronic devices.
- On or around the womb/stomach if pregnant or possibly pregnant.
- In the presence of flammable gases (e.g., oxygen, nitrous oxide).
- On highly irritable or insensate skin.
- Patients with following diseases or symptoms are prohibited to use this product: high fever, vasculitis obliterans, ophthalmopathy, vascular compensatory insufficiency, active tuberculosis, acute soft tissue infections, bleeding tendency, skin sensory disturbances and skin allergies.
- Do not use this device if your skin is light sensitive or you are currently using medication that may cause skin sensitivity to light. Doing so may result in photosensitive reaction. Stop use immediately if you experience sensitivity.
- Patients with pacemakers, defibrillators or other electronic implants.

Cautions

- Consult your doctor prior to using especially if you:
 - Are pregnant
 - Have any suspicious or cancerous lesions
- Read all instructions and safety precautions before using
- Do not use on infants
- Use only the supplied power supply
- Unplug from outlet when not in use to avoid tripping hazards
- Do not unplug by pulling cord, grasp the plug itself when unplugging from an outlet.
- In rare instances people get light or heat sensitivity from the LED therapy light. Each person using this device for the first time should only use it for 5 minutes for each area that it's applied. If you have any pain, discomfort, or redness that lasts more than 2 hours then stop immediately. If not then repeat 5 minute therapy for first 3 days. After 3 days if there are no negative effects then increase time to 10 minutes for each area for the next 3 days. Then increase to 15 minutes.
- Do not use if you feel excessive heating.

Warnings

- Do not stare directly at LED lights.
- Do not use near the face or eyes without infrared-blocking protective eyewear.
- Do not exceed five 15-minute sessions per day.
- Wait at least 2 hours between sessions.
- Do not use if the device or skin is wet.
- Do not tamper with or modify the device.
- Do not use while driving or operating machinery.
- Keep away from children & individuals with diminished capacity.
- This device is not to be used by sleeping, unconscious, or intoxicated persons.
- This device is not to be used by people with skin numbness caused by medicine or other reasons.

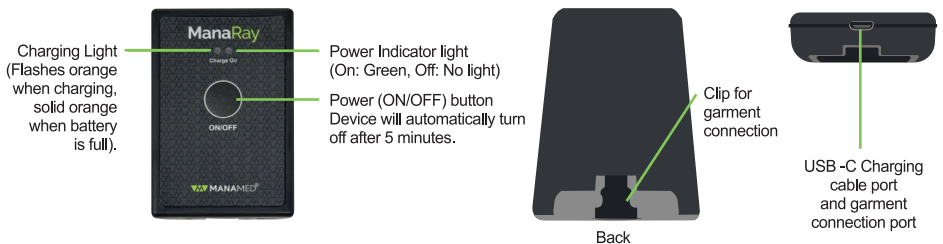
To avoid electrical shock:

- Do not stand on device.
- Do not wash electrical parts with water.
- Do not touch the plug or device with wet hands.
- Do not use if the device or skin is wet (you already have this in here but adding it here).
- Do not use in humid/wet atmosphere.
- Do not use if cord or plug appears to be damaged.
- Do not use if the unit has been damaged, torn, or has come in contact with water.
- Do not pull, lift, or carry the device by the power cord.
- Do not use the cord as a handle, close a door on the cord, or pull the cord against sharp edges or corners.
- Do not use near heated surfaces.
- Do not crease or fold the device.
- Use the provided packaging for storing the device to protect from potential creases and folds.
- Do not use the unit on an open wound, as heat may increase circulation and cause bleeding.
- This product contains neoprene, if you are allergic to neoprene, do not use this product without first consulting a physician.
- Do not use with liniments, salves, or ointments that contain heat-producing ingredients as a skin burn could occur.
- Do not use any objects to cover the device during use.
- Only to be used by competent adults and trained caregivers.

Instructions for Use

Device description:

Review these images before proceeding to page 6.



ManaRay

Read prior to use. Follow steps below.



Charging: Connect the USB-C cable to the controller and a power source. A blinking orange light indicates charging; solid orange means fully charged.

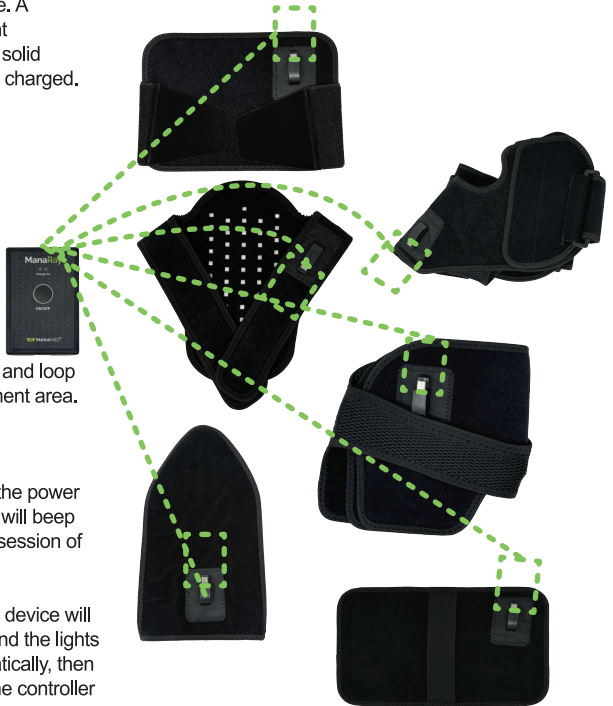


Setup: Attach the controller to the LED pad and secure it with hook and loop straps to the treatment area.



Operation: Press the power button. The device will beep and begin a timed session of 15 minutes.

Session End: The device will beep three times and the lights will shut off automatically, then beep once when the controller powers down.



Cleaning, Disinfecting, and Reuse

Wipe the LED pad with a slightly damp cloth or antiseptic wipes weekly.

Do not fold or bend the LED strips.

Do not use alcohol-based cleaners or sprays.

Limited Warranty

ManaMed warrants to the original purchaser of its ManaRay purchased by the purchaser directly from ManaMed that the ManaRay conforms to ManaMed's manufacturing specifications. This warranty will be in effect for a period of 120 days from the date of purchase.

In the event of a material breach of this warranty, upon timely written notice, ManaMed will either repair or replace the ManaRay or refund the original purchase price. This will constitute the Purchaser's sole remedy. This limited warranty does not extend to any resale or other transfer of the ManaRay by Purchaser to any other person or entity.

MANAMED EXPRESSLY DISCLAIMS ANY AND ALL OTHER WARRANTIES, EITHER EXPRESSED OR IMPLIED, RELATING TO THE SYSTEM OR ITS PERFORMANCE, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY AND ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.

Customer Service

E-mail: support@ManaMed.com

For General Information: Visit www.ManaMed.com

Mail: ManaMed Customer Service, 2612 Sirius Dr., Denton, TX 76208

Battery and Charging Safety

Battery

- Do not attempt to replace the lithium-ion battery.
- Do not attempt to replace the battery with non-approved batteries. Incorrect replacement of batteries could result in damage to the device.
- Be sure to only use the battery charger provided with ManaRay. Other chargers may cause the battery to overheat and damage the battery, ManaRay or the user.
- Do not use an extension cord with the battery charger as it may cause overheating.
- Do not use the battery charger with other devices as it may cause damage to the device or battery charger.
- If the battery area on the ManaRay becomes overheated, discontinue using and contact ManaMed Customer Service by emailing support@manamed.com

Charging

Important: Charge device before first use.


The battery will charge whether ManaRay is turned on or off.

If the battery power decreases quickly even after recharging for four or more hours, contact Customer Service.

Do not recharge the battery in any of the following locations:

- Where the temperature is below 41°F (5°C) or above 104°F (40°C).
- Any areas where people could walk on the charger cable or trip over the charger cable.
- in a wet damp location.
- In direct sunlight outdoors.
- Within reach of small children.

Adverse Event Reporting

 **Stop using and consult your healthcare professional immediately** if you experience any adverse reactions, such as: increased pain, burning, increased swelling, itching, blisters, increased redness, discoloration, welts, irritation and other changes in skin appearance, or any other reaction identified by your healthcare professional.

Disposal


ManaRay is an electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in landfill. For details on how to dispose of ManaRay correctly, consult local requirements for proper disposal instructions. Pump control units contain rechargeable batteries. Do not discard the pump in regular waste. Bring the unit to your local recycling center or contact support@ManaMed.com.

Warning: Do not throw any part of ManaRay into fire.

Compliance Statements & Declarations Electromagnetic Compatibility (EMC) Tables

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS			
The ManaRay is intended for use in the electromagnetic environment specified below. The customer or the user of the ManaRay should assure that it is used in such an environment.			
Emissions Tests	Compliance	Electromagnetic Environment Guidance	
RF Emissions CISPR11	Group 1	The ManaRay uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF Emissions CISPR11	Class B	The ManaRay 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		
Voltage Fluctuations IEC 61000-3-3	Complies		
GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY			
The ManaRay is intended for use in the electromagnetic environment specified below. The customer or the user of the ManaRay should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8kV contact ±15kV air	±8kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5%UT (>95% dip in UT) for 0.5 cycle 40%UT (80% dip in UT) for 5 cycles 70%UT (30% dip in UT) for 25 cycles <5%UT (>95% dip in UT) for 5 seconds	<5%UT (>95% dip in UT) for 0.5 cycle 40%UT (80% dip in UT) for 5 cycles 70%UT (30% dip in UT) for 25 cycles <5%UT (>95% dip in UT) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ManaRay requires continued operation during power mains interruptions, it is recommended that the ManaRay be powered from an uninterrupted power supply or a battery.
Power Frequency (50/60Hz) Magnetic Fields IEC61000-4-8	30 A/m at 50 or 60 Hz	30 A/m at 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c mains voltage prior to application of the test level.			

Compliance Statements & Declarations Electromagnetic Compatibility (EMC) Tables

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY			
The ManaRay is intended for use in the electromagnetic environment specified below. The customer or the user of the ManaRay should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC61000-4-6	3Vrms 150 kHz to 80 MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the ManaRay, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1.2 \sqrt{P}$ 150 KHz to 80 MHz $d = .35 \sqrt{P}$ 80 MHz to 800 MHz $d = .70 \sqrt{P}$ 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 survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, 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.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to the fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ManaRay is used exceeds the applicable RF compliance level above, the ManaRay should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ManaRay. ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.			
RECOMMENDED SEPARATION DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE ManaRay			
The ManaRay is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ManaRay can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ManaRay 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 $d = .35 \sqrt{P}$	800 MHz to 2.5 GHz $d = .70 \sqrt{P}$
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 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.			

Manufactured for:



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