

Specification

Product name: Laser Therapy Device

Item	LM-L808A
Input power	1200VA(Peak)
Operation mode	Pulse output
Wavelength	808nm±10nm
Pulse duration	5ms~750ms
Energy density (Fluence/Laser energy output)	1~100J/cm ²
Light spot area	12mm*12mm
Skin cooling	Contact cooling



Contraindication

- Diabetics;
- Pregnant women; People with immune suppression;
- Patients with hemorrhagic disease or people with history of anticoagulant use, people with photosensitivity, open wound or infectious wound;
- Patients with skin disease;
- People with the history of invasive repairing operation carried out during the past three years;
- Patients with epilepsy;
- The treatment is not allowed to be applied to people that have used 13-cis-retinoic acid during the past six months;
- People with the history of keloid;
- People with the history of infection in the treated area or infection in the herpes;
- Patients that have used other methods to apply depilation (for example depilatory wax) during the past six weeks;
- People who are allergic to hydroquinone or other bleaching agents;
- People who have used Isotretinoin (13-cis- retinoic acid) during the past six months;
- Avoid tattoos and other pigmented skin area;
- The patient with skin diseases is not recommended to accept treatment;
- Cancer; in particularly, skin cancer;
- Use of photosensitive medication and herbs for which laser exposure is contraindicated;
- Diseases which may be stimulated by laser exposure;
- Prolonged exposure to sun or artificial tanning during the 3 to 4 weeks prior to treatment and post treatment;
- Fragile and dry skin;
- Hormonal disorders (that are stimulated under intense light);
- Use of anticoagulants;
- History of coagulopathies.



WARNING

Tattoos in the treatment area cause stronger side effects, too. Moreover, the color will be partly removed. Therefore, tattoos should not be treated.

Patients with tanned skin, especially fresh tanned – develop more intensive side effects, particularly subsequent pigment changes. They should postpone the laser epilation!

The intensive laser can cause thermal damage to skin structures. Therefore, it is NOT PERMITTED to use Light treatment for pregnant women or children because clinical studies do not exist for these patients.

The intensive laser can cause thermal damage to the eyes. Therefore, it is NOT PERMITTED to Light the area of the eyes! Occasionally, eye inflammation and a reduction of the visual function were observed although the eyes were protected by eye shields!

The device emits high levels of radiation may cause serious damage to the eye if the device is used improperly. Absolutely observe the instructions given in this User Manual for equipment and procedures for operating, maintaining, checking, or calibrating purposes.

The light radiation of the device can cause, whenever low, the risk of fire. Under no circumstances the device may be used in an explosive atmosphere (classified as AP and APG under IEC 60601-1). Take care to preclude the existence of vapors from solvents or flammable liquids (these have been possibly used for cleaning or disinfection) in the room before you start working with the device.

Please note that this product is subject to scheduled technical safety tests that must be performed at annual intervals to ensure the safety of the staff and patients. If the tests are not performed regularly serious health problems can be caused.

Work for service, repair or modification may not be performed by anyone other than Shenzhen LeafLife Technology Co., Ltd. personnel or other bodies duly authorized to handle such work to ensure the safety of the staff and patients.
If unauthorized persons carry out service works, repairs, or modifications to the device serious health problems can be caused.

To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.

The device is operated with line voltage. There is the risk of an electrical shock! Do not open the device, if you are neither trained nor authorized to do so. The device is only to be operated with reliably grounded and perfectly installed sockets with earthing contact.

The contact surface of the handpiece contacts the patient's skin during the treatment, There is the risk of microorganisms being transferred. The handpiece must be deep cleaned and disinfected directly after each application!

Medical devices are subject to specific precaution measures concerning electromagnetic compatibility (EMC). The device emits low levels of electromagnetic radiation that may have an effect on devices that do not comply with the standard. Unintended settings at these devices could be the result of such an effect.

The use of accessories and cables not authorized by the manufacturer may result in an increased interference emission or a decreased immunity of the device with the above-mentioned consequences. Use only accessories and cables that have been authorized by Shenzhen Leaflife Technology Co., Ltd for this result.

The device must not be stacked/arranged close to or in combination with other devices. If the device is operated close to or with other devices it must be checked if the device is working properly in this arrangement. The device must not be used in a strong magnetic field environment to avoid affecting the performance of the device.

Because of the Light radiation of the devices, there is a risk of fire or explosion if the Light is used in the presence of flammable materials, solutions, or gases or in an environment that is enriched with oxygen.



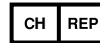
Shenzhen Leaflife Technology Co., Ltd.
Address: 4F, Bldg. C, JMD Industrial Park, No.39 Qingfeng Blvd.,
Baolong Industrial Area, Longgang Dist., Shenzhen, China
Tel: 0086 755 27216609
Website: www.leaflifetech.com



Rx only



Name: CMC Medical Devices & Drugs S.L
Address: C/Horacio Lengo No.18, 29006, Malaga, Spain
Tel.: +34 951214054
Email: Info@cmcmedicaldevices.com



Name: CMC Medical Devices GmbH.
Address: Registered place of business at Bahnhofstrasse
32, CH-6300 Zug, Switzerland.
Tel.: +41415620395
Email: mmateos@cmcmedicaldevices.com