



OMNILUX™
— CLEAR —



User Guide



Users of this device can obtain benefit from using it only if they read and comprehend all information in the User Guide. You must follow all of the instructions in the User Guide.

Please feel free to contact us if you have any comments about the Omnilux CLEAR™ device or this User Guide.

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1. Introduction

Thank you for choosing Omnilux CLEAR™.


The Omnilux CLEAR LED device emits light in the red and blue region of the light spectrum and is indicated for the treatment of mild to moderate acne vulgaris on the face.

(See “Who should use Omnilux CLEAR” section 2 - page 4, for more information about how to tell if you have mild to moderate acne and if Omnilux CLEAR is right for you).

Users of this device can obtain benefit from using it only if they read and comprehend all information in the User Guide.






You must follow all the instructions in the User Guide.

Please feel free to contact us if you have any comments about Omnilux CLEAR or this User Guide.

 Before using the Omnilux CLEAR device, you must carry out a sensitization test and wait 6 hours. (see section 6.3 - page 9).

2. Who should use Omnilux CLEAR?

The typical appearance of acne is a mixture of the following: greasy skin, red pimples or spots, yellow pus-filled spots and scars. Use this chart to determine whether Omnilux CLEAR is suitable for you.

Acne Type	Description	Suitable for Omnilux CLEAR
Clear Skin	 No pimples or spots or yellow pus-filled spots. No whiteheads or blackheads	NO Omnilux CLEAR is NOT indicated for clear skin. Omnilux CLEAR should NOT be used to prevent pimples or spots forming.
Mild Acne	 A few pimples or spots, a few pus-filled spots, some whiteheads or blackheads	YES Mild acne is suitable for treatment with Omnilux CLEAR
Moderate Acne	 Some pimples or spots, some pus-filled spots, only a few small nodules. Some whiteheads or blackheads	YES Moderate acne is suitable for treatment with Omnilux CLEAR
Severe Acne	 Many pimples or spots, many pus-filled spots. many nodules	NO Omnilux CLEAR is NOT indicated for severe acne. Please consult your doctor for a more appropriate treatment.
Whiteheads or Blackheads or Comedonal Acne	 Many whiteheads or blackheads. No pimples or spots. No pus-filled spots	NO Omnilux CLEAR is NOT indicated for whiteheads or blackheads. Please consult your doctor for a more appropriate treatment.



To find out if Omnilux CLEAR is right for you and to find a full list of who can and who can't use the Omnilux CLEAR, scan the QR code.

3. Device description

1. Flexible silicone CLEAR device with integrated eye-wear
2. Controller (containing a lithium battery) & power supply
3. Country specific adapters
4. 2x adjustable straps
5. Carry bag



Omnilux CLEAR is a home-use wearable LED light therapy device. It produces a cool, narrow band of light which reduces mild to moderate acne vulgaris on the face. It consists of a flexible silicone device that contains light emitting diodes (LEDs) and a controller. The LEDs generate the light. The device is worn on the face and is held in place by adjustable Velcro straps. The controller turns the LEDs ON/OFF and controls power to the mask. The controller contains a rechargeable lithium-ion polymer battery and uses a visible display comprising of 3 micro LEDs to show the user the battery charge status of the device. The power supply is used to charge the lithium battery and is connected to a suitable mains outlet via a 2 or 3 pin input socket and wall plug. The power cable is connected to the controller by a standard micro USB A-C connector.

Omnilux CLEAR cannot be operated while charging.

The device is not used to make measurements of any sort, or to draw any conclusions regarding the indication to treat. The device does not require checks on the light output as the LEDs do not dim with age to any practical extent.

3.1. Intended use

Omnilux CLEAR is an over-the-counter LED device that emits energy in the red and blue region of the light spectrum, and is specifically indicated to treat mild to moderate acne vulgaris on the face through a non-thermal mechanism called endogenous Photodynamic Therapy.

4. When should Omnilux CLEAR NOT be used?

4.1 Contraindications, warnings and precautions

Contraindications

- **DO NOT** share Omnilux CLEAR with any other person. The Omnilux CLEAR device is for single person use only.
- **DO NOT** use Omnilux CLEAR to treat any other conditions apart from those listed in the indications for use (mild to moderate acne vulgaris). The Omnilux CLEAR device has not been tested for any other conditions than those listed, and the risk is unknown.
- **DO NOT** use Omnilux CLEAR if you are pregnant, planning on becoming pregnant, or breastfeeding. The Omnilux CLEAR device has NOT been tested on pregnant or breastfeeding women and therefore the risk to the fetus, neonate, or pregnant woman is unknown.
- **DO NOT** use Omnilux CLEAR if you are a child under 14 years of age. The safety of the device for children younger than 14 years of age has NOT been tested and the risk is unknown.
- **DO NOT** use Omnilux CLEAR if you suffer from light-induced headaches.
- **DO NOT** use Omnilux CLEAR if you suffer from any genetic conditions of the eyes. The Omnilux CLEAR device has NOT been tested on subjects who suffer with genetic conditions of the eyes and therefore the risks are unknown. If you are unsure about any related eye condition and using Omnilux CLEAR, contact your ophthalmologist or doctor.
- **DO NOT** use Omnilux CLEAR if you suffer from any photosensitive disorder (sensitization to light) of the eye. The Omnilux CLEAR device has NOT been tested on subjects who suffer with photosensitive disorders of the eye and therefore the risks are unknown. If you are unsure about any related eye condition, contact your ophthalmologist or doctor.
- **DO NOT** use Omnilux CLEAR if you suffer from Lupus erythematosus, photosensitive eczema, or albinism. If you use the Omnilux CLEAR device to treat lupus erythematosus, photosensitive eczema, or albinism you may cause a severe skin reaction.
- **DO NOT** use Omnilux CLEAR if you suffer from any photosensitive disorder (sensitization to light) of the skin. If you use the Omnilux CLEAR device and you suffer from a photosensitive disorder, you may cause a severe reaction.
- **DO NOT** use Omnilux CLEAR if you are taking any medication that can cause photosensitivity. If you use the Omnilux CLEAR device and you are taking any medication that can cause photosensitivity, you may cause a severe skin reaction.

For a full list of drugs that can cause photosensitivity, please visit: www.omniluxled.com

⚠ Photosensitivity is a common side effect of various medications. These can include certain antibiotics, chemotherapy drugs, and diuretics. If you are unsure about any medication you may be taking consult your healthcare provider.

⚠ Other substances not listed above can also cause photosensitivity.

- Common examples of these substances are:
St John's Wort, coal tar, deodorants, antibacterial soaps, artificial sweeteners, naphthalene (mothballs), petroleum products, brightening agents found in laundry detergent, and cadmium sulphide (a chemical injected into the skin during tattooing).

⚠ Warnings

- Before using Omnilux CLEAR, you must carry out a sensitization test (see section 6.3 - page 9).
- **DO NOT** use Omnilux CLEAR in any way that is not exactly as specified in these instructions for use. Use of Omnilux CLEAR other than exactly as specified in these instructions for use has not been tested and the risk is unknown.
- **TURN OFF** and **REMOVE** Omnilux CLEAR immediately if it feels hot or your skin feels uncomfortably warm.
- **STOP** using Omnilux CLEAR if you experience headaches, changes in vision or pain in your eyes.
- **DO NOT** use Omnilux CLEAR without first removing creams, serums, lotions, and make-up **BEFORE** treatment.
 - Some ingredients in these products may cause light sensitization or may reduce the effect of the treatment.
- **DO NOT** use Omnilux CLEAR near water or anywhere water can spill onto the equipment.
- **DO NOT** use Omnilux CLEAR if you think it may have come into contact with water.
- Keep Omnilux CLEAR away from **HOT** surfaces.
- **DO NOT** attempt to modify Omnilux CLEAR in any way. Modifying the Omnilux CLEAR device will void your warranty. Modifying the Omnilux CLEAR device could cause an electric shock when the device is used again. The device contains no serviceable parts.
- **DO NOT** use Omnilux CLEAR if the device, battery, or charging plug are damaged in any way.

General safety

The Omnilux CLEAR device is an electrical device, which under certain circumstances could present an electrical shock hazard to the user. Please read the accompanying User Guide thoroughly and follow directions stated in the manual to assure maximum safety during operation.

Precautions

- The Omnilux CLEAR straps contains a mixture of polyester, nylon and lycra. If you are allergic to any of these materials, you may not be able to use the head straps provided.
- **The Omnilux CLEAR device cannot be used in charging mode.**
- Before each use, with the device off, clean the device. All surfaces of the Omnilux CLEAR device may be cleaned by following the cleaning instructions in Section 8.1 - page 11.
- Do NOT use any other cleaning products other than those stated in the cleaning instructions. Use of other cleansing products may damage Omnilux CLEAR.
- Store Omnilux CLEAR flat and at room temperature in dry conditions, away from direct sunlight.

5. Risks and benefits

5.1 Potential risks

- Immediately after treatment skin may appear red. Skin should return to normal within 1-2 hours.
- Some users have reported pigmentation, skin flaking or peeling, associated pruritis and dryness. This is transient and clears within a few days.
- Temporary headaches immediately following the light treatment. Headaches can be treated with an appropriate over the counter analgesic and rehydration.
- This list although not exhaustive lists the most commonly reported side effects.

5.2 Potential benefits

People who have undergone a course of 4 weekly treatments for 6 weeks using the Omnilux CLEAR device report a reduction of mild to moderate acne vulgaris.

6. First time setup

6.1 Unpacking and charging your Omnilux CLEAR

- The Omnilux CLEAR device uses a controller which contains a lithium-ion polymer battery. Omnilux CLEAR cannot be used in charging mode.
- The lifetime of the lithium battery can be maximized by allowing it to fully charge and then fully discharge during regular use.
- Unpack Omnilux CLEAR and check off the parts described in Section 3 page 5.
- Before use, fully charge the battery.
- To charge the Omnilux CLEAR battery, insert the USB-C cable into the controller. Insert the power supply into a suitable electrical outlet and press ON/OFF button on controller.
- The 3 LEDs in the controller will start to flash to indicate charging. The Omnilux CLEAR battery is fully charged when the three indicator LEDs on the controller stay illuminated.

6.2 Connecting Omnilux CLEAR to the controller


Connect the Omnilux CLEAR mask by inserting the USB A connector of the mask into the USB port of the controller.

6.3 Sensitization test

Before carrying out your first treatment, you must carry out a sensitization test. Follow the step by step guide below:

1. Place the Omnilux CLEAR device over your inner arm.
2. Press the ON/OFF button on the controller until lights are illuminated and allow device to run for its full 10-minute treatment program.
3. At any time if your skin feels HOT or uncomfortable, immediately turn OFF your device and remove from skin.
4. After the treatment, wait at least 6 hours. If your skin on your inner arm is red or itchy then Omnilux CLEAR is not suitable for you.

7. Using the Omnilux CLEAR device

-  **Regarding electromagnetic compatibility (EMC) and electromagnetic fields (EMF), in and around the home environment the Omnilux CLEAR device should be kept away from radio frequency (RF) equipment to avoid interference.**

7.1 Treatment recommendations

- People who have undergone a course of 4 weekly treatments for 6 weeks using the Omnilux CLEAR device report a reduction of mild to moderate acne vulgaris.

7.2 Wearing the Omnilux CLEAR device

- Omnilux CLEAR comes with two adjustable Velcro straps that allow you to comfortably wear the mask.
- To fit the mask, thread the straps through the inlet holes on either side of the mask.
- Loop the straps around your head and secure firmly. Adjust if necessary.

7.3 Carrying out a treatment

1. Cleanse and exfoliate skin to remove any traces of skincare.
2. Place Omnilux CLEAR on the face, secure with the adjustable straps.
3. Connect the Omnilux CLEAR device to the controller and press the ON/OFF button on controller. The device turns off after its 10-minute treatment. You may stop the treatment at any time by pressing the ON/OFF button on the controller.
4. Remove the device, apply your normal skincare.
5. Clean the device using a water-based wipe or a damp, clean cloth. Ensure that the device is NOT being charged when cleaning.
6. For best results, treat for 4 days a week for 6 weeks.

8. Care and maintenance

- The lifetime of the lithium battery can be maximized by allowing it to fully charge and then fully discharge during regular use.
- Store the Omnilux CLEAR device flat and at room temperature in dry conditions. Use the carry bag provided to store your device.
- Avoid storing the Omnilux CLEAR device in dusty conditions, in direct sunlight or in damp and humid conditions.
- The Omnilux CLEAR device contains no serviceable parts.
- Before each use, with the device turned off, clean the device following the cleaning instructions below.

If you follow the care and maintenance for your Omnilux CLEAR, then Omnilux CLEAR has a minimum lifetime of 2 years.

8.1 Cleaning the Omnilux CLEAR device



DO NOT use any other cleansing products as these may damage the plastics.

- Clean the front and back of the device with a water-based wipe or damp, clean cloth. Stubborn stains can be removed by wiping gently with 70% alcohol.

8.2 Disposal



DO NOT dispose of any part of the device at a domestic waste facility.



The Omnilux CLEAR controller contains a lithium-ion polymer battery. For protection of the environment, please package and return this unit to the manufacturer or their representative at the end of its working life or safely dispose of the device following your local guidelines.



8.3 Troubleshooting

Problem	Possible Cause	Action
No blue or red light from Omnilux CLEAR	Not charged	Plug in the controller to the charger making sure that the connections are attached and leave charging until the three indicator LEDs on the controller remain lit and do NOT flash
No blue or red light from Omnilux CLEAR	Device connected to an electrical outlet	Unplug USB connector from controller
LEDs do NOT turn OFF after 10 minutes	Device is faulty	Return to your supplier
LEDs flicker continuously during treatment	Omnilux CLEAR is not fully inserted into controller	Ensure the controller and Omnilux CLEAR device are connected correctly

If the actions suggested fail to fix the problem, or the problem reoccurs, and your device is within the warranty period please return to your provider.



- Do NOT attempt to investigate any further.
- Do NOT attempt to modify the device in any way. Omnilux CLEAR has NO parts you can repair yourself.

9. Labeling

The labeling supplied with the device contains the following information

- Date of manufacture
- Catalogue number and batch code
- Operating environment

10. Recycling



This symbol indicates: this product shall not be disposed of with normal household waste (2012/19/EU).



This symbol indicates: this product contains a built-in rechargeable battery which shall not be disposed of with normal household waste (2006/66/EC). We advise you to take your product to an official collection point to have a professional remove the rechargeable battery. Follow your country's rules for the separate collection of electrical and electronic products and rechargeable batteries. Correct disposal helps prevent damage to the environment and human health.

11. Technical specification

- Program time: 10 minutes fixed
- Controller: 102.8mm max (L) x 46.3mm (W) x 34.9mm max (H)
- Operating temperature: 0°C to 40°C
- Storage and transport temperature: -5°C to 55°C
- Operating humidity: 30% to 95% without condensation
- Storage and transport humidity: 20% to 85% without condensation
- Electrical input from power adapter: 100-240Vac, 50/60Hz. 0.25A
- Electrical output: 5V

12. Explanation of symbols



This symbol indicates: A warning to read the enclosed documents before use and take all safety precautions required.



This symbol indicates: Read the User Guide before you start using the device.



This symbol indicates: Omnilux CLEAR is specified as applied part type BF. B indicates that it is used on the Body and F indicates that it is not connected to the mains voltage.



This symbol indicates: Conformity to UK Directives on health, safety, and environmental protection standards. UKCA stands for UK Conformity



This symbol indicates: "Manufactured by" and provides the name and address of the legal manufacturer.



This symbol indicates: Input for the power supply. This symbol means that the device may only be charged with the adapter that is supplied in the package. Usage of other adapters may not be safe and could lead to electrical shock. The adapter has the following electrical specification: 100-240Vac, 50/60Hz. 0.25A. Electrical Output; 5V.



This symbol indicates: Keep dry.

SN

This symbol indicates: The serial number of the device.

REF

This symbol indicates: The catalogue number for the Omnilux CLEAR device.

LOT

This symbol indicates: The batch code for the Omnilux CLEAR device.



This symbol indicates: The USB connector.



This symbol indicates: The device uses a lithium ion polymer battery.



This symbol indicates: Made in China.



This symbol indicates: Keep the device away from direct sunlight.



This symbol indicates: The upper and lower operating temperatures that the Omnilux CLEAR device can be safely used at.



This symbol indicates: The upper and lower operating humidity that the Omnilux CLEAR device can be safely used at.



This symbol indicates: The cardboard packaging that Omnilux CLEAR came in can be recycled.

IP22

This symbol indicates: The device is protected against a solid object greater than 12.5mm such as a finger and against vertically falling drops of water at up to 15 degrees from vertical.

13. Warranty

Please register your warranty at

<https://omniluxled.com/pages/product-registration>

13.1 Standard warranty:

Under normal use this product is guaranteed for 2 years after its original purchase date against manufacturing defects in materials or workmanship.

13.2 Warranty exceptions:

The lithium battery is guaranteed for 1 year after its original purchase date against manufacturing defects in materials or workmanship.

This warranty extends only to the original purchaser.

This warranty does not cover damage caused by the following:

- Accident, misuse, abuse or alteration
- Servicing by unauthorized persons
- Connection to incorrect power sources
- Use with unauthorized accessories

13.3 What to do if your product is faulty

GlobalMed Technologies Co. or its authorized distributor shall not be responsible for any incidental, special or consequential damages resulting from the use of this product. All implied warranties, including but not limited to implied warranties of fitness and merchantability are limited in duration to one year from date of original purchase.

This warranty gives you specific legal rights, and you may also have other rights that vary from country to country. Some countries do not allow the exclusion or limitation of incidental or consequential damages, or limitations on how long an implied warranty lasts, so some of the above limitations and exclusions may not apply to you.

This warranty is given in lieu of all other warranties, written or oral, whether expressed by affirmation, promise, description, drawing, model or sample. Any and all warranties other than this one, whether expressed or implied, including implied warranties of merchantability and fitness for a particular purpose are hereby disclaimed.

Please register your warranty at **www.omniluxled.com**

If the product is defective within the warranty period, please contact your provider.