



OMNILUX™

— CONTOUR —



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 the instructions in the User Guide.

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

GlobalMed Technologies Co.

163 Camino Dorado Suite B
Napa, CA 94558
Tel: +1-707-224-0200
www.omniluxled.com



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1.0. Omnilux Contour Face

As we age, our skin becomes thinner and drier and develops sags and wrinkles due to the loss of collagen and elastic tissue. Aging skin is also much more susceptible to the development of sun spots and pigmentation. The dermis can lose 20-80% of its thickness during the aging process.

Omnilux Contour Face uses two proven wavelengths of light: 633nm red light and 830nm near-infrared light. These wavelengths have been shown in clinical studies to increase collagen production and to reduce the appearance of fine lines and wrinkles. These effects help skin cells absorb topical skincare products more effectively and helps rebuild the damage caused by the aging process. Omnilux Contour Face has been designed to deliver light directly to the skin, ensuring that the maximum amount of light is hitting its cellular targets, leaving the Face feeling softer, smoother, and with a visible improvement in fine lines, wrinkles, age spots, and overall skin tone and texture.

1.1. Intended use

The Omnilux Contour Face device emits light in the red and near-infrared (NIR) region of the light spectrum and can be used to help reduce the signs of aging.

It is also indicated for the alleviation of pain; increased blood flow and temporary relaxation of muscles can provide pain relief.

2.0. Device description

1. Flexible silicone Face device
2. Controller (containing a lithium battery)
3. Power supply & country specific adapters
4. 2x adjustable straps
5. Carry bag



Omnilux Contour Face is a home-use wearable LED light therapy device. It produces a cool, narrow band of light which helps reduce the appearance of aging skin, sun spots, redness, and inflammation.

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 that allow the device to contour to the skin.

The controller turns the LEDs ON/OFF and controls power to the mask. The controller contains a rechargeable lithium-ion polymer battery. The controller 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. The Omnilux Contour Face device 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. The Omnilux Contour Face device emits light energy in the red and near-infrared (NIR) region of the light spectrum and is intended to treat aging skin and age spots and through a non-thermal mechanism called photobiomodulation.

3.0. Contraindications, warnings and precautions



Contraindications

- **DO NOT** use Omnilux Contour Face to treat any other conditions apart from those listed in the indications for use. The Omnilux Contour Face device has NOT been tested for any other conditions than those listed, and the risk is unknown.
- **DO NOT** use Omnilux Contour Face if you are pregnant, planning on becoming pregnant, or if you are breastfeeding. The Omnilux Contour Face 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 Contour Face if you suffer from light-induced headaches.
- **DO NOT** use Omnilux Contour Face if you suffer from any genetic conditions of the eyes. The Omnilux Contour Face device has NOT been tested on subjects who suffer from genetic conditions of the eyes and therefore the risks are unknown. If you are unsure about any related eye condition please contact your ophthalmologist or doctor prior to using Omnilux Contour Face.
- **DO NOT** use Omnilux Contour Face if you suffer from Lupus erythematosus, photosensitive eczema, or albinism. If you use the Omnilux Contour Face device to treat these conditions, you may cause a severe skin reaction.
- **DO NOT** use Omnilux Contour Face if you suffer from any photosensitive disorder (sensitization to light). If you use the Omnilux Contour Face device and you suffer from a photosensitive disorder, you may cause a severe skin reaction.
- **DO NOT** use Omnilux Contour Face if you are taking any medication that can cause photosensitivity. If you use the Omnilux Contour Face device and you are taking any medication that can cause photosensitivity, you may cause a severe skin reaction.



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).

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

Warnings

- Before using Omnilux Contour Face, you must carry out a sensitization test (see section 5.2 - page 10).
- **DO NOT** use Omnilux Contour Face in any way that is not exactly as specified in these instructions for use. Use of the Omnilux Contour Face device other than exactly as specified in these instructions for use has not been tested and the risk is unknown.
- **TURN OFF** and **REMOVE** the Omnilux Contour Face device immediately if it feels hot or if your skin feels uncomfortably warm. Omnilux Contour Face LEDs do not produce any heat.
- **DO NOT** use Omnilux Contour Face 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.
 - If you use the Omnilux Contour Face device without first removing these products, you may cause a skin reaction, damage your device, or you may reduce the effect of the LED treatment.
- **DO NOT** use the Omnilux Contour Face device near water or anywhere water can be spilt onto the equipment.
- **DO NOT** use the Omnilux Contour Face device if you think it may have come into contact with water. Keep the Omnilux Contour Face device away from HOT surfaces.
- **DO NOT** attempt to modify the Omnilux Contour Face device in any way. Modifying the Omnilux Contour Face device will void your warranty. Modifying the Omnilux Contour Face device could cause an electric shock when the device is used again. The device contains no serviceable parts.
- **DO NOT** use Omnilux Contour Face if the device, battery, or charging plug are damaged in any way.

General safety


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

Precautions

- The Omnilux Contour Face straps contain a mixture of polyester, nylon and lycra. If you are allergic to any of these materials, you may not be able to use the straps.
- Omnilux Contour Face CANNOT be operated while it is in the charging mode.
- Before each use with the device turned off, clean the device. All surfaces of the Omnilux Contour Face device may be cleaned by following the cleaning instructions in Section 7.1. - page 11.
- **DO NOT** use any other cleansing products other than those stated in the cleaning instructions. Use of other cleansing products may damage the Omnilux Contour Face device. Store the Omnilux Contour Face device flat and at room temperature in dry conditions, away from direct sunlight.

4.0. Risks and benefits

4.1. Potential adverse effects


-  • Immediately after treatment, skin may appear red. Skin should return to normal within 1-2 hours.

4.2. Potential benefits

- People who have undergone a course of 12 Omnilux Contour Face treatments report a visible improvement in skin tone and texture.


5.0. First time setup

5.1. Unpacking and charging your Omnilux Contour Face

-  The Omnilux Contour Face device uses a lithium-ion polymer battery. When in the charging mode, the device will not illuminate.
 - Before use, it is important to fully charge the Omnilux Contour Face battery.
 - Unpack the Omnilux Contour Face device and check off parts described in Section 2.0. - page 5.
 - To charge Omnilux Contour Face, insert the micro USB cable into the controller. Insert the USB connector into the USB port of the power supply.
 - Insert the power supply into a suitably grounded outlet and press ON/OFF button on the controller.

- The 3 LEDs in the control unit will start to flash to indicate charging. The Omnilux Contour Face battery is fully charged when the three indicator LEDs on the battery stay illuminated.

5.2. 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 Contour Face 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 Contour Face is not suitable for you.

6.0. Using Omnilux Contour Face

6.1. Treatment recommendations:

- For best results, treat for 3-5 days a week for a minimum of 4 weeks.
- Maintenance treatments should be carried out as desired, according to lifestyle and skin condition.

6.2. Wearing Omnilux Contour Face

- Omnilux Contour Face comes with adjustable straps that allows you to comfortably wear the device on your face.
- To fit, thread the straps through the inlet holes on either side of the device.
- Loop the straps around the back of your head and secure firmly.
- Adjust if necessary.

6.3. Carrying out a treatment


1. Cleanse and exfoliate the face to remove any traces of skincare
2. Place Omnilux Contour Face on the face and secure with the straps provided and press ON/OFF button on the controller. The device turns off after a 10-minute treatment. You may stop the treatment at any time by pressing the ON/OFF button on the controller.

3. Remove the device, apply your normal skincare and sunscreen.
4. Clean the device using a water-based wipe or a damp clean cloth. Ensure that the device is NOT being charged when cleaning.
5. Repeat 3 – 5 days a week for a minimum of 4 weeks.





7.0. Care and maintenance

- Store the Omnilux Contour Face device flat and at room temperature in dry conditions. Use the carry bag provided to store your device.
- Avoid storing the Omnilux Contour Face device in dusty conditions, in direct sunlight, or in damp and humid conditions.
- The Omnilux Contour Face device contains no serviceable parts.
- Before each use, with the device off, clean the device following the cleaning instructions below.

7.1. Cleaning the Omnilux Contour Face device

-  **DO NOT** use any other cleansing products as these may damage the plastics.
- Clean both sides of the Omnilux Contour Face device with a water-based wipe or a damp clean cloth. Place the mask on a clean dry surface to air dry. Visually inspect the surfaces to ensure they are clean. Stubborn stains can be removed by wiping gently with 70% alcohol.


7.2. Disposal

-  **DO NOT** dispose of any part of the device at a domestic waste facility.
-    The Omnilux Contour Face 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.

7.3. Troubleshooting

Problem	Possible Cause	Action
No red or near-infrared light coming from Omnilux Contour Face	Not charged	Plug the charger into the controller making sure that the connectors are attached and leave charging until the three indicator LEDs on the controller remain lit and do NOT flash
No red or near-infrared light from Omnilux Contour Face	Device is connected to electrical outlet	Unplug micro USB connector from controller
LEDs do not turn off after 10 minutes	Device is faulty	Return to your supplier
LEDs flicker during treatment	Omnilux Contour Face is not fully inserted into controller	Ensure the controller and Omnilux Contour Face 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. The Omnilux Contour Face device has no parts you can repair yourself.

8.0. Labeling

The labeling supplied with the device contains the following information:

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

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.

Technical specification

- LEDs: Red: 633nm+/-10nm. NIR: 830nm+/-17.5nm
- Controller: 102.8mm max (L) x 46.3mm (W) x 34.9mm max (H)
- Program time: 10 minutes fixed
- 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
- Mains electrical input from power adapter: 100-240Vac, 50/60Hz. 0.25A
- Electrical output: 5V


Compliance


The Omnilux Contour Face device complies with the standard of basic safety for medical devices EN60601-1:2006/A12:2014 and with the relevant collateral and particular standards for non-laser light source medical equipment for home use EN 60601-1-11:2015, EN 60601-2-57:2011, and EN 60601-1-2:2015 and IEC 62471:2006 Photobiological Safety of Lamps and Lamp Systems. EN 55014-1.2006+A1: 2009+A2 2011 Electro Magnetic Compatibility – requirements for household appliances, electric tools and similar apparatus – Part 1 emissions. EN 55014-2:2015 Electromagnetic compatibility- requirements for household appliances electric tools and similar apparatus – part 2: immunity – product family standard.


Regarding electromagnetic compatibility (EMC) and electromagnetic fields (EMF), the device should be kept away from radio frequency (RF) equipment to avoid interference.


Explanation of symbols


There are several safety warning labels on the Omnilux Contour Face device and associated packaging and in the user manual. Not following these warnings may result in one or more of the following hazards: electrical shock and/or fire.


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

 This symbol indicates: Read the user manual before you start using the device.

 This symbol indicates: The device 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: Conforms to certain EC Directives on health, safety, and environmental protection standards. CE stands for 'Conformit Européenne'.


 This symbol indicates: "Manufactured by" and provides 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.

 This symbol indicates: The serial number of the device.

 This symbol indicates: The catalogue number for the device.


 This symbol indicates: The batch code of the 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 device away from direct sunlight.

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

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

 This symbol indicates: The cardboard packaging that the device came in can be recycled.

9.0. Warranty

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

This warranty extends only to the original purchaser. If the product should become faulty within the warranty period, contact your provider.

- GlobalMed Technologies Co. or its authorised distributor reserves the right to repair a defective product.
- GlobalMed Technologies Co. or its authorised distributor reserves the right to replace a defective product with the most compatible product currently available.

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

GlobalMed Technologies Co. or its authorised 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.