



faceLITE

natural-facelift.com

USER GUIDE

faceLITE

FROM THE NATURAL FACELIFT COMPANY



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

Please feel free to contact us at hello@natural-facelift.com if you have any comments about the faceLITE™ LED system or this User Guide.

faceLITE™ and the Natural facelift Company™ are trademarks of; iSMART Developments Ltd, Registered office Fulford House Newbold Terrace, LEAMINGTON SPA. CV32 4EA. United Kingdom



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1.0. faceLITE from the Natural Face Lift Company™

As we age 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 brown spots and pigmentation. The skins dermis can lose from 20-80% of its thickness during the aging process.

faceLITE uses two proven wavelengths of light; 633nm, red light and 830nm or near infra-red light. These wavelengths have been shown in clinical studies to stimulate collagen and elastin production cells and to improve blood flow and tissue oxygenation through a process called photobiomodulation. These effects help skin cells absorb topical skincare products more effectively and helps rebuild the damage caused by the aging process.

faceLITE has been designed to deliver light directly to the skin, ensuring that the maximum amount of light hits its cellular targets and is not wasted.

1.1. Intended use

The faceLITE™ LED system emits light in the red and near infra-red (NIR) region of the light spectrum and is indicated for the treatment of cosmetic indications including facial wrinkles.

2.0. Device Description

The faceLITE consists of

1. Silicon flexible face mask
2. Controller
3. Power supply and country specific adaptors
4. USB C to USB A connector
5. Head straps
6. Carry bag



faceLITE is a home use wearable LED phototherapy device whose purpose is to produce an even, cool, narrow-band of light for the treatment of cosmetic indications including facial wrinkles.

The system consists of a flexible silicon mask that contains light emitting diodes (LEDs) and a controller. The LEDs generate the light. The mask is worn on the face and is held in place by an adjustable Velcro strap.

The controller switches 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 faceLITE cannot be operated while charging.

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


The faceLITE Light emitting diode (LED) system emits light energy in the red and near infra-red (NIR) region of the light spectrum and is intended to treat facial wrinkles through a non-thermal mechanism called Photobiomodulation.


3.0. Contraindications, Warnings and Precautions

Contraindications

- **DO NOT** use faceLITE LED system to treat any other conditions apart from those listed in the indications for use. The faceLITE LED system has not been tested for any other conditions than those listed, and the risk is unknown.
- **DO NOT** use faceLITE LED system if you are pregnant, planning on becoming pregnant or breastfeeding. The faceLITE LED system has NOT been tested on pregnant or breast-feeding women and therefore the risk to the foetus, neonate or pregnant women is unknown.
- **DO NOT** use faceLITE LED system if you suffer from Lupus erythematosus, photosensitive eczema or Albinism. If you use the faceLITE LED system to treat Lupus erythematosus, photosensitive eczema or Albinism you may cause a severe skin reaction.
- **DO NOT** use faceLITE LED system if you suffer from any photosensitive disorder (sensitization to light). If you use the faceLITE LED system and you suffer from a photosensitive disorder you may cause a severe skin reaction.

- **DO NOT** use faceLITE LED system if you are taking any medication that can cause photosensitivity. If you use the faceLITE LED system 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).

Warnings

- Before using the faceLITE you must carry out a sensitization test (see section 5.2-page 9). **DO NOT** use the faceLITE if you are sensitive to faceLITE.
- **DO NOT** use the faceLITE system in any way that is not exactly as specified in these instructions for use. Use of the faceLITE LED system other than exactly as specified in these instructions for use has not been tested and the risk is unknown.
- **TURN OFF** and **REMOVE** the faceLITE immediately if it feels hot or your skin feels uncomfortably warm.
- Only use faceLITE with the proprietary hydrogel mask recommended and supplied with the device. Other masks are available but have not been tested with the faceLITE system.
- **DO NOT** use the faceLITE without first removing creams, lotions or 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 faceLITE without removing these products, you may cause a skin reaction, or you may reduce the effect of the treatment.
- **NEVER** use faceLITE near water or where water can be spilt onto the equipment. **DO NOT** use the faceLITE if you think it has come into contact with water.
- Keep the faceLITE away from **HOT** surfaces.
- **DO NOT** attempt to modify the faceLITE in any way. Modifying the faceLITE will void your warranty. Modifying the faceLITE could cause an electric shock when the system is used again. The system contains no serviceable parts.
- **DO NOT** use the faceLITE if the mask, controller, charging plug or cord are damaged in anyway.

General Safety


The faceLITE system 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 faceLITE strap 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 strap provided.
- The faceLITE system cannot be used in charging mode.
- Before each use, with the device switched off, clean the facemask. All surfaces of the faceLITE system may be cleaned by following the cleaning instructions in Section 7.1 - page 10.
- Do NOT use any other cleansing products other than those stated in the cleaning instructions. Use of other cleansing products may damage the faceLITE
- Store the faceLITE at room temperature in dry conditions, away from direct sunlight.

4.0. Risks and Benefits

4.1. Known Risks


-  • Immediately after treatment skin may appear red. Skin should return to normal within 1-2 hours.
- Temporary headaches immediately following the light treatment. Headaches can be treated with an appropriate pain killer and rehydration.

4.2. Known Benefits

- People who have undergone a course of 12 faceLITE LED treatments report a reduction in fine facial lines and improvements in texture and pigmentation.


5.0. First Time Setup.

5.1. Unpacking and Charging your faceLITE

-  The faceLITE system uses a Lithium ion polymer battery. When in the charging mode the faceLITE will not illuminate.
- Before use it is important to fully charge the faceLITE battery.
- Unpack the faceLITE device and check off the parts described in Section 2 page 5.

- To charge faceLITE 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 switch on.
- The 3 LEDs in the control unit will start to flash to indicate charging. The faceLITE battery is fully charged when the three indicator LED's on the control unit 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 faceLITE over your inner arm.
2. Switch ON the controller and allow the faceLITE to run for its full 10-minute treatment program.
3. At any time if your skin feels HOT or uncomfortable STOP using the device immediately.
4. After the treatment wait at least 6 hours. If the skin on your inner arm appears red and/or itchy then faceLITE is unsuitable for you. Return the device to the retailer within 14 days of purchase.

6.0. Using faceLITE Device

6.1. Treatment Recommendations:

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

6.2. Wearing the faceLITE LED system

- faceLITE comes with an adjustable Velcro strap that allows 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.


6.3. Carrying out a treatment

1. Cleanse and exfoliate skin to remove any traces of skincare
2. Apply the hydrogel mask (use at least once a week).
3. Place faceLITE device on the face, secure with the Velcro strap and switch on the controller. The device switches off after a ten-minute treatment time. You may stop the treatment at any time by pressing the ON/OFF button on the controller.
4. Remove the mask, apply your normal moisturiser and sunscreen.
5. Clean the mask using a water-based wipe or a damp clean cloth. Ensure that the device is NOT connected to the mains when cleaning.
6. Repeat 3 – 5 times a week for four weeks.


7.0. Care and Maintenance

- Store the faceLITE LED system at room temperature in dry conditions. Use the carry bag provided.
- Avoid storing the faceLITE LED system in dusty conditions, in direct sunlight or in damp and humid conditions.
- The faceLITE LED system contains no serviceable parts.
- Before each use, with the device switched off, clean the facemask following the cleaning instructions below.

7.1. Cleaning the faceLITE LED system

-  **DO NOT** use any other cleansing products as these may damage the plastics.
- Clean the transparent (Face side) of the mask and rear with a water based wipe or damp clean cloth. Stubborn stains can be removed by wiping gently with 70% alcohol.

7.2. Disposal

-  **DO NOT** dispose of any part of the faceLITE at a domestic waste facility.
- The faceLITE 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 infra-red light from faceLITE.	Not charged	Plug in the controller to the charger making sure that the connectors are attached and leave charging until the three indicator LED's on the controller remain lit and do NOT flash.
No red or infra-red light from faceLITE.	Device connected to the mains	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	Device is faulty	Return to your supplier

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 faceLITE LED System has NO parts you can repair yourself.


8.0. Labelling

The labelling supplied with the device contains the following information

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

Recycling

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

 This symbol means that 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

- Weight: 600g (controller and face mask)
- LEDs: Red: 630nm+/-10nm. NIR: 830nm+/-17.5nm
- Total Device Dimensions:
 - Facemask:- 406mm max (w) x 196mm max (h)
 - Controller: 23mm max (dia) x 104mm (l)
- 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 adaptor: 100-240Vac/47-63Hz. 0.6A
- Electrical Output: 5V


Compliance


The faceLITE LED mask 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.


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 faceLITE 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 warning symbol on the device label is a warning to read the enclosed documents before use and take all safety precautions required.


 This symbol on the device label means: Read the user manual before you start using the device.


 This symbol means: that the faceLITE 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 means: Conforms to certain EC Directives on health, safety, and environmental protection standards. CE stands for 'Conformité Européenne'.


 This symbol means "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/47-63Hz. 0.6A. Electrical Output; 5V.


 This symbol means keep dry


 This symbol indicates the serial number of the device.


 This symbol refers to the catalogue number for the faceLITE mask.

 This symbol refers to the batch code of the faceLITE mask.

 This symbol indicates the USB connector.

 This symbol means that the device uses a Lithium ion Polymer battery.

 This symbol means made in China

 This symbol means keep the device away from direct sunlight.



This symbol means the upper and lower operating temperatures that the faceLITE can be safely used at.



This symbol means the upper and lower operating humidity that the faceLITE can be safely used at.



This symbol means that the cardboard packaging that the faceLITE 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.

- iSMART Developments Ltd or its authorised distributor reserves the right to repair a defective product.
- iSMART Developments Ltd 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

iSMART Developments Ltd or its authorised distributors 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.natural-facelift.com

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

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According to MDD 93/42/EEC, the faceLITE LED mask is classified as a cosmetic device within the European union. However, for purposes of safety we have conducted additional testing so that you can be ensured of the safety and efficacy of the faceLITE system.

The faceLITE system has been tested to or complies with the following standards;

EN 60601-1:2006/A12:2014. Medical electrical equipment. General requirements for basic safety and essential performance.

EN 60601-1-2:2015 Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests

IEC 60601-1-6 2010 AMD12013 Medical Electrical Equipment – Part 1 General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability.

IEC/EN60601-1-11:2015 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC/EN 60601-2-57:2011 Medical electrical equipment. Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.

EN 62471:2008 Photobiological Safety of Lamps and Lamp Systems

EN 62366-1:2015 Application of usability engineering to medical devices.

EN ISO 10993-1:2010-04 Biological evaluation of medical devices Part 1: Evaluation and testing

EN ISO 15223-1:2017 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

EN ISO 14971:2012 Medical devices - Application of risk management to medical devices