

SMOOTHSKIN

DuoLux™

LED Face Mask

USER MANUAL



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It is Mandatory that users of this device read and comprehend all information in this User Manual prior to using the DuoLux™ device. You must follow all the instructions in the User Manual.

Please contact us if you have any comments about the device or this User Manual or if you experience any side effects that are not mentioned in this guide or are more severe than those described.



smoothskin.com



help@smoothskin.com

DuoLux™ is a trademark of SMOOTHSKIN



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Before using the device you must carry out a sensitisation test and wait 6 hours.

WHO SHOULD USE DuoLux™

Thank you for choosing DuoLux™. The device is suitable for adults wishing to treat full facial wrinkles.

If you have purchased the device and find that it is NOT suitable for you, please contact your supplier to return the device within 30 days with proof of purchase.

INTRODUCTION

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.

The device uses the clinically proven and trusted wavelengths of light of 630nm or red light and 830nm or near-infrared light. These wavelengths have been shown in clinical studies to stimulate collagen and elastin production cells and to improve facial wrinkles, blood flow and tissue oxygenation through a process called photobiomodulation.

The device 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.

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

INTENDED PURPOSE

The DuoLux™ Light emitting diode (LED) device emits light energy in the red and near-infrared (NIR) region of the light spectrum and is intended for use in the treatment of full facial wrinkles through a non-thermal mechanism called Photobiomodulation.

The device is to be used at home by adults only.

DEVICE DESCRIPTION

The device consists of:

1. Silicone Flexible LED Face Mask
2. Controller (Containing a Lithium Battery)
3. Power Supply and Country Specific Adaptors
4. Head Strap
5. Carry Bag
6. User Manual
7. Eyewear*

The device is a home use wearable LED phototherapy device.

The device consists of a flexible silicone face 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 LEDs produce red (630nm \pm 10nm) and near-infrared (830nm \pm 10nm) light in the visible spectrum for the treatment of full-facial wrinkles. The device works through a non-thermal mechanism called Photobiomodulation.

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 device is connected to the controller by a USB A connector.

The power supply is used to charge the Lithium battery and is connected to a suitable electrical outlet via a 2 or 3 pin plug. The power cable is connected to the controller by a standard USB C connector. The device 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.


***Eyewear is provided for comfort only and clips easily into the eye holes of the mask. The use of eyewear is optional as this mask complies to all relevant eye safety standards (IEC 62471:2006).**

CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS



Contraindications

- **DO NOT** share the device with any other person. The device is for single person use only.
- **DO NOT** use the device to treat any other medical conditions apart from those listed in the intended purpose. The device has not been tested for any other conditions than those listed, and the risk is unknown.
- **DO NOT** use the device if you are pregnant, planning on becoming pregnant or breastfeeding. The device 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 the device if you have an allergy to Silicone. The mask is made from a medical grade silicone. To arrange a return, please contact our team immediately at help@smoothskin.com.
- The 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. To arrange a return, please contact our team immediately at help@smoothskin.com.
- **DO NOT** use the device if you suffer from light induced headaches.
- **DO NOT** use the device if you suffer from any genetic conditions of the eyes. If you are unsure about any related eye condition and using the device contact a health care professional.
- **DO NOT** use the device if you suffer from lupus erythematosus, photosensitive eczema or albinism. If you use the device to treat lupus erythematosus, photosensitive eczema or albinism you may cause a severe skin reaction.
- **DO NOT** use the device if you suffer from any photosensitive disorder (sensitisation to light) of the eyes or skin. If you use the device and you suffer from a photosensitive disorder you may cause a severe skin reaction.
- **DO NOT** use device if you are taking any medication that can cause photosensitivity. If you use the device and you are taking any medication that can cause photosensitivity you may cause a severe skin reaction.
- **For a list of drugs that can cause photosensitivity, please visit: smoothskin.com**

 **Photosensitivity** is a common side effect of various medications, including 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 device you must carry out a sensitisation test. Please read the section "Sensitisation Test" on page 12 on how to carry one out.
- **DO NOT** use the device in any way that is not exactly as specified in this User Manual. Use of the device other than exactly as specified in this User Manual has not been tested and the risk is unknown.
- **DO NOT** use the device in an environment that is **NOT** specified by the manufacturer, as this may cause damage to the device or harm to the user.
- Only use the proprietary hydrogel mask recommended. Other masks are available but have not been tested with the device, may block light penetration and reduce the effects of the treatment.
- **TURN OFF** and **REMOVE** the device immediately if it feels hot or your skin feels uncomfortably warm and **DO NOT** continue to use the device. To arrange a return, please contact our team immediately at help@smoothskin.com.
- **STOP** using the device during a treatment if you experience headaches or changes in vision or pain in the eyes. Should this occur, contact a healthcare professional.
- **DO NOT** use the device without first removing creams, lotions, or make-up **BEFORE** treatment. Some ingredients in these products may cause light sensitisation or may reduce the effect of the treatment. If you use the device without removing these products, you may cause a skin reaction, or may reduce the effect of the treatment.
- **NEVER** use the device near water or where water can be spilt onto the equipment. **DO NOT** use the device if you think it has come into contact with water.
- Keep the device away from **HOT** surfaces and do not use or store in direct sunlight.

- **DO NOT** use the device if it has been exposed to environmental conditions outside of those specified in the Technical Specification on page 15.
- **DO NOT** attempt to modify the device in any way. Modifying the device will void your warranty and could cause an electric shock or burns. The system contains no serviceable parts.
- **DO NOT** use the device any longer if it shows any signs of damage to the material through wear and tear. If you follow the care and maintenance for your device, then it has a minimum lifetime of 2 years.
- **DO NOT** use the device if the face mask, controller, packaging, charging plug or cord are damaged in any way.
- **DO NOT** dispose of any part of the device with normal household waste as this could cause environmental damage from the components contained in the device.

General Safety

The device is an electrical device, which under certain circumstances could present an electrical shock hazard to the user. Please read this User Manual thoroughly and follow directions to assure maximum safety during operation.

The device may only be charged with the power supply that is supplied with the device. The use of other power supplies may not be safe and could lead to electric shock.

If you need to urgently terminate the treatment, you should use the on/off switch on the top of the controller. This will instantly terminate the treatment.

Precautions

- **The device cannot be used in charging mode.**
- **DO NOT** stare directly at the LED light source.
- Before each use, with the device switched off, clean the face mask. All surfaces of the device may be cleaned by following the cleaning instructions on page 13.
- **DO NOT** use any other cleansing products other than those stated in the cleaning instructions. Use of other cleansing products may damage the device.
- Store the device at room temperature in dry conditions, away from direct sunlight.
- Take care when using the device around young children. Electrical cables can present a strangulation hazard.
- **DO NOT** mishandle or allow children to mishandle the device or leave it unattended when it is switched on as there is a risk of fire or burns.

- Check if the voltage indicated on the device power supply corresponds to the local mains voltage before you connect it, to avoid risk of electrocution or permanent damage to the device.
- Check that the device power supply is properly installed into the wall socket, and they have a good connection, otherwise there is a risk of the device power supply becoming hot and causing a fire or burns.
- **DO NOT** subject the device to heavy shocks or vibrations to avoid risk of damage to the device. If you drop and damage the device, **DO NOT** use it any longer.
- **DO NOT** use the device near other electromagnetic compatibility (EMC), electromagnetic fields (EMF) or radio frequency (RF) equipment, such as pacemakers to avoid potential interference and disturbances. These interferences and disturbances could cause malfunction of essential medical equipment.
- **DO NOT** use the device to overtreat - only use per the recommended treatment protocols.

RISKS AND BENEFITS



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 itchiness and dryness. This is short lived and clears within a few days.
- Temporary headaches immediately following the light treatment.

Although this device emits levels of visible and near-infrared light that are considered to be safe for the skin, if you have an adverse reaction after using the device, you should stop using the device.

If you experience a side effect that is not described above or is of greater severity than described above, please **STOP** using the device immediately and contact a healthcare professional and iSMART Developments Limited or the SMOOTHSKIN team and your representative Competent Authority if you deem it applicable.

Potential Benefits

People who have undergone a course of 3-5 weekly treatments for a minimum of 6 weeks using the device report a reduction in full facial wrinkles.

FIRST TIME SETUP

Unpacking and charging your DuoLux™

Unpack the device and check off the parts described in the Device Description on page 6.

Visually inspect the parts and connections. Return the device to your supplier if you think the device or connecting parts or components are damaged or have been previously used.

DO NOT use the device if you notice the face mask, packaging, connecting parts or components are damaged.

Charging your DuoLux™

Before use, fully charge the battery.

The device uses a controller which contains a lithium-ion polymer battery. When the controller is connected to the power supply and charging; do not attempt to use the mask as the LEDs will not illuminate.

- To charge the controller insert the USB C cable from the power supply into the controller.
- Insert the power supply into a suitable electrical outlet and press the ON/OFF button.
- The LEDs on the controller will flash to indicate charging. The battery is fully charged when the three indicator LEDs on the controller stay illuminated.

When fully charged the battery will deliver a minimum of 10 treatments. The lifetime of the Lithium battery can be maximized by allowing it to fully charge and then fully discharge during regular use.

If the indicator LED's do not illuminate, please charge the device. If the indicator LEDs do not illuminate during charging, then the device may be faulty. Please refer to the Troubleshooting Section on page 14.

Connecting to the Controller

- Connect the device mask by inserting the USB A connector of the face mask into the USB A port of the controller.

SENSITISATION TEST



Before carrying out your first treatment you must carry out a sensitisation test to see if you are sensitive to light when using the device.

Follow the step-by-step guide below.

1. Connect the device mask to the controller.
2. Cleanse your inner arm to remove any skincare such as sunscreens.
3. Place the device over your inner arm (Light emitting diodes towards your skin).
4. Switch ON the controller and allow the device to run for its full 10-minute treatment program.
5. At any time if your skin feels **HOT** or uncomfortable **STOP** using the device immediately.
6. After the treatment wait at least 6 hours. If your skin on your inner arm is red or itchy then the device is unsuitable for you. Please contact our team at help@smoothskin.com to arrange a return within 30 days of purchase.

USING THE DuoLux™

Treatment Recommendations:

- For best results treat for 3-5 days a week for a minimum of 6 weeks.
- Maintenance treatment should be carried out as required, according to lifestyle and skin condition.

Wearing the DuoLux™

- The device comes with an adjustable Velcro strap that allows you to comfortably wear the mask.
- To fit the mask, thread the strap through the inlet holes on either side of the mask.
- Loop the straps around your head and secure firmly.
- Adjust if necessary.

Carrying out a Treatment

1. Cleanse and exfoliate skin to remove any traces of skincare.
2. Apply the hydrogel mask (if desired).
3. Insert the Eyewear if you would like.
4. Place the device on the face and secure with the Velcro strap.

5. Connect the device to the controller 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 top of the controller.
6. Remove the mask, apply your normal skincare.
7. Clean the transparent (Face) side of the mask and the rear of the mask with a water-based wipe. Ensure that the device is **NOT** being charged when cleaning.
8. Repeat 3 - 5 times a week for a minimum of six weeks.

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 device at room temperature in dry conditions. Use the carry bag provided.
- Avoid storing and using the device in dusty conditions, in direct sunlight or in damp and humid conditions. **DO NOT** use the device if it has been exposed to environmental conditions outside of those specified in the Technical Specification on page 15.
- The device contains no serviceable parts.
- Before each use, with the device switched off, clean the face mask following the cleaning instructions below.
- Before each use visually inspect the device, controller, packaging and cables for damage. **DO NOT** use the device if you notice any signs of visible damage to the material through wear and tear.
- **DO NOT** use the device any longer if it shows any signs of damage to the material through wear and tear. If you follow the care and maintenance for your device then the device has a minimum lifetime of 2 years.

CLEANING THE DuoLux™



DO NOT use any other cleaning products as these may damage the face mask.

- Before cleaning ensure that the device and controller is unplugged from the mains outlet.
- Clean the transparent (Face) side of the mask and the rear of the mask with a water-based wipe. Stubborn stains can be removed by wiping gently with 70% alcohol.
- Place the device on a clean surface and allow to air dry.

DISPOSAL



DO NOT dispose of any part of the DuoLux™ device at a domestic waste facility (2006/66/EC).



The device controller contains a Lithium-ion polymer battery. 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.



The outer packaging is recyclable, the device components (mask, straps, controller, power supply and connecting cables) are not and should not be disposed of in household waste.

TROUBLESHOOTING

Problem	Possible Cause	Action
No red or near-infrared light from the device. Indicator light is not illuminated.	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 red or near-infrared light from the device.	The device is connected to an electrical outlet.	Unplug USB connector from controller.
Indicator lights on controller do not illuminate and do not illuminate during charging. No red or near-infrared light from the device even after battery is fully charged.	Device is faulty.	Contact our team to arrange a return: help@smoothskin.com
Red and near-infrared LEDs do NOT turn OFF after 10 minutes.	Device is faulty.	Contact our team to arrange a return: help@smoothskin.com

Problem	Possible Cause	Action
The mask, controller, packaging, charging plug or cord are damaged in any way.	Device is faulty.	Contact our team to arrange a return: help@smoothskin.com
Red and near infra-red LEDs flicker continuously during treatment.	Device is faulty.	Contact our team to arrange a return: help@smoothskin.com

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 place of purchase or contact the Customer Service team to arrange a return:

help@smoothskin.com



- **DO NOT** attempt to investigate any further.
- **DO NOT** attempt to modify the device in any way. Modifying the device will void your warranty. Modifying the device could cause an electric shock when the system is used again. The system contains no serviceable parts.

LABELLING

The labelling supplied with the device contains the following information.

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

TECHNICAL SPECIFICATION

- Model Number: TN2010
- UDI Number: 5060534510968
- Program Time: 10 minutes ± 11 Seconds
- Wavelengths: 630nm and 830nm +/- 10nm
- Standard Operating Intensity: 30mW/cm²
- Operating Temperature: 0°C to 30°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 Adaptor: 100-240Vac, 50/60Hz, 0.25A
- Electrical Output; 5V, 1A
- IP22

EXPLANATION OF SYMBOLS

There are several safety warnings on the 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.



Warning.



It is mandatory to read and comprehend all the information in the User Manual prior to using the device.



Refer to the User Manual for guidance on using the device.



Applied part type BF.



The device is single patient multiple use.



Conforms to certain EC Directives on health, safety, and environmental protection standards. CE stands for 'Conformité Européenne'.



Conformity to UK Directives on health, safety, and environmental protection standards. UKCA stands for UK Conformity Assessed.



Manufacturers information.



Date of manufacture.



Keep dry.



Serial number.



Model number for the device (**TN2010**).



Batch code.



Unique device identifier 5050534510968.



DuoLux® is a medical device. (in Australia and USA).



Made in China.



Keep away from direct sunlight.



Temperature limit (Operation).



Humidity limitation (Operation).



The cardboard that the device was packaged in can be recycled. The device components (face mask, straps, controller, power supply and connecting cables) are not and should not be disposed of in household waste.



The device is protected against solid objects over 12.5mm in diameter (such as fingers) and vertical water droplets when the device is tilted 15°.



Product shall not be disposed of with normal household waste (2012/19/EU).



This symbol indicates: Input for the power supply. This symbol means that the device may only be charged with the adapter that is supplied with the device. 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, 1A.**



Class II Double Insulated Electrical Appliance.



An electronic version of the User Manual is available at smoothskin.com



Australian Sponsor Details (Australia Only).

WARRANTY

To start a claim against the warranty, you will need to show proof of purchase within 2 years. To start a claim contact, help@smoothskin.com.

Standard Warranty:

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

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 conditions:

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

What to do if your product is faulty

If the product should become faulty within the warranty period, contact your place of purchase.

CyDen Limited or iSMART Developments Limited or its authorised distributor reserves the right to replace a defective product with the most compatible product currently available.

CyDen Limited or iSMART Developments Limited 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.

Warranties of merchantability and fit

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.



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