LED Light Therapy Mask

Instructions for Use

Model: E43-8A

(Sub-models: E43-6，E43-10，E43-11，E43-13)

Note: Sub-models differ only in cosmetic appearance (color/finish). Technical specifications are identical to E43-8A.

Shenzhen Eyco Technology Co., Ltd.

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⚠️ **IMPORTANT: This device is an Over-the-Counter (OTC) medical device.**
Read all instructions before use.

Document No.: YKM-E43-8A-UM | Version: V1.0 | Effective Date: 2025-08-29

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Chapter 1: Device Description

This chapter describes the design features, materials, light source configurations, treatment modes, and key technical parameters of the E43-8A Series Magnetic-Attachment LED Light Therapy Mask.

1.1 Product Overview

Model: E43-8A

Product Name: LED Light Therapy Mask

Material: Silicone， PC , magnetic connectors

1.2 LED Light Source Configuration

LED Count: 72 bulbs

Light Source Types and Wavelengths:

- Red: 630nm±10nm,
- Blue: 415nm±10nm,
- NIR: 850nm±10nm,

1.3 Treatment Modes

5 treatment modes:

- Mode 1 — Red + NIR: Anti-aging & Wrinkle Reduction (630nm+ 850nm)
- Mode 2 — Blue: Acne Treatment (415nm)
- Mode 3 — Red +Blue + NIR: Full Spectrum Skin Care (All wavelengths)

1.4 Embedded Controller

The E43-8A controller embedded includes:

- LCD Display: Shows current mode number, and battery status in real time
- Power Button (short press): Cycles through the 3 treatment modes
- Brightness Control: Not adjustable (default low level)
- Power Button: Long press to power on/off

1.5 Remote Control

- LCD Display: Shows current mode number, remaining treatment time, brightness level, and battery status in real time
- Mode Button (short press): Cycles through the 3 treatment modes
- Brightness Control: short press Power Button, to toggle the display from 1-line to 5-line view.

It can cycle between the intensity levels of "1 (1st gear) -2 (2nd gear) -3 (3rd gear)-4 (4th gear)-5(5th gear)".

- Power Button: Long press to power on/off
- Time Control: When the Time key is short pressed, It can cycle between the time of "10min-20min -30min".The display screen can cycle to show the number"10 -20 -30”.

1.6 Power and Treatment Parameters

Power Supply: DC 5V/1A, Rechargeable Li-ion 3.7V 1000mAh *2

Charging Time: About 3.5 hours

Default Treatment Time: 10 minutes (default), adjustable 10/20/30 min

Brightness Levels: 3 (Low / Medium / High)

1.7 Physical Specifications

Mask Dimensions: 203mm × 227 mm × 127 mm (mask); ~90 × 36 × 11 mm (Remote Controller)

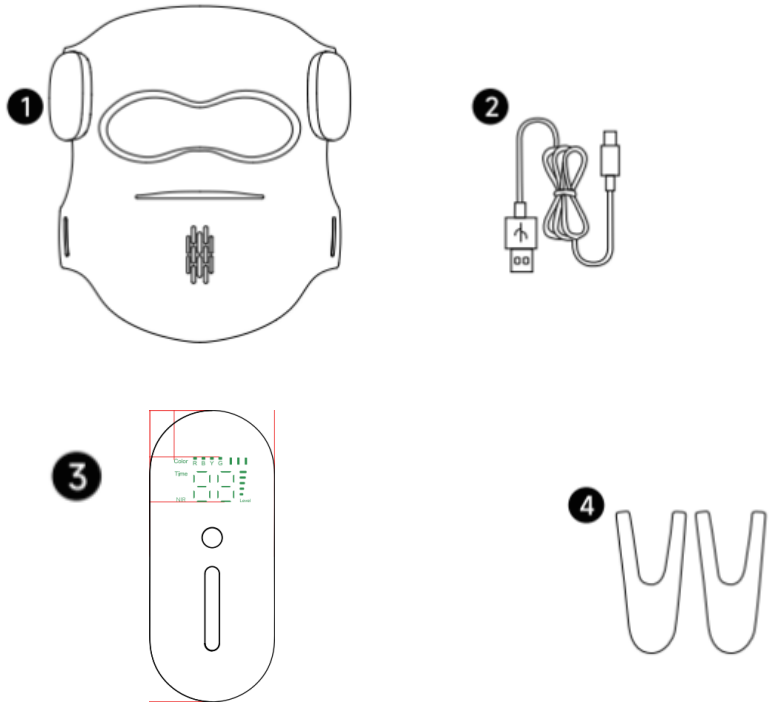
Photobiological Safety: RG Exempt (Risk Group Exempt)

Electrical Protection Class: Type BF Applied Part

Ingress Protection Rating: IPX2

1.8 Package Contents

- LED Light Therapy Mask with Controller ×1
- Remote controlr ×1
- USB Charging Cable ×1
- Elastic Adjustable Straps ×1 set
- Instructions for Use ×1



Chapter 2: Intended Use / Indications for Use

The LED Light Therapy Mask is an over-the-counter (OTC) device intended for use in a home healthcare environment.

The device is indicated for:

Red + Infrared light: treatment of full face wrinkles.

Blue light: Treatment of mild to moderate inflammatory acne.

Yellow light:Treatment of Skin Soothing & Repair.

Mixed light: Treatment of mild to moderate inflammatory acne.

Chapter 3: Contraindications

DO NOT use this device if any of the following apply:

1. History of light-triggered seizures or epilepsy
2. Photosensitive conditions (porphyria, lupus erythematosus, photosensitive eczema, albinism, etc.)
3. Skin cancer or suspicious/cancerous lesions on the treatment area
4. Pregnancy, attempting pregnancy, or breastfeeding
5. Taking photosensitizing medications (antibiotics, diuretics, NSAIDs, retinoids, antihistamines, statins, antidepressants, St. John's Wort)
6. Recent steroid injection at the treatment area (within 30 days)
7. Open wounds, active skin infections, or lesions on the treatment area
8. Laser treatment, chemical peel, or cosmetic surgery in the treatment area within the past 6 months
9. History of migraines or chronic headaches triggered by light within the past 2 years
10. Bleeding disorders or anticoagulant/antiplatelet medication use
11. Sensory impairment in the treatment area (e.g., diabetic neuropathy) that prevents detection of discomfort or overheating

⚠️ **If you have any skin condition or health concern, consult a physician before use.**

Chapter 4: Warnings

This chapter sets forth safety warnings that must be observed when using this device. Failure to comply may result in personal injury or device damage.

4.1 Eye Safety

- Always wear the provided silicone eye shields during treatment.
- Do not stare directly at the LED light sources, as this may cause temporary visual disturbance.
- If visual abnormalities occur during treatment, stop immediately and consult a physician.

4.2 Skin Burn Risk

- If you experience excessive heat or discomfort, stop use immediately.
- Do not use on broken, sunburned, or wounded skin.
- Do not use the device on the same treatment area more than once per day.

4.3 Electrical Safety

- Use only the supplied USB charging cable.
- Do not use the device while charging.
- Do not touch the controller or charging cable with wet hands.
- Do not use if the controller or charging cable is damaged.

4.4 Use Environment Safety

- Do not use in bathrooms, showers, or near water sources.
- Do not use in oxygen-rich environments or in the presence of flammable anesthetic gases.

4.5 EMC Warnings

- Portable RF communications equipment (including antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this device.
- Do not use this device in a Magnetic Resonance Imaging (MRI) environment.
- This device complies with IEC 60601-1-2 EMC standards. Use of accessories not specified by the manufacturer may increase emissions or decrease immunity.

4.6 Device Overheating

- If the device becomes abnormally hot during treatment, turn off immediately and discontinue use.
- Allow the device to cool for at least 10 minutes after continuous use exceeding 30 minutes.

4.7 Allergic Reactions

- If rash, hives, or any allergic reaction occurs, discontinue use immediately and consult a dermatologist.

Chapter 5: Precautions

5.1 Before Use

- Fully charge the device before first use..
- Cleanse your face and ensure the skin is dry and free of cosmetic products.
- Inspect the device for any visible damage or deformation.
- Remove all metallic jewelry.

5.2 During Use

- Maintain a seated or semi-reclined comfortable position during treatment.
- Ensure the magnetic controller is securely attached before starting treatment.
- If the controller detaches accidentally, reattach it — the device will resume its current operating state.
- Do not use while driving or operating machinery.
- Do not fall asleep during treatment.

5.3 After Use

- Turn off the device and clean according to Chapter 9.
- Temporary mild redness in the treatment area is a normal reaction and typically resolves within 30-60 minutes.
- If redness persists for more than 2 hours, reduce treatment time or frequency.
- Store in a cool, dry place away from direct sunlight.

Chapter 6: Adverse Reactions

6.1 Common Temporary Reactions (Normal)

- Temporary mild redness in the treatment area (typically resolves within 30-60 minutes)
- Temporary sensation of warmth in the treatment area
- Temporary mild skin dryness

6.2 Abnormal Reactions — Discontinue Use and Consult a Physician

- Persistent erythema (lasting more than 24 hours)
- Skin burns or blistering
- Pigmentation changes in the treatment area
- Persistent headache or eye strain
- Rash, hives, or itching
- Dizziness or nausea

Chapter 7: Fitzpatrick Skin Type Applicability

This device is indicated for Fitzpatrick Skin Types I-IV. The following table is provided for reference:

Skin Type	Skin Tone Description	Sun Reaction	Applicability
I	Very fair, often with freckles	Always burns, never tans	Suitable
II	Fair	Usually burns, tans minimally	Suitable
III	Medium fair to olive	Sometimes burns, tans gradually	Suitable
IV	Olive to light brown	Rarely burns, tans easily	Suitable
V	Brown to dark brown	Very rarely burns, tans very easily	Physician Guidance Required
VI	Dark brown to black	Almost never burns	Physician Guidance Required

Note: This device is not suitable for white, blonde, gray, or red hair (insufficient melanin content for effective light therapy).

TABLE 1 Fitzpatrick Classification of Skin Types I through VI

Type I	Type II	Type III	Type IV	Type V	Type VI
White skin. Always burns, never tans.	Fair skin. Always burns, tans with difficulty.	Average skin color. Sometimes mild burn, tan about average.	Light-brown skin. Rarely burns. Tans easily.	Brown skin. Never burns. Tans very easily.	Black skin. Heavily pigmented. Never burns, tans very easily.

TABLE 1, Fitzpatrick Classification of Skin Types I through VI - Cutaneous Melanoma - NCBI Bookshelf

Note: Fitzpatrick Skin Types V-VI should use this device under physician guidance. This device is not intended for use on white/gold/gray/red hair.

⚠️ **If unsure of your skin type, consult a physician before use.**

Chapter 8: Operating Instructions

8.1 Charging

- Connect the USB charging cable to the controller charging port.
- Plug the USB end into a DC 5V/1A power adapter (not included).
- The LCD screen displays a battery charging icon; a full-battery icon appears when charging is complete.

Charging Time: About 3 hours

8.2 Pre-Treatment Preparation

- Cleanse your face and ensure the skin is dry.
- Attach the silicone eye shields.
- Secure the mask to your face using the elastic straps, ensuring a comfortable fit.
- The remote control can only operate after the mask body controller is triggered.

8.3 LCD Display Overview

The E43-8A Embedded controller features an LCD display that shows the following information in real time:

- Mode Number: Displays 1-3 (corresponding to the 3 treatment modes,”E1”-”E2”-”E3”).
- Remaining Time: Countdown display in minutes.
- Battery Level: Battery icon indicator.

The E43-8A Remote controller features an LCD display that shows the following information in real time:

- LCD Display: Shows current mode number, brightness level,remaining treatment time, and battery status in real time
- Power Button (short press): Displays 1-3(corresponding to the 3 treatment modes)
- Brightness Control: Short press”M”Button,LCD Display Shows”Level”, press “+”Button and “-”Button.

  It can cycle between the intensity levels of "1 (1st gear) -2 (2nd gear) -3 (3rd gear)".L1 / L2 / L3 (Low / Medium / High)
- Power Button: Long press to power on/off.
- Time Control: When the M key is short pressed, the display screen changes from” Level” to “Time”, press “+”Button and “-”Button.It can cycle between the time of "1 (10min) -2 (20min) -3 (30min)".The display screen can cycle to show the number"1 -2 -3”.
- Remaining Time: Countdown display in minutes.
- Battery Level: Battery icon indicator.

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8.4 Power On and Mode Selection

• Long press the Power button of Embedded controller for approximately 2 seconds to turn on; the LCD illuminates, showing the default mode.Long press the Power button of Remote controller for approximately 2 seconds to activate the controller.

• Short press the Power button of Embedded controller or the Mode button of Remote controller to cycle through the 3 treatment modes:

- M1 — Red + NIR (Anti-aging & Wrinkle Reduction)
- M2 —Blue (Acne Treatment)
- M3 — Red + blue + NIR (Full Spectrum Skin Care)

8.5 Brightness Adjustment

• short press Power Button of Remote controller, to toggle the display from 1-line to 5-line view.

It can cycle between the intensity levels of "1 (1st gear) -2 (2nd gear) -3 (3rd gear)-4 (4th gear)-5(5th gear)".

• First-time users are advised to start at L1 and gradually increase as tolerated.

8.6 Treatment Time Setting

Default treatment time is 10 minutes. Press the time setting button to adjust to 20 or 30 minutes.

• When the Time key of Remote controller is short pressed, It can cycle between the time of "10min-20min - 30min".The display screen can cycle to show the number"10 -20 -30”.

• When the countdown reaches zero, the device automatically stops and emits an alert tone.

• To stop mid-session, long press the Power button to turn off.

8.7 During Treatment

• Keep your face in the recommended position to ensure even light coverage across the full face.

• Keep eyes closed at all times and wear the provided eye shields.

• If you experience excessive heat or discomfort, stop immediately.

8.8 After Treatment

• Long press the Power button to turn off.

• Remove the straps, mask, and eye shields.

• Clean the device as described in Chapter 9.

8.9 Recommended Treatment Plan

• Weeks 1-4: 3-5 sessions per week, 10 minutes each

• Weeks 5-12: 2-3 sessions per week, 10-20 minutes each (maintenance phase)

• After Week 12: 1-2 sessions per week for maintenance

Chapter 9: Cleaning and Disinfection

Clean the device (especially the treatment window) after every use.
Turn off the device and disconnect the USB cable from the power source. Allow the device to cool.

Gently wipe the mask surface (both inner and outer), eye shields, and controller with a soft cloth lightly moistened with 70% isopropyl alcohol (IPA) wipe.

Allow the device to air-dry naturally for at least 10 minutes. Ensure no residual liquid remains on any surface before the next use or storage.

Clean the device with medical-grade alcohol wipes before the first use and after each subsequent use. If the treatment window remains visibly soiled after cleaning, discontinue use and contact customer service.

DO NOT use soap, water, steel wool, abrasive cleaners, or corrosive chemical solvents to clean the device.
DO NOT immerse the device in water or any liquid.

The elastic straps can be removed and hand-washed separately with mild detergent and water. Allow to air-dry completely before reattaching.

If the device becomes wet or damp, allow it to dry completely before use. For servicing and repairs, contact the manufacturer only.

Chapter 10: Maintenance

10.1 Routine Maintenance

- Clean the device after every use (see Chapter 9).
- Periodically inspect the device for cracks, deformation, or wear.
- Check the USB charging cable for any damage.

10.2 Long-Term Storage

- Charge to approximately 50%-80% before long-term storage.
- Store in a cool, dry place (-20°C to 50°C, 10%-80% RH).
- If not used for an extended period, recharge every 3 months to preserve battery health.
- Avoid direct sunlight and high-temperature environments.

10.3 Returning to Service

- Fully charge the device before first use after extended storage.
- Inspect all components for integrity.
- Test the device at a low brightness setting before regular use.

10.4 Troubleshooting

Problem	Possible Cause & Solution
Device won't power on	Battery depleted. Charge for at least 30 minutes and retry.
Charging indicator off	Check USB cable connection and power adapter (DC 5V/1A).
LCD display abnormal	Power off and restart. If persistent, contact customer service.
LEDs not illuminating	Check that controller is firmly attached; try reconnecting.
Auto shut-off mid-treatment	Low battery. Recharge and retry.

If the above solutions do not resolve the issue, contact manufacturer customer service. Do not attempt to disassemble or repair the device yourself.

Chapter 11: Technical Specifications

The following specifications apply to the E43-8A

11.1 General Information

Parameter	Specification
Product Name	LED Light Therapy Mask
Model	E43-8A (including variants: E43-6，E43-10，E43-11，E43-13)
FDA Classification	Class II
Regulation Number	21 CFR 878.4810
Product Code	OLP/OHS

11.2 Light Source Parameters

Parameter	Specification
LED Count	72 bulbs
Red Wavelength	630nm±10nm,
Blue Wavelength	415nm±10nm,
NIR Wavelength	850nm±10nm,
Photobiological Safety	RG Exempt (Risk Group Exempt)

11.3 Irradiance by Mode

Treatment Mode	Irradiance (Intensity)
Red + NIR Mode	15 mW/cm²+/-20%
Blue Mode	20 mW/cm²+/-20%
Red + Blue +NIR Mode	15 mW/cm²+/-20%

11.4 Treatment Modes

Mode	Function	Wavelengths Used
M1 — Red + NIR	Anti-aging & Wrinkle Reduction	630nm+850nm
M2 — Blue	Acne Treatment	415nm/
M3 — Red + Blue + NIR	Full Spectrum Skin Care	All wavelengths

11.5 Electrical Parameters

Parameter	Specification
Power Supply	DC 5V/1A, Rechargeable Li-ion 3.7V,1000mAh*2

Charging Time	About 3 hours
Treatment Time	10 minutes (default), adjustable 10/20/30 min
Brightness Levels	3 (Low / Medium / High)
Electrical Protection	Type BF Applied Part
Ingress Protection	IPX2

11.6 Physical Parameters

Parameter	Specification
Mask Dimensions	203 mm × 227 mm × 127 mm
Remote Controller Dimensions	~36 mm × 90 mm × 11 mm
Mask Material	Silicone + PC,
Eye Shield Material	Detachable silicone eye shields
Weight	288g

11.7 Environmental Parameters

Parameter	Specification
Operating Environment	0-35°C, 30-95% RH, 700-1060 hPa
Storage/Transport Environment	-20-50°C, 10-80% RH, 700-1060 hPa
Shelf Life	2 years

Chapter 12: Warranty and Service

12.1 Warranty Policy

This product is covered by a one-year limited warranty from the date of purchase.

- Within 7 days of purchase: If a quality defect is present, you may return the product for a refund or exchange.
- Within 15 days of purchase: If a quality defect is present, you may exchange the product.
- Within 1 year of purchase: If a quality defect is present, free repair service is provided.

12.2 Warranty Exclusions

- Damage caused by accident, misuse, abuse, negligence, or unauthorized repair.
- Normal wear and tear, including fading or scratching of surface coatings.
- Damage caused by failure to follow the instructions in this manual.
- Damage caused by use of accessories or chargers not specified by the manufacturer.
- Damage caused by disassembly or modification by the user.
- Failure to provide valid proof of purchase.

12.3 After-Sales Service

For after-sales service, please contact:

Shenzhen Eyco Technology Co., Ltd.

Address: 2/F, Building 1, Jiashitai Science Park, 164# Fengtang Avenue, Fuhai Street, Baoan District, Shenzhen, Guangdong, China 518103

Email: info@eycotech.com

Web: https://www.eycobeauty.com/

Chapter 13: Symbol Glossary

The symbols used on the device label and packaging comply with the following standards: EN ISO 15223-1:2021, IEC 60417, ISO 7000, IEC 60529, EN 50419, ASTM F2503.

Symbol Glossary	Symbol Name	Reference Standard & Clause
	Manufacturer	ISO 15223-1:2021, Clause 5.1.1; ISO 7000-3082
	Date of Manufacture	ISO 15223-1:2021, Clause 5.1.3; ISO 7000-2497
LOT	Batch Code (LOT)	ISO 15223-1:2021, Clause 5.1.6; ISO 7000-2492
SN	Serial Number (SN)	ISO 15223-1:2021, Clause 5.1.7; ISO 7000-2498
	Refer to instruction manual/booklet	IEC 60601-1 tabel D.2-10,ISO7010-M002
	Caution / Warning	ISO 15223-1:2021, Clause 5.4.3; ISO 7000-0434A
	Keep Dry	ISO 15223-1:2021, Clause 5.3.4; ISO 7000-0626
	Fragile, Handle with Care	ISO 15223-1:2021, Clause 5.3.5; ISO 7000-0621
	Keep Away from Sunlight	ISO 15223-1:2021, Clause 5.3.6; ISO 7000-0624
	This Way Up	ISO 15223-1:2021, Clause 5.3.8; ISO 7000-0623
	Type BF Applied Part	IEC 60601-1, Table D.1, Symbol 20; IEC 60417-5333
IPX2	IPX2	IEC 60529, Table 7
	Alternating Current	IEC 60417-5032; IEC 60601-1, Table D.1, Symbol 1
MR	MR Unsafe	ASTM F2503-20, Section 6.3; IEC 62570:2014
UDI	Unique device identifier	ISO 15223-1:2021, Clause 5.7.10
MD	Indicates the item is a medical device	ISO 15223-1:2021, Clause 5.7.7

Chapter 14: Manufacturer Information

Item	Information
Manufacturer	Shenzhen Eyco Technology Co., Ltd.
Address	2/F, Building 1, Jiashitai Science Park, 164# Fengtang Avenue, Fuhai Street, Baoan District, Shenzhen, Guangdong, China 518103
Email	info@eycotech.com
Website	https://www.eycobeauty.com/

⚠️ **This device has not been approved by FDA. It has been cleared by FDA under 510(k).**

FCC Statement

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-- Reorient or relocate the receiving antenna.

-- Increase the separation between the equipment and receiver.

-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-- Consult the dealer or an experienced radio/TV technician for help

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions (1)this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.