

Eye Brightener

User Guide





It is mandatory that users of this device read and comprehend all information in this User Guide prior to use of the Omnilux™ Mini Eye Brightener device.

**You must follow all the instructions in the User Guide.**

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

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**Before using the Eye Brightener device you must carry out a sensitization test and wait 6 hours.**

## Who should use the Eye Brightener device

Thank you for choosing the Eye Brightener device. The Eye Brightener device is suitable for adults wishing to treat facial wrinkles.

If you have purchased the Eye Brightener 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.

## Device Description

The Eye Brightener device is a battery operated, cordless wearable Light emitting diode (LED) device intended to emit light in the red (630nm) and near infrared (830nm) regions of the light spectrum for the treatment of facial wrinkles and help reduce the appearance of eyebags and puffy skin.

The Eye Brightener device system consists of the following key components.

1. 1 x Silicone LED Patch
2. 1 x Magnetic 2 pin, 4mm to USB A Charging Cable
3. 14 x Individually Wrapped Hydrocolloid Patches including 1 Sensitization Test Patch
4. 1 x User Guide

The Eye Brightener device is a silicone flexible patch containing LEDs. The LEDs generate the light.

The LEDs produce Red: (630nm +/- 10nm) and Near Infra-Red (830nm +/-10nm) light in the visible spectrum.

The device works through non-thermal mechanisms called Photobiomodulation.

## OMNILUX™ MINI EYE BRIGHTENER

The LEDs are driven by an integrated 3.7V, 37mAh Lithium Polymer battery.

The battery is charged via a magnetic 2 pin, 4mm to USB A connector that plugs into a standard 5v USB A power adaptor. The device cannot be operated while in charging mode.

The charging status of the device is indicated by a single indicator LED on the rear of the Eye Brightener devices and the treatment LEDs.

### **In charging mode.**

- i. Solid green – battery is fully charged.
- ii. Solid orange – battery charging.

The Eye Brightener device contains a simple ON/OFF button (⏻) on the rear of the device that switches the LEDs ON/OFF. The treatment time is 10 minutes. The device automatically turns OFF after the 10-minute treatment cycle. The user may stop the treatment program during the 10 minutes by pressing the ON/OFF button.

The LED device is worn on the face and held in place by an adhesive hydrocolloid patch. The adhesive hydrocolloid patch is impregnated on both sides with an elastomer and hydrogenated petroleum resin that acts as an adhesive. The hydrocolloid contains CMC Carboxymethyl cellulose (Cellulose Gum), Styrene/Isoprene Copolymer, Homopolymer, Hydrogenated Rosin, Paraffinum Liquidum (Mineral oil), PET, Niacinamide, Sodium Hydroxide, Sodium Hyaluronate, Pentaerythritol Tetrakis and Oligopeptide-10.

You are supplied with a set of 14 adhesive hydrocolloid patches for treatment, one of which must be used to carry out a Photosensitivity patch test before starting your treatment course.

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.

### Intended Use

The Eye Brightener device is an over-the-counter device intended to emit energy in the Red and Near Infra-red region of the light spectrum and is intended for use in the treatment of facial wrinkles.

The Eye Brightener device is intended to be used in the home by adults.

### Contraindications, Warnings and Precautions



#### Contraindications

- **DO NOT** share the Eye Brightener device with any other person. The Eye Brightener device is for single person use only.
- **DO NOT** reuse the hydrocolloid patches between treatment sessions. The hydrocolloid patches are for single use only.
- **DO NOT** use the Eye Brightener device to treat any other conditions apart from those listed in the intended use. The Eye Brightener device has not been tested for any other conditions than those listed, and the risk is unknown.
- **DO NOT** use the Eye Brightener device if you are pregnant, planning on becoming pregnant or breastfeeding. The Eye Brightener device has NOT been tested on pregnant or breast-feeding women and therefore the risk to the foetus, neonate or pregnant women is unknown.

## OMNILUX™ MINI EYE BRIGHTENER

- **DO NOT** use the Eye Brightener device if you have an allergy to Silicone or Polyethylene terephthalate. The treatment surfaces of the Eye Brightener device contain medical grade silicone and Polyethylene terephthalate.
- **DO NOT** use the Eye Brightener device if you have an allergy to Hydrocolloid bandages or any of the ingredients in the hydrocolloid patches outlined above. The LED device fixes to your face using an adhesive hydrocolloid patch.
- **DO NOT** use the Eye Brightener device if you suffer from light induced headaches.
- **DO NOT** use the Eye Brightener device if you suffer from any genetic conditions of the eyes. If you are unsure about any related eye condition and using the Eye Brightener device, contact a health care professional
- **DO NOT** use the Eye Brightener device if you suffer from lupus erythematosus, photosensitive eczema, or albinism. If you use the Eye Brightener device to treat lupus erythematosus, photosensitive eczema, or albinism you may cause a severe skin reaction.
- **DO NOT** use the Eye Brightener device if you suffer from any photosensitive disorder (sensitization to light). If you use the Eye Brightener device and you suffer from a photosensitive disorder; you may cause a severe skin reaction.
- **DO NOT** use the Eye Brightener device if you are taking any medication that can cause photosensitivity. If you use the Eye Brightener 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](http://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 the Eye Brightener device you must carry out a sensitization test. Please read the section "Sensitization test" on how to carry out the test.
- **DO NOT** over flex the Eye Brightener device. Although it is flexible, it is not designed to withstand excess bending or folding.
- Keep the Eye Brightener device away from Sharp Objects.
- **DO NOT** use the Eye Brightener device in any way that is not exactly as specified in this User Guide. Use of the Eye Brightener device other than exactly as specified in this User Guide has not been tested and the risk is unknown.
- **DO NOT** use the Eye Brightener device in an environment that is NOT specified by the manufacturer as this may cause damage to the device or harm to the user.
- **TURN OFF** and **REMOVE** the Eye Brightener device immediately if it feels hot or your skin feels uncomfortably

warm. **DO NOT** continue treatments and contact customer services.

- **STOP** using the Eye Brightener device during a treatment if you experience headaches or changes in vision. **DO NOT** continue treatments and contact customer services.
- **DO NOT** use the Eye Brightener device 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 Eye Brightener device without removing these products, you may cause a skin reaction, or may reduce the effect of the treatment.
- Only use the adhesive hydrocolloid patches recommended. Other adhesive patches are available but have not been tested with the device and may block light penetration and reduce the effects of the treatment.
- **NEVER** use the Eye Brightener device near water or where water can be spilt onto the equipment. **DO NOT** use the Eye Brightener device if you think it has come into contact with water.
- **DO NOT** use the hydrocolloid after its expiry date.
- Keep the Eye Brightener device away from **HOT** surfaces or direct sunlight.
- **DO NOT** attempt to modify the Eye Brightener device in any way. Modifying the Eye Brightener device will void your warranty. Modifying the Eye Brightener device could cause an electric shock when the system is used again. The system contains no serviceable parts.
- **DO NOT** use the Eye Brightener device if the device, packaging, or cable are damaged in any way.

- **DO NOT** use the Eye Brightener device any longer if it shows any signs of damage to the material through wear and tear.
- **DO NOT** leave the Eye Brightener device unattended when it is switched on. Accidental mishandling of the device could lead to the risk of fire or burns.

### **General Safety**

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

The Eye Brightener device may only be charged with the charging cable that is supplied with the device. Use of other charging cables may not be safe and could lead to electric shock.

### **Precautions**

- **DO NOT** stare directly at the LED light source.
- **DO NOT** use the Eye Brightener device without a hydrocolloid.
- The Eye Brightener device cannot be used in charging mode.
- Unplug The 2-pin charging cable from the USB charging port when not in use.
- Before each use, with the device switched off, clean the Eye Brightener device. All surfaces of the Eye Brightener device may be cleaned by following the cleaning instructions.
- **DO NOT** use any other cleansing products other than those stated in the cleaning instructions. Use of other cleansing products may damage the Eye Brightener device.

- Store the Eye Brightener device at room temperature in dry conditions, away from direct sunlight.
- Don't use the Eye Brightener device in Direct Sunlight.
- Take care when using the Eye Brightener device around young children. Electrical cables can present a strangulation hazard.
- Take care when removing the patch and hydrocolloid, as there is a risk of damaging the top layer of the skin if it is removed too vigorously.
- **DO NOT** charge the Eye Brightener device if the USB socket or wall adapter you are using has poor connections or becomes hot. Make sure you plug the device into a high quality, CE certified USB charging socket or adapter to avoid the risk of fire and burns.
- **DO NOT** subject the Eye Brightener device to heavy shocks to avoid risk of damage to the device, if you damage the device, do not use it any longer.



### Risks and Benefits

#### Potential Risks

This list although not exhaustive, lists what are considered to be among the mostly likely adverse effects that could occur with use of the device.

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 fades within a few days.

Temporary headaches may occur immediately following the

light treatment.

Although this device emits levels of visible and infrared light that are considered to be safe for the skin, if you have adverse reactions after using the device that do not resolve, you should stop using the device immediately.

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 Ltd or your provider and your representative Competent Authority if you deem it applicable.

## Potential Benefits

People who have undergone a course of 3-5 treatments per week for 6 weeks using the Eye Brightener device report a reduction in facial wrinkles and eyebags.

### First Time Setup

## Unpacking and charging the Eye Brightener device

Unpack the the Eye Brightener device and check off the parts described in Device description.

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 Eye Brightener device if you notice device or connecting parts or components are damaged.

### Charging the Eye Brightener device


Before use, fully charge the device.


The Eye Brightener device uses an integrated lithium-ion polymer battery. When the LED device is connected to the power supply do not attempt to use the device as the LEDs will not illuminate.

1. To charge the Eye Brightener device connect the 2-pin connection cable to the port on the upper side of the LED device.
2. Insert the USB A connector into a suitable USB power supply or laptop port.
3. The indicator LED will illuminate Orange to show that the device is charging. The device is fully charged when the indicator LED is solid green.
4. When fully charged the battery will deliver 3-4 treatments before recharging. The lifetime of the Lithium battery can be maximized by allowing it to fully charge and then fully discharge during regular use.
5. Always ensure the LED device is fully charged before commencing a treatment session.
6. Unplug the 2-pin charging cable from the USB A charging port when not in use.

### Charging Status of the Eye Brightener device

The Eye Brightener device uses a single display LED on the rear of the LED device and treatment LEDs to indicate the status of charging.


 **Solid Green** – Battery is fully charged.

 **Solid Orange** – Battery is charging (Charging Mode).

**Low Battery Mode** – Identified by Treatment LEDs

Flashing – There is not enough battery charge to complete a treatment cycle please recharge your device.

### Sensitization test

 **Before carrying out your first treatment you must carry out a sensitization test to see if you are sensitive to light or the adhesive hydrocolloid patch. Follow the step-by-step guide below.**

**DO NOT attach the Eye Brightener device to your face, the sensitization test should be carried out on your arm.**

1. Ensure the Eye Brightener device is fully charged.
2. Remove one of the adhesive hydrocolloid patches from its packaging.
3. See the “**How to use the Hydrocolloids**” section for a step-to-step guide to using the hydrocolloids.
4. Unpeel the device side of the backing paper off the adhesive hydrocolloid patch.
5. Place the sticky side of the adhesive hydrocolloid patch onto the LED side (white) of the Eye Brightener device. Ensure the adhesive hydrocolloid patch aligns with the shape of the Eye Brightener device.
6. Press down across the entire surface of the adhesive

hydrocolloid patch.

7. Peel the face side of the backing paper from the adhesive hydrocolloid patch.
8. Attach the Eye Brightener device to the inside of your left or right forearm and push down gently.
9. Switch ON the Eye Brightener device and allow it to run for a full treatment (10 minutes)
10. At any time if your skin feels HOT or uncomfortable **STOP** using the device immediately.
11. After the treatment, carefully remove the Eye Brightener device and adhesive hydrocolloid patch from the treatment area. Discard the test adhesive hydrocolloid patch in the general waste.
12. Wait at least 6 hours. If your skin on your inner arm is red or itchy, then the treatment is unsuitable for you. Return the device to the retailer within (30) days of purchase.

### Using the Eye Brightener device



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

### Treatment Recommendations:

For the treatment of facial wrinkles, the best results are seen by treating for 3-5 times a week for 6 weeks.

Maintenance treatment should be carried out as required, according to lifestyle and skin condition.



## Carrying out a treatment

**DO NOT** over flex the Eye Brightener device. Although it is flexible, it is not designed to withstand excess bending or folding.

**DO NOT** use the Eye Brightener device without a Hydrocolloid.

1. Ensure the Eye Brightener device is fully charged before commencing a treatment session.
2. Cleanse or exfoliate the skin to remove any traces of skincare.
3. Use a new hydrocolloid every treatment session.
4. See the "**How to use the Hydrocolloids**" section for a step-to-step guide to using the hydrocolloids.
5. Unpeel the device side of the backing paper off an adhesive hydrocolloid patch.
6. Place the sticky side of the adhesive hydrocolloid patch onto LED side (white) of the Eye Brightener device. Ensure the adhesive hydrocolloid patch aligns with the shape of the Eye Brightener device.
7. Press down across the entire surface of the adhesive hydrocolloid patch.
8. Peel the face side of the backing paper from the adhesive strip.
9. Using a mirror position the Eye Brightener device over the treatment area.
10. Switch ON the Eye Brightener device. The device will automatically switch OFF after 10 minutes. You

may stop the treatment at any time by pressing the ON/OFF button.

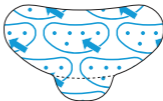
11. After the treatment, carefully remove the Eye Brightener device and adhesive hydrocolloid patch from the treatment area.
12. Remove the adhesive hydrocolloid patch from the Eye Brightener device and discard in general household waste. If you would like to keep the hydrocolloid patch on after the LED treatment cycle has finished, press the hydrocolloid patch onto the face using the tab and carefully peel the LED device from the hydrocolloid patch.
13. Clean the Eye Brightener device by following the instructions in "**Cleaning the Eye Brightener device**". Ensure that the device is **NOT** being charged when cleaning.
14. You may treat more than one treatment area in a treatment session.

**DO NOT** repeat a treatment on the same treatment area in the same treatment session.

### How to use the Hydrocolloid Patches



**FACE SIDE**



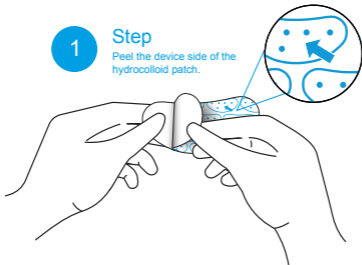
**DEVICE SIDE**

## Step-to-step diagram for using the Hydrocolloids

1

### Step

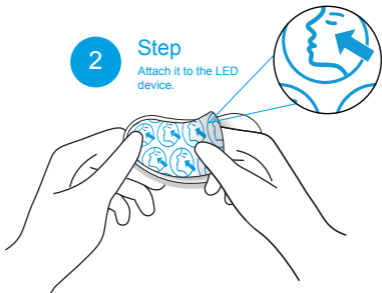
Peel the device side of the hydrocolloid patch.



2

### Step

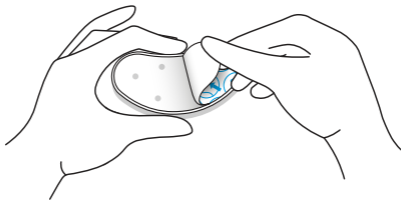
Attach it to the LED device.



3

### Step

Once secured to the device, peel the face side of the hydrocolloid patch.



4

### Step

Press firmly on the face in the desired treatment area.



## Re-order

Refill Adhesive Hydrocolloid patches can be purchased from [www.omniluxled.com](http://www.omniluxled.com)

Part number	Description	Quantity
HCR01	The Eye Brightener device adhesive hydrocolloid patches	20 per Box

## 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 Eye Brightener device at room temperature in dry conditions.
- Avoid storing the Eye Brightener device in dusty conditions, in direct sunlight or in damp and humid conditions.
- The Eye Brightener device contains no serviceable parts.
- Before each use, with the device switched off, clean the Eye Brightener device following the cleaning instructions below.
- **DO NOT** use the Eye Brightener device any longer if it shows any signs of damage to the material through wear and tear.
- **DO NOT** use the hydrocolloid after its expiry date.
- **DO NOT** use the Eye Brightener device if it has been exposed to environmental conditions outside of

those specified in the Technical Specification.

### Cleaning the Eye Brightener Device

- Before cleaning ensure that the charging cable is disconnected from the Eye Brightener device and that the device is not charging
- Clean the Eye Brightener device with a water-based wipe. Stubborn stains or adhesive residue can be removed by wiping gently with 70% alcohol.
- **DO NOT** use water to clean the Eye Brightener device.
- **DO NOT** use the device if you think it has come into contact with water.

### Disposal/Recycling



**DO NOT** dispose of the Eye Brightener device LED device or charging cable at a domestic waste facility. The adhesive hydrocolloid patch can be disposed of in general household waste.



The Eye Brightener device 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.



The outer box packaging is recyclable.

The adhesive hydrocolloid patch can be disposed of in general household waste.

## Troubleshooting

Problem	Possible Cause	Action
No light from the Eye Brightener device. Indicator light is not illuminated.	Battery drained.	Connect the 2-pin connection cable to the port on the upper side of the LED device. Insert the USB A connector into a suitable USB port power supply or laptop and charge until indicator light turns from orange to green.
When the Eye Brightener device is switched on the Treatment LEDs flash.	Insufficient battery to complete a treatment.	Connect the 2-pin connection cable to the port on the upper side of the LED device. Insert the USB A connector into a suitable USB port power supply or laptop and charge until indicator light turns from orange to green.
Indicator light is not illuminated and does not illuminate during charging. No red or infrared light from the Eye Brightener device.	The Eye Brightener device is faulty.	Contact your place of purchase to arrange a return or contact the Omnilux Customer Service email: <a href="mailto:info@omniluxled.com">info@omniluxled.com</a>
No red or infrared light from the Eye Brightener device.	The Eye Brightener device connected to an electrical outlet.	Ensure that the indicator light is solid Green. Remove the magnetic charging connector from the Eye Brightener and ensure that the charging cable is unplugged from the charging source.

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Problem	Possible Cause	Action
Treatment LEDs do NOT turn OFF after 10 minutes.	The Eye Brightener device is faulty.	Contact your place of purchase to arrange a return or contact the Omnilux Customer Service email: <a href="mailto:info@omniluxled.com">info@omniluxled.com</a>
Treatment LEDs flicker continuously during treatment.	The Eye Brightener device is faulty.	Ensure that the Eye Brightener device is fully charged, and the green light is illuminated. If the green light is illuminated and the LEDs continue to flicker contact your place of purchase to arrange a return or contact the Omnilux Customer Service email: <a href="mailto:info@omniluxled.com">info@omniluxled.com</a>

If the actions suggested fail to fix the problem, or the problem reoccurs, and the Eye Brightener device is within the warranty period, please return to your place of purchase or contact the Omnilux Customer Service email:

[info@omniluxled.com](mailto:info@omniluxled.com)



- **DO NOT** attempt to investigate any further.
- **DO NOT** attempt to modify the Eye Brightener device in any way. The Eye Brightener device has **NO** parts you can repair yourself.

### Labeling

The labeling supplied with the device contains the following information

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

### Technical specification

- Model Number: TN2189
- LEDs: Red: 630nm +/-10nm, NIR 830nm +/-10nm



- Total Intensity: 30mW/cm<sup>2</sup>
- Total Device Dimensions: Approx 68mm max (L) x 36mm max (W)
- Program time: 10 minutes +/- 11 Seconds
- 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
- Mains Electrical Input for charging: Any USB A Charger (5V)
- IP25

## Explanation of symbols

There are several safety warnings on the Eye Brightener device and associated packaging and in the User Guide. Not following these warnings may result in one or more of the following hazards: electrical shock and/or fire.



Caution.



It is Mandatory to read and comprehend the information in the User Guide prior to using the Eye Brightener device.



Refer to the User Guide for Guidance on using the Eye Brightener Device.



Applied part type BF.



The Eye Brightener 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.



Manufacturer.



Date of manufacture.



Keep dry.

SN

Serial number.

REF

Model Number for the Eye Brightener device - **TN2189**

LOT

Batch Code.

UDI

Unique device identifier.

MD

The Eye Brightener device is a Medical Device.



Made in China.



Keep away from direct sunlight.



Shows the lower and upper temperature limits.



Shows the lower and upper humidity limits.



The cardboard packaging that the Eye Brightener device came in can be recycled.



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



Input- 5V (USB A).

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Australian sponsor details (AUS only)

## Warranty

Please register your warranty at [www.omniluxled.com](http://www.omniluxled.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:

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

### **What to do if your product is faulty**

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

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

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.



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