



Blemish Eraser

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 Blemish Eraser device.

You must follow all the instructions in the User Guide.

Please contact us if you have any comments about the Blemish Eraser 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 Blemish Eraser device you must carry out a sensitization test and wait 6 hours.

Who should use the Blemish Eraser device

Thank you for choosing the Blemish Eraser device. The Blemish Eraser device is suitable for persons ≥14 years of age who are suffering from mild to moderate acne vulgaris. The typical appearance of acne is a mixture of the following: a greasy skin, red pimples or spots, yellow pus-filled spots and scars.

Use this chart to determine whether the Blemish Fraser device is suitable for you.

Acne type	Description	Suitable for the Blemish Eraser device
Clear skin	No pimples or spots or yellow pus-filled spots. No whiteheads or blackheads	NO the Blemish Eraser device is NOT indicated for clear skin. The Blemish Eraser device should NOT be used to prevent pimples or spots forming
Mild acne	A few pimples or spots, a few pus-filled spots, some whiteheads or blackheads	YES Mild acne is suitable for treatment with the Blemish Eraser device
Moderate acne	Some pimples or spots, some pus-filled spots, only a few small nodules. Many whiteheads or blackheads	YES Moderate acne is suitable for treatment with the Blemish Eraser device

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Acne type	Description	Suitable for the Blemish Eraser device
Severe acne	Many pimples or spots, many pus-filled spots. Some nodules. Many whiteheads or blackheads	NO the Blemish Eraser device is NOT indicated for severe acne. Please consult your doctor for a more appropriate treatment
Whiteheads or Blackheads – Comedonal acne	Many whiteheads or blackheads. No pimples or spots. No pus-filled spots	NO the Blemish Eraser device is NOT indicated for whiteheads or blackheads. Please consult your doctor for a more appropriate treatment

If you have purchased the Blemish Eraser 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 Blemish Eraser device is a battery operated; cordless wearable Light emitting diode (LED) device intended to emit light in the blue (415nm) and red (630nm) regions of the light spectrum for the treatment of mild to moderate acne vulgaris.

The Blemish Eraser 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 Blemish Eraser device is a silicone flexible patch containing LEDs. The LEDs generate the light.

The LEDs produce blue (415nm \pm 10nm) and red (630nm \pm 10nm) light in the visible spectrum. The device works through a non-thermal mechanism called endogenous photodynamic therapy.

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 Blemish Eraser device and the treatment LEDs.

In charging mode.

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

The Blemish Eraser device contains a simple ON/OFF button (\emptyset) 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 patch contains the following ingredients: CMC Carboxymethyl cellulose (Cellulose Gum), Styrene/ Isoprene Copolymer, Hydrogenated Rosin, Homopolymer, Paraffinum Liquidum (Mineral oil), PET, Niacinamide, Camellia Sinensis Leaf Extract (Green Tea), Sodium Hydroxide, Sodium Hyaluronate, Salicylic Acid and Pentaerythritol Tetrakis.

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 Blemish Eraser device is an over-the-counter device intended to emit energy in the red and blue region of the light spectrum, specifically indicated to treat mild to moderate acne vulgaris of the face.

The Blemish Eraser device is intended to be used in the home by people \geq 14 years of age.

Contraindications, Warnings and Precautions

A Contraindications

- DO NOT reuse the hydrocolloid patches between treatment sessions. The hydrocolloid patches are for single use only.
- DO NOT share the Blemish Eraser device device with any other person. The Blemish Eraser device is for single person use only.
- DO NOT use the Blemish Eraser device to treat any other conditions apart from those listed in the intended use. The Blemish Eraser device has not been tested for any other conditions than those listed, and the risk is unknown.

- DO NOT use the Blemish Eraser device if you are pregnant, planning on becoming pregnant or breastfeeding. The Blemish Eraser device has NOT been tested on pregnant or breastfeeding women and therefore the risk to the foetus, neonate or pregnant women is unknown.
- DO NOT use the Blemish Eraser device if you are a child under 14 years of age or on children under 14 years of age. The safety of the device for children younger than 14 years of age has NOT been tested and the risk is unknown
- DO NOT use the Blemish Eraser device on open cuts, wounds, oozing acne pustules and broken skin.
- DO NOT use the Blemish Eraser device if you have an allergy to Silicone or Polyethylene terephthalate. The treatment surfaces of the Blemish Eraser device contain medical grade Silicone and Polyethylene terephthalate.
- DO NOT use the Blemish Eraser 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 you face using an adhesive hydrocolloid patch.
- DO NOT use the Blemish Eraser device if you suffer from light induced headaches.
- DO NOT use the Blemish Eraser device if you suffer from any genetic conditions of the eyes. If you are unsure about any related eye condition and using the Blemish Eraser device contact a health care professional
- DO NOT use device if you suffer from lupus erythematosus, photosensitive eczema, or albinism.
 If you use the Blemish Eraser device to treat lupus erythematosus, photosensitive eczema, or albinism you may cause a severe skin reaction.

- DO NOT use device if you suffer from any photosensitive disorder (sensitization to light). If you use the Blemish Eraser 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 Blemish Eraser 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
- 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 Blemish Eraser 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 Blemish Eraser device. Although it is flexible, it is not designed to withstand excess bending or folding.
- Keep the Blemish Eraser device away from Sharp Objects.
- DO NOT use the Blemish Eraser device in any way that is not exactly as specified in this User Guide. Use of the Blemish Eraser device other than exactly as specified in this User Guide has not been tested and the risk is unknown.
- DO NOT use the Blemish Eraser 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 Blemish Eraser device immediately if it feels hot or your skin feels uncomfortably warm. DO NOT continue treatments and contact customer services.
- STOP using the Blemish Eraser device during a treatment if you experience headaches or changes in vision. DO NOT continue treatments and contact customer services.
- DO NOT use the Blemish Eraser 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 Blemish Eraser 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.
- DO NOT use the hydrocolloid after its expiry date.

- NEVER use the Blemish Eraser device near water or where water can be spilt onto the equipment. DO NOT use the Blemish Eraser device if you think it has come into contact with water.
- Keep the Blemish Eraser device away from HOT surfaces or direct sunlight.
- DO NOT attempt to modify the Blemish Eraser device in any way. Modifying the Blemish Eraser device will void your warranty. Modifying the Blemish Eraser device could cause an electric shock when the system is used again. The system contains no serviceable parts.
- DO NOT use the Blemish Eraser device if the device, packaging, or cable are damaged in any way.
- DO NOT use the Blemish Eraser device any longer if it shows any signs of damage to the material through wear and tear.
- DO NOT leave the Blemish Eraser device unattended when it is switched on. Accidental mishandling of the device could lead to the risk of fire or burns.

🕂 General Safety

The Blemish Eraser 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 Blemish Eraser 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.

A Precautions

- DO NOT stare directly at the LED light source.
- DO NOT use the Blemish Eraser device without a hydrocolloid.
- The Blemish Eraser 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 Blemish Eraser device. All surfaces of the Blemish Eraser 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 Blemish Eraser device.
- Store the Blemish Eraser device at room temperature in dry conditions, away from direct sunlight.
- · Don't use the Blemish Eraser device in Direct Sunlight.
- Take care when using the Blemish Eraser 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 Blemish Eraser 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 Blemish Eraser device to heavy shocks to avoid risk of damage to the device, if you damage the device, do not use it any longer.

A 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 with prolonged and repeated use on the same area. 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 blue and red 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 4 weekly treatments for 6 weeks using the Blemish Eraser device report a reduction in mild to moderate acne vulgaris.

First Time Setup

Unpacking and charging The Blemish Eraser device

Unpack the Blemish Eraser 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 Blemish Eraser device if you notice device or connecting parts or components are damaged.

Charging the Blemish Eraser device

Before use, fully charge the device.

The Blemish Eraser 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.

- To charge the Blemish Eraser device battery 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 power supply or laptop port.
- 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 Blemish Eraser device

The Blemish Eraser 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 Blemish Eraser device to your face, the sensitization test should be carried out on vour arm.

1 Ensure the Blemish Eraser device is fully charged.

- Remove one of the adhesive hydrocolloid patches from its packaging.
- 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.
- Place the sticky side of the adhesive hydrocolloid patch onto the LED side (white) of the Blemish Eraser device. Ensure the adhesive hydrocolloid patch aligns with the shape of the Blemish Eraser 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 Blemish Eraser device to the inside of your left or right forearm and push down gently.
- Switch ON the Blemish Eraser device and allow it to run for a full treatment (10 minutes)
- At any time if your skin feels HOT or uncomfortable STOP using the device immediately.
- After the treatment, carefully remove the Blemish Eraser 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 Blemish Eraser device



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

Treatment Recommendations:

For the treatment of mild to moderate acne vulgaris the best results are seen by treating for 4 days a week for 6 weeks.

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

Carrying out a treatment

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

DO NOT use the Blemish Eraser device without a Hydrocolloid.

- 1. Ensure the Blemish Eraser device is fully charged before commencing a treatment session.
- Cleanse or exfoliate the skin to remove any traces of skincare.
- 3. Use a new hydrocolloid every treatment session.
- See the "How to use the Hydrocolloids" section for a step-to-step guide to using the hydrocolloids.
- Unpeel the device side of the backing paper off an adhesive hydrocolloid patch.
- Place the sticky side of the adhesive hydrocolloid patch onto LED side (white) of the Blemish Eraser device. Ensure the adhesive hydrocolloid patch

aligns with the shape of the Blemish Eraser 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 Blemish Eraser device over the treatment area.
- Switch ON the Blemish Eraser device. The device will automatically switch OFF after 10 minutes. You may stop the treatment at any time by pressing the ON/OFF button.
- After the treatment, carefully remove the Blemish Eraser device and adhesive hydrocolloid patch from the treatment area.
- Remove the adhesive hydrocolloid patch from the Blemish Eraser device and discard in general household waste.
- Clean the Blemish Eraser device by following the instructions in "Cleaning the Blemish Eraser 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



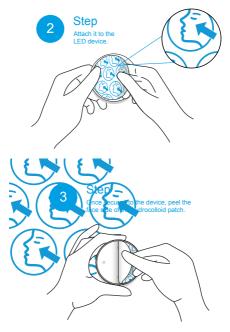
FACE SIDE

DEVICE SIDE

Step-to-step diagram for using the Hydrocolloids



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Re-order

Refill packs of adhesive Hydrocolloid patches can be purchased from **www.omniluxled.com**

Part number	Description	Quantity
HCC01	The Blemish Eraser device adhesive hydrocolloid patches	20 pcs 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 Blemish Eraser device at room temperature in dry conditions.
- Avoid storing the Blemish Eraser device in dusty conditions, in direct sunlight or in damp and humid conditions.
- The Blemish Eraser device contains no serviceable parts.
- Before each use, with the device switched off, clean the Blemish Eraser device following the cleaning instructions below.
- DO NOT use the Blemish Eraser 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 Blemish Eraser device if it has been exposed to environmental conditions outside of those specified in the Technical Specification.

Cleaning the Blemish Eraser Device

- Before cleaning ensure that the charging cable is disconnected from the Blemish Eraser device and that it is not charging
- Clean the Blemish Eraser 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 Blemish Eraser device.
- DO NOT use the device if you think it has come into contact with water.

Disposal/Recycling



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



The Blemish Eraser device contains a Lithiumion 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 Blemish Eraser 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.

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Problem	Possible Cause	Action
When the Blemish Eraser 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 Blemish Eraser device.		Contact your place of purchase to arrange a return or contact the Omnilux Customer Service email: info@omniluxled.com
No blue or red light from the Blemish Eraser device.	The Blemish Eraser device connected to an electrical outlet.	Ensure that the indicator light is solid Green. Remove the magnetic charging connector from the Blemish Eraser device and ensure that the charging cable is unplugged from the charging source.
Treatment LEDs do NOT turn OFF after 10 minutes.		Contact your place of purchase to arrange a return or contact the Omnilux Customer Service email: info@omniluxled.com
Treatment LEDs flicker continuously during treatment.	The Blemish Eraser device is faulty.	Ensure that the Blemish Eraser 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: info@omniluxled.com

If the actions suggested fail to fix the problem, or the problem reoccurs, and the Blemish Eraser device is within the warranty period please return to your place or purchase or contact the Omnilux Customer Service email: info@omniluxled.com



- DO NOT attempt to investigate any further.
- DO NOT attempt to modify the Blemish Eraser in any way. The Blemish Eraser 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: TN2197
- LEDs: Red: 630nm ±10nm. Blue: 415nm ± 10nm
- Total Intensity: 44mW/cm²
- Total Device Dimensions: Max diameter 55mm x 3mm (±5%) (Circular)
- 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 Blemish Eraser 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 Blemish Eraser Device.



Refer to the User Guide for Guidance on using the Blemish Eraser Device.



Applied part type BF.



The Blemish Eraser 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.





Keep away from direct sunlight.



Shows the lower and upper temperature limits.



Shows the lower and upper humidity limits.



The cardboard packaging that the Blemish Eraser device came in can be recycled.



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

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Input- 5V (USB A).

Australian sponsor details (AUS only)

Warranty

Please register your warranty at www.omniluxled.com

Standard Warranty:

Sponsor

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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