# Glotech™ Acne Wand INSTRUCTION MANUAL



ESTHETICS



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#### 1 THE BENEFIT OF LIGHT THERAPY

Congratulations on choosing the Glotech™ Acne Wand to tackle your most stubborn outbreaks. This wand is designed to treat active and future outbreaks as well as, redness, and inflammation within a few sessions.

The device uses blue LEDs (415 nm) to treat existing acne. Blue light has been proven to be effective in killing acne- causing bacteria residing in the skin. Blue light also helps in regulating sebum, preventing overproduction and therefore, future breakouts.

The treatment also uses red LEDs (630 nm) to reduce inflammation, redness and improve overall skin tone. Red light penetrates deep into the skin layers to help stimulate collagen production without side effects like inflammation, redness, and dryness.

## 2. HOW TO USE THE DEVICE

#### 2.1 INDICATIONS FOR USE

Glotech<sup>™</sup> Acne Wand is designed for the treatment of treatment of mild to moderate (inflammatory) acne. Use the device every day of the week. Results can appear as early as after 2-3 uses. It is not recommended to use the device more than once per day on one spot.

#### 2.2 OPERATION INSTRUCTIONS

#### 1. ENSURE THE DEVICE IS FULLY CHARGED

Follow the charging instructions below to ensure the device is fully charged prior to use.

#### 2. CLEANSE THE AFFECTED AREA AND CLEAN THE DEVICE

Gently cleanse the area that will undergo treatment to ensure that any topical creams are fully removed. Clean the device with 70-80% alcohol on a cotton ball. Make sure your skin is completely dry before using.

#### 3. TURN ON THE DEVICE

Ensure the device is unplugged. Press the power button at the bottom of the wand for 0.5 seconds to turn the device on. Once powered on, the device will vibrate and the wand tip will light up.

#### 4. COMPLETE A TREATMENT

Hold the tip of the wand to the affected area for 3 minutes. The device will automatically power off after 3 minutes, indicated by a vibration.

#### 5. CLEAN AND STORE THE DEVICE

Clean the device using a water-based wipe or a damp clean cloth. Ensure the device is NOT connected to the power supply when cleaning.

#### 2.3 CHARGING

Charge your wand fully for 2 hours before your first use. Only use a 5V adapter (avoid fast chargers as they can damage the battery).

Unplug the device from socket when it is fully charged to avoid damaging battery.

To charge the wand, insert the USB-C end of the charging cable into the wand. Insert the larger USB-A end into a 5V USB power supply.

When charging, the LED indicator on the side of the wand flashes white. When the battery is fully charged, the indicator will be steady.

Before charging, make sure that the plug and socket are completely dry.

Failure to do so may result in electric shock, short circuit, or fire.

Note: Always unplug the wand from the charging cable before use. It will not work while being charged.

#### 2.4 CARE AND STORAGE

The lifetime of the Lithium battery can be maximized by allowing it to fully charge and then fully discharge during regular use. Avoid charging longer or more frequently than necessary.

Store the device at room temperature in dry conditions.

Store the device in the supplied travel case. Make sure the device will not get crushed during storage or travel.

The product has a lifecycle of approximately two years under normal use.

#### 2.5 CL FANING

Clean the device with an alcohol-based wipe or lightly damp clean cloth. Stubborn stains can be removed by wiping gently with 70% alcohol.

DO NOT use any other cleansing Devices as these may damage the Device.

DO NOT clean the device while it is turned on or while charging.

DO NOT submerge the device in any liquid. It is NOT waterproof.

#### 2.6 DISPOSAL

DO NOT dispose of the device with household waste. The Device should be recycled. The Device contains a Lithium-ion battery. For protection of the environment, please safely dispose of the device following your local guidelines.

# 3. PRODUCT INFORMATION

#### 3.1 SPECIFICATIONS

LED WAVELENGTH	415nm (Blue) and 630nm (Red) combination of these wavelengths appears as a purple/pink glow			
POWER DENSITY	Blue: 11.7 J/cm2, Red: 14.4J / cm2			
LED BULBS	3 Dual-core LEDs			
TREATMENT TIME	3 minutes, 3 times per day			
OPERATING ENVIRONMENT	Temperature: 32 °F to 104 °F Humidity: 30% to 95%			
STORAGE ENVIRONMENT	Temperature: 23°F to 131°F Humidity: 20% to 85%			
CHARGING SUPPLY	5V / 2A			
CHARGING PORT	USB-C			
CHARGING CABLE	USB-C to USB-A			
BATTERY	160 mAh battery, 3.7V, 0.592 Wh			
BATTERY TYPE	Lithium-ion			
TREATMENT TIME	3 minutes per treatment area			

#### 3.2 DEVICE ACCESSORIES

- Glotech™ Acne Wand
- Travel Case
- Charging Cable
- Instruction Manual

#### 3.3 ADVERSE REACTION

If you have any adverse reaction, such as discomfort, skin discoloration, skin irritation or other concerns, from using this device, stop using it immediately and consult your health professional.

# 3.4 WARNINGS & PRECAUTIONS

Single patient use only. Do not share the device with anyone else.

For use by adults age 21 years and over.

STOP using the device and consult your healthcare provider if you experience an adverse reaction, any discomfort or difficulty breathing or swallowing, or symptoms of hypotension (dizziness or light-headedness) while using the device.

STOP using the device if it is overheating. Turn off the device immediately. STOP your treatment if it feels hot or your skin feels uncomfortably warm.

DO NOT let children play with the device. Cleaning and charging the device shall not be done by children.

DO NOT use the device to treat rosacea, moles, warts, open sores, cancerous lesions, or any skin condition.

DO NOT shine the light from the LEDs directly into your eyes or someone else's eyes. This may cause temporary loss of sight.

DO NOT place the device directly over an open wound.

DO NOT use the device outdoors or place the device in direct sunlight.

DO NOT sit, lay down or step on the device. This will break the device.

DO NOT drop or insert any object into any openings of the device.

DO NOT use solvents or abrasive cleaners on the device.

DO NOT use the device if it is not working properly, or if it has been dropped or damaged. For warranty and repairs contact customer support.

DO NOT use or store the device near hot surfaces, in extreme heat or cold.

DO NOT charge the device when it might get in contact with water.

DO NOT attempt to modify the device in any way. Modifying or opening the device will void your warranty. The device contains no serviceable parts.

DO NOT use the device if damaged or when the charging cable is damaged.

DO NOT use the device with non-manufacturer-approved accessories.

DO NOT use solvents or abrasive cleaners on the device unless explicitly specified in this manual or by customer service.

DO NOT use the device in any other way then specified in this manual.

DO NOT use the device over a bacterial infection.

DO NOT use the device on painful areas. Consult your healthcare

provider when you experience painful areas during use.

 $\operatorname{DO}\operatorname{NOT}$  use the device with any topical other than those specified by LED Esthetics.

#### 3.5 CONTRAINDICATIONS

DO NOT use the device if you have any active cancer or cancerous lesion.

DO NOT use the device if you are pregnant, planning on becoming pregnant, or breastfeeding without first consulting your healthcare provider.

DO NOT use the device if you have severe acne.

DO NOT use the device if you have a known allergic reaction to plastics. The device contains plastics that come into contact with the skin during use. When in doubt of allergies contact your healthcare provider before using the device.

DO NOT use the device if you suffer from any photosensitive disorder (sensitization to light).

DO NOT use the device if you suffer from any skin condition (apart from acne).

DO NOT use the device if you are taking any medication or drugs that can cause photosensitivity.

DO NOT use the device if you suffer from light-induced headaches

DO NOT use the device if you have epilepsy or a medical history of seizures that can be triggered by light.

Note: For reasons of hygiene, do not share your device with anyone else.

Note: We highly suggest taking caution when taking any (skin related) damaging medications. If in doubt, consult your healthcare provider.

Note: If you are under the care of a physician, consult your physician before using this device.

#### 3.6 DISCLAIMER

DO NOT use the Device to treat any other conditions apart from the conditions that are indicated in the Indications for Use statement in Chapter 2.

### 4. POTENTIAL RISKS

Immediately after treatment skin may appear red. Skin should return to normal within 1-2 hours. Temporary headaches may appear after the light treatment. Consult your health professional if the headaches last for a longer period of time.

#### 5. LIGHT SENSITIVITY TEST

We highly recommend users perform a light sensitivity test before their first use of the device.

- 1 Turn on the device and hold to one spot on inner forearm
- Wait for 3 minutes to complete a treatment.
- If your skin feels hot or uncomfortable during the treatment, immediately stop. You might be sensitive to light.
- The device will automatically turn off after the treatment is done.
   Remove the device and wait for at least 24 hours.

Check your skin regularly over those 24 hours, if your skin appears red and/or itchy the device is unsuitable for you.

#### 6. WARRANTY

This Device is warranted to be free from defects in material and workmanship for 12 months from its original purchase date under normal use. This warranty only extends if the device is used in conjunction with authorized Device accessories. If the Device should become defective within the warranty period, contact our customer support. This warranty does not cover damage caused by:

- · Accident, misuse, abuse, or alteration,
- . Use with unauthorized accessories or use other than instructed.
- Connecting to incorrect current and voltage.

LED Esthetics shall not be responsible for any incidental, special or consequential damages resulting from the use of this Device.

# 7. CONTACT INFORMATION

Legal Manufacturer:

Light Tree Ventures Europe B.V. Laan van Ypenburg 108

2497 GC, the Hague, The Netherlands

Regulatory@ lighttreeventures.com

Light Tree Ventures is an ISO13485:2016 and MDSAP certified company.

Distributed By:

JK Supply LLC, d/b/a/ LED Esthetics

ledesthetics.com/contact

hello@ledesthetics.com

#### 8. SAFETY & FMC

The 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.

The Device has been tested to or complies with the following standards:

- EN 60601-1:2006/A12:2014. Medical electrical equipment. General requirements for basic safety and essential performance.
- EN 60601-1-2:2015 Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests.
- IEC 60601-1-6 2010 AMD12013 Medical Electrical Equipment / Part 1General Requirements for Basic Safety and Essential Performance /Collateral Standard: Usability.
- IEC/EM60601-1712015 Medical electrical equipment Part 1-11.
   General requirements for basic safety and essential performance
   Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC/EN 60601-2-57:2011 Medical electrical equipment. Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic monitoring and cosmetic/ aesthetic use.
- EN 62471:2008 Photobiological Safety of Lamps and Lamp Systems.
- EN 62366-1:2015 Application of usability engineering to medical devices

- EN ISO 10993-1:2010-04 Biological evaluation of medical devices Part 1: Evaluation and testing
- . EN ISO 10993-5 Cytotoxicity.
- FN ISO 10993-10 Sensitization
- EN ISO 14971:2012 Medical devices Application of risk management to medical devices.
- Restriction of Hazardous Substances (RoHS) Directive (2011/65/EU)
- This device is cleared for marketing in the United States of America with 510k number K 203271 with model number HD-07A
- Registration, Evaluation, Authorisation and Restriction of chemicals (REACH) directive (EC 1907/2006)

For additional tips and information visit: www.ledesthetics.com



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