SOLAWAVE

User Manual

Date of issuance: Jan 2022 Version: 1 We're not here to discuss flaws. In fact, we don't believe in them. Lines, spots, bumps, and textures get bad press, but they're just different terrains you might encounter on your unique, ongoing skincare journey. After years of working in the skincare and beauty industries, we're flipping the script on who has access to the best tools and technologies to support that journey.

At Solawave, we believe everyone has the right to high-quality skincare. We know the best tools for any journey are simple (even when the science powering them is revolutionary), easy to use anywhere (even when their results are incredible), and designed for everyone. Our mission is to put the power of Solawave in the palms of all people. We're taking restorative rituals and acts of renewal out of the doctor's office - to support your skin journey, wherever you are.

Bye Acne was designed for anyone who suffers from acne and breakouts. This handheld, portable device fits in your pocket - ready and available to tackle a pimple the moment you feel it coming on. Leave breakouts behind!

Table of Contents

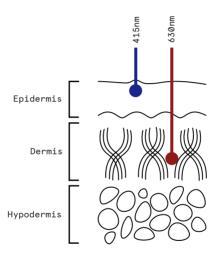
1.	Company Information	2	6.3	Charging	14
2.	Introduction	4	6.4	Care and Storing	15
3.	General Device Information	6	6.5.	Cleaning	15
3.1.	Description of the Device	6	6.6.	Troubleshooting	16
3.2.	Device Specifications	8	6.7	Disposal	18
3.3.	Device Accessories	10	7.	Contraindications	18
3.4.	Adverse Reaction	10	8.	Warnings	19
3.5.	Travel and International Use	11	9.	Precautions	2
3.6.	Disclaimer	11	10.	Limited Warranty	2
4.	Risks and Benefits	11	11.	Safety	2
4.1	Potential Risks	11	12.	Symbols	2
4.2.	Potential Benefits	12	13.	Contact Information	2
5.	Light Sensitivity Test	12			
6.	How to use the Device	13			
6.1	General Use	13			
62	Treatment Protocol	14			

Bye Acne combines red and blue LED light 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 acnecausing 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.

Note: the LED therapy lamp does not use any form of UV light and therefore will not burn the skin.



3. General Device Information

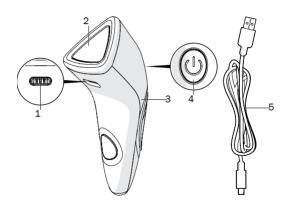
The Blue + Red Light is intended for the treatment of mild to moderate (inflammatory) acne.

This Device is not intended to be used by someone suffering from a sunburn, or under medical care for diseases that involve photosensitivity and/or persons receiving photosensitizing medications.

The Device is not intended for professional use.

3.1 Description of the Device

- USB-C charging slot
- 2. LED Light surface
- 3. LED Light therapy device
- 4. On/off button
- USB-C to USB-A cable



3.2 Device Specifications

LED wavelengths	415 nm (Blue) and 630 nm (Red) (combination of these wavelengths appears visually as a purple/pink glow)	
Max. output optical power density	Blue: 11.7 J/cm2, Red: 14.4J/ cm2	
LEDs	3 Dual-core LEDs	
Operating temperature	0°C to 40°C / 32°F to 104°F	
Storing and transport temperature	-5°C to 55° C / 23° F to 131° F	
Operating humidity	30% to 95% without condensation	
Storage and Transport Humidity	20% to 85% without condensation	

Charging supply	5V 2A	
Charging port	USB-C	
Charging cable	USB-C to USB-A	
Charging cable length	1 meter / 3.28 feet	
Charging adapter power output	2A	
Battery	160 mAh battery, 3.7V, 0.592 Wh	
Battery type	Lithium-ion	
Charging time	30 minutes	
Recommended use	3 minutes per target area 3-5 treatments per week for 6 weeks	
Treatment time	3 minutes per treatment area	

Dimensions of the device	80 x 30 x 30 mm / 3.1 x 1.2 x 1.2 inch
Weight of the device	20 g / 0.7 oz

3.3 Device Accessories

USB-C to USB-A cable.



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3.4 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.

Skin irritation, bruising, contact burns, dizziness, nausea, and headaches are rare but possible side effects. Immediately stop using the device and contact your healthcare provider.

3.5 Travel and International Use

The device's lightweight design makes it a perfect travel companion. Here are some travel tips before you pack: If you are travelling to a different region of where you bought the device, please assure that the device is only supplied with a 5V DC low voltage power source.

Confirm with the steward that the device can be carried and or used on the airplane prior to flight.

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 4.0.

4. Risks and Benefits



1 4.1 Potential Risks

Immediately after treatment, skin may appear red. Skin should return to normal within 1-2 hours.

Temporary headaches immediately following the light treatment. Headaches can be treated with an appropriate pain killer and rehydration.

4.2 Potential Benefits

For anti-acne (Blue Light and Red Light): Clearing of mild to moderate acne.

△ 5. Light Sensitivity Test

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

- Place the device on the inner forearm.
- 2. Turn on the device to start a treatment
- Wait till the treatment is done. The treatment will take 3 minutes to complete.
- If your skin feels hot or uncomfortable during the treatment directly 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. In the case of light sensitivity, please contact customer support.

6. How to use the Device

6.1 General Use

- Prior to using the device, make sure it is fully charged.
- Clean the skin that you want to treat. Make sure your skin is completely dry before using.
- Make sure the device is unplugged and place the device on the skin.
- 4. Turn on the device and enjoy the treatment.
- Press the on/off button for 1 second to turn on the LED light therapy lamp. You will hear a beep to indicate the device is turned on.
- The device switches off after a 3 minute treatment automatically. You may stop the treatment at any time by pressing the on/off button.
- 7. Take the device off the treatment area.
- 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.
- Repeat these steps based upon the treatment protocol described in the next part.

6.2 Treatment Protocol

Use the device every day of the week. Results can show up as early as after 2-3 uses. It is not recommended to use the device more than once per day on one spot.

6.3 Charging

Charge your Solawave device fully for +/- 30 minutes before your first use. Only use a 5V adapter or computer USB port (avoid fast chargers as they can damage the battery).

To charge the device, insert the USB-C cable into the device. Insert the USB-A side of the cable into a USB power supply.

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 device before use. The device will not work while being charged.

6.4 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.
- Store the device at room temperature in dry conditions.
- Avoid storing the device in dusty conditions, in direct sunlight or in damp and humid conditions.
- This device contains no serviceable parts.
- Before each use, with the device switched off, clean the device following the cleaning instructions below.

IMPORTANT

- The product has a limited lifecycle of two years under nominal use. Following the treatment protocol for two years is considered as nominal use.
- The device must be handled with care

6.5 Cleaning

Clean the Device with a water-based wipe or 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.



 $\ensuremath{\mathsf{DO}}$ NOT clean the device while it is turned on.

DO NOT clean the device while charging.

6.6 Troubleshooting

If the actions suggested fail to fix the problem, or the problem reoccurs, and your device is within the warranty period, please reach out to Solawave's customer service for a refund-exchange.



DO NOT attempt to investigate any further.

DO NOT attempt to modify the device in any way. The device has no parts you can repair yourself.

16

Problem	Cause	Solution
The device doesn't switch on.	The device is not fully charged, because the charging cable was not properly inserted into the power outlet.	Insert the charging cable properly into the power outlet.
	The device is not fully charged, because the charging cable was not properly inserted into the device.	Insert the charging cable properly into the device and charge the device.
	The power outlet didn't work during charging.	Try a different power outlet.
	The on/off button has not been pushed one full second.	Push the on/off button for 1 second straight.
The device switches off unexpectedly.	The battery level is too low. Charge the device.	Charge the device.



⚠ 6.7 Disposal

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



7 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.
- DO NOT use the device on people under the age of 18.
- DO NOT use the device if you have severe acne.
- DO NOT use the device over areas with phlebitis, thrombophlebitis, and varicose veins
- DO NOT use the device if you have Fitzpatrick Skin Types V and VI.
- 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 first 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 mildto-moderate acne)
- DO NOT use the device if you are taking any medication or drugs that can cause photosensitivity. If you are not sure about your medication contact your health professional.
 - DO NOT use the device if you suffer from light-induced headaches
- DO NOT use the device if you have a medical history of seizures that was triggered by light.

DO NOT use the device if you have a history of epilepsy.

Note: For reasons of hygiene, we do not recommend sharing 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.



8. Warnings

- STOP using the device and consult your healthcare provider if you experience an adverse reaction from using the device.
- STOP using the device if you experience any discomfort or difficulty breathing or swallowing occurring from application of the device on the neck.
- STOP using the device if you experience 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 use the device on spots without pigmentation or areas on the skin that have vitiligo.
- DO NOT stare directly at the LEDs when the device is turned on. This may cause temporary loss of sight.
- 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 to prevent damage to the product.

- 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.
- DO NOT charge the device when it is close to or might get in contact with water.
- DO NOT submerge the device with water.
- DO NOT store the device in extreme heat or cold.
- DO NOT place the device in direct sunlight.
- 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. This device contains batteries that are non-replaceable
- DO NOT perform maintenance or take apart the product. In case of malfunctioning or damage, contact customer support.
- 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 if you have had a recent surgery or other surgical procedures.
- DO NOT use the device over a bacterial infection as this may result in the worsening of symptoms.
- DO NOT use the device on painful areas. Consult your healthcare provider when you experience painful areas during use.
- DO NOT use the device on, near, or by children or those with reduced physical and mental abilities. Close supervision is necessary when this device is used, cleaned or stored near children or those with reduced physical or mental abilities
- DO NOT use the device with any USB-C cable other than the one provided by Solawaye.
- DO NOT use the device with any other topical other than those specified by

Solawave.

- DO NOT use the device on swollen, infected or inflamed areas or skin eruptions.
- DO NOT apply excessive pressure when using the device on the anterior neck.
- Note: The device should only be supplied with 5V DC low voltage. If any part
 of the main adapter or cable is damaged, discontinue use. Contact Solawave
 customer support (support@trvsolawave.com) to arrange a cable replacement.



9. Precautions

- Do not scratch or damage the light-emitting surface.
- It will void your warranty if you do not operate the device in accordance with the instructions in the manual.
- · Read all instructions carefully before using this device.
- Inspect the device before use in case of the damage.
- Store the device according to the protocol worked out in this manual.
- This device is intended to be used by one person, please do not share it with other people.
- The device is designed for cosmetic use only, for individuals with good health.
 Please contact your healthcare provider if you are unsure about your health status.
- The battery of the device is not removable by the user. If the device is to be disposed of, do not put into a fire. Dispose of the device per local regulations. Assure the device is recycled.
- Inspect the device and do not use the device if you see any signs of internal battery leaks. If you suspect any issues, please contact our customer support.
 The device should only be supplied with 5V DC low voltage. If any part of the
- main adapter or cord is damaged, discontinue use, and contact customer support to arrange a replacement.
- Consult your healthcare provider before using the device if you have a fever, acute inflammation, severe circulatory disorder, light sensitivity, anaesthetic, or desensitized areas.
- We highly suggest exercising caution when taking any medications. If in doubt,consult your healthcare provider.

21

10. Limited Warranty

The 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 extends only to the original retail purchaser with original roof of purchase and only when purchased from an authorized retailer or reseller. 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 the retailer that you purchased the device. This warranty does not cover devices damaged by:

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

Solawave will not be responsible for any incidental, special or consequential damages resulting from the use of this device. 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. If the device is defective within the warranty period, please contact the Customer

Service Team (support@trysolawave.com).

11. Safety

The device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (f) 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/EN60601-1-11:2015 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.
- EN 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 K203271 with model number HD-07A.
- Registration, Evaluation, Authorisation and Restriction of chemicals (REACH) directive (EC 1907/2006)

12. Symbols



This warning symbol on the device label is a warning to read the enclosed documents before use and take all safety precautions required.



This symbol on the device label means: Read the user manual before you start using the device.



Indicates that the electromagnetic radiation from the device is below the limits specified by the Federal Communications Commission and the manufacturer has followed the requirements of the Supplier's Declaration of Conformity authorization procedures.



This symbol means "Manufactured by" and provides the name and address of the legal manufacturer.



This symbol means keep the device dry.

LOT

This symbol refers to the batch code of the device.



This symbol indicates the USB connector.



This symbol means that the device uses a Lithium-ion Polymer battery.



This symbol means the upper and lower operating temperatures that the device can be safely used at.



This symbol means the upper and lower operating humidity that the device can be safely used at.



This symbol means that the cardboard packaging that the device came in can be recycled.



This symbol means that the device is protected against a solid object greater than 12.5mm such as a finger and against water drops.

13. Contact Information

Legal Manufacturer

Light Tree Ventures Europe B.V. Laan van Ypenburg 108 2497 GC, the Haque The Netherlands Regulatory@lighttreeventures.com

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

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