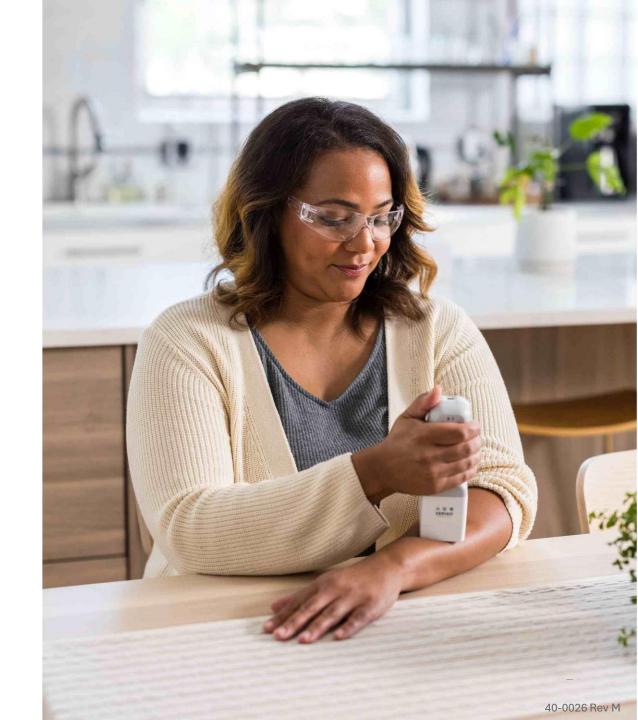


# Member Guide

# Welcome

to the Zerigo Skin Health Program





### Welcome

At Zerigo Health, our goals are to set you up for success, to help you reach your treatment goals, and to ensure your experience using the Zerigo Skin Health Program is a positive one.

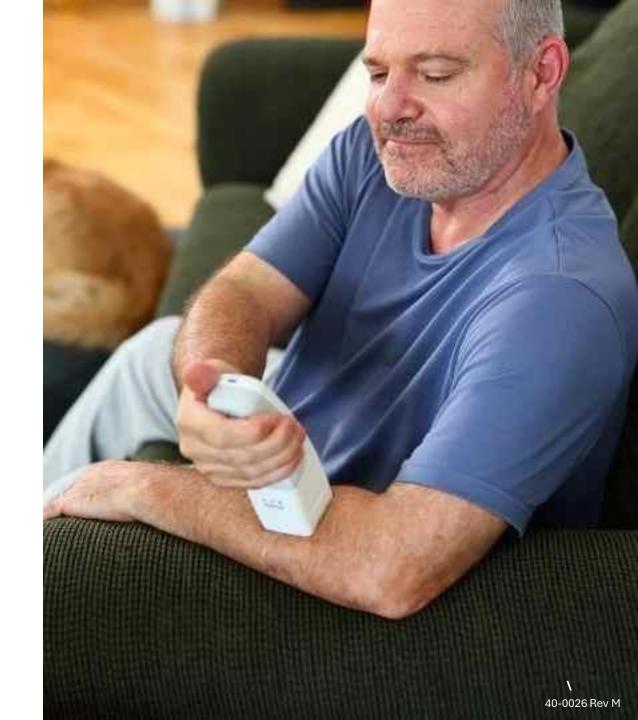
Success with home light therapy involves a partnership between you, your provider, and your Zerigo Care Guide. We are here to teach you how to use the Zerigo Skin Health Program and support you along the way. This Member Guide and the Quick Start Guide provide helpful information on how to start and manage your home treatments.

More information is available through the information pages (look for the (i) icon) in the Zerigo Health Mobile App.

### Indications For Use

The Zerigo Device is an ultraviolet light-emitting medical device. It is intended for use in localized phototherapeutic treatment of dermatologic conditions such as psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis and leukoderma on all skin types (I-VI).

Use the device only as prescribed. UVB phototherapy has been proven safe and effective for decades, but there are some patients for whom UVB phototherapy is less safe.



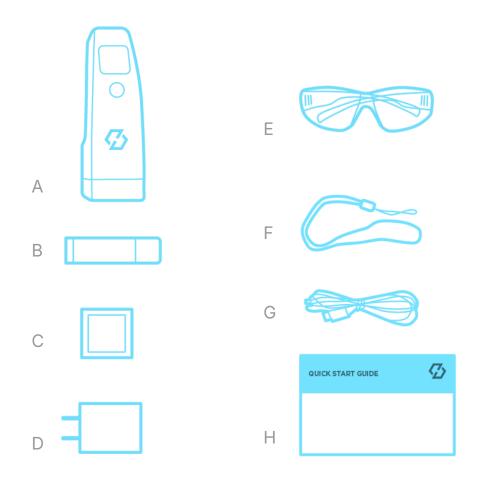


## **Guide Contents**

6	Kit Contents	27	Dose Adjustments	
8	Program Overview	30	Progress Checks & Photos	
9	The Zerigo Device	32	Maintaining Control of Your Condition	
11	Set-Up	33	Key Safety Information	
13	Prepare for Treatment	36		
15	Proper Treatment Technique			
20	Treatment Steps	38	Symbol Definitions	
26	Skin Examination After Treatment	40	Troubleshooting & Specifications	



### **Kit Contents**



Ref.	Product
А	Zerigo Device
В	Sunscreen Stick
С	Alcohol Pads
D	Charger
Е	UV Safety Glasses
F	Wrist Lanyard
G	Charging Cable
Н	Quick Start Guide



## Program Overview

We're committed to your success using the Zerigo Skin Health Program. Your results may depend on several factors, including how well you follow your prescribed treatment plan. After two or three sessions, most people feel confident treating themselves. During onboarding, we will show you how to set up the mobile app, use the device, and how to do your first treatment so you feel comfortable completing treatments on your own.

The program includes a dedicated Zerigo Care Guide, a trained home phototherapy coach who is there to support and connect with you every step of your treatment journey.

Care Guides are not medical professionals, and do not practice medicine nor provide medical advice.



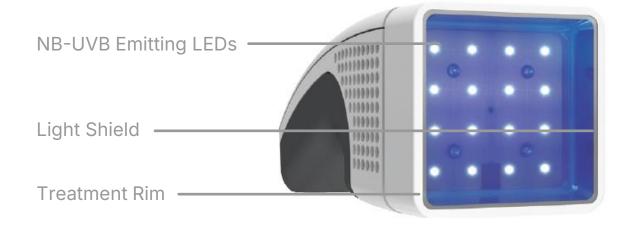
#### TIP

Engage with your Zerigo Care Guide! They are here to support your treatment journey and can answer questions that you have along the way. They give great tips!



## The Zerigo Device

#### **Treatment Head**







# The Zerigo Device

Button Activation Options					
Single-Click	Turn on device, start/pause treatment				
Double-Click	Advance to next body location; Complete your treatment session after treating all body locations				
Press and Hold	Turn off device				

Button Light	
Flashing Blue	Ready to deliver treatment, UVB treatment light off
Solid Blue	UVB treatment light on

## Set-Up

### 1. Unpack & Charge Device

Please plug in the device using the charger provided and charge it for at least 8 hours (refer to Page 42 for device charging times). It is best to keep your device charging until its next use to ensure adequate battery life for your next treatment.

### 2. Download the Zerigo Health App

#### **Android:**

- Search for Zerigo Health in the Google Play store
- Download Zerigo Health App
- You will need to allow access to Bluetooth, camera and photos, and enable notifications

#### iPhone:

- Search for Zerigo Health in the App store
- Download Zerigo Health App
- You will need to allow access to Bluetooth, camera and photos, and enable notifications





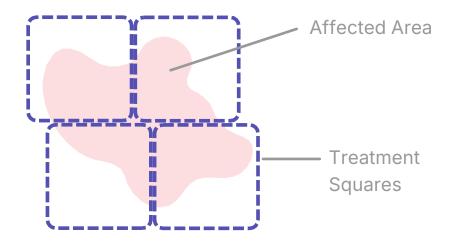
## Prepare For Treatment

### 1. Wash Hands and Remove Skin Creams

Before each treatment session, wash your hands and clean affected skin that may have topical medications, moisturizers and/or sunscreen, as these could block the therapeutic light.

### 2. Disinfect Device Treatment Rim

Before each treatment, disinfect the device treatment rim by gently wiping with alcohol; 70% isopropyl alcohol pads or wipes are recommended. Only the treatment rim should be wiped with isopropyl alcohol. If there is a possibility that the skin you are treating is infected, then the treatment rim should be disinfected after each treatment square.



During treatment, use multiple treatment squares to fully cover an affected area in a body location One treatment square is the size of the device treatment rim.

## Prepare For Treatment

### 3. Wear UV Safety Glasses

Use caution. UV light emitted from the device may be hazardous. To avoid eye injury, wear UV safety glasses and do not look directly at the light coming out of the device during use. Ensure that others who are closer than 1.5 feet (or 0.5 meters) during use also wear UV safety glasses.

### 4. Apply Sunscreen

It's recommended that you apply sunscreen around the affected skin to focus the light therapy where it's needed and prevent unwanted tan lines. For those treating eczema or psoriasis, be sure to leave a narrow area of bare skin around the treatment area, about the width of a Q-tip. This step will be important later when adjusting your treatment dose.

#### **IMPORTANT SAFETY INSTRUCTIONS**

- Do not let your skin touch the glass inside the treatment head
- Do not overlap treatment squares

## Proper Treatment Technique

- Treat affected areas at the prescribed initial dose by adding each area as a body location in the mobile app (see pages 16-17 for information on body locations names).
- When treating, gently place the device on the skin area to be treated. Apply only enough
  pressure to just close the proximity sensor gap.
- Skin should be taut, smooth, and as flat as possible.
- Use the wrist lanyard to help avoid dropping the device.
- Consistently use sunscreen to protect unaffected skin.
- Examine your skin before and after completing treatments (see page 26).
- Follow the dose adjustment guidelines (see page 27) when adjusting the dose.
- Use sun precautions outdoors to limit UV exposure on treatment areas.

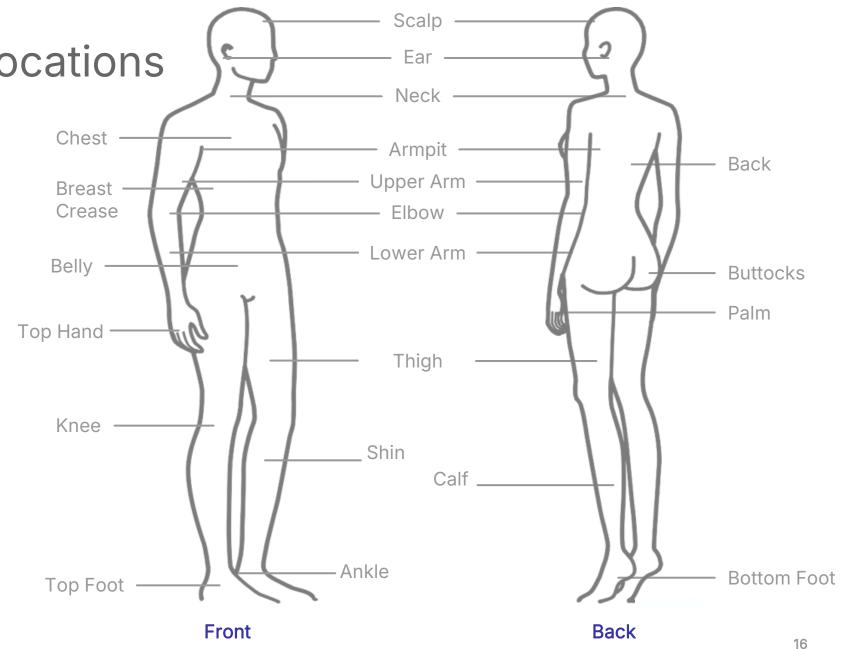


**Common Body Locations** 

When adding treatment areas to the mobile app, please use these terms to name your body locations. Include "Right" or "Left" as appropriate.

#### **CAUTION:**

It's not recommended to treat eyelids or genitals unless specifically prescribed by your physician.



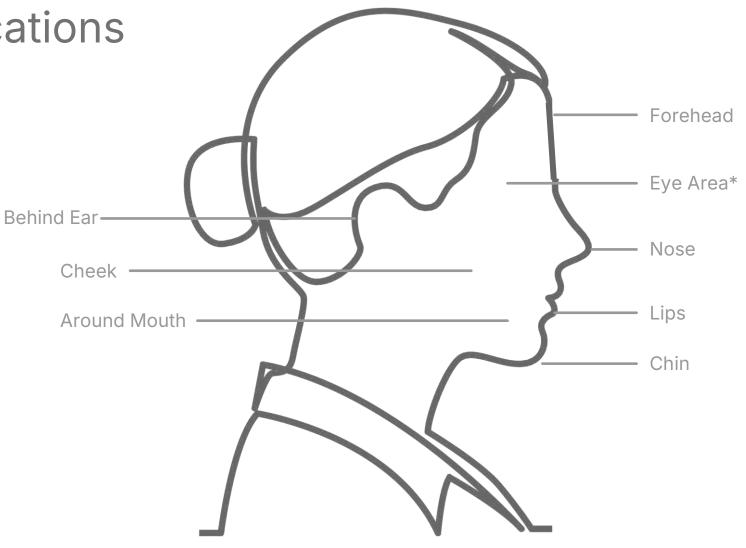


## Specific Head Locations

When adding treatment areas to the mobile app, please use these terms to name your Body Locations. Include "Right" or "Left" as appropriate.

#### \*CAUTION:

It's not recommended to treat eyelids unless specifically prescribed by your physician.



## **Treatment Tips**

Follow these tips when treating these specific body areas:

#### **Behind Ears**

Try holding your hair back with head bands, hair ties, or bobby pins to prevent your hair from interfering with the light therapy. If treating behind your ear is difficult to do alone, ask a family member if they can help you hold the device in place. **Do not** let your skin touch the glass inside the treatment head.

#### Mouth and Nose

Please contact your Care Guide for specific direction. **Do not** let your skin touch the glass inside the treatment head.

## **Treatment Tips**

#### Joints

For optimal light exposure to wrinkly skin:

- 1. Bend at the joint to stretch the skin surface and treat either side of the tip of the joint.
- 2. Straighten the joint, then treat the tip of the joint while the joint is flat and extended.

Do not let your skin touch the glass inside the treatment head.

### Bony or Contoured/Curved Surfaces

During treatment on bony, contoured, or curved surfaces, all four sides of the treatment rim may not touch the skin, and light may emit outside of the treatment rim. Do not push or press skin tissue into the device. Instead, gently place the device on the skin area to be treated and apply only enough pressure to just close the proximity sensor gap. Be sure to direct light away from eyes and wear the provided UV safety glasses. **Do not** let your skin touch the glass inside the treatment head.

#### 1. Connect Your Phone and Device

Unplug the device from the charger – the device will not operate while plugged in. Turn on the device by clicking the round button once. You will need to pair the device with your phone for your first treatment:

#### **iPhone**

On the treatment screen in the calendar tab of the mobile app, press "start treatment." On the next screen, press "scan for handheld." The "pair" button will turn blue when your device is found. Press "pair" and you will return to the treatment page. Press "start treatment" again and a Bluetooth pairing request will appear. Enter the code shown on the screen of your device and press "pair"

#### Android

On the treatment screen in the calendar tab of the mobile app, press "start treatment." On the next screen, press "allow" when the Bluetooth pairing request appears. Enter the code shown on the screen of your device and press "pair" and you will return to the treatment screen.

### 2. Review Treatment Sequence

On the treatment page, the mobile app will list body locations in the order you plan to treat. You may rearrange the treatment sequence to be most convenient for you.



#### 3. Start Your Treatment

#### **IMPORTANT SAFETY INSTRUCTIONS**

- Do not let your skin touch the glass inside the treatment head
- Do not overlap treatment squares

Press the "Start Treatment" button on the treatment screen within the app. Your prescription will be sent from your phone to the device. Put the wrist lanyard around your wrist when holding the device. Gently place the device over the affected area of skin (see page 22 for guidance on treatment square placement). Hold the device on the skin so that the proximity sensor gap is closed between the handle and treatment head. As a safety precaution, treatment will not begin until the gap is closed. Click the button on the device to begin treatment.

### **Proximity Sensor Gap**



Gap Open – Deactivated Device

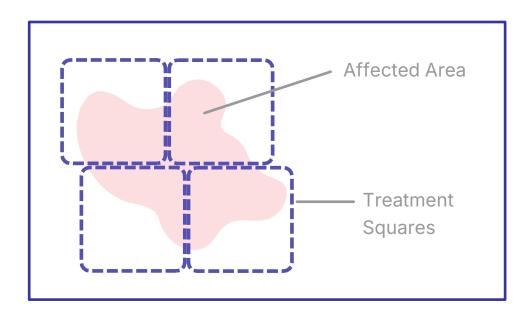


Gap Closed – Activated Device

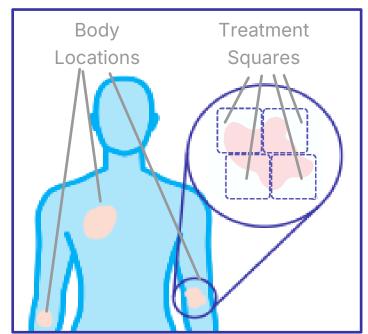
The treatment can be paused by lifting the device off of the skin during treatment. Place the device back on the skin and click the button to resume the treatment.

### 4. Treating Additional Treatment Squares

If the affected skin in your body location is larger than one treatment square, you can treat the adjacent area with additional treatment squares. Place the device on an adjacent area and click the device button to start the treatment. Be careful not to overlap treatment squares, as double treatment may lead to a sunburn-like reaction and potential worsening of your skin condition.



During treatment, use multiple treatment squares to fully cover an affected area in a body location. One treatment square is the size of the device treatment rim.



### 5. Treating Additional Body Locations

Once you've finished treating all treatment squares for your first body location, double-click the device button to advance to your next body location. The device screen will display the next body location you will be treating.

### 6. Completing Your Treatment Session

After you have treated all of your body locations, double-click the device button to complete your treatment session. You will see a "thumbs up" on the screen confirming you are done. The device will shut off automatically.

### 7. Clean-Up

The whole device can be gently cleaned using a damp cloth with mild detergent to remove dirt and oils. Do not scrub the reflective surfaces inside the treatment rim as this may cause premature wear. The device should be cleaned after each treatment session.

### 8. Recharge Your Device

It is best to keep the device charging until its next use to ensure adequate battery life for your next treatment. Please refer to Page 42 for device charging times.

Caution: Use only the provided Zerigo Charger to charge the device.

### 9. Apply Other Skin Care Products After Treatment

If you would like to apply additional skin care products, apply them *after* treatment so as not to block treatment light transmission.



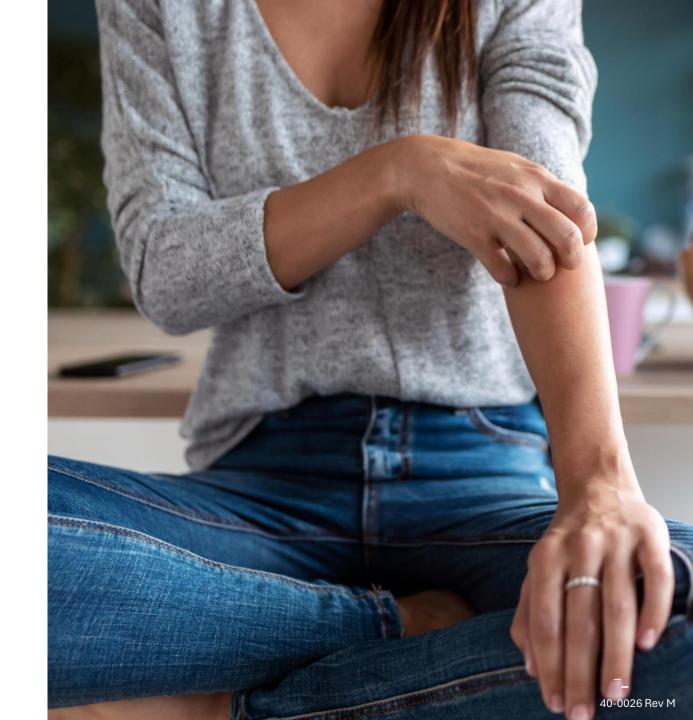
### Skin Examination After Treatment

The look of your skin after treatment determines if your next dose should be higher or lower.

Your treatment, skin type, and your specific response to each treatment determines if and how doses should be adjusted (higher, lower, or stay the same). It takes some time for your body to respond to UV light, so you'll need to check your skin right before your next treatment.

## Dose Adjustments

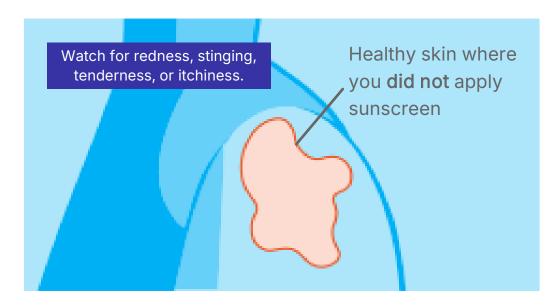
At the beginning of each treatment (each treatment after your first treatment), the app will ask you about adjusting your dose. When you open the mobile app and select "Treatment" on the calendar, the "Dose Adjustment" screen will appear. You can make dose adjustments (changes to the amount of light on your skin during treatment) based on your skin's response to the last treatment.



## Dose Adjustments – Psoriasis or Eczema

Adjust the dose based on how the healthy skin around the treated area responded to your last treatment. You may see or feel a skin response similar to a mild sunburn (redness, stinging, tenderness, or itchiness).

**NOTE:** For the treatment of psoriasis, the recommended max dose for areas above your neck should not exceed 1,000 mJ/cm<sup>2</sup>.



#### In the app, select:

- "Increase dose" if the skin response described above did not occur or the response occurred but lasted less than 1 day.
- "Maintain dose" if the skin response described above lasted more than 1 day but less than 2 days.
- "Skip Treatment" if the skin response described above lasted more than 2 days.

**NOTE:** While you are getting to the right dose for your skin, if you select "Skip Treatment" during dose adjustment, your dose for that body location will be lower during your next treatment.



## Dose Adjustments – Vitiligo

**NOTE:** While you are getting to the right dose for your skin, if you select "Skip Treatment" during dose adjustment, your dose for that body location will be lower during your next treatment.

#### Examine the skin without color.

- If your skin did not change color, increase the dose.
- If your skin becomes light pink, do not change the dose.
- If your skin is red, itchy or painful, reduce the dose and skip treatments until your skin has healed.



No color change: Increase dose



Slight color change: Do not change dose



Red, itchy or painful: Reduce dose and skip treatment

## Progress Checks & Photos

#### An Important Part of Your Care

The Zerigo Skin Health Program requires regular Progress Checks. Your feedback and photos are important for maintaining control of your condition. Scheduled Progress Checks will appear on the calendar screen within the app. Your progress is recorded and can be viewed by you, your provider, and your Care Guide.



#### TIP

#### When taking photos:

- Find a neutral background like a wall, floor, or tabletop that has a single color without a lot of objects or patterns in the photo.
- Be in a well-lit area to take the photo without the flash.
- Capture the entire treatment area and some of the healthy skin surrounding the treatment area.
- Take the photo directly above your skin—not at an angle.
- Take the photo at the same angle and distance during every progress check.
- Take a clear, focused photo and make sure it isn't blurry.



## Maintaining Control of Your Condition

#### Maintenance Treatment

When one or more treatment locations appear to be cleared, congratulations! Your commitment to completing scheduled treatments has shown great results.

During your weekly Progress Check, select "Clear" or "No Longer Noticeable" for all body locations that look clear. This will officially begin your *Maintenance Treatment* schedule, which will reduce the number of weekly treatments you need to complete. Even though you've made great progress, following the maintenance treatment schedule may increase your overall remission time.

If you have any questions, contact your Zerigo Care Guide. They are always here to help you on your journey towards healthy skin!

## **Key Safety Information**

While there are no formal contraindications to using the device, please talk with your provider to find out if this treatment is right for you. In general, there are few contraindications to phototherapy. These may include a history of photosensitivity or history of skin cancer. It is also important for you to talk to your provider if you have very fair skin or a history of atypical moles.



## **Key Safety Information**

#### **Prevent Tan Lines**

Tanning, your skin's natural protection against UV rays, is the most common side effect of light therapy. One method used to protect unaffected skin is to use a sunscreen. If you are treating psoriasis or eczema, be sure to leave a narrow area of bare skin around the treatment area, about the width of a Q-tip. This step will be important when adjusting your treatment dose. Should tanning become a concern for you, contact your Zerigo Care Guide for other helpful tips.



#### TIP

Apply sunscreen to the healthy skin around your affected area to protect the healthy skin and prevent unwanted tan lines.

## **Key Safety Information**

#### **New Medications**

Some medications and dietary supplements, when combined with light therapy, can increase risk of a sunburn-like reaction. If you are unsure about your current medications, please talk with your provider to review all prescriptions and supplements that you are taking.

#### Prevent & Monitor for Skin Cancer

Narrow Band Ultraviolet B (NB-UVB) light therapy is considered by dermatologists to be safe and effective when used responsibly. A link between NB-UVB and skin cancer has not been made. People with a higher risk of skin cancer (those with a history of melanoma or using certain medicines) may not be eligible for NB-UVB therapy. Talk with your provider to make sure the therapy is safe for you



## Cautions

- Caution: Federal law requires
   Physician prescription.
- Caution: Device is intended for a single user.
- Caution: Use of device in a way other than how specified herein may result in hazardous UV light exposure to skin or eyes.
- Caution: Avoid eye exposure and unintended skin exposure. Protect skin outside of the treatment area from incidental exposure.
- Caution: It's not recommended to treat eyelids or genitals unless specifically prescribed by your physician.

- Caution: For psoriasis only, the recommended max dose for areas above the neck should not exceed 1,000 mJ/cm<sup>2</sup>.
- Follow the prescribing physician's instructions.
- **Do not** let your skin touch the glass inside the treatment head.
- Do not use the device if it looks physically damaged or malfunctions.
- Do not open or tamper with the device. There are no user-serviceable parts.
- Do not get the device wet.
- Do not block the device vents or holes.
- Do not use the device in an oxygenrich environment or with flammable anesthetics/agents.

- Do not operate the device while operating a vehicle or engaging in any activity that may require concentrated effort.
- Do not allow unauthorized use of the device.
- Do not use device if the device becomes hot (116.6 °F).
- Keep your device away from extreme temperatures.
- **Dispose** in accordance with local regulations: contains Lithium battery.
- Ensure USB receptacle is dry before charging or operating device.
- Ensure the wrist lanyard is worn during use to prevent dropping the device.





**Symbol Definitions** 



Refer to Member Guide



Keep Dry



Body Floating Isolation Rating



Device Alert: See
Troubleshooting section for
definition



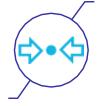
Storage and Transport Temperature



Product Model



UV Hazard. Avoid looking directly at light



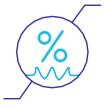
Storage and Transport Pressure



**Product Serial Number** 



Battery Charger Plugged In



Storage and Transport Humidity



Press "Start Treatment" on smartphone



Manufacturer



**Troubleshooting & Specifications** 

## Troubleshooting

Issue	Туре	What To Do
ALERT 1001: Device failure	Alert	Restart device. If condition persists, contact Zerigo Health.
ALERT 1002: LED High Temperature	Alert	Power delivery is reduced due to temperature (treatment times extended). Continue to use or operate at a lower temperature to return to full power
ALERT 1003: LED Failure	Alert	Restart device. If condition persists, contact Zerigo Health.
ALERT 1004: Battery Critical	Alert	Charge device to operate.
ALERT 1007: Battery Low	Alert	Charge device soon.
<b>ALERT 1008:</b> High Ambient Temperature	Alert	Restart device. Operate in a cooler location. If condition persists, contact Zerigo Health.

Contact us at <a href="mailto:support@zerigohealth.com">support@zerigohealth.com</a> or call 877-738-6041



## Electrical, Mechanical, & Optical Specifications (Typical)

Manufacturing Warranty: one year

UV Safety Glasses Rating: ANSI Z87.1 U6

Safe Distance for Unintended Exposure:

1.5 feet for 20 minutes

Contains FCC ID: 2AA9B04



This device complies with part 15 of the FCC rules.

Operation is subject to the following two conditions: (1)

This device may not cause harmful interference. (2) This device must accept any interference received, including interference that may cause undesirable operation.

Compliant to IEC 60601-1-2 Ed 4.0 2014-02 for electromagnetic emissions and immunity.

Charge Time	Charge Power	Device Charging Input	Optical Output Wavelength	Maximum UV Dose
8 Hours	100-240V, 50/60Hz	5V @ 3A	Monochromatic 300-320nm LED	Controlled by prescription

### **Operating Conditions (Typical)**

Ambient temperature: 41 - 95 °F

Maximum device temperature: 118.4 °F

Humidity: 5 – 95%, non-condensing

Atmospheric pressure: 80 – 106 kPa.

### **Storage and Transport Conditions**

Ambient temperature: -13 - 122 °F

Humidity: 5 – 95%, non-condensing

Atmospheric pressure: 70 - 106 kPa

### Service and Support

For specific questions about using the Device, contact us:

Email: support@zerigohealth.com

Phone: 877-738-6041

Address: 12651 High Bluff Drive, Suite 300

San Diego, CA 92130.

### Additional Device Specifications

**NB-UVB** Irradiance

• HD-01: ≥4mW/cm2

• HD-02: ≥20.75mW/cm2 (HD-02)

**Treatment Square Size** 

HD-01: 4.5cm X 4.5cm

HD-02: 4.2cm X 4.2cm

#### Weight

• HD-01: 330q

HD-02: 376g

