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Please read the entire instruction manual before operating the ClearWave® Phototherapy System for Acne.

# **Table Of Contents**

Glossary
Product Description
Indications for Use
Contraindications
Important Safeguards
Risks, Benefits and Alternative Procedures and Treatments
Decision Framework
Guide for Use in the Home or in a Mobile Environment
Before Procedure or Treatment Information
Instructions, Operation and Directions for Use16
After Procedure Treatment Information23
Alternative Procedures and Treatments
Troubleshooting
When to Call your Healthcare Provider
User Assistance (toll free number)
Travel with the Device
Warranty Information

CW01\_MAN\_Rev52.indd 3 8/2/11 12:38 PM

### **Glossary**

**Acne:** Acne is the term for plugged pores (blackheads and whiteheads), pimples and even deeper lumps (cysts or nodules) that occur on the face, neck, chest, back, shoulders and even the upper arms. The sebaceous glands lie just beneath the skin's surface. They produce oil called sebum, the skin's natural moisturizer. These glands and the hair follicles within which they are found are called sebaceous follicles. These follicles open onto the skin through pores. At puberty, increased levels of androgens (male hormones) cause the glands to produce too much sebum. When excess sebum combines with dead, sticky skin cells, a hard plug, or comedo, forms that blocks the pore.

**Acne Vulgaris:** The medical term for common acne; inflammatory disease of pilosebaceous glands

**Comedones:** Uninfected sebaceous plugs impacted within follicles, the signature of noninflammatory acne. Comedones appear as whiteheads or blackheads. Whiteheads (closed comedones) are flesh-colored or whitish palpable lesions 1 to 3 mm in diameter; blackheads (open comedones) are similar in appearance but with a dark center.

**Hair Follicle:** A sac from which a hair grows and into which the sebaceous (oil) glands open. The follicle is lined by cells derived from the epidermal (outside) layer of the skin.

**Mild Acne:** Several inflamed pimples - red in color. Less than 20 whiteheads/blackheads or less than 15 inflammatory red pimples or less than 30 total pimples not all inflamed.

**Moderate Acne:** Many inflamed pimples - red in color - and pustules (visible accumulation of pus in skin) 20-100 whiteheads/blackheads or 15-50 inflammatory (red in appearance) lesions (pimples) or 30-125 total lesions not all inflamed.

**Neutral pH Cleanser:** The pH of solutions range from a value of 1 to a value of 14. Cleansers with a pH of 7 are neutral. Cleansers with a pH above 7 are alkaline.

**NSAID:** Non-steroidal anti-inflammatory drugs. These are drugs with analgesic and antipyretic (fever reducing) effects.

**Photosensitivity:** Cutaneous reaction to sunlight probably involving the immune system. It may be due to an unknown cause or occur after exposure to certain drugs or chemicals, and it is sometimes a feature of systemic diseases.

**Severe Cystic Acne:** Many nodular cystic lesions (with signs of scarring). Scarring occurs when new skin cells are laid down to replace damaged cells.

# **Glossary** — continued

**Severe Nodular Acne:** Inflamed pimples and pustules (visible accumulation of pus in skin) with a few deep nodular lesions (solid mass can be felt under skin) that may be raised.

# **Product Description**

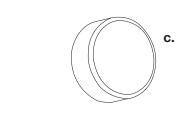
The ClearWave® Phototherapy System for Acne is an over-the-counter phototherapeutic device designed to treat mild to moderate inflammatory acne.

#### Contents Include:

- a. ClearWave® Phototherapy System (Device)
  - (a<sub>1</sub>) Light emitting surface with 32 LED lamps
- b. Device Body
- c. Replaceable Treatment Head

New Treatment Heads may be purchased at www.verilux.com or by calling Customer Service at 1-800-786-6850

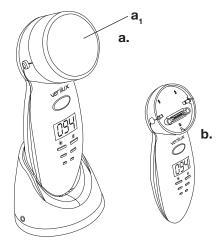
- d. Charging Stand
- e. Power Supply (adapter)
- f. Rechargeable battery
- g. Protective Eyewear (goggles)

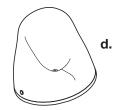


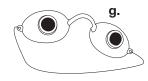




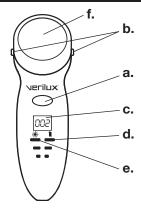
f.







# **Product Description — continued**



#### **Controls**

- a. Power Button
- b. Head Latch Buttons

#### **Status Indicators**

- c. Information Display
- d. Battery Life Indicator Lights
- e. Treatment Head Life Indicator Lights
- f. 32 LED Lamps

#### **Electrical**

- Input: 10.5 VDC, 0.75 A
- Electrical Class: Class 2 ( )
- Electrical Type: Type BF ( ♠)
- Battery: Nickel Metal Hydride (NiMH) Battery Pack: 7.2 VDC, 300 mAh
- Power Adapter:
  - Medical grade power adapter
  - Model No.: UE15WCP-105075SPA
  - Part No.: UE080820HKKD1-R
  - Input: 240 VAC, 50-60 Hz, 400 mA
  - Output: 10.5 VDC, 0.75 A maximum

# **Treatment Specification**

- Peak Wavelength: 414 nm
- Treatment time: 3 minutes
- Max Operating Temperature: 41°C (106°F)

# **Operating Environmental Specification**

- Ambient Temperature: 15°C to 35°C (59°F to 95°F)
- Relative Humidity: 15% to 75%, non-condensing

# **Transport and Storage Specification**

- Ambient Temperature: 0°C to 60°C (32°F to 140°F)
- Humidity: 0% to 90%, non-condensing

#### **Dimensions**

- 7.0" L x 2.5" W x 2.4" D
- Net Weight: 14.5 Ounces

#### **READ ALL INSTRUCTIONS BEFORE USE**

#### **Indications for Use**

The ClearWave® Phototherapy System for Acne is intended to treat mild to moderate inflammatory acne. It is intended for over the counter use.

#### **Contraindications**

None known.

## **Important Safeguards**

#### **▲WARNING**:

- Do not use this device if you are pregnant until your healthcare provider authorizes you to use it.
- Do not use this device over any lesion other than mild to moderate inflammatory acne. Failure to do so can result in delaying best medical treatment.
- Do not use this product if you are taking any medications or topical creams that are known to cause photosensitivity. Examples of such medications include Clemastine (Tavist), Chlordiazepoxide (Limbitrol), Estrogen, Doxycycline (Vibramycin) or NSAIDS for pain. If you are unsure if medication you are taking may cause a light sensitive reaction, contact your healthcare provider before using this product.
- If you are experiencing prolonged redness or sensitivity of the treatment area, discontinue use and consult a healthcare provider.
- Do not use this product if you believe you have severe acne. If you are unsure of
  the type of acne which you may have, are currently being treated for acne or have
  a history of sensitivity to acne treatments, you should consult your healthcare
  provider or dermatologist before using the ClearWave Phototherapy System for
  Acne.
- Do not use over the thyroid gland (neck area). Doing so may stimulate the gland.
- Do not use over topical steroids or a recent steroid injection. Doing so may result in a photosensitive reaction.
- Do not use this device on children under 10 years of age.

#### **▲WARNING:** — continued

- TO REDUCE THE RISK OF FIRE, ELECTRIC SHOCK OR PERSONAL INJURY:
  - Always attach the AC/DC power adapter to device first, then into the outlet.
  - 2. Do not place or store the device where it can fall or be pulled into a tub or sink. Do not place in or drop into water or other liquid.
  - **3.** Keep all electrical appliances (including the ClearWave Phototherapy System) away from water (including bath and shower). If the unit accidentally falls in water unplug immediately.
  - 4. Turn off and unplug device before cleaning.
- Do not operate the device in close proximity to flammable or combustible vapors, such as aerosol (spray) products or where oxygen is being administered or where tanks are stored.
- Always use eye protection while operating the ClearWave Phototherapy for Acne to avoid potential eye damage.
- Stop use immediately if you experience any adverse effect or have a concern regarding use. Contact your healthcare provider. You may be having a photosensitive reaction.
- Do not use if you are taking drugs known to cause photosensitive reactions. Doing so can result in skin discoloration, discomfort or pain. Common examples of drugs that may have made you sensitive to light are: antihistamines, used in cold and allergy medicines; nonsteroidal anti-inflammatory drugs (NSAIDs), used to control pain and inflammation in arthritis; and antibiotics, including the tetracyclines and the sulfonamides, or "sulfa" drugs.

### ACAUTION:

- No user serviceable parts. Do not attempt to disassemble the ClearWave®
   Phototherapy for Acne. This may cause the device to be damaged, malfunction or may cause personal injury.
- Do not use if you are sensitive to light. Doing so can result in skin discoloration, discomfort or pain.
- Do not operate the unit if the cord or unit has been damaged. Electric shock could occur. Refer all servicing to qualified service personnel. Servicing is required when the apparatus has been damaged in any way, such as power-supply cord or plug is damaged, liquid has been spilled on or objects have fallen into the apparatus, the apparatus has been exposed to rain or moisture, the apparatus does not operate normally or it has been dropped.

CW01 MAN Rev52.indd 9 8/2/11 12:38 PM

### **▲CAUTION:** – continued

- Discontinue use if you encounter any discomfort. You may have sensitivity to light or another condition which can result in skin discoloration, discomfort or pain.
   Consult with your healthcare provider.
- Adjustments or performance of procedures other than those specified herein may result in injury.
- Read all instructions before using your ClearWave Phototherapy System. Failure to do so may result in failure to understand safety information or how the device is used.
- Inspect this device prior to each use. Check for damage. Damage includes cracks
  in the device, frayed wires, power button not present, broken display, battery
  compartment not closed or signs of warping. Failure to do so may result in
  improper delivery of the light.
- Persons with known sensitivities to non-drug "sensitizers" could have a
  photosensitive reaction, which can result in skin discoloration, discomfort or pain.
  Common examples of non-drugs that may make a person sensitive to light are:
  deodorants, antibacterial soaps, artificial sweeteners, fluorescent brightening
  agents for cellulose, nylon and wool fibers such as in laundry detergent,
  naphthalene (mothballs), petroleum products and in cadmium sulfide, a chemical
  injected into the skin during tattooing.
- Failure to use and maintain the ClearWave Phototherapy System for Acne according to instructions will void the warranty.
- Do not place device near any heat sources such as radiators, heat registers, stoves or other apparatus that produce heat.
- Do not attempt to use alternate battery types or power supplies. Only use attachments/accessories specified by the manufacturer.
- Do not allow children to use the device unsupervised Failure to do so can result in injury to eyes.
- It is recommended that you test a small less sensitive patch of skin (i.e. like your forearm; refer to page 15 for instructions).
- Use with the protective goggles provided.
- Dispose of device in accordance with local and national regulations and codes. Failure to do so may result in violation of the law.
- Do not look directly at the light source of the Treatment Head of this device while it is in operation.
- Turn off immediately, if the ClearWave Phototherapy System begins to overheat.
- This product is not intended to treat non-inflammatory blackheads or whiteheads.

CW01\_MAN\_Rev52.indd 10 8/2/11 12:38 PM

#### **▲CAUTION:** – continued

- Keep the cord away from heated surfaces.
- Never drop or insert any object into any openings on the device.
- Use only the power adaptor provided with the ClearWave Phototherapy System.
- Do not operate this device in an environment where other devices, which
  intentionally radiate electromagnetic energy in an unshielded manner, are being
  used. Portable or mobile Radio Frequency communication equipment can affect
  the ClearWave Phototherapy System. Doing so may result in the device not
  functioning properly.
- Do not scratch, mar or otherwise damage the light emitting surface. To do so may diminish the effectiveness of the light.
- Do not shine the light source into someone else's eyes.
- Operate, transport and store the device per manner specified in this manual. Failure to do so may result in damage to the unit.

#### SAVE THESE INSTRUCTIONS

#### Risks

#### Risks associated with the ClearWave® system

Individuals taking medications that cause photosensitivity cannot use the ClearWave system. The product can cause these individuals redness, rashes or burning. Individuals that are photoreactive and not taking medications that cause photosensitivity will also experience redness, rashes or burning. Patients with severe acne cannot use this device. Their acne will not improve with use of this device.

#### **Benefits**

#### Benefits of using the ClearWave system

The treatment may result in less blemishes. Individuals using the ClearWave system will not experience prescription medication side effects. Examples of side effects for antibiotics prescribed to treat acne include potential liver damage (Minocycline), stomach upset (Tetracycline) or risks associated with birth defects (Accutane).

Individuals with mild to moderate acne using the ClearWave product may not see results for 4-11 weeks.

#### **Alternative Procedures and Treatments**

#### Risks associated with alternate acne treatment

Retin-A is a prescription treatment. It is meant to be applied twice daily, and it causes the skin to shed its outer layer and thicken the epidermis at the same time. It can also cause side effects such as redness, irritation and peeling. Tretinoin is a prescription medication. Its side effects include redness, itching, peeling and increased sensitivity to the sun.

#### Benefits of using alternate acne treatments

Individuals with severe acne should consult a dermatologist for optimal treatment options. Proper medications for these individuals may result in decreased number of blemishes.

# **Decision Framework**

The ClearWave® Phototherapy System for Acne is an over-the-counter device designed to treat mild or moderate inflammatory acne. There are clinically defined levels of acne. The definitions below are provided as a guide for you to determine if this device is right for you. Dermatologists are specialized in the treatment of acne and should be consulted for an assessment of acne. This device is not intended for severe acne.

Acne Type	Description of Condition	ClearWave Use
No Acne	Total absence of blemishes and acne	Not necessary
Mild Acne	Several inflamed pimples- red in color. Fewer than 20 whiteheads/blackheads or fewer than 15 inflammatory red pimples or fewer than 30 total pimples not all inflamed	Yes*
Moderate Acne	Many inflamed pimples (red in color) and pustules (visible accumulation of pus in skin) 20-100 whiteheads/ blackheads or 15-50 inflammatory (red) lesions (pimples) or 30 to 125 total lesions (pimples) not all inflamed (red in appearance)	Yes*
Severe Nodular Acne	Inflamed pimples and pustules (visible accumulation of pus in skin) with a few deep nodular lesions (solid mass can be felt under skin-can sometimes be raised)	No. Consult a dermatologist for recommended treatment.
Severe Cystic Acne	Many nodular cystic lesions (with signs of scarring)	No. Consult a dermatologist for recommended treatment.

<sup>\*</sup>Not for treatment of non-inflammatory blackheads or whiteheads.

#### **Decision Framework — continued**

#### What other conditions can imitate acne

A number of skin conditions have commonly been mistaken for acne. The device is not intended for people with other skin conditions known to resemble acne.

**Pseudofolliculitis (PFB)** This is sometimes called "razor bumps". When cut close to the skin, curly hairs bend under the skin and produce pimples.

**Rosacea** This condition is characterized by pimples along with redness, flushing and superficial blood vessels, however, there are no blackheads or whiteheads in rosacea.

**Folliculitis** Pimples can occur on other parts of the body, such as the abdomen, buttocks or legs. These do not represent acne but, rather, inflamed follicles.

If unsure, please consult your healthcare provider.

#### Guide for Use in the Home or in a Mobile Environment

The ClearWave® Device may be used at home. You may also take it with you on trips.

- **Step 1** To use the ClearWave device at home or on trips, ensure that the device is first fully charged before initial use. Refer to the Operation, Directions and Instructions for Use section of this manual for charging methodology.
- Step 2 Review the Important Safeguards section in this manual to ensure that you are not operating the device in an environment where it is not suited. Please refer to the Product Description section for ambient temperature ranges for operation. Please refer to the Important Safeguards section for environments which may be unsuitable for using the device. Examples of such unsuitable environments would be on lakes or on rivers.
- **Step 3** Review the Travel with the Device section of this manual regarding the storage of the device prior to plane travel.

#### **Before Procedure or Treatment Information**

Before using the device it is necessary to conduct a skin sensitivity test.

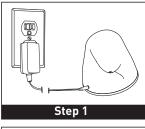
Ensure that you follow the instructions to completely charge the device found on page 16.

- **Step 1** Read the Important Safeguards section on pages 8-11 to ensure you do not fall into any of the categories mentioned. If you do fall into any of the categories, do not use the device.
- **Step 2** Wash the proposed test area on your forearm with a pH neutral cleanser. Ensure it is dry before treatment.
- Step 3 Place the goggles provided with the unit on so that your eyes are covered. Adjust the strap on the goggles to ensure that they fit snugly. Look through the goggles and ensure that there are no visible cracks. Do not use the goggles or the device if the goggles are cracked, damaged or will not fit snugly on your face.
- **Step 4** Activate the device by pushing the power button until the device beeps.
- **Step 5** Place the device on your forearm and complete one 3 minute cycle.
- **Step 6** If you experience redness, rashes, pain or discomfort during the 24 hours following this treatment do not use the device again before consulting your healthcare provider.
- **Step 7** If no reactions have occurred on your forearm following 24 hours, you may begin treatment.

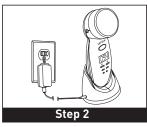
# **Instructions, Operation and Directions for Use**

#### **Getting Started**

Before you use the ClearWave® Phototherapy System, you will need to install the battery (see page 21 - How to replace the battery) and fully charge the device. It takes approximately 12 hours to fully charge the battery for the first time.



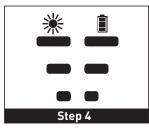
Step 1 Connect the power adapter to the Charging Stand and the adapter into a 110 VAC grounded electrical outlet.



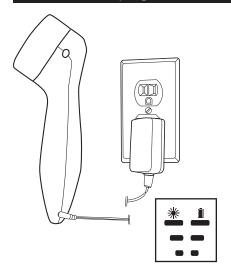
**Step 2** Place the ClearWave Phototherapy System for Acne on the Charging Stand as shown.



**Step 3** The battery life indicator lights will provide information to you on the status while charging.



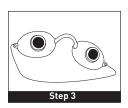
Step 4 When all 3 battery indicator lights are illuminated, the battery is fully charged and the device is ready for use. Once fully charged, the indicator lights will illuminate for 3 minutes, and then turn off.



#### To Charge WITHOUT Charging Stand:

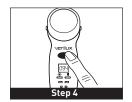
- Step 1 Connect the power adapter to the device and adapter into a 110 VAC grounded electrical outlet.
- **Step 2** The Battery Life Indicator Lights will provide information to you on the status while charging.
- **Step 3** When all 3 Battery Indicator Lights are illuminated (as shown), the battery is fully charged and the device is ready for use.

# Directions for Using the ClearWave® Phototherapy System for Acne



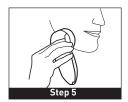
#### **Normal Use Operation**

- **Step 1** Wash your face or the area which will be treated with the ClearWave device with a neutral pH cleanser.
- **Step 2** Verify that you know the area you will treat and the location of the button to activate the device as the goggles may reduce your visibility.



- **Step 3** Put on the goggles provided with the unit. Ensure that the goggles are fitting snugly and are not cracked.
- **Step 4** Before placing the device onto your skin, activate the device by pushing the power button until it beeps one time.

CW01\_MAN\_Rev52.indd 17 8/2/11 12:38 PM



Step 5 Place the device against the desired treatment area of your skin. The treatment lights will automatically turn on once in contact with the skin. This indicates that the treatment cycle is beginning.

**Step 6** Hold the device in place until the device beeps 2 times, indicating the completion of a 3-minute treatment cycle.

**Step 7** For each additional location to be treated, press the button until it beeps once, place the device against the new area and the light will again illuminate signifying the beginning of the next 3-minute treatment cycle.

**Notes:** • Treat only one area per treatment cycle.

- Your daily treatment regime should not exceed three treatment cycles per location.
- A second consecutive treatment to the same area may be performed.
- Waiting a short time between treatment cycles is suggested to prevent the device from entering heat protection mode.

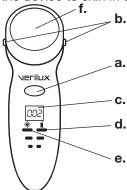
#### **Interrupted Treatment**

**Note:** You can continue treatment of the same area if you remove the device from your skin prior to the completion of a 3 minute treatment cycle.

**Step 1** If the device is removed from the skin during a treatment cycle and 3 minutes have not elapsed, the device will beep for 30 seconds.

**Step 2** If you wish to continue treating the same area you were treating and 30 seconds have not elapsed, reapply the device to your skin.

**Step 3** The display on the device will show the remaining treatment time if you do not reapply the device to your skin. The Treatment Head life indicator and the battery indicator will display the status of the device. If you do not reapply the device to skin in 30 seconds, the device will shut off.



#### Controls

- a. Power Button
- b. Head Latch Buttons

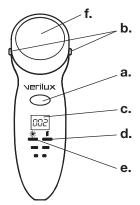
#### **Status Indicators**

- c. Information Display
- d. Battery Life Indicator Lights
- e. Treatment Head Life Indicator Lights
- f. 32 LED Lamps

#### Checking the Status of the Clearwave® Device

- **Step 1** Be sure the device is turned off. To place the device into status mode, press and quickly release the power button. The device will remain in status mode for approximately 30 seconds.
- Step 2 The battery life indicator displays the respective status of battery charge levels. The display will show the number of cycles remaining on the Treatment Head.

**Step 3** When 30 seconds have elapsed, the device will shut off.



#### Controls

- a. Power Button
- b. Head Latch Buttons

#### **Status Indicators**

- **c.**Information Display
- **d.**Battery Life Indicator Lights
- e.Treatment Head Life Indicator Lights
- f. 32 LED Lamps

# **Information Display Indicators**

Display	Mode	Explanation	Reference
Number	Operating	Time remaining on current treatment cycle	See Page 18
Number	ldle	Number of treatment cycles remaining on head	See Page 19 or 20
0	ldle	Treatment Head is exhausted	See Page 20
		Treatment Head is not correctly attached	See Page 20
LO		Battery is low	See Page 21
HP		Device requires cooling	See Page 22
CP		Device is too cold to operate	See Page 22

# Treatment Head Life Indicator and Battery Life Indicator

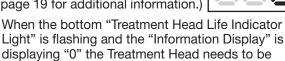
	Treatment Head Life Indicator Light **	Battery Life Indicator Light	
3 lights	More than 75 treatments remaining	More than 75% of the battery is charged	
2 lights	Between 75 and 25 treatments remaining	25% to 75% of the battery is charged	
1 light	Fewer than 25 treatments	Less than 25% of the battery is charged	
Flashing light	Head needs to be replaced	Battery needs to be charged	

#### **Replacing the Treatment Head**

**Note:** The device monitors each treatment cycle to ensure that the Treatment Head is delivering a complete and effective dose. Once the LEDs have passed their guaranteed 100% output life where a complete treatment dose cannot be assured, the Treatment Head will expire and the device will cease to function until the Treatment Head is replaced. To purchase new Treatment Heads, contact Verilux Customer Service at 1-800-786-6850 or visit www.verilux.com. Dispose of used Treatment Heads per local regulations for electronic waste.

The number of treatment cycles remaining on a Treatment Head is displayed by both the device's Information Display and on the Treatment Head Life Indicator (See page 19 for additional information.)

replaced.

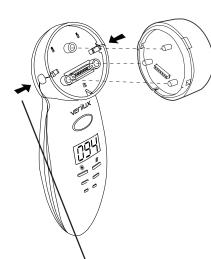




- Step 1: Press and hold both Head Latch Buttons shown on each side of the Treatment Head.
- Step 2: Separate the Treatment Head from the Device Body.

#### To install a new Treatment Head:

- Step 1: Align the three round plastic posts on the back of the new Treatment Head with the three post sockets on the Device Body. This will also align the square latch holes on the new Treatment Head with the Head Latch buttons on the Device Body.
- Step 2: Press and hold both Head Latch Buttons on each side of the new Treatment Head.
- Step 3: Press the new Treatment Head into place against the Device Body and release the Head Latch Buttons.
- Step 4: Press Power Button for approximately 1 second to activate Status Mode (see page 19). The Information Display should now display the amount of cycles remaining on the new Treatment Head.
- Step 5: Three dashed lines will appear if the new Treatment Head is incorrectly installed. Repeat the removal and installation process if 3 dashed lines appear.



Push and release latch buttons

New Treatment Heads may be purchased at www.verilux.com or by calling Customer Service at 1-800-786-6850





**Step 1:** With the charger unplugged, loosen the screw to the battery compartment using a Phillips head screwdriver.



Step 2: Unplug the battery cable attached to the battery.



**Step 3:** Remove the battery and dispose in accordance with local environmental regulations.



**Step 4:** Insert new battery and plug in cable.

**Step 5:** Replace the compartment cover and tighten the screw.

The ClearWave® Phototherapy System for Acne battery is made specially by Verilux®. It is comprised of NiMH (Nickel metalhydride) cells. Do not attempt to replace with other brands.

Remove battery pack when device is not in use for prolonged periods of time.

#### **Care and Maintenance**

Avoid scratching Treatment Head or placing device in a dusty or dirty environment. This may affect the efficiency of your treatment.

Using a soft cloth, apply a small amount of rubbing alcohol and clean the surface of the device. Pay particular attention to the clear lens of the Treatment Head. Clean before each use. Do not attempt to use other cleaning products. Use of other cleaning products may damage the plastic. Do not submerse device in water. This will damage the device electronics. Routinely check before each use to determine that the device functions properly. If the device becomes wet or does not work properly, do not attempt to use. Contact Verilux® customer service.

**AWARNING:** TO REDUCE THE RISK OF ELECTRIC SHOCK OR PERSONAL INJURY: Turn off and unplug device before cleaning.

CW01\_MAN\_Rev52.indd 21 8/2/11 12:38 PM

#### **Cold Protection Mode**

When the "Information Display" is displaying "CP", the device has been exposed to temperatures below -15° Celsius (5°F) and will not operate properly. Set the device aside and allow it to reach room temperature before using.



#### **Heat Protection Mode**

**Note:** Consecutive uses and high ambient temperatures can cause the Treatment Head surface to become hot. The device monitors the Treatment Head surface temperature during each treatment cycle to ensure that the Treatment Head maintains an optimum temperature. If the device exceeds the optimum temperature limit, it will enter Heat Protection Mode and device will limit operation until sufficient surface cooling has been achieved.

When the "Information Display" is displaying "HP" the device has reached or exceeded its optimum temperature limit and will not continue to operate until a cool down period has been completed.



#### If your device enters Heat Protection Mode:

The "Information Display" will display "HP" and the device will beep 10 times and immediately terminate the treatment cycle.

- Step 1: Set the device back on the Charging Stand and allow cooling.
- **Step 2:** Once "HP" is no longer visible in the Information Display, the device is ready for use.
- Step 3: Resume normal operation as outlined on page 18 of this manual.

**Note:** Heat protection mode can be avoided by allowing the unit a short cool down period between treatment cycles.

An additional head may be purchased and interchanged if many consecutive treatments are required on a regular basis.

#### **After Procedure Treatment Information**

After treatment, you will not see noticeable changes to your skin immediately. The visible results may take some time. Visible results may be seen between 4 and 11 weeks. Individual results do vary. It is recommended to continue treating the area three times a day. The device should be used 2-3 times per week for a maximum of 33 treatments in 11 weeks. It is not recommended to treat any single area for more than 3 minutes, three times per day. Two consecutive treatments to one area may be performed. If you observe any adverse reaction such as discomfort, pain, redness or a rash, discontinue use of the device and consult your healthcare provider before using the device again.

### **Alternative Procedures and Treatments**

Topical lotions and gels used to treat mild to moderate acne may contain benzoyl peroxide and salicylic acid. The active ingredient benzoyl peroxide may result in skin irritation or dry skin. The use of topical solutions can result in discoloration or bleaching of fabrics, towels and wash cloths. Another topical acne treatment is commonly sold as Retin-A®, Renova® or Avita™. A dermatologist must be consulted in order to obtain prescription medications. For severe acne cases, a dermatologist may prescribe Isotretinoin, also known as Accutane®, which is a very powerful oral retinoid. Each of these medications is effective on certain types of acne and each has its own benefits, risks and potential side effects.

In addition to providing effective medications for acne treatment, a qualified dermatologist can also administer effective procedures to address an acne problem. Chemical Peels can remove the blackheads and papules associated with mild acne. Pulsed light treatments can be administered by a dermatologist to assist in treatment for the bacteria that causes acne.

# **Troubleshooting**

Please refer to page 20 for troubleshooting the installation of the Treatment Head.

The Issue		The Problem	The Solution
The treatment cycle will not start	The audio signals: 5 beeps The Information Display signals:	Treatment head may not be attached, or the Treatment head is defective	Properly and fully attach treatment head.
	The audio signals: 3 beeps The Treatment Head Indicator Light displays:  **  The Information Display signals:	The treatment head has no remaining treatment cycles	Replace the treatment head.
	The audio signals: 3 beeps The Treatment Head Indicator Light displays:  **  The Information Display signals:	The battery is low	Recharge the battery.
	The audio signals: 5 fast beeps The Treatment Head Indicator Light displays:	The device is too cold to operate	Set the device aside until it reaches room temperature.
	The audio signals: 10 beeps The Information Display signals:	The device is too hot to operate	Set the device aside until it reaches room temperature.
Battery will not hold a charge		The battery needs to be replaced	Order a replacement battery.
Device will not turn on		The battery is dead	Charge battery
Device shuts off in cycle	The audio signals: 10 beeps The Information Display signals:	The device needs to cool down	Set the device aside and let it cool down.

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# When to Call your Healthcare Provider

#### **Call your Healthcare Provider**

If you are unsure if the medication you are taking may cause a light sensitive reaction, contact your healthcare provider.

- If you are unsure of the type of acne you have, are currently being treated for acne or have severe acne, do not use this device until you have consulted your healthcare provider.
- If you are experiencing prolonged redness or sensitivity of the treatment area, discontinue use and call your healthcare provider.
- If you are experiencing any adverse effect or have a concern regarding use, discontinue use and contact your physician.

# **User Assistance (toll free number)**

If problems occur with the ClearWave® device which are not discussed in the troubleshooting section, please contact Verilux Customer Service at 1-800-786-6850. Do not disassemble the device. Any damage caused by an attempt to disassemble the ClearWave device will void the warranty. This excludes the Treatment Head which can be replaced.

#### **Travel with the Device**

The ClearWave device battery charger is designed for an input of 100-240 VAC. International use (Europe) will require an adapter to charge the device from household current. In order to conform with airport regulations, the battery pack must be removed from the device prior to packing the device in luggage.

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CW01\_MAN\_Rev52.indd 26 8/2/11 12:38 PM

# **One Year Limited Warranty**

**ATTENTION!** ONCE OPENED, PLEASE **DO NOT** RETURN THIS PRODUCT TO THE STORE WHERE IT WAS PURCHASED FOR REPAIR OR REPLACEMENT!

Many questions may be answered by visiting www.verilux.com, or you may call our Customer Service Department at 800-786-6850 during normal business hours.

This limited warranty is provided by: Verilux, Inc., 340 Mad River Park, Waitsfield, VT 05673

Verilux warrants this product to be free from defects in material and workmanship for a period of one year from the date of the original retail purchase from Verilux or an authorized Verilux distributor. **Proof of purchase is required for all warranty claims.** During the limited warranty period, Verilux, Inc. will, at its option, repair or replace defective parts of this product, at no charge to the customer, subject to the following limitations: This limited warranty does not include any postage, freight, handling, insurance or delivery fees. This warranty does not cover damage, defect or failure caused by or resulting from accident, external destruction, alteration, modification, abuse, misuse or misapplication of this product.

This warranty does not cover damage to the product resulting from return shipping or handling. The use of shipping insurance is recommended to help protect your product.

**Return Authorization is required for all returns.** To obtain a Return Authorization, please contact the Verilux Customer Service Department at 800-786-6850.

If, during the first year of ownership, this product fails to operate properly\*, it should be returned as specified at www.verilux.com/warrantyreplacement or as instructed by a Verilux customer service representative at 800-786-6850.

**Note:** Verilux recommends using a quality surge suppressor on all electronics equipment. Voltage variations and spikes can damage electronic components in any system. A quality suppressor can eliminate the vast majority of failures attributed to surges and may be purchased at electronics stores.

Due to ongoing improvements, actual product may have slight variations from the product described in this manual.

\*Failure to operate properly refers to mechanical or electrical malfunctions with the device that did not result from misuse, abuse, accident, alteration or modification. If your acne does not improve, please consult a dermatologist. If you or your healthcare provider determine that you are unable to use the device due to photosensitivity, please contact Customer Service.

Please visit our website at www.verilux.com or call our Customer Service Department at

1-800-786-6850

Representatives are available Monday — Friday, 9am — 5pm ET



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CW01 MAN Rev52.indd 27 8/2/11 12:38 PM

June 2011
This product is covered by US Patent(s) and foreign equivalents. Other patent(s) pending.

Manufactured for Verilux, Waitsfield, VT 05673
Printed in China for Verilux, Inc.

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