

# CareWear Light Patches Light Therapy System

Pain Relief & Muscle Recovery

 **User Manual CWC-1**

**CareWear**<sup>®</sup>  
Wearable Therapeutics





CareWear®

**carewear.net**



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## INTRODUCTION

### **WHAT IS THE CAREWEAR LIGHT PATCH?**

The Carewear Light Therapy Patch is a wearable medical device for Photobiomodulation (PBM). The light patch is intended to emit optical power in the blue or blue and red spectra using non-coherent light emitting diodes (LEDs) and thermal conduction to treat pain, relieve stiffness in muscles and joints, accelerate recovery from exercise and soft tissue injury; by increasing blood circulation and elevating tissue temperature.

Its award-winning and patented technology uses micro printed LEDs on body contouring flexible light patches powered by a rechargeable wireless controller. The system is intended for use by medical professionals or consumers in clinics, homes, workplaces, training facilities, hotels, and in the outdoors, when operated within the environmental limits.

### **HOW DOES THE CAREWEAR LIGHT PATCH WORK?**

The CareWear light patches emit blue and red wavelengths of light that warm tissues to relax muscles, improve circulation, decrease inflammation to relieve pain, and stimulate energy production to improve cellular function that facilitates healing, repair and recovery from overuse.

## GLOSSARY & SYMBOLS

DVT – Deep Vein Thrombosis

FDA – Food and Drug Administration

LED – Light Emitting Diode

nm – nanometer

PBM – Photobiomodulation

SWD – Shortwave diathermy

Symbol	Used for	Symbol	Used for
	Serial number		Protect the product from humidity
	Date of manufacture		Type BF medical device
	Caution, consult accompanying documents		Manufacturer name
	Do not dispose of with regular household waste		Caution, electrical precautions
	Observe the user manual	<b>IP66</b>	Classification against water intrusion

## INDICATIONS

The Carewear Light Therapy Patch is a wearable medical device for Photobiomodulation (PBM). The light patch is intended to emit optical power in the blue or blue and red spectra using non-coherent light emitting diodes (LEDs) and thermal conduction to treat pain, relieve stiffness in muscles and joints, accelerate recovery from exercise and soft tissue injury; by increasing blood circulation and elevating tissue temperature.

The CareWear Light Therapy Patch and its adhesive medical grade hydrogel can be temporarily adhered to clean, unbroken skin directly over the involved area (see page 28 for suggested patch placements). The device is powered by a built-in, non-exchangeable rechargeable battery. The CareWear Light Therapy Patch should always be used in accordance with the indications, contraindications, cautions, safety procedures and operating instructions included in this user manual.

## CONTRAINDICATIONS

## RATIONALE

Pregnancy

Do not use the device during pregnancy or nursing. Areas of special concern are over the low back, abdomen or pelvis of a pregnant woman.

Reproductive Organs

Do not apply the device over reproductive organs (testes, ovaries).

Malignancy

Do not use over confirmed or suspected malignancy.

Operating SWD

Do not use within 5 feet (1.5 meters) of an operating shortwave diathermy.

Active Deep Vein Thrombosis,  
Thrombophlebitis

Do not apply patch directly over an active or suspected deep vein thrombosis or thrombophlebitis.

Tuberculosis

Do not use the device on persons with tuberculosis.

## CAUTIONS

## RATIONALE

Eyes

Do not apply the device over the orbital area of the eye(s) nor stare into an activated patch.

Infection

Soft tissue infections should be treated with caution.



**CAUTIONS****RATIONALE**

Individual Use

The light patch is limited to use by a single person to avoid cross contamination.

Photosensitivity

Use caution if the skin is light sensitive or sensitized to light from medication(s).

Skin Temperature

Discontinue treatment if the patch becomes uncomfortably warm against the skin.  
Use caution when applying to desensitized skin.

Impaired Cognition or  
Communication

The ability to understand and comply with use instructions is necessary for correct product use. Read instructions for use before operating device.

Undue Pressure

Do not sit or lie on device. Do not fold, drop or step on device.

Activity Use

Do not use the device during bathing, showering, sleeping, driving or operating machinery.

Electrical Safety



Always check the CareWear patch, controller, charger and adapter plug for damage before use to avoid a hazard. Never use any object to short connectors on the device.

Temperature and Humidity

Do not use, charge, store or transport device outside the recommended temperature and humidity ranges.

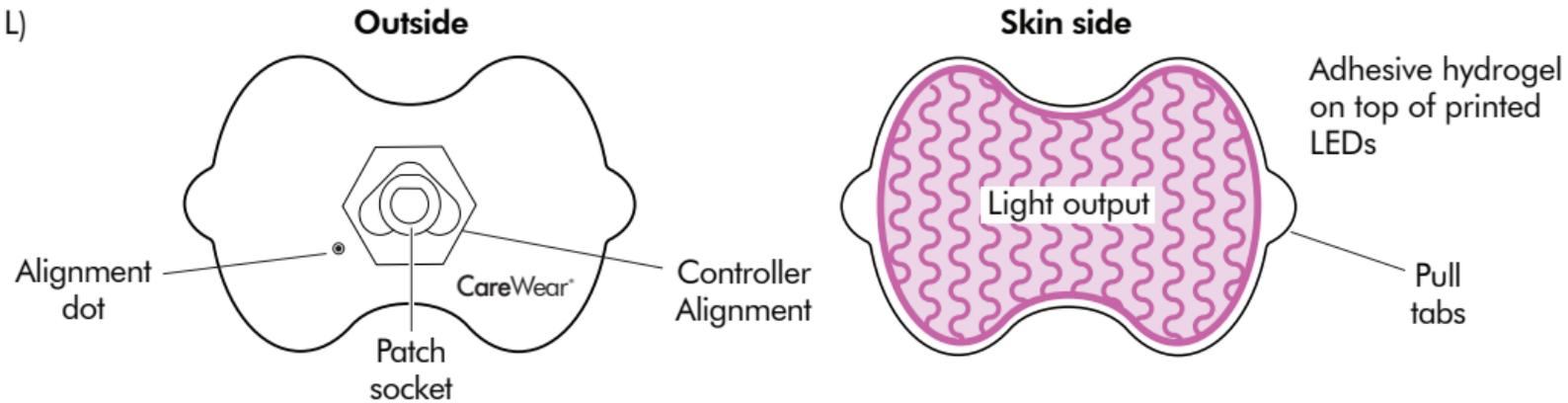
Children and Pets

Keep the device out of the reach of children under the age of 13 and pets.

# DEVICE FEATURES

## Patches

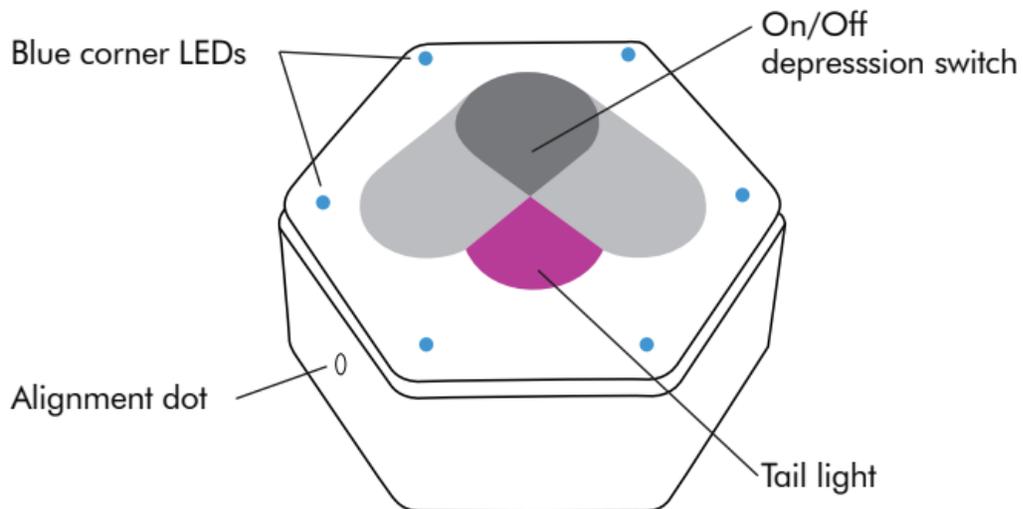
**Butterfly** (M, L)  
on liner



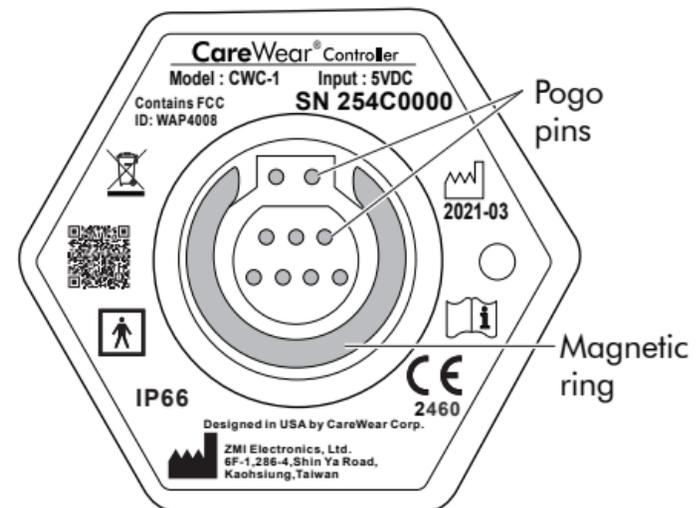
# DEVICE FEATURES

## Wireless Controller

Top Side

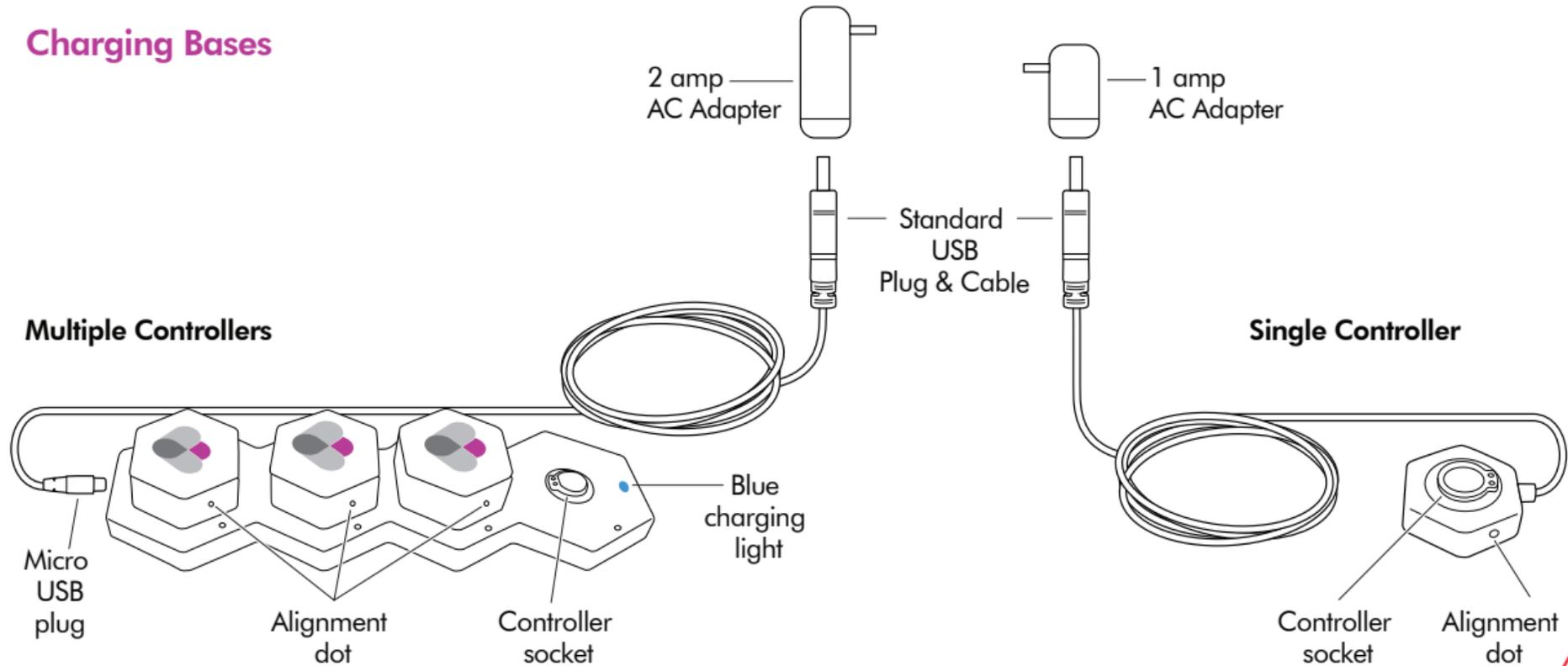


Underside



# DEVICE FEATURES

## Charging Bases



## DIRECTIONS FOR USE

## STEP-BY-STEP INSTRUCTIONS

**1** Charge the controller fully prior to use.



Treatments remaining



Charge controller



Reconnect controller



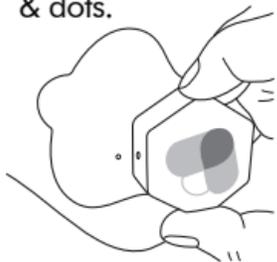
Replace patch



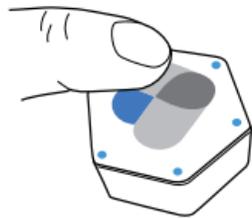
Excess temperature

**2** Place patch on clean, dry skin.

**3** Attach controller to patch via alignment outline & dots.



**4** Click then hold until blue lights come on.



**5** Blue tail with corner LEDs show charge level.

Green tail with corner LEDs show remaining patch life.

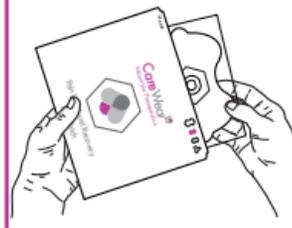
The treatment starts with slow buzzing for 5 seconds.

**6** During treatment, tail light flashes magenta while the corner LEDs deactivate sequentially every 5 minutes. The 30 minute treatment ends with controller lights off and slow buzzing for 5 seconds.

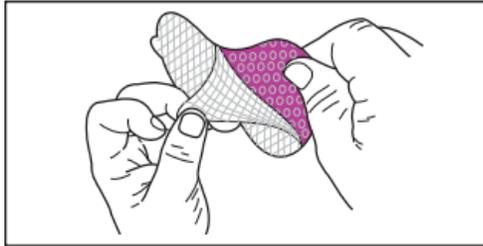
**7** Remove controller and recharge. Corner LEDs show charge level.



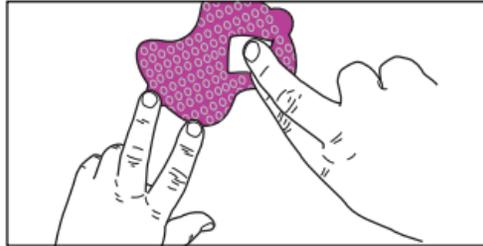
**8** Replace patch on liner and store in sealed zip bag.



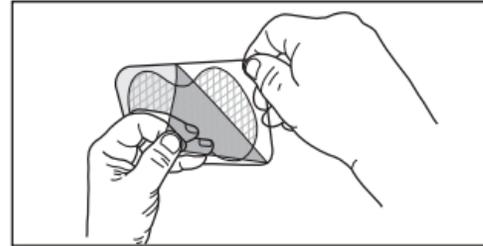
## DIRECTIONS FOR USE : REPLACEABLE HYDROGEL



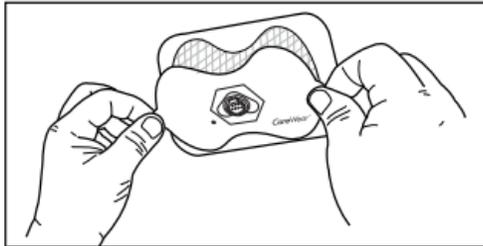
Peel off the used hydrogel from the Light Patch starting from the corner tab. Remove the entire sheet and discard.



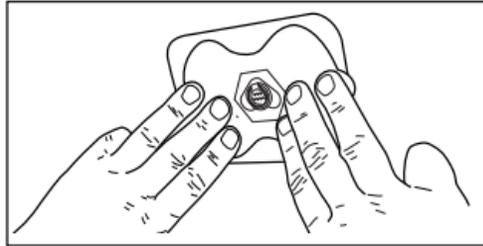
Clean the smooth surface of the Light Patch to remove any hydrogel residue using a paper towel and water.



Select the correct hydrogel size to match the Light Patch. Peel off the blue liner from the new hydrogel.



Place the clear liner on a hard surface with the hydrogel facing up. Apply the smooth side of the Light Patch to the hydrogel, making sure alignment is correct.



Apply pressure evenly over the surface of the patch using your fingers to ensure good bonding of the patch to the hydrogel. Be sure to press firmly around the entire patch edge.



Remove the Light Patch from the clear liner and apply to clean unbroken skin. Position and activate controller. Following treatment place the Light Patch back on the clear liner and store in the sealed zip bag.

## DIRECTIONS FOR USE : CONTROLLER

### **TURN CONTROLLER ON**

To activate the controller, click then hold the firefly logo using a short click followed by a longer hold until the controller turns on. Initially the blue tail with blue corner LEDs will display indicating the controller's charge level (p12). The blue tail light will then turn green with the blue corner LEDs indicating the final six treatments remaining. The 30 minute treatment will then start with a slow buzzing for 5 seconds followed by the patch turning on and the tail flashing magenta. During treatment, the blue corner LEDs represent the remaining treatment time by sequentially turning off every 5 minutes. The 30 minute treatment ends with a slow buzzing for 5 seconds followed by the light patch and controller turning off.

### **TURN CONTROLLER OFF**

To turn the controller off, click then hold the firefly logo with a short click followed by a longer hold until the tail light stops flashing and the blue corner LEDs turn off.

### **STOP TREATMENT**

If for any reason, the treatment needs to stop, either turn the controller off or interrupt the treatment by disconnecting the controller from the patch.

### **INTERRUPTED TREATMENT**

If at any time during the treatment the controller is detached, fast buzzing and yellow flashing will occur. Reconnect the controller within two minutes in order to complete the treatment. Reconnection time is expressed by the deactivation of blue corner LEDs every 20 seconds. If the controller is disconnected longer than two minutes, it will turn off.

## **DIRECTIONS FOR USE : CONTROLLER**

### **FAILED TREATMENT**

#### **DUE TO INSUFFICIENT CONTROLLER CHARGE**

Controller tail light and corner LEDs flash blue with fast buzzing for 10 seconds. Recharge controller.

#### **DUE TO DISCONNECTED CONTROLLER**

Controller tail light flashes yellow with fast buzzing for 10 seconds at start-up. Make sure the light patch socket is properly seated in the controller. Controller tail light flashes yellow during treatment with fast buzzing, blue corner LEDs sequentially deactivate every 20 seconds until 2 minutes reconnect time runs out. Reconnect the controller to the light patch.

#### **DUE TO SPENT PATCH**

Controller tail light is continuous red with fast buzzing for 10 seconds when the light patch has reached its end-of-life. Start treatment again with new patch.

#### **DUE TO DEFECTIVE PATCH OR BAD CONTACT WITH CONTROLLER**

Controller tail light flashes red with fast buzzing for 10 seconds if the patch is defective and/or the controller is poorly connected to the patch. Clean controller and/or patch contacts (p14) or replace the light patch.

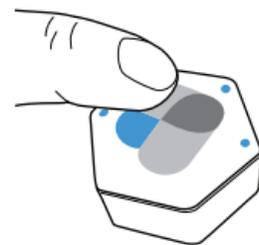
#### **DUE TO OUTSIDE OF TEMPERATURE RANGE**

Controller tail light flashes orange with fast buzzing for 10 seconds. Allow the controller to warm up or cool down prior to use.

## CHARGE LEVEL AND CHARGING

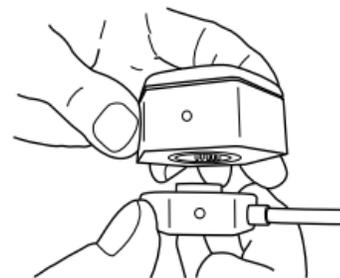
### CHARGE LEVEL

To check the charge level, click then hold the firefly logo using a short click followed by a longer hold until the controller turns on. Small blue LEDs will light up in the corners of the controller and represent the controller's charge level. If the battery is very low the display will not activate. If there are fewer than 5 blue corner LEDs lit, then the controller should be charged. If the controller has insufficient charge for the light patch, the controller will buzz at a rapid rate for 10 seconds and the tail light and corner LEDs will flash blue.



### CHARGING

Fully charge the CareWear controller for the first time and anytime power is low. It takes about an hour to fully charge the controller. If there are fewer than 5 blue corner LEDs lit, then the controller should be charged. Place controller on the charging base socket, making sure to align the dot on the controller (near the left wing of the firefly logo) with the dot on the charging base. You will feel a magnetic pull and hear a click when the controller is properly aligned. Connect the adapter plug to the USB cable and plug into the wall outlet. The firefly tail light will turn blue indicating that the controller is connected correctly to the charging base. Small blue LEDs will systematically light up in the corners of the controller approximately every 10 minutes in a clockwise manner. A minimum of 5 blue LEDs are suggested for any one treatment. The controller is fully charged on the charging base when all 6 corner LEDs are off but the blue tail light remains on.



## CLEANING

### CONTROLLER

Periodically clean the controller with a germicidal disposable wipe containing ammonium chloride and/or isopropyl alcohol. The controller should be “off” and removed from the charger base before cleaning. If debris is present, use a soft bristle brush to clean in between and around the pogo pins and magnetic ring. Allow to dry completely before using. Dispose of used wipe and/or brush in accordance with local regulations for normal or infectious waste disposal.

### CHARGING BASE

Periodically clean the charging base with a disposable wipe containing ammonium chloride and/or isopropyl alcohol. If debris is present, use a soft bristle brush to clean in and around the controller socket. Allow to dry completely before using. Dispose of used wipe and/or brush in accordance with local regulations for normal or infectious waste disposal.

### LIGHT PATCH AND LINER

Periodically clean the white outside patch surface and liner as well as the smooth patch under surface (after removing hydrogel sheet) with a disposable wipe containing ammonium chloride and/or isopropyl alcohol. Use a soft bristle brush to clean in or around patch socket. Do not use a steel brush or steel wool as this may damage the light patch and cause a short in the connector. The controller should not be on the patch during cleaning. Allow to dry completely before using or storing in the zip bag. Dispose of used hydrogel, wipe and/or brush in accordance with local regulations for normal or infectious waste disposal.



Do not submerge controller, light patch or charger accessories in water.  
Do not clean in dishwasher, washing machine or automated cleaners.

## STORAGE AND TRANSPORTATION

### STORAGE

Light patches should be placed back on the liner and stored in the resealable zip bag. To minimize cross contamination, the patch, liner and zip bag are for individual use only and should not be shared.

It is recommended to store the CareWear controller and light patches in a controlled environment with constant ambient temperature of 14°F (-10°C) to 113°F (45°C), relative humidity to 90% no condensation.

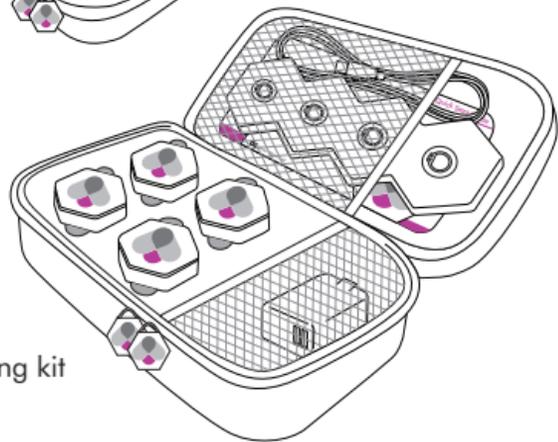
The CareWear carrying case includes storage spaces for the controller and all accessories. Use the carrying case to provide extra protection during storage and/or transportation.

### TRANSPORTATION

The CareWear device has a universal (100-240V, 50/60Hz) power adapter so you can use it all over the world. However, when traveling outside your home country, you may need a conversion plug for the AC adapter.



Small carrying kit



Large carrying kit

## DISPOSAL

### DISPOSAL



Do not throw out the CareWear controller with normal domestic waste at the end of its life. The controller is an electronic device and should be disposed of as you would any electronic waste in accordance with your local recycling regulations.



Discard the used hydrogel sheet when it no longer sticks to the skin or is contaminated by body fluids. Discard the CareWear light patch when the patch is spent (p12) with no treatments remaining. Dispose of used light patch and hydrogel in accordance with local regulations for normal or infectious waste disposal.

## TROUBLESHOOTING

The most common problems and solutions associated with the CareWear controller and the light patch are listed below for easy reference. If the CareWear controller and/or light patch does not function correctly after performing the suggested solution(s), contact [customercare@carewear.net](mailto:customercare@carewear.net).

PROBLEM	CAUSE	SOLUTION
<b>LIGHT PATCH</b>		
Does not stick to skin	Dehydrated hydrogel	Replace hydrogel
	Dirt or oil absorbed by hydrogel	Replace hydrogel
Does not light up	Controller not seated correctly on patch socket	Reposition controller correctly on patch socket
		Clean pogo pins on controller and/or socket on light patch
	Controller has insufficient battery charge or is "dead"	Recharge controller
	Defective or spent patch	Replace light patch
Defective controller	Replace controller	

## TROUBLESHOOTING

PROBLEM	CAUSE	SOLUTION
<b>CONTROLLER</b>		
Not charging	Controller not positioned properly on charging base	Reposition controller properly on charging base
		Clean pogo pins on controller and/or socket on charging base
	Charging base not powered	Check that power adapter and cord are connected and in good condition
		Check that wall outlet has power
	Defective controller	Replace controller
Does not turn on	Controller top was not clicked correctly	Click then hold down controller top
	Controller has insufficient battery charge or is "dead"	Recharge controller
	Defective controller	Replace controller

## TROUBLESHOOTING

PROBLEM	CAUSE	SOLUTION
<b>CONTROLLER</b>		
Flashing Yellow	Disconnected controller	Reconnect controller to patch
Flashing Blue	Controller has insufficient battery charge for full treatment	Recharge controller
Continuous Red	No treatment time remains, light patch end-of-life	Replace light patch
Flashing Red	Light patch defective	Replace light patch
Flashing Orange	Temperature outside of operating range	Alter temperature

## Q&A

### Q: How do I make the patch stick better to the skin?

A: Try to position the light patch so it curves along its long axis (tab ends move closer) instead of its short axis (sides move closer). If the hydrogel is dried out replace the hydrogel or apply a few drops of water to the surface of the gel and evenly spread it over the surface. Wait 5 minutes for the water to absorb. This will often enhance the hydrogel adhesion throughout its use life.

### Q: Can you make the light patch last longer?

A: Proper skin cleansing prior to patch placement can minimize build-up of sweat, oils, dead skin and hair on the patch's adhesive hydrogel. Proper patch handling to avoid air drying and UV light exposure can improve patch use life. After each treatment, be sure to place patch back on the clear liner and store in its resealable zip bag. Also avoid cutting, folding or pulling patch at non-tab points. Do not step on or provide excessive pressure to the patch socket.

### Q: Can I use the CareWear light patch with other pain management and tissue recovery therapies?

A: Yes. CareWear light patches are a non-drug therapy that can be used in combination with other therapies.

### Q: Can I use the CareWear light patch in combination with topical creams/gels?

A: Yes. However, topical creams/gels should be applied to the treatment site **after** the light treatment to prevent damage to the hydrogel.

### Q: Do I need to shield my/the patient's eyes during treatment?

A: No. The light patches are safe for ocular exposure according to IEC 62471-2/TR:2009. However, it is not recommended to apply the patch over the orbital area of the eye(s) nor stare into an activated patch.

## WARRANTY

CareWear Corp warrants this product to be free from defects in material and workmanship for a period of one (1) year for controller, charger, cable or adapter plug from the date of purchase, by the original owner, from CareWear Corp or an authorized CareWear Corp distributor/dealer. This warranty covers the original purchase only and is not assignable or transferrable to another party. During the limited warranty period, CareWear Corp will at its discretion, repair or replace defective parts or product, at no charge to the customer, subject to the following limitations. This limited warranty does not include any postage, freight, insurance or delivery fees. This warranty does not cover damage, defect or failure caused by or resulting from:

- accident, misuse, abuse
- unauthorized repair, alteration, modification
- use with unauthorized accessories
- misapplication or negligence by the user
- war, fire, earthquake, flood or other natural disaster

### WARRANTY REGISTRATION

For questions, or to activate your warranty, visit [carewear.net/warranty](http://carewear.net/warranty)

## CUSTOMER CARE

Mon-Fri: 9am – 5pm Pacific Time  
Phone: 888.988.8797 or 775.473.4684  
Email: [customercare@carewear.net](mailto:customercare@carewear.net)  
Website: [carewear.net](http://carewear.net)

1225 Financial Blvd.  
Reno, NV 89502 USA

## TECHNICAL SPECIFICATIONS

### Controller

Rated Voltage	3.3 – 4.2VDC
Ingress of Water	IP66 Waterproof
Battery Type	Lithium Polymer
Battery Capacity	420 mAh, 30 minute treatment is typical (1.26 Watt Hours)
Controller Operating Temperature	0°C (32°F) to 45°C (113°F)
Controller Storage Temperature	-10°C (14°F) to 45°C (113°F)
Recovery time temp cut off	Over temperature 45°C to 20°C immediate Under temperature -10°C to 20°C immediate
Operating - Storage Relative Humidity	Up to 90% No condensation
FDA Classification	Class II Medical Device
EU Classification	Class IIa Medical Device
Maintenance Instructions	There is no user maintenance of the controller other than cleaning

## TECHNICAL SPECIFICATIONS

### Light Patch

IEC 62471 Risk Class	Exempt
Wavelengths	Available in 450nm, 640nm or combined 450nm/640nm light patches
Pulsed Mode	The emission is pulsed at 33% Duty Factor at 33KHz
Irradiance	Nominal 2.5 mW/cm <sup>2</sup> (patch dependent)
Treatment Duration	30 Minutes
Fluence	Nominal 4.5 J/cm <sup>2</sup> (patch dependent)
Maximum Radiant Power	Up to 80 mW average, 240 mW peak (Patch Dependent)
Maximum Radiant Energy	Up to 144 Joules during 30 minute treatment (Patch Dependent)
Maintenance	There is no user maintenance of the light patch other than cleaning
Patch Operating Temperature	0°C (32°F) to 45°C (113°F)
Patch Storage Temperature	-10°C (14°F) to 45°C (113°F)
Operating-Storage Relative Humidity	Up to 90% No condensation

## TECHNICAL SPECIFICATIONS

### Charger Adapter

Rated Input Voltage	100-240VAC
Rated Frequency	50/60 Hz
Rated Power Input	0.4A
Rated Output	5V 2.1A max
Charging Bases	USB 2.0 with custom pogo pin connector cable

## TECHNICAL SPECIFICATIONS

### (EMC) Electromagnetic Compliance

Medical electrical devices series are subject to special precautions with regard to electromagnetic compatibility and must be installed and commissioned in accordance with the advice given in the instructions for use and accompanying documents. Portable and mobile RF communication systems (e.g. mobile phones) may interfere with medical devices. The CareWear® controller should only be operated with the original charge cable specified in the list of contents delivered.

### Guidelines and manufacturer's declaration – Electromagnetic Interference

The CareWear controller is intended for operation in an electromagnetic environment as indicated below. The customer or user of the device should ensure that it is operated in such an environment.

Interference tests	Conformity	Electromagnetic environment guideline
RF emissions (conducted)	Group 1	The device uses RF energy solely for its internal functioning. Its RF emission is therefore very low and it is unlikely that this will cause interference to neighbouring electronics.
RF emissions (radiated)	Class B	The device is suitable for use in all installations including those in a residential environment and those which are directly connected to the public mains network which also supplies buildings which are used for residential purposes.
IEC 61000-3-2 Harmonic emissions	Conforms	
IEC 61000-3-3 Voltage fluctuation & flicker	Conforms	

## TECHNICAL SPECIFICATIONS

Immunity test	IEC 60601 test level	Compliance
IEC 61000-4-2 Electrostatic discharge	$\pm 8$ kV contact $\pm 15$ kV air	PASS
IEC 61000-4-3 Susceptibility	80 ~2700 MHz, 3V/m, 80% AM, 1kHz, 385 MHz, 27V/m, 50% Duty Cycle, 18Hz, 450 MHz, 28V/m, 50% Duty Cycle FM (5kHz deviation), 1kHz, 710, 745, 780MHz, 9V/m, 50% Duty Cycle, 217Hz, 810, 870, 930MHz, 28V/m, 50% Duty Cycle, 18Hz, 1720, 1845, 1970, 2450 MHz, 28V/m, 50% Duty Cycle, 217Hz, 5240, 5500, 5785MHz, 9V/m, 50% Duty Cycle, 217Hz	PASS
IEC 61000-4-4 Electrical fast transient	$\pm 2$ kV for power supply lines	PASS
IEC 6100-4-5 Surge	$\pm 1$ kV line to ground	PASS
IEC 6100-4-6 Conducted RF disturbances	0.15 MHz to 80 MHz The ISM (Industrial, scientific and medical) & amateur radio band	PASS

## TECHNICAL SPECIFICATIONS

Immunity test	IEC 60601 test level	Compliance
IEC 61000-4-8 Power frequency & magnetic field	50/60Hz, 30 A/m	PASS
IEC 61000-4-11 Voltage dips & variation	Voltage Dips: <ul style="list-style-type: none"><li>• 0% reduction for 0.5 cycle at 50Hz,</li><li>• 0% reduction for 1 cycle at 50Hz</li><li>• 70% reduction for 25/30 cycles at 50/60Hz</li></ul> Voltage Interruptions: <ul style="list-style-type: none"><li>• 0% reduction for 250/300 cycles at 50/60Hz</li></ul>	PASS

## LIGHT PATCH APPLICATIONS



Back



Neck



Shoulder



Elbow



Knee



Ankle

For optimal treatment, apply the light patch(es) directly over the involved area(s). The skin under the patch(es) should be clean, intact and unbroken. Some common application locations are shown above.

**Injury:** Apply light patch(es) directly over injured tissue as soon as possible following injury. Treat twice daily for the first 3-4 days, then daily until resolved.

**Pain:** Apply light patch(es) over the painful area or joint twice daily for the first week then as needed to reduce pain.

**Muscle Recovery:** Apply light patch(es) to the muscle belly up to 4 hours prior to exercise (preferred). If unable, apply immediately after exercise. During strenuous exercise apply the light patch before and after exercise.

# CareWear<sup>®</sup>

Wearable Therapeutics



[carewear.net](http://carewear.net)



**FDA**  
REGISTERED  
OTC Medical Device

**CE**  
2460

EC REP

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SE-11246 Stockholm, Sweden



ZMI Electronics Ltd.  
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Chien Chen District  
Kaohsiung, Taiwan 806



Designed in USA. Manufactured in Taiwan (controller) and USA (patches)  
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LPR-CWC-1-CE (Rev 7)