

curavi

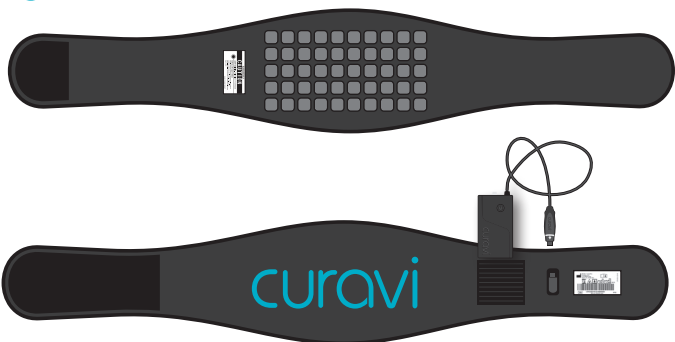


User Instruction Manual

Models: CuraviUltra™ • CuraviPlus™ • CuraviPro™

FIGURES

A



B



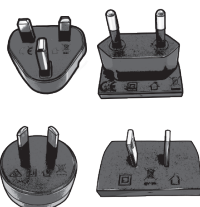
G



D



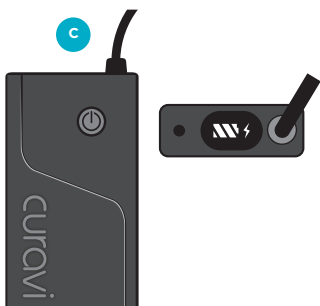
E



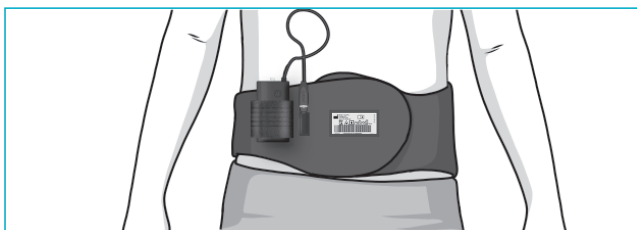
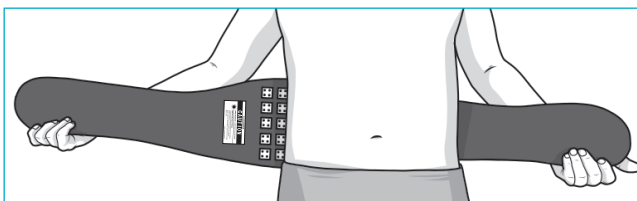
F



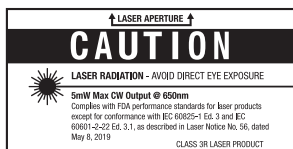
C



H



I



J





IMPORTANT SAFETY INSTRUCTIONS

When using this device, basic safety precautions should always be followed, including the following:

SAVE THESE INSTRUCTIONS. PLEASE READ ALL INSTRUCTIONS BEFORE USE

Please read all instructions before using your Curavi™ device. Keep this user manual for future reference and be sure to follow all warning and safety instructions included herein. If you have any questions, please contact our toll-free customer care center at 1-844-748-3338 or via email at support@curavi.com.

1. DO NOT STARE DIRECTLY AT LASER LIGHT OR ITS REFLECTION FOR EXTENDED PERIODS. PROLONGED EYE EXPOSURE CAN CAUSE EYE DAMAGE.
2. Use this device only for its intended use and according to the instructions provided. Any other use may result in injury.
3. To protect against the risk of electric shock, do not immerse the appliance in water or other liquids. Do not place or store the unit where it can fall or be pulled into a tub or sink.
4. If, while battery pack is plugged in and charging, it falls into water or other liquid, unplug it from the electrical outlet immediately. DO NOT REACH INTO OR TOUCH THE LIQUID.
5. Always connect the plug into outlet first, then attach to battery pack for charging. Always unplug the power adapter from the power outlet immediately following charge. The Battery Pack should always be turned off when connecting/disconnecting from power supply.
6. Do not operate the device when it or any of its components are damaged, or if the Battery Pack or power supply have been dropped or damaged. To avoid the risk electric shock, do not disassemble any part of the appliance or its accessories. Contact Curavi Customer Service for examination and repair.
7. This device is not intended for use by persons (including children) with reduced physical, sensory, or mental capabilities, or lack of experience and knowledge, unless they have been given supervision or instruction concerning use of the device by a person responsible for their safety.
8. Children should be supervised to ensure that they do not play with the device or its accessories and components. Do not leave the device unattended while connected to Battery Pack.
9. Conditions that will void warranty: a) Commercial use, b) inappropriate use, c) failure to comply with the instructions, d) connecting your Battery Pack to the device incorrectly as this may cause irreparable damage.
10. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this device.
11. If the power supply is damaged, contact Curallux for replacement to avoid electrical hazard or damage.
12. Do not adjust or modify the device as this may result in hazardous radiation exposure. Do not use any power adapters or other sources of power, other than that provided with the device. Use only the power supply provided with the device.

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, and (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

TABLE OF CONTENTS

Figures	1
Important Safety Instructions ..	3
Corporate Information	4
Regulatory Compliance.....	4
About the Curavi™ Device	5
• Introduction	
• Indications for Use	
• Intended Usage	
• Frequency of Use	
• Duration of Use	
What's Included	5
Instructions for Charging Battery.....	5
Instructions for Use	6
Safety Labels.....	6
Contraindications	7
Maintenance Instructions	7
Operating & Storage Information	7
Warranty	8
Electromagnetic Interference - EMC/EMF.....	8
Troubleshooting	8
Curavi™ Device Specifications	9

CORPORATE INFORMATION



Curallux, LLC
 1715 NW 82 Ave., Miami, FL 33126
 Toll-Free USA: 1 (888) 272-9599
 Phone: +1 (786) 888-6249
 Email: support@curavi.com
 Website: www.curavi.com

Curavi and the Curavi logo are trademarks of Curallux, LLC registered in the USA and other countries. Patent Pending. Curavi devices are made in the USA from foreign-sourced raw materials. All product information and articles are intended to be for informational purposes only.

REGULATORY COMPLIANCE

Curavi lasers comply with 21 CFR 1040 for Class 3R Laser Products as administered by the Center for Device and Radiological Health of the US Food and Drug Administration and standard IEC60825 of the International Electrotechnical Commission.

Curallux' Quality System for medical device design and manufacturing is registered by Intertek certification #0051805-02 and is compliant with the following:

ISO13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

ABOUT THE CURAVI™ DEVICE

The Curavi™ Laser Therapy Belt is a portable home-use photobiomodulation device embedded with laser diodes (<5mW) and powered by a certified rechargeable Battery Pack that connects to the device. The laser device is worn around the lower back with an adjustable strap for fitting. Keep the belt as comfortably tight as possible to the body. Use the belt directly on clean skin (with no clothing in between). Place the Battery Pack inside the elastic pouch on the belt. Please note that it is normal to experience a sensation of heat which enhances laser light therapy for pain relief while using the Curavi Belt.

INDICATIONS FOR USE

The Curavi™ Laser Therapy Belt is a non-invasive, non-pharmaceutical alternative intended to temporarily relieve mild to moderate muscle pains, aches and inflammation due to arthritis and muscle spasms.

IS CURAVI LASER LIGHT THERAPY RIGHT FOR YOU?

The Curavi™ Laser Therapy Belt may be a great treatment option if you experience mild to moderate muscle pain in the lower back area.

This non-invasive and non-pharmaceutical treatment uses a precise wavelength of laser light to penetrate the skin and stimulate an increase in local blood circulation; modulating the inflammatory process for instant relief.

Check with your insurance company for any potential cost coverages.

INTENDED USAGE

The Curavi™ Laser Therapy Belt should be used only for the purpose described in this manual and on the external lower back. Any other use is not recommended.

FREQUENCY OF USE

The Curavi™ Laser Therapy Belt can be used every day. The total time of each session is 30 minutes.

DURATION OF USE

The Curavi™ Laser Therapy Belt may be used for 30-minute sessions whenever you experience muscle pain.

WHAT'S INCLUDED

FIGURES A-J: CURAVI LASER LIGHT THERAPY COMPONENTS

Refer to Page 1-2 to see referenced figures. The Curavi™ Laser Therapy Belt is packaged inside a lightweight carrying case which can be used to store the device between uses and protect it from dust and moisture. Unpack the components and make sure all the parts are present according to Page 1. Inside the Fig. G case, the following components can be found: Fig. A the Curavi laser light therapy belt, Fig. B detachable extension belt for optional adjusting of device size, Fig. C a rechargeable lithium-ion battery pack, Fig. D a corresponding Universal AC Adapter, and Fig. E 4 interchangeable plug adapters for use in international markets. If there are parts missing, contact Curavi Customer Care at 1-844-748-3338 or email support@curavi.com.

INSTRUCTIONS FOR CHARGING BATTERY PACK

Before initial use, please charge the Battery Pack overnight as per the following instructions for optimal battery life. Only charge Battery Pack with provided AC Adapter.

STEP 1

Fig. D: Insert provided AC Adapter into power outlet and then connect Fig. C Battery Pack to Fig. D AC Adapter. Make sure access to AC adapter is unobstructed, for safety. The display panel will indicate charge level.

STEP 2

Fig. C and D: Once the Battery icon is fully illuminated and static, the Battery Pack is ready for use. Disconnect Battery Pack from AC Adapter for use. Disconnect AC Adapter from power outlet. We recommend storing all parts of your device in the Carrying Case, Fig. G when not in use.

Battery should also be disconnected from laser device between uses for optimal battery life and performance. Recharge Battery when icon indicates half capacity or less.

INSTRUCTIONS FOR USE

The figures in this section refer to the items illustrated on Page 1 and 2.

STEP 1

Refer to Fig. F and A: Connect the Laser Light Therapy Belt to the Battery Pack by matching up the small white indicator arrow on the cable to the connector on the belt. Important: The connector must be aligned for the cable to make a proper connection. Once the connector is aligned, push cable end into connector and secure. Use the stretchable band on the front of the belt to hold the battery while belt is in use.

STEP 2

Refer to Fig. H: Place Laser Light Therapy Belt on your back as shown and tap on the power button on front of Battery Pack to view charge level. Press and hold to begin treatment. Battery level indicators on top of Battery Pack will light up when turned on. The emission indicator light on top of the Battery Pack will glow red to indicate that treatment has begun, and lasers are operational.









NOTE: The Curavi™ Laser Therapy Belt will not operate if the Battery Pack is connected to the AC Adapter.

STEP 3

When the automatically programmed treatment session is finished (30 minutes), you will hear three longer successive beeps to indicate the treatment period is over, the lasers will automatically shut off, and the emission indicator light on the Battery Pack will turn off. When treatment is over after 30 minutes, the Battery Pack will turn off automatically. Disconnect Battery Pack from laser light therapy belt and store until next use.

SAFETY LABELS

Refer to Fig. I: The laser safety label can be found on the inside face of the Laser Device, Refer to Fig. J: Label can be found on the Laser Device. Actual image may differ.

LEGEND	
SYMBOL	EXPLANATION
	indicates manufacturing company.
	indicates the device should not be disposed of in the normal waste stream; it should be taken to a recycling center for proper disposal.
	indicates laser light radiation as described on label (i).
	indicates Type BF applied part (60335); B=Body, F=Floating applied part. No conductive contact to patient.
	indicates country of manufacture.
	indicates date of manufacture, in year-month format. date is adjacent to the symbol.
	READ ACCOMPANYING DOCUMENTS.
	indicates the unique device identifier.
	indicates no protection against moisture or dust.

The Curavi™ Laser Therapy Belt gives off no harmful radiation, causes no pain and does not require the use of drugs or topical applications.

EYE SAFETY CAUTION: Class 3R 5 MilliWatts, 650 Nanometers Red Laser Diodes. DO NOT STARE DIRECTLY INTO THE LASER LIGHT FOR EXTENDED PERIODS.

CONTRAINDICATIONS

- Laser therapy should not be used in conjunction with medications or products that are photosensitizing.
- Consult with your physician before using the Curavi™ Laser Therapy Belt if you have any concerns.

MAINTENANCE INSTRUCTIONS

If it is necessary to clean the surfaces of your Curavi™ Laser Therapy Belt, please follow these instructions. To maintain the cleanliness of device, only use on clean skin. Note: the Curavi™ Laser Therapy Belt cannot be serviced by the user. If service is required, contact Curallux, LLC.

- DISCONNECT ALL CABLES ON THE CURAVI™ LASER THERAPY BELT BEFORE CLEANING
- The Curavi™ device is water repellent, NOT waterproof
- To clean the Curavi™ Laser Therapy Belt, gently wipe the inner surface of the laser device with an alcohol wipe or a water moistened cloth. Do not use excessive pressure or force as this may damage the unit.
- DO NOT use Acetone or any other solvents on any part of the device. Acetone and other solvents will damage the unit and void the warranty.

OPERATING INFORMATION

The Capillus® laser therapy cap is designed to work in ambient temperature between -4° and 140° F (-20° and 60° C).

 60° C -20° C	 90% RH 15% RH	 1060 hPascals 700 hPascals
---	--	---




STORAGE, TRAVEL & TRANSPORT INFORMATION

Use carrying case provided to store and protect your device from dust and moisture between uses. The Curavi™ laser therapy belt is designed to be shipped or stored in temperatures between -13° and 158° F (-25° and 70° C). Battery life may be shortened if stored outside of these temperature ranges. After transport or storage in extreme temperatures, it is recommended to keep the device in normal room temperature for at least 3 hours before charging or using.

 70° C -25° C	 93% RH 15% RH	 1060 hPascals 700 hPascals
---	--	---

You can also travel with your Curavi™ Laser Therapy Belt. Use the lightweight carrying case that protects your device for storage and travel. A universal AC adapter with interchangeable input plugs is included so you can recharge your portable battery pack when traveling abroad. For air travel, we recommend including your device in your carry-on bag. If you decide to check the device as baggage, please keep the battery pack on the plane with you. Lithium-ion batteries are not allowed in checked baggage, per TSA restrictions.

LEGEND

SYMBOL	EXPLANATION
	INDICATES TEMPERATURE RANGE.
	INDICATES HUMIDITY RANGE.
	INDICATES ATMOSPHERIC PRESSURE RANGE.

LIMITED WARRANTY

Please refer to limited warranty details below for your Curavi laser therapy belt model.

CURAVI™ULTRA	CURAVI™PLUS	CURAVI™PRO
LASER DEVICE WARRANTY PERIOD		
1 Year	2 Years	3 Years
BATTERY PACK & AC ADAPTER WARRANTY PERIOD		
1 Year		

Curallux, LLC warrants the device against defects in materials or workmanship for a 3 year period indicated above starting from the date of purchase from a Curavi authorized seller. To activate your warranty, register your device within 30 days of purchase at www.curavi.com/warranty. If a defect in material or workmanship exists, Curallux will repair or replace the necessary parts with new or reworked parts at no charge. Any replaced parts will be covered under the original limited warranty. This Warranty is not transferable & does not cover damages caused by acts of God, misuse, negligence, accident, or modification of any part of the unit as determined by our service department. This Warranty does not cover damage due to improper operation or maintenance, connection to improper voltage supply, or attempted repair by anyone other than the company. Failure to use and maintain the device in accordance with the instructions in this manual will void the product warranty.

Batteries will need to be replaced over time through Curallux. Please contact Curavi Customer Care should you need to get warranty service or order replacement parts such as Battery Packs or AC adapters.

Do not disassemble any part of the Curavi™ Laser Therapy Belt device and don't attempt to repair the device by yourself. Disassembling the device may damage it or may cause injury to you. If the Curavi™ device is damaged, malfunctions, or comes in contact with liquid, contact Curavi Customer Care. The lithium-ion battery should be replaced only by Curallux.

ELECTROMAGNETIC INTERFERENCE - EMC/EMF

This appliance complies with all applicable standards regarding electromagnetic fields (EMF). If handled properly and according to the instructions in this user manual, the appliance is safe to use based on scientific evidence currently available.

MATERIALS

This product is compliant with the current Restriction of Hazardous Substances (RoHS) regulation; there are no materials used with known allergens or adverse health effects.

TROUBLESHOOTING

For any problems operating the Curavi™ Laser Therapy Belt, please call Curavi Customer Care at 1-844-748-3338, email support@curavi.com, or visit support.curavi.com. If you experience any discomfort during or after use, please discontinue use immediately and contact your physician.

NOTICE: Do not attempt to repair any portion of the Curavi™ Laser Therapy Belt. If a malfunction occurs, disconnect the Curavi™ Laser Therapy Belt from the electrical source and call Curavi Customer Care toll-free at 1-844-748-3338, or email support@curavi.com.

DEVICE SPECIFICATIONS

Please refer to specifications below for your Curavi™ Laser Therapy Belt.

	CURAVI™ULTRA	CURAVI™PLUS	CURAVI™PRO
	LASER LIGHT THERAPY BELT		
TYPE	5 mW		
WAVELENGTH	650 nm +/- 5		
OUTPUT MODE	Continuous Wave		
NO. OF DIODES	84	160	200
TOTAL OUTPUT	420 mW	800 mW	1000 mW
	BATTERY PACK		
TYPE	Lithium-Ion		
INPUT	DC5V/1.5A		
OUTPUT	DC5V/5A		
CAPACITY	3500mAh/3.6V		
	AC ADAPTER		
INPUT	AC100-240V, 50/60Hz, 0.6A		
OUTPUT	DC5V, 3A		
	SERVICE LIFE EXPECTANCY*		
	5 Years		

The power supply for the Curavi™ Laser Therapy Belt has been designed for use in the United States and select international regions with power inputs as mentioned above. We also include 3 alternate plugs for use in other countries. If the power outlets in your country use plugs different than the type supplied, you will need to obtain an appropriate country-specific plug adapter.

*In the case that a device needs repair, this indicates how long a particular model can be serviced after purchase, due to the availability of parts in inventory.

AMBIENT OPERATING CONDITIONS

- Operating Temperature: -20° Celsius (-4° Fahrenheit) to 60° Celsius (140° Fahrenheit)
- Humidity: 15% to 90% RH
- Atmospheric Pressure: 700 hPascals to 1060 hPascals

CLASSIFICATIONS

- IEC 60825 Classification: Class 3R Laser Product; output power <5mW
- FDA Medical Device Class: Class II

EYE SAFETY

UNLESS WEARING SUITABLE LASER SAFETY EYE-WEAR PROTECTION, DO NOT STARE AT THE LASER LIGHT FOR LONG PERIODS AS IT CAN DAMAGE YOUR EYES.



curavi™

WWW.CURAVI.COM | +1 (844) 748-3338



© 2021 Curallux, LLC. All rights reserved.

CMPT19004_R1.00621