

A circular graphic containing a grid of red dots, resembling a laser or light array.

Medlight™

630PRO

Pain Therapy Device
Instructions for Use



***Effective Pain Therapy for the
Temporary Relief from Minor Pain***

To ensure the best results and long term satisfaction with your Medlight 630PRO, we recommend that you read the following instructions carefully before use.

Intended Use

Medlight 630PRO Pain Therapy Device is a hand held device used for the treatment of chronic pain emitting energy in the Near-IR spectrum for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting relaxation of muscle tissue; and to temporarily increase local blood circulation.

Contraindications

There are no known contraindications for the use of the Medlight 630PRO.

Warnings

- Keep the Medlight 630PRO out of reach of young children who are not able to read and understand the 'Warnings' and 'Cautions' listed below.
- Do not allow device to come in contact with water; contact with water may cause electric shock.
- Do not use other Power Supplies or Car Adaptors with device. Using other products may cause electrical shock or device failure.
- Do not exceed three (3) treatment cycles per session. Exceeding treatment cycles may cause excessive skin warming. This may result in skin irritation or discomfort.

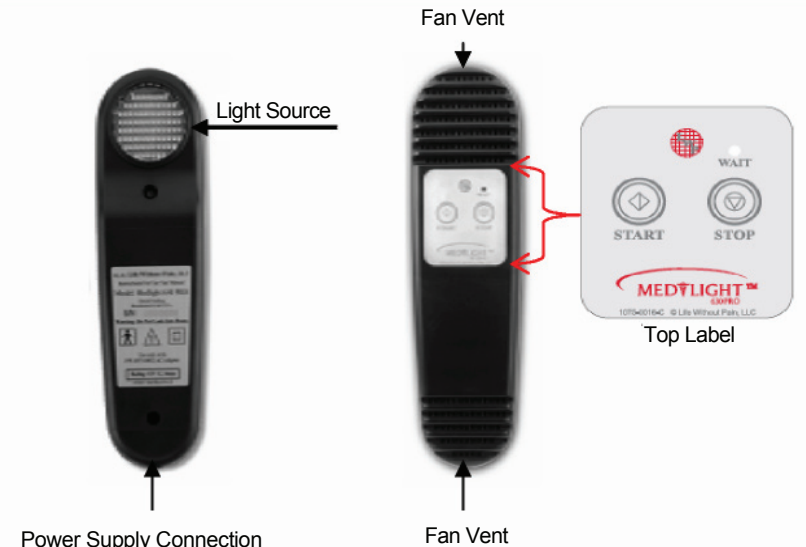
Cautions

- Do not block device fan vents by placing device under clothing, under or between any body part(s) or with Velcro Strap. Blocking vent may cause device to overheat and turn off.
- Do not look directly at the light source. The Medlight 630PRO emits high intensity light and prolonged exposure of your eyes directly to the light may cause discomfort. Use of the supplied goggles is recommended during facial treatments to reduce the intensity of the light to your eyes.
- Do not allow the unit to come in contact with broken skin. The device is not sterile and may cause infection. If necessary, cover the broken skin with a bandage.

C. Contents of the Medlight 630PRO



A. Medlight 630PRO Detail



Treatment Recommendations

Medical Devices, Inc. recommends the use of three, 4-minute treatment cycles per session. During the first 4-minute treatment cycle your skin temperature will rise to a therapeutic level. Continue two additional treatment cycles to achieve optimal therapeutic benefit.

In general, Medical Devices, Inc. recommends two to three sessions spaced throughout the day. However, treatment may be repeated as often as needed.

Usage Tips

For minor muscle pain and/or spasm:

- Identify the location of pain and apply the device directly to area.

For joint pain and arthritis:

- Apply the device to the joint line area where the two bones meet (Fig. 1).

For hard-to-reach areas:

- A Flexible Velcro Holding Strap is included with the Medlight 630PRO to provide hands free operation during treatment. Insert the device into the loop of the strap being careful not to cover fan vents (Fig 2 and 3).

Hold the LED light source over the treatment area and fasten the Velcro holding strap to comfortably and securely hold the device in place.

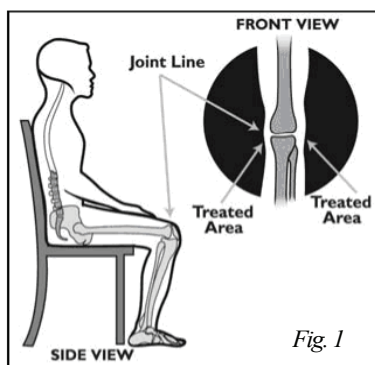


Fig. 2



Fig. 3

Operating Instructions

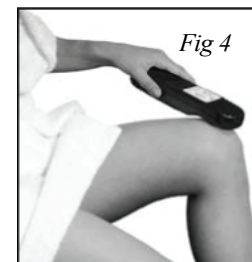
(Refer to page 3(b) for illustrations)

1. Plug the power supply into the Medlight 630PRO power supply connection, and then into a wall outlet.

2. To operate, press the START button. A Red light will be emitted from the light source.

If you desire to stop treatment before the 4-minute cycle is complete press the STOP button at any time.

3. Hold the Medlight 630PRO over the area to be treated.



4. The Medlight 630PRO has a built in spacer lip that will help you maintain the optimal distance from the treatment area. If using the Medlight 630PRO on intact skin, you may place the device directly on your skin.

If using the Medlight 630PRO over broken skin, hold the device slightly above the skin so that it does not come in contact with the broken skin. When using the device correctly, you should feel a gentle warming of your skin.

5. The Medlight 630PRO treatment cycle is 4-minutes. Completion of the treatment cycle is indicated by an audible alarm.
6. To achieve the desired pain relief, two additional 4-minute treatments are recommended.
7. After treatment is complete, unplug the POWER SUPPLY CORD from the wall outlet.

Wait Light

The Medlight 630PRO has an internal automatic temperature sensor that will turn the device off and illuminate the Wait Light to prevent the device from overheating. When the device has cooled to an acceptable temperature the WAIT Light will turn off allowing the device to resume treatment. (Please refer to "Cautions" in Instructions for Use to help prevent overheating of device.)

Clinical Performance Data			
Model	MEDLIGHT 630PRO		
Time (treatment cycle)	4 min (1)	8 min (2)	12 min (3)
Bicep skin temp. (°F)	103.9	106.0	107.8
Forearm skin temp. °F)	104.1	106.9	108.0
Calf skin temp. (°F)	103.8	105.2	108.2

Note: Data was collected from two subjects by performing three repetitive tests on three different body parts using a digital thermometer with an insulated cover attached to the skin of the subjects. The Medlight 630PRO was placed directly onto the treatment site with the LED lights 1cm (depth of lip on Medlight 630PRO device) from the skin. Prior to the start of the test, subjects skin temperature ranged from 94° F to 97° F.

FDA requires devices that use thermal energy to provide pain relief must demonstrate the ability to generate temperatures of 40-42° C (104-107.6° F) at the treatment site for a duration of 5-10 minutes.

Maintenance

Clean the surface of the lens and body with a damp cloth only. Do not use any type of solvent or other cleanser. To protect the Medlight 630PRO mechanism, store at room temperature in a dry place, out of the reach of children and in the original packaging when not in use. The MEDLIGHT contains no user serviceable parts. Do not disassemble.

Problem	Cause	Solution
No red light emitted from the light source. WAIT light is illuminated.	Device Overheating	Wait until WAIT light goes off before resuming treatment
No red light emitted from light source.	No Power to device	<p>* Check to make sure the power supply is securely plugged into the MedLight 630 Pro.</p> <p>* Check to make sure the power supply is securely plugged into the wall outlet</p>

International Use

The POWER SUPPLY included with the MEDLIGHT 630PRO is universal input (100-240 VAC, 50/60 Hz) and can be used anywhere in the world. User needs to supply appropriate plug-in adaptor.

Product Life Cycle

MEDLIGHT 630PRO product life cycle: 100,000 treatment cycles. End of device life cycle will be demonstrated by L.E.Ds no longer emitting light.






Environmental conditions for transport and storage:

Temperature range:
within -40°C to +70°C

Relative humidity range:
within 10% to 75%

Technical Specifications

Treatment area:	14 cm ²
Wave length of light emitted:	630 nm
Joules per minute:	12
Joules per 4-minute treatment cycle:	48

CLASSIFICATIONS PER UL/IEC/EN 60601-1	
Degree of protection against electric shock: Type BF Applied Part	 Class II 
Attention, Consult accompanying documents	  START  STOP
Degree of protection against the ingress of water: IPX0	
USE ONLY WITH	P/N 1075-0030 AC Adapter - Rating: 100-240VAC 50/60 Hz, 0.5-0.8A or P/N 1075-0034 Car Adapter - Rating: 12 VDC Nominal



MEDICAL EQUIPMENT
WITH RESPECT TO ELECTRICAL SHOCK
FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL/IEC/EN 60601-1
And CANCSA C22.2 No. 601.1



Limited Warranty

Medical Devices, Inc. (MDI) warrants the Medlight 630PRO device to be free from defects in workmanship and materials under normal use for a period of one (1) year from the date of purchase. MDI's sole obligation under this warranty will be to repair or replace (new or refurbished), at its option, the Medlight 630PRO Unit that proves to be defective during the warranty period. The foregoing shall be the sole remedy under the warranty.

Except as set forth herein, MDI makes no warranties, either expressed or implied, including the implied warranties of merchantability and fitness for a particular purpose. No warranty is provided if any Medlight 630PRO Unit is modified without the express written consent of MDI.

This warranty is not assignable and is applicable only to the original purchaser.

The instructions contained in this manual in no way represent a guarantee for successful treatment. SEEK MEDICAL ATTENTION IF PAIN PERSISTS. DO NOT discontinue your regular medication without consulting your doctor. The Medlight 630PRO Pain Therapy Device will not eliminate disease that causes pain.

Replacement Parts

Please use the part numbers below when ordering replacement parts. Be sure to use only Medlight 630PRO parts.

1075-0030	Power Supply
1075-0031	Power Supply Cord
1075-0033	Flexible Velcro Holding Strap
1075-0034	Car Adapter
1075-0038	Goggles

Warranty Replacement Procedure

Below is the procedure for replacing your Medlight 630PRO unit due to defect in workmanship or materials within the one (1) year warranty period:

1. The Medlight 630PRO device must be returned with copy of original purchase receipt and in original product packaging.
2. Call Medical Devices Customer Service at (727) 451-7160. The Customer service representative will provide you with a Return Merchandise Authorization (RMA) number and a return address.
3. The return shipment must be prepaid and the RMA number must be displayed on the outside of the shipping container or the shipment will not be accepted by Medical Devices, Inc..

Returns not in the original packaging will not be honored under the terms of this warranty.

Customer Service and Technical Support

For all Customer Service and Technical Support issues including warranty returns and replacement parts please contact our Customer Support Department at:

Medical Devices, Inc.
Customer Service Department
4600 140th Ave. North
Suite 200
Clearwater, Florida 33762



The MedLight™ 630 Pro was manufactured in the USA under license from Life Without Pain, LLC. All rights to the MedLight™ 630 Pro were acquired by Medical Devices, Inc. Medical Devices, Inc. will provide all product support and Warranty management for units sold by Medical Devices Inc. or any of its authorized distributors or resellers.

PATENT PENDING

MADE IN USA

FDA CLEARED



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