

DuoTherm™ User Manual

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 New User must read User Manual prior to operating the DuoTherm™ device

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Warranty:

When used as directed, your DuoTherm™ should last for at least 3 years with intermittent use. This product's warranty covers any type of malfunction or defect that may appear in all parts of the product with normal use. The warranty lasts 3 years from date of purchase. We will replace your product or refund your purchase. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

Guarantee:

Previous medical history and intrinsic physiologic differences may make DuoTherm™ less effective for some people. If not completely satisfied, contact Pain Care Labs within 30 days of purchase to arrange for return and refund.

How To Order/Additional Information:

Please visit PainCareLabs.com for a complete list of FAQ's, other pain management tips, how-to videos, accessories, and replacement parts.

Contact Information

MMJ Labs, LLC dba Pain Care Labs
 195 Arizona Ave LW08 • Atlanta, GA 30307, U.S.A.
PainCareLabs.com • info@PainCareLabs.com
 1.877.805.2899











BF Applied Part

Patents Pending;

United States Patent Nos. 11357698, 10118003, 10058476, 8740960, 8147533, 9333144, 9358152 - China ZL2020307452472 - Australia 2007303111 - Great Britain 2455695

Symbols Defined:

Symbol	Description
	Indicates the instruction manual/booklet must be read
	General warning sign
	Caution – User must consult important cautionary information such as warnings and precautions that cannot be presented on the device itself
	(WEEE) Waste products should not be disposed of with household waste. e.g. at a local authority
	Type BF Applied Part
	Temperature Limit - To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used.
	Humidity limitation - Indicates the range of humidity to which the medical device can be safely exposed.
	Atmospheric pressure limitation Indicates the range of atmospheric pressure to which the medical device can be safely exposed.

Introduction

WARNING:

- For intended use only. Do not apply creams, ointments, or other liquids directly to the metal plate. Many pain ointments can cause chemical irritations when occluded.
- Do not overheat the clay pack. In the event of excessive overheating, the clay pack may break. Clay pack or its contents can irritate skin on contact when overheated.
- DuoTherm™ was tested with a certified power adaptor that is included in your purchase. Any other adaptors may cause inadvertent interference with other household electronics and/or medical devices, including electronic implantables such as pacemakers.
- DO NOT USE WHILE CHARGING IN A RESIDENTIAL SETTING. Do not modify the device or its accessories in any way. Modifications may inadvertently harm the user, damage the device, and will void the warranty.
- Keep devices and accessories out of reach of children or pets. Failure to observe this precaution could result in injury through strangulation of the belt or charging cord, or inhalation of small parts.
- Do not use electronic equipment in the presence of flammable gas, as this could result in explosion or fire.
- This product should not be used by persons with sensory deficiencies or the inability to operate the controls.
- Do not remove the battery or open the battery case. Exposure of skin or eyes to leakage from the battery can cause irritation. If exposed, rinse in clean water. Seek medical attention if needed.

⚠ Cautions:

- The device must be turned OFF while charging.
- Never use while sleeping.
- Do not leave the battery charging over 24 hours.
- Clay pack must be microwaved for best effect (warm/hot). Pack will burst if overheated.
- Clay pack must be frozen solid for best effect (cold).
- Do not use dry ice to freeze clay pack unless supervised by a healthcare professional.
- Do not puncture the clay pack. Discard clay pack if punctured. Do not ingest clay.
- Spot clean only. Do not immerse in water. Do not dry clean.

⚠ Contraindications:

- Consult a physician for new onset low back pain or pain that has changed.
- This device should not be used over swollen or inflamed areas or skin eruptions.
- Do not place directly on a thermal burn.
- Do not use ice pack with underlying sensitivities to ice or cold (e.g. Sickle Cell Disease, Reynaud's Disease, Cold Urticaria, CRPS).
- DO NOT USE in the context of nerve injury or acute injury resulting in decreased strength, radiating pain, or point tenderness on the spine. Seek immediate physician evaluation.

Disposal:



Please contact your local authorities to determine the proper method of disposal of Lithium-Ion batteries. When discarding the unit, comply with local rules or regulations. Batteries should never be thrown away or incinerated but disposed of in accordance with the local regulations concerning battery disposal. Do not attempt to replace battery: this could result in a HAZARD (such as excessive temperatures, fire or explosion).

Troubleshooting:

Failure to charge - When the device fails to charge and/or the charging light is not on, debris may be preventing the connection.

1. Blow gently into the charging port. Do not attempt to clean with liquid.
2. Blow gently onto the magnetic end of the charging cord. Wipe magnetic end with alcohol swab.

If the device stops working, or you encounter any malfunctions, please contact support@PainCareLabs.com. In the event of malfunction, the product should be repaired only by a qualified technician. For lost or damaged accessories, please contact Pain Care Labs directly.

DO NOT SERVICE WHILE IN USE

The belt may be spot cleaned if either the nylon/inner or neoprene/outer side becomes visibly soiled. Cover the charging port with the cap. If cleaning the fabric near the controller, wrap the controller with plastic cling to protect the controller from moisture.

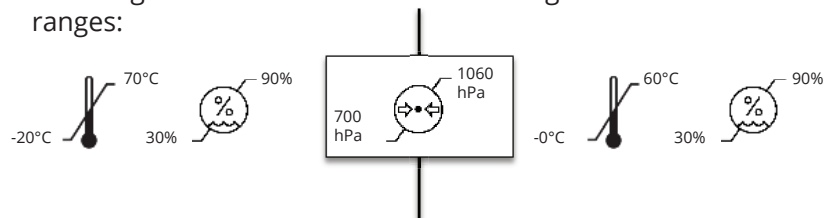
Place a few drops of liquid dish detergent onto a brush or toothbrush and lightly moisten, then scrub the soiled area. Moisten half of a washcloth or towel, and blot the area that has been cleaned well with the moist area, then blot with the dry area. Do not allow moisture to sit or drip into the control panel. Allow to air dry for 24 hours before using.

- Do not wash or dry clean.
- Do not immerse in liquid.
- Do not autoclave (high-pressure steam sterilize).
- Clay packs can be cleaned with a mild soap or detergent. Hand wash only. Soiled or burst clay packs should be disposed of and replaced.
- Because the belt cannot be washed or autoclaved. DuoTherm should not be shared without disinfection protocol.

Storage & Operational Conditions:

DuoTherm™ is supplied with an optional storage bag.

Device must be stored & transported between the following min. and max ranges:

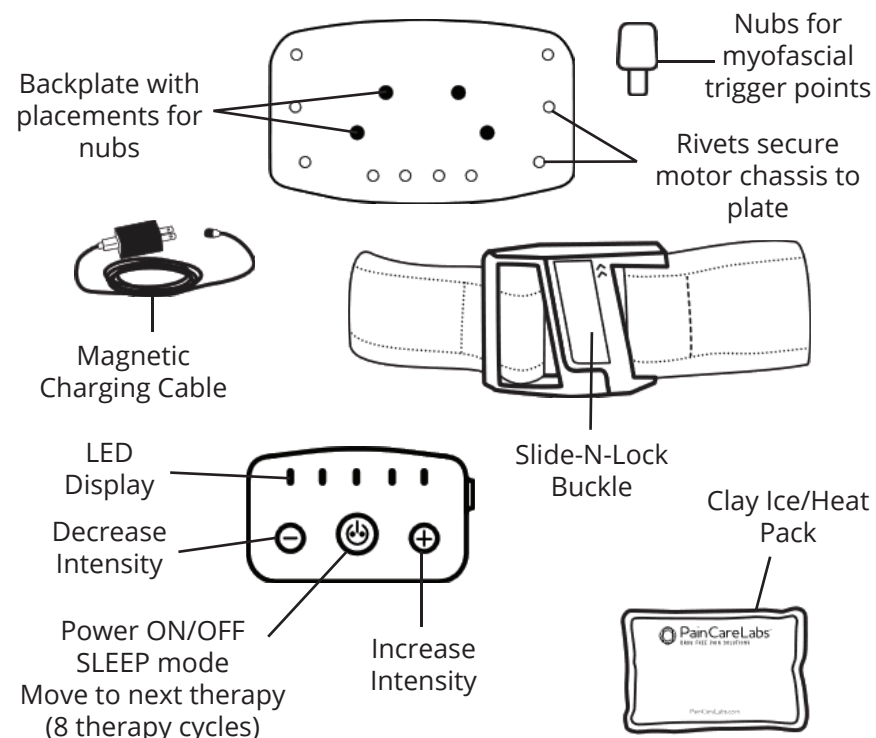


Indications For Use:

DuoTherm™ is intended to treat myofascial pain in the low back caused by trigger points, restricted motion and muscle tension for temporary relief of musculoskeletal pain after surgery, before or during physical therapy, or fascial pain resulting from chronic spine, disc, or other etiology.


Contents of the DuoTherm™ Device

1. Ergonomically contoured metal plate
2. 53.5 in. (136 cm) neoprene belt (stretches to 60 in.) with magnetic slide buckle
3. Control panel with Power/Therapy Cycle button, "+," and "-" intensity buttons, & LED indicators showing setting in use
4. 2 Reusable thermal clay packs to freeze or heat
5. Magnetic USB charger block and cable



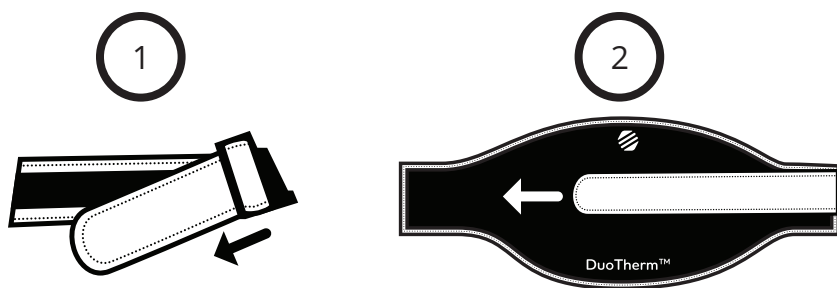
OPERATING INSTRUCTIONS

In Preparation for Use:

-  *To avoid risk of electronic interference with nearby devices, DuoTherm™ is not intended to be used while charging.*


Before use, place clay pack in freezer for 2 hours, or heat in microwave per instructions on pg9.

Before the first use, ensure that the belt is connected properly to the buckle. Loop the free end of the belt into the unconnected end of the buckle.



1. Pull the belt loop until the device fits comfortably.
2. Secure the free end of the belt to the black soft outside material.

Batteries & Charging:

-  *To avoid risk of electronic interference with nearby devices, DuoTherm™ is not intended to be used while charging.*

A Lithium-Ion battery is used to charge the DuoTherm™ device by use of a USB connector. If using a voltage higher than the U.S. standard of 110V, a power convertor must be used. When the device is powered ON, the LED indicators immediately light up to indicate the current battery charge.

- 4 LED lights signify full charge
- 3 LED lights signifies approximately 75% charge
- 2 LED lights signifies approximately 50% charge
- 1 LED light signifies approximately 25% charge

12. Freezing Clay Pack Instructions

- 12.1 Freeze for at least 2 hours in conventional freezer (-10 to 0°F (-18°C)) prior to use.
- 12.2 Place in pouch behind metal plate of DuoTherm.
- 12.3 Clay Pack will lower metal plate to a minimum of 16°C; expected to reduce skin temperature to 20°C.
- 12.4 Apply cold for no more than 20 minutes per use.

13. Heating Clay Pack Instructions

- 13.1 Microwave for 20 seconds. Hold edges while removing to reduce risk of burns. Knead pack in a cloth to even out temperature. Add additional 5 second intervals until a desired temperature is reached. Do not exceed 30 seconds in the microwave, pack will burst. Temperatures are expected to reach 55°C - 65°C after 20 seconds.
- 13.2 Place clay pack in pocket behind metal plate of DuoTherm.

Using DuoTherm™ - Trigger Point Nubbin Use

14. For small pain areas in a muscle (myofascial trigger points) place DuoTherm™ and identify the hole on the metal plate nearest to the pain location. Remove DuoTherm™.
15. Insert single nubbin into the hole identified.
16. Position nubbin over pain area. Activate DuoTherm™.
 - *A second replacement nubbin is included. Using two nubbins at once is not recommended.*
 - *The nubbin will reduce thermal and vibration intensity.*

Cleaning:

DuoTherm™ is a durable medical equipment device. The metal plate, plastic control panel, and buckle may be cleaned with alcohol-based sanitation wipes as often as needed. Do not clean metal plate with ammonia, bleach, or abrasives as they can cause corrosion or pitting to the surface.

If the neoprene belt has been shared with another user, cover the charging port with the cap. Spray the skin-contacting inner nylon (smooth, colored) side of the neoprene with rubbing alcohol, then let the disinfectant sit for ten minutes before blotting dry to ensure bacteria are killed. Allow to air dry 24 hours before using.

8. Try multiple intensities and therapy cycles to find the optimal pain relief. Because pain changes both with time, activity, and other factors, different therapy cycles may be more effective at different times. The harmonic concentration of intensity will differ based on body type and location of the pain source. If unsure, setting eight includes samples of all cycle patterns.

Using DuoTherm™ - Personalizing Relief:

9. DuoTherm™ is intended to administer mechanical stimulation therapy with or without thermal (heat or cold) therapy.
 - 9.1 For temporary relief of restricted muscles from spasm or injury, begin with 30 minutes of therapy two to three times a day, or as recommended by your clinician.
 - 9.2 There is no upper limit on the duration the M-Stim® may be safely used. DuoTherm's battery will last up to 2 hours on a full charge. Do not charge the device while wearing or operating the device.
10. Thermal Considerations: In general, heat is used for chronic pain and to reduce spasm, while ice is used to reduce acute pain from injury and inflammation. Alternating heat and cold may give additional pain relief.
 - 10.1 Heat and cold packs will return to room or body temperature after 20 - 30 minutes to reduce the risk of cold or heat injury.
 - 10.2 Allow the treated area to return to room temperature prior to applying additional ice or heat therapy.

Using DuoTherm™ - Hot and Cold Clay Packs:

11. Place pack between metal plate and neoprene belt before use. **DO NOT PLACE PACK** directly against skin. Thermal damage is likely with prolonged direct skin exposure leading to skin temperatures below 14°C (low) or above 43°C (high).
CAUTION: PACKS can REACH 63.5°C (150°F) with 20 seconds of microwave heating.

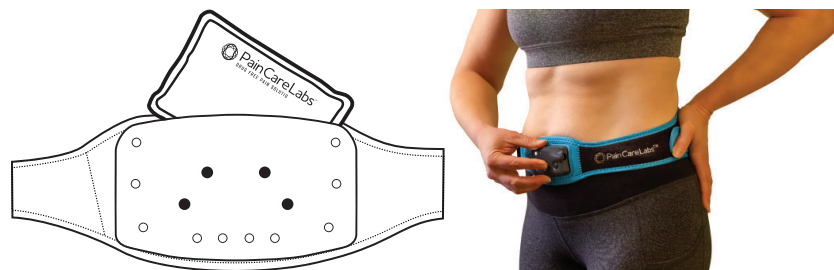
- If the central LED is yellow/orange, the device is low on battery and needs to be charged soon.
- If the device does not turn on at all, the device needs to be charged.

To recharge your DuoTherm™ device:

1. Ensure the charging cable is connected to a wall electrical outlet, car USB port, or computer USB port.
2. Introduce the magnet end of the charging cable into the circular opening on the side of the control panel.
Note: It will click magnetically in place and turn blue while charging.
3. The center LED will blink yellow/orange while charging and will turn green when fully charged. To remove the cable, gently pull out the magnetic charging end.

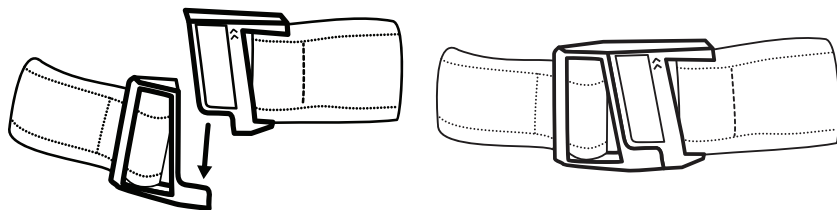
Using DuoTherm™:

Prior to use, if using heat or cold, place your designated therapy (hot pack or cold pack) in the pouch created by the metal plate and neoprene backing. The opening of the pouch is on the top so that the thermal pack will not fall out during use. Remove clay pack when not in use.

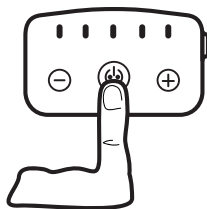


Rivets along the bottom;
pocket opens at the top

1. Apply with thermal plate against the low back, with the opening of the pouch facing up. When properly applied, the controller will be on the left side of the body.
 - 1.1 Place the metal plate against your low back directly against skin (for more intense thermal therapy) or over a thin shirt.
The device does not need to be warmed up or cooled down prior to use, however the metal will feel cool initially.



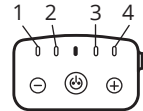
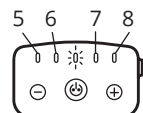
2. To connect the belt buckle, hold ends together and slide down. The magnetic buckle slides up and down, and clicks into place when properly attached.
3. Turn the device ON by pressing and holding the center Power button on the control panel for approximately two seconds.
 - 3.1 White LEDs will illuminate, displaying battery charge. The center LED is green and four white LEDs light up when the unit is fully charged. Orange light indicates low battery.
 - 3.2 The first therapy cycle will begin upon turning the device on, indicated by the leftmost white LED.



Using DuoTherm™ - Choosing a Therapy Cycle:

4. Press the center Power button to advance to the next cycle. There are eight therapy cycles. Cycles five through eight are indicated when the yellow central LED is lit.
5. To increase the intensity of a therapy cycle, press the plus "+" button. To decrease intensity, press the minus "-" button.
Note: There are 5 intensity levels. White LEDs will display the intensity level being used (1 through 5).

Therapy Cycle Legend

<p>1st set of therapy cycles (Central LED light off)</p> 	<p>Setting 1 = steady high pitch Setting 2 = steady firm/low pitch Setting 3 = two motors Setting 4 = three motors</p>
<p>2nd set of therapy cycles (Central LED yellow)</p> 	<p>Setting 5 = up and down Setting 6 = up and down with rumble Setting 7 = full and deep Setting 8 = All cycles in 30 second intervals repeating for a 20 minute session</p>

Note: Pressing a 9th time will return back to the first therapy cycle.

6. Each cycle will remain active for 20 minutes and then automatically go into "Sleep" mode. The middle LED will begin to slowly blink purple 5 minutes before going into "Sleep" mode. The purple LED will blink more rapidly as it nears the end of the 5 minutes.
Note: "Sleep" mode will allow you to return to the last therapy cycle that was in use for up to 3 minutes before the device completely shuts down. Press the center Power button to re-start a 20-minute cycle while the device is in "Sleep" mode.
7. To turn the unit OFF or PAUSE a cycle, press and hold the center button on the control panel for approximately 2 seconds. For the first 3 minutes, the device will stay in "Sleep" mode before shutting down, so re-starting the device will continue with the cycle previously used.