User Guide

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Para obtener la versión en español de esta guía del usuario, visite nuestro sitio web en: www.orthocormedical.com/patient-resources/

# INTRODUCTION

## ABOUT THIS USER GUIDE

This guide describes the Activ8™ System and provides instructions for using it. Please read the entire manual carefully before use. This manual contains information, contraindications, and warnings, which must be observed to assure safe operation and to maintain the device in a safe condition. This device must be used in accordance with the instructions and warnings.

## TECHNICAL DESCRIPTION

The Activ8 System is a portable, compact, lightweight, non-invasive system designed to deliver pulsed electromagnetic field (non-thermal shortwave diathermy) therapy for temporary relief of pain, such as pain associated with over-exertion, strains, sprains, and arthritis. The device consists of a multiple-use pulsed electromagnetic field (non-thermal shortwave diathermy) therapy device, referenced as the 'Activ8 System,' and a multiple-use, rechargeable battery pack.

# USAGE & PACKAGE COMPONENTS

## RECOMMENDED USAGE

The Activ8 System is recommended to be worn for two 30-minute treatments per day by adults users. However, your care provider may modify this recommendation to optimize your care.
For prescription use (Rx) only, use adjunctively with standard of care treatment.

## YOUR ACTIV8 SYSTEM CONTAINS:

**Activ8 System:**

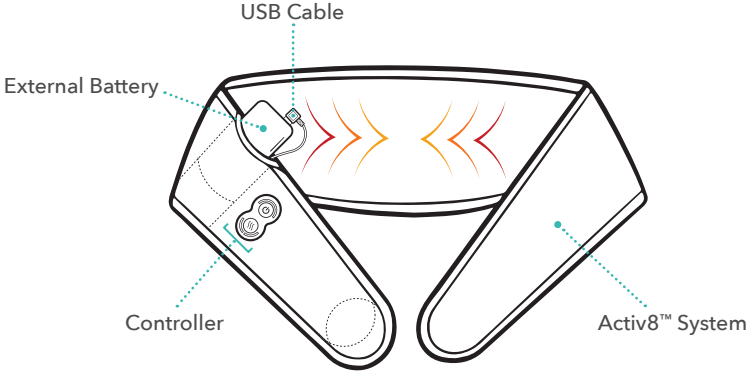
Multiple-use system designed to provide therapy to specified areas of the body.

**External Battery Pack:**

Rechargeable battery designed to power the Activ8 System.
Input (Micro USB):5V⎓2.0A
Output (USB1 or USB2):5V⎓2.7A

**AC Adapter/Charger:**

Micro USB compatible AC charger used to charge the external battery pack.



# INDICATIONS & CONTRAINDICATIONS

Before using the Activ8 System, please read all of the indications, contraindications, warnings, and cautions in the following sections.

## INDICATIONS FOR USE

The OrthoCor Activ8 System is indicated for adjunctive use in the temporary relief of pain, such as pain associated with over-exertion, strains, sprains, and arthritis.

## CONTRAINDICATIONS

- Do not use on patients with a cardiac pacemaker, cardioverter defibrillator, neurostimulator, infusion pump or any implantable electronic device.
- Do not use on patients who have ANY implanted metallic leads (wires) or any type of wire coil implant, or any implanted system that may contain a lead (wire).
- Do not use on patients who are or may be pregnant.
- Do not use on patients with an open wound at the area of application.
- Do not use on patients who are not adults or individuals with open growth plates.
- Do not use on patients not fully aware of the sensation of heat.
- Do no use on patients with poor circulation or heart disease.
- Do no use on patients with diabetes.

# SAFETY INFORMATION

## SAFETY INFORMATION

- This device has been manufactured and tested in accordance to IEC 60601-1 and IEC 60601-1-2 (Class B).
- There are no serviceable parts inside the Activ8 System.
- Energy from non-thermal shortwave diathermy therapy can be transferred through an implanted system with metallic leads or electrodes, resulting in severe injury or death.
- The Activ8 System may interfere with appliances that are designed to detect and amplify weak radio signals. This includes television, radios, citizen band radios, phones, and other consumer devices in these categories. The interference may be heard as a repetitive tick in an FM radio and may cause tearing of a TV picture.

## CLEANING INSTRUCTIONS

- Visually inspect the system for dirt or debris, if any is present wipe clean with a damp cloth. Repeat the inspection, if any dirt or debris remains repeat the cleaning process.

## DISPOSAL

- The Activ8 garment contains no hazardous materials.
- The Activ8 external battery is a lithium-ion component and must be disposed of according to local environmental regulations.

## ⚠ WARNINGS

**WARNING:** This device should be used under the continued supervision of a licensed health care practitioner.

**WARNING:** Use carefully. Remove immediately if discomfort occurs.

**WARNING:** Precaution should be taken when using this device on the elderly or incapacitated persons.

**WARNING:** Precaution should be taken when using this device on patients with sensitive skin. If the patient experiences skin irritation, discontinue the use of the device and consult your licensed health care practitioner before using the Activ8 System again.

**WARNING:** Do not over-tighten the Activ8 System as this may restrict blood flow and result in injury.

**WARNING:** Switching the Activ8 System to low heat mode during therapy may result in non-therapeutic heat.

## ⚠ CAUTIONS

**CAUTION:** Use this device only in the prescribed manner and for the prescribed diagnosis.

**CAUTION:** KEEP AWAY FROM WATER. Use in dry environment.

**CAUTION:** The device is not indicated for treatment of deep tissue such as internal organs.

**CAUTION:** Do not use while the Activ8 System is charging.

**CAUTION:** Do not machine wash the Activ8 System.

**CAUTION:** Do not crush the Activ8 System as this may damage the electronics.

**CAUTION:** NEVER heat the Activ8 System or battery pack in the microwave as the system could catch on fire.

**CAUTION:** Pressing the power button will stop the treatment.

**CAUTION:** The AC adapter/charger must be disconnected from the battery pack for treatment to occur.

**CAUTION:** Keep out of reach of children and pets.

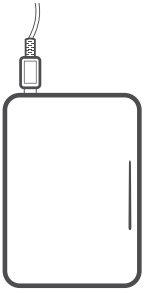
**CAUTION:** For external human use only.

**CAUTION:** Keep device at least 1" from electrostatic discharge disturbances while charging. Failure to do this could result in a temporary delay in battery charging, or require unplugging the device and plugging it back in.

# SYSTEM SETUP

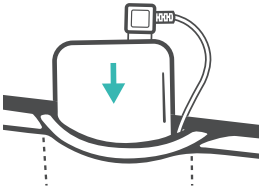
## STEP 1:

With the battery removed from the garment pocket and unplugged from the system, charge the external battery using the provided AC charger, which may take up to 3 hours.



## STEP 2:

Insert the fully charged battery into the Activ8 System, logo facing outward. Connect the battery to the system using the garment USB cable.

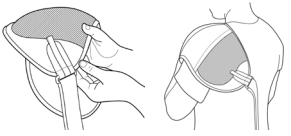


# GARMENT APPLICATION

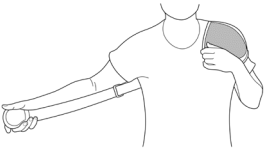
## STEP 3:

Find your system configuration below and follow the instructions. Adjust to fit comfortably but do not overtighten.

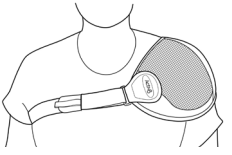
## SHOULDER



1. Determine which shoulder needs to be treated. Using the hook and loop, attach the end of the large strap without a logo to the garment so the strap runs behind the shoulder to be treated.

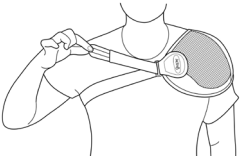


2. Place system on shoulder, let the strap hang down the back. Then reach around with your opposite hand and grab the strap from behind your back, pulling it up and across your chest.



3. Affix the logoed hook portion of the strap to the loop portion of the system on the front of your chest.

   *(Fit Tip: for a tighter fit across the front of the shoulder, instead attach to the loop portion on top of the shoulder.)*



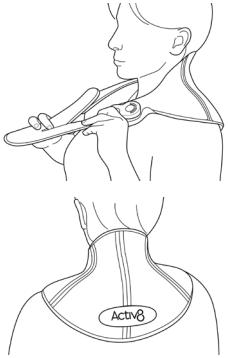
4. Adjust the strap using the adjustable strap glider until it is comfortable.

   *(Fit Tip: for larger adjustments, the strap and system may need to be removed from the body before adjusting).*

# GARMENT APPLICATION (CONT.)

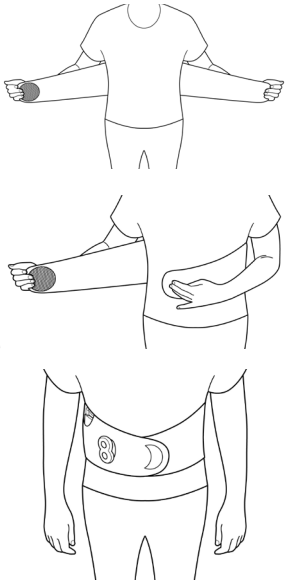
## NECK

1. Slide the system over the neck with the therapy logos on the inside of the device on the back of the neck.
2. Ensure that the top of the back of the system lays against the top of the neck.




## BACK

1. Position the back system around the waist, centering the two therapy logos on the inside of the device on either side of the spine – they should be positioned directly over the intended treatment area.
2. Fasten the system comfortably around the front of the body. Adjust to fit, but do not overtighten.



# GARMENT APPLICATION (CONT.)

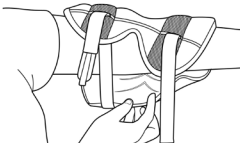
## ELBOW

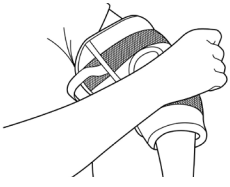
***Left Elbow***

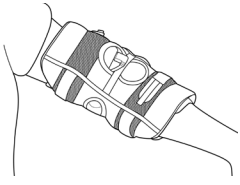
1. To treat the left elbow, put the battery in the logo-side pocket. Slide the system on so that the logo and battery are on the outside of your upper arm.
2. Position the system on the arm so that the therapy location markers are positioned over each side of the elbow.
3. Pull the elastic straps to tighten the system. Wrap the elastic around your arm until you can fasten the hook and loop.

***Right Elbow***

1. To treat the right elbow, put the battery in the pocket furthest from the logo. Slide the system on so the logo is on your forearm and the battery is on your upper arm.
2. Position the system on the arm so that the therapy location markers are positioned over each side of the elbow.
3. Pull the elastic straps to tighten the system. Wrap the elastic around your arm until you can fasten the hook and loop.





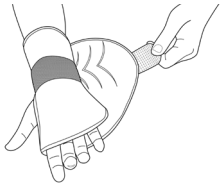


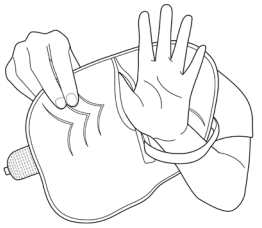
# GARMENT APPLICATION (CONT.)

## HAND/WRIST

***Wrist Fitting***

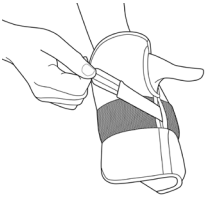
1. Place hand through the elastic strap on the inside of the system, and thumb in the hole.
2. Tighten the elastic adjustment strap until the system is snug, do not overtighten.
3. Close the system around the wrist using the hook and loop attachment.

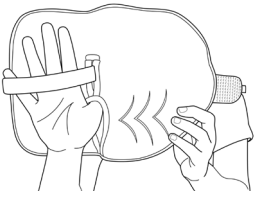


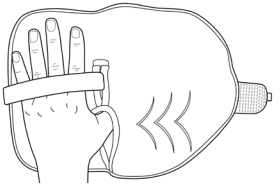


***Hand Fitting***

1. Place fingers through the elastic strap on the inside of the system, and thumb through the hole.
2. Tighten the elastic adjustment strap until the system is snug, do not overtighten.
3. Close the system around the hand using the hook and loop attachment.



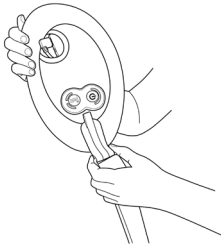


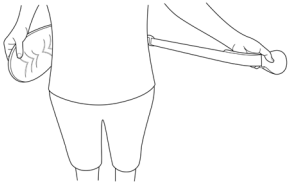


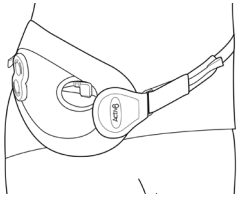
# GARMENT APPLICATION (CONT.)

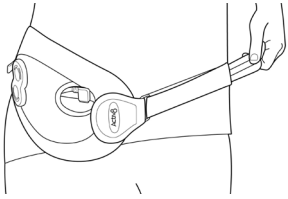
## UNIVERSAL/HIP

1. Determine the size of strap needed based on the body part to be treated. *(Limbs/Extremities: small strap, Waist/Hip/Torso – large strap)*
2. Attach the logo-free hook portion of the strap to the loop perimeter of the universal system.
3. Position the therapy location markers on the inner portion of the system over the intended treatment area.
4. Wrap the strap around your body and secure it to ring of loop on the system wherever needed to hold the device in place securely.
5. Use the adjustable strap glider to adjust fit until snug, do not overtighten.



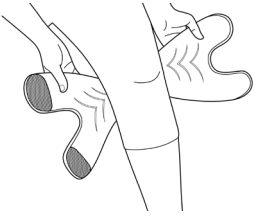






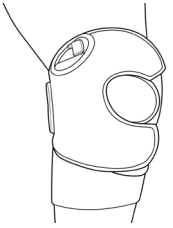
# GARMENT APPLICATION (CONT.)

## KNEE

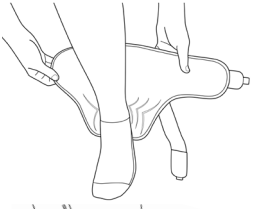


1. Position the smallest portion of the system behind the knee, and the therapy location markers centered on either side of the knee joint.
2. Attach the hook and loop portions of the system across the front of the knee – the opening for the battery pocket should be facing upwards (the logo text should be right side up).

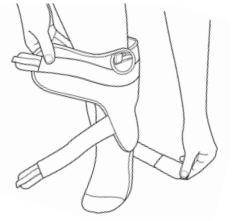
   Adjust to fit but do not overtighten.

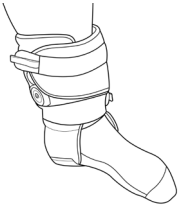


## ANKLE



1. Place the heel of the ankle that is to be treated into the elastic stirrup, with the open portion of the system facing the front of the foot.
2. Tighten or loosen the elastic stirrup using the hook and loop adjustment until the therapy location markers on the inside of the system are centered over the ankle bone or intended treatment area.
3. Attach both of the other straps across the front of the ankle onto the loop portion of the system to secure it.

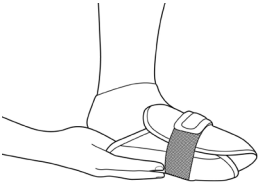


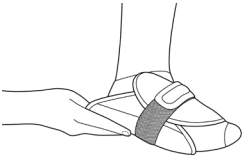


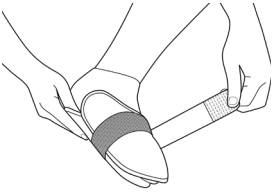
# GARMENT APPLICATION (CONT.)

## FOOT

1. With the smaller flap on the top of the foot, slide the system onto the front of the foot until the therapy location markers are centered over the intended treatment area.
2. Adjust the elastic strap until snug, do not overtighten







# CONDUCTING A THERAPY SESSION

## STEP 4:

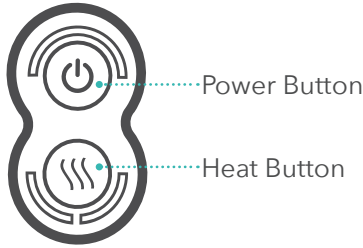
Start the PEMF and heat therapy by pressing the power button on the Activ8 Controller.

If no other buttons are pressed, the following will happen:

- The PEMF therapy will operate for 30 minutes before automatically turning off.
- While the PEMF therapy is running, heat therapy will run simultaneously for 20 minutes on high, then 10 minutes on low, then turn off.

## CONTROLLER FEATURES:

- Power Button: Turns system on and off. "On" activates therapy. "Off" stops therapy.
- Heat Button: Cycles between high, low, and off heat modes to adjust heat during therapy.




## NOTE:

If the power button is accidentally pressed, turning off the device during a therapy session, pressing the power button again will initiate a new 30-minute therapy session.

# LED INDICATIONS

## EXTERNAL BATTERY

| | |
|---|---|
| Pressing the button on the side of the pack indicates the battery charge level. |  |
| When charging, the battery charge level will be indicated by solid and flashing LEDs. |  |
| When plugged into the Activ8 System, the charge level of the battery will be indicated by solid LEDs. |  |

## ACTIV8 CONTROLLER

| Status | Light | Indication |
|---|---|---|
| Therapy is Running | Solid green LED above the power button. |  |
| High Heat | Both orange LEDs below the heat button are on, with the power LED also on. |  |
| Low Heat | One orange LED below the heat button is on. |  |
| No Heat | No orange LEDs below the heat button are on. |  |
| Device Failure Contact Customer Service | LEDs flash for ten seconds and then turn off. | |

# WARRANTY & SUPPORT

## WARRANTY

OrthoCor Medical offers a six-month limited warranty on any defects in materials and workmanship.

## RETURN POLICY

OrthoCor Medical does not accept returns or offer refunds, except for unopened product within 60 days of shipment.

## SUPPORT

If you have questions not covered in this user guide, please email, call, write, or visit our website.

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Blaine, MN 55449

888-583-6268
customersupport@orthocormedical.com
**www.orthocormedical.com**

**Customer Support Hours:**
8:00 AM to 4:30 PM Central Time

# SYMBOL DEFINITION TABLE

| | |
|---|---|
|   | Indicates that federal (US) law restricts this device to sale by or on the order of a physician. |
|   | Indicates the item is a medical device. |
|  | Indicates the need for the user to consult the instructions for use. |
|  | Indicates a medical device that is intended for one single use only. |
|  | To identify a type BF applied part complying with IEC 60601-1. |
|  | Keep dry. |
|   | Indicates a medical device that has not been subjected to a sterilization process. |
|  | Indicates that attention must be given before using the product. |

# SYMBOL DEFINITION TABLE (CONT.)

| | |
|---|---|
|   | Indicates the temperature limits to which the medical device can be safely exposed. |
|  | Indicates the medical device manufacturer. |
|   | Indicates the medical device is for single-patient, multiple use. |
|   | Indicates a carrier that contains Unique Device Identifier information. |
|   | Indicates the manufacturer's batch code so that the batch or lot can be identified. |
|   | Indicates the manufacturer's catalogue number so that the medical device can be identified. |
|  | Indicates when the medical device was manufactured. |
|  | Indicates the date after which the medical device is not to be used. |
|   | An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment. |

# CLINICAL EFFICACY

## CLINICAL EFFICACY

A clinical trial conducted by MediCept showed for patients with soft tissue and joint pain, the Active System as an adjunctive therapy was significantly more effective at reducing pain than the Standard of Care (SOC) alone. Specifically, the study primarily enrolled participants in the foot, knee and shoulder groups. The clinical data was clinically meaningful in the foot, knee and shoulder. The study examined the change from baseline in pain assessment scores at the end of 2 weeks of study treatment using the Mankowski scale. The SOC group experienced a 10% reduction in pain while the Active System group had 36% reduction in pain.

## NON-THERMAL SHORTWAVE DIATHERMY TECHNICAL SPECIFICATIONS

Average Output Power: 5.5 mW
Peak Output Power: 1.35 W
Frequency: 27.12 MHz
Burst Duration: 2.0 ms
Burst Frequency: 2.0 Hz

## HEATING TECHNICAL SPECIFICATIONS

Number of Heat Generators: 2
Temperature Range of Heat Generators Between System and Patient: 35°C-45°C
Area Under Each Heat Generator Affected: 4.5 $in^2$
Heating Volume for Each Heat Generator: 1.5 $in^3$

## ESSENTIAL PERFORMANCE

- The device outputs therapeutic pulses (see NON-THERMAL SHORTWAVE DIATHERMY TECHNICAL SPECIFICATIONS).
- The device outputs heat corresponding to the heating level the device is set at.

Manufactured by
OrthoCor Medical - Blaine, MN 55449

Made in the USA
U.S. and foreign patents issued.
DC Rating: 5.0V ⎓ 2.7A

This system is intended for a home use environment.


www.orthocormedical.com