

# E2<sup>CPM</sup>

## Setup and Operating Manual





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# E2 CPM Device Setup and Operating Manual

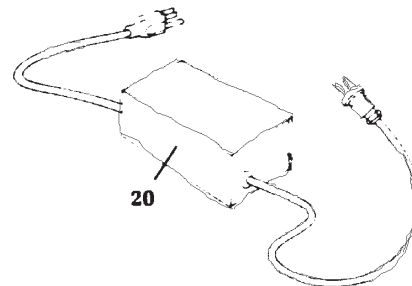
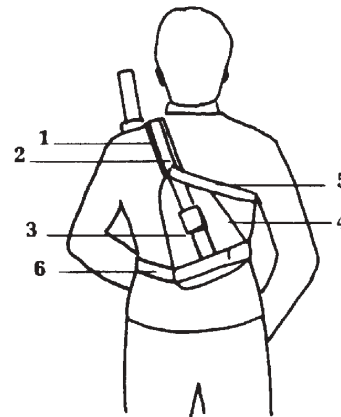
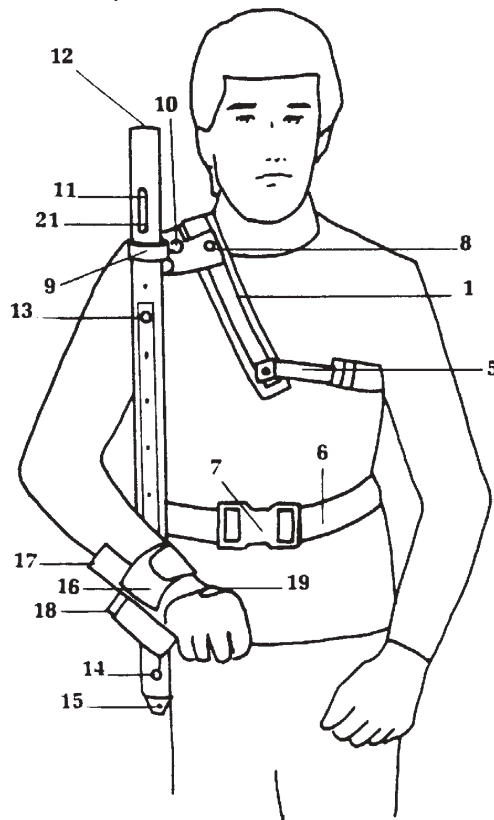
## Components

### Front View

1. Shoulder Frame
2. Shoulder Frame Pad
3. Back Plate
4. Back Plate Pad
5. Chest Strap
6. Waist Belt
7. Buckles
8. Left Right Adaptor Plate
9. Machine Clamp
10. Clamp Lock Knob
11. ON/OFF Switch
12. Recharger Plug (see page 4)
13. Flexion Stop
14. Extension Stop
15. Overhead Frame Loop
16. Cock Up Splint
17. Cock Up Splint Pad
18. Supination Pronation Adjustment Knob
19. Velcro Straps
20. Battery Recharger Power Unit
21. Battery Charge LED (see page 4)

### Back View

1. Shoulder Frame
2. Shoulder Frame Pad
3. Back Plate
4. Back Plate Pad
5. Chest Strap
6. Waist Belt



## Operating Sequence

### Indications

Immediate post-operative management after the following where indicated.

Arthrotomy

Stable fractures

Synovectomy

Reconstructive surgery on bone, cartilage, tendons and ligaments

Prolonged joint immobilization; manipulation; and joint replacement

### Application

Continuous Passive Motion (CPM) is best applied immediately post-operative and continued, uninterrupted, for up to six weeks as prescribed by the physician.

### Clinical Advantages

Maintenance of a good range of motion.

Prevention of intra-articular adhesions.

Prevention of extra-articular contractures.

Reduction of post-operative pain.

Supination and pronation is achieved simultaneously during limb flexion.

**Note:**

Allow device to reach room temperature for a minimum of one hour prior to use.

# E2 CPM Device Setup and Operating Manual

## Control Function & Power Supply

### Power Supply and Battery Charging

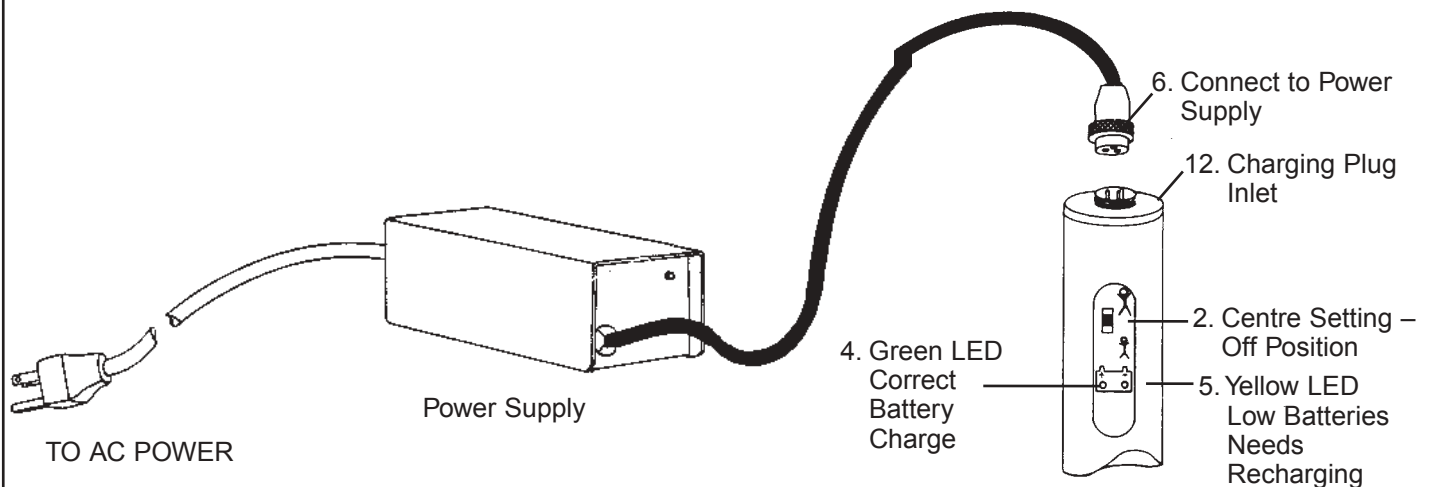
1. Connect Power Supply/Charger to a grounded A/C outlet.
2. Connect Power Supply to charging plug 12.

### Charging Instructions

1. The Elbow CPM Device when fully charged will run continuously for 8-10 hours with the patient fully ambulatory. A Yellow Light will appear on the control plate when the battery pack needs to be charged.
2. Recharging will take 6-8 hours and can be carried out overnight while the patient is sleeping without interruption of the Treatment Cycle. A Green Light on the control panel indicates correct charging is in place.

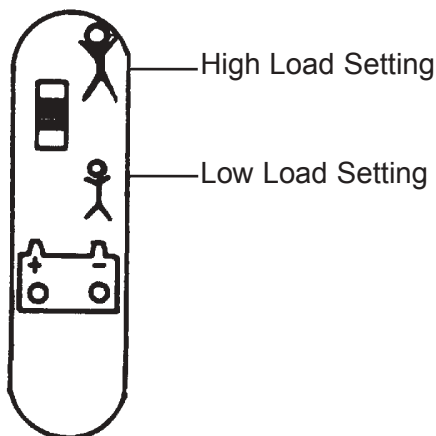
### NOTE:

When the Power Unit/Charger is attached all power to operate the device is delivered from the power unit and the device will operate with or without the Battery Pack.



Note: The power supply is electrically grounded and should be connected to a properly grounded incoming electrical supply.

## Range of Motion



### Load Setting

- High Load Setting  
– Maximum force 8 kg (18 lb.)
- Low Load Setting  
– Minimum Force 5 kg (11 lb.)

### Load Explanation

The Load Control mechanism is a fail-safe system which causes the device to reverse direction whenever patient resistance to motion or obstruction occurs. "Load" refers to the amount of resistance/pressure against the direction of motion that must be applied to make the device reverse.

### Rate of Motion

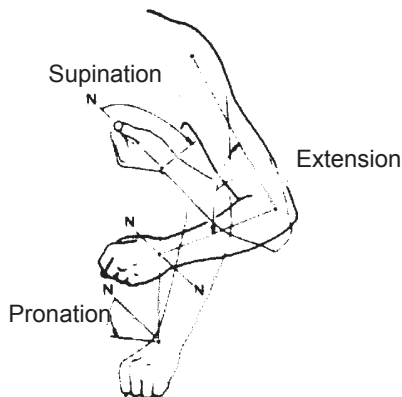
3 minutes per cycle

#### Maximum Range of Motion (Extension)

Patient Height	Elbow	Wrist
120 cm (4')	60° - 180°	(90°) <sup>1</sup> - 85°
150 cm (5')	70° - 175°	(90°) - 80°
180 cm (6')	70° - 160°	(90°) - 80°
	(80° - 170°) <sup>2</sup>	

<sup>1</sup> Supination

<sup>2</sup> By lowering machine on clamp

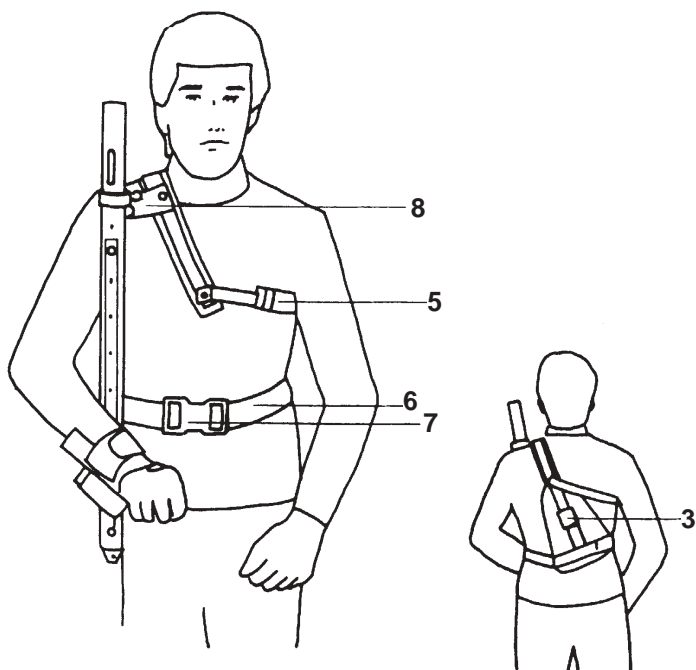


### Harness

1. Install a new set of softgoods with each patient.
2. Fit device to involved side, bending shoulder frame to contour of body.
3. Position Adaptor Plate (8) away from patient's face (see illustration on left)
4. Adjust Back Plate (3) so that Waist Belt (6) fits comfortably around waist.
5. Adjust Chest Strap (5) and Waist Belt (6) as required and secure with buckles (7).

**NOTE:** An absorbent garment should be worn under the device for greater patient comfort and an absorbent padding placed around the patient's hand to prevent the velcro straps from causing irritation.

### Softgoods Replacement Kit #A2E-101SY



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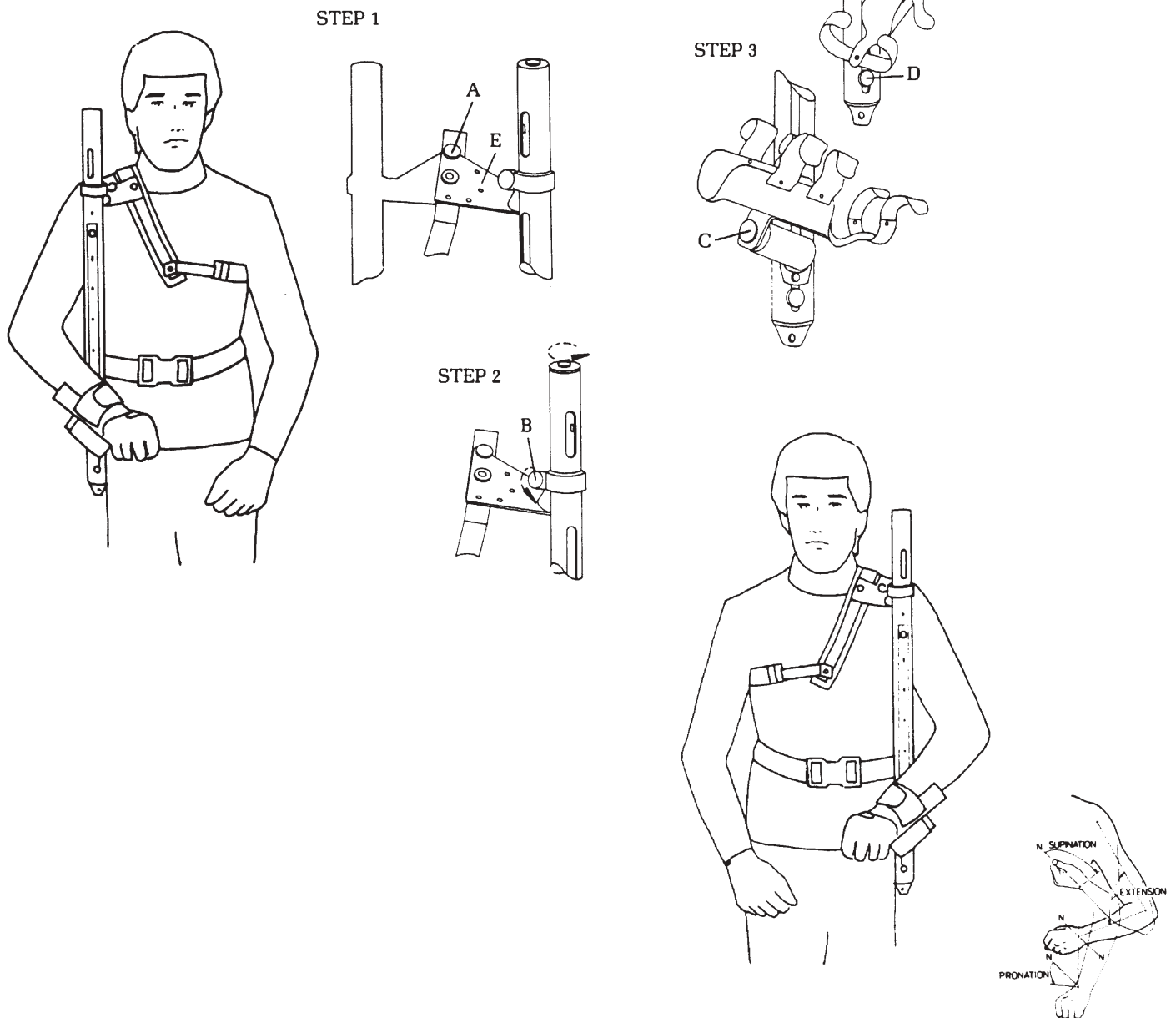
## Right to Left Hand Adjustment

### To Change from Right to Left Hand Position

Place the device on left side of patient.

1. Remove Knob (A) and Swivel Offset Plate (E) through 180°. Replace Knob (A) and tighten securely.
2. Loosen Clamp Knob (B) and rotate device to position slot away from patient's face. Tighten Knob (B).
3. Remove Extension Screw (D), turn on device to bring cock up splint to bottom of stroke.
4. Loosen Supination/Pronation Adjustment Knob (C) and place hand in cock up splint with narrow velcro strap between thumb and forefinger. Replace Extension Screw (D) and tighten.
5. Rotate hand so that fingers and palm of the hand point downwards (fully pronated). Tighten Adjustment Knob (C).

REVERSE PROCEDURE FOR LEFT TO RIGHT HAND POSITION.



## Maintenance

- The device is equipped with a rechargeable battery. Connecting the device's power supply to the power input recharges the battery.
- The battery requires 6-8 hours to fully recharge. Battery charging status is indicated by the green light emitting diode (LED) just above the power switch. A yellow LED indicates that the battery needs to be recharged.
- The device can be operated independently by the batteries for approximately 8-10 hours depending on the battery charge, load setting, and the mass of the patient.

### Maintenance by Patients

- Patients are responsible for using the device according to the Setup and Operating Manual. Do not wash softgoods.

### Maintenance Between Patients

- Softgoods for the device are for single patient use only and cannot be washed for reuse.
- Check the entire device for any visible evidence of damage, such as bent components, cracked or broken covers, frayed or damaged wires, etc. If any signs of damage are found, the device must be repaired before use.
- Ensure that all knobs and/or levers are usable and in place.
- Ensure that all moving components move freely as required.
- Check all displays and electronic controls for proper operation.
- Check all mechanical pivot and linkage points for smooth operation and secure mechanical connection. Make sure all screws, nuts, bolts, rivets, pivot pins, and other fasteners are secure.
- Gently wipe clean all exposed surfaces with a soft cloth dampened with a mild soap solution or alcohol. Do not use abrasive cleansers. To disinfect, wipe all exposed surfaces with a 10% solution of bleach and water, or other suitable disinfectants.
- Ensure that all labels are present.
- Replace the patient softgoods kit.
- Verify that the device operates to its set limits over several complete cycles.

### Maintenance Every Six Months

- Repeat steps under "Maintenance Between Patients".
- Every 2000 hours or 6 months, run machine unloaded and listen for unusual sounds. Squeaking usually results from inadequate lubrication.
- Perform a complete check of electronic and mechanical safety systems including Reverse-On-Load function, motion stops and stop screws.

### Maintenance Every Twelve Months

- Verify electrical ground continuity where applicable from the device frame to ground pin of the power supply, if so equipped, using a Safety Analyzer or appropriate device.
- Repeat "Maintenance Between Patients" procedures.
- Repeat "Maintenance Every Six Months" procedures.

### Maintenance Every Eighteen Months

- A full inspection of the device by a properly trained Service technician is recommended every 18 months.
- Repeat steps "Maintenance Every Twelve Months".
- Fully inspect all internal and external mechanical and drive components, and repair or replace as necessary.
- Fully inspect all internal and external electrical components (including wire connectors and solder joints), and repair or replace as necessary.
- Complete a final check of the device in accordance with OrthoMotion Inc. Final Inspection criteria. (These are available through your OrthoRehab representative, OrthoMotion Customer Service, or your local distributor.)

### Sterilization

- This device does not require sterilization for use.
- Exposing the device to sterilization conditions will damage the device and may result in a potential hazard.

## Cautions and Warnings

- Use the device only in accordance with the Physician prescription and Setup and Operating Manual. Failure to do so may result in damage to the device and/or personal injury.
- Softgoods are for single patient use only.
- The device should not be used in the presence of flammable anesthetics.
- Use only manufacturer's supplied replacement components.
- Do not use the device if there are mental or physical conditions that preclude patient compliance.
- To prevent potential physical injury, such as strangulation and choking hazards, keep the device away from children or individuals with mental or physical conditions that preclude the safe use of the device.
- Position the device in a comfortable and secure position. Ensure that the device is stable through its full range of motion.
- Keep hair, loose clothing, fingers and all parts of body away from moving components of the device.
- Do not expose the device to water or extreme temperatures. See recommended Operating and Storage Conditions.
- Do not use the device near exposed flames, while smoking or near excessive heat.
- Disconnect the electrical supply before servicing or cleaning. Failure to do so could result in electrical shock or personal injury.
- Turn the power off before unplugging.
- Unplug the power supply by grasping the plug, not the cord.
- Unless using the device or recharging the battery, turn the device off and unplug from the power supply.
- Do not use the device, power supply or controller if it appears damaged or if there are exposed wires.
- Store the device in its carrying case (if applicable) when not in use.
- Do not pour cleaning solution directly onto the device. This may allow fluids to enter the device and cause electrical problems, or wash lubricants away from running components, reducing the life span of the device.
- Select a location for the device and device components (controller, straps, cables and power supply) to prevent a tripping hazard during use or storage.

## Contraindications







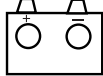









Do not use the device if any of the following are present:

- Untreated or uncontrolled infection
- Unstable fractures
- Spastic paralysis
- Hemorrhage

**Note:** Upon using the device, if signs of infection such as hyperthermia, fever, redness, irritation, warmth, swelling, bleeding, and/or increased persistent pain are present, discontinue operation of the device and contact the patient's physician. Do not proceed with treatment until the physician has approved continued use of the device.

# E2 CPM Device Setup and Operating Manual

## Symbols and Specifications

	<b>Power On, High Load Setting</b>		<b>Caution:</b> FDA Policy. Federal U.S. Law restricts this device to sale by or on the order of a licensed healthcare practitioner.				
	<b>Power Off</b>		<b>Type B Applied Part</b>				
	<b>Power On, Low Load Setting</b>		<b>Alternating Current</b>				
	<b>Green LED: Battery Charging</b> <b>Yellow LED: Low Battery Needs Recharging</b>		<b>Direct Current</b>				
	<b>Attention,</b> Consult accompanying documents		<b>Protective Earth (ground)</b>				
	<b>Danger Electric Shock:</b> Service by qualified individual only		<b>Use specified power supply only</b>				
	<b>Danger Explosive Risk:</b> If used with flammable anaesthetic		<b>This Way Up</b>		<b>Fragile</b>		<b>Keep Dry</b>

Weight of Device:	approx. 2.5 kg (5 lbs.) including softgoods
Dimensions of Device:	91.4cm x 3.8cm (36" x 1.5")
Ranges of Motion:	Fully adjustable flexion/extension and corresponding pronation/supination
Rate of Motion:	3 minutes per cycle (full range)
Reversing Force Settings:	
Low	5 kg (11 lbs.)
High	8 kg (18 lbs.)
Mode of Operation:	Continuous
Power Source:	External Power Supply Input 100-240 VAC 50-60 Hz Output 12 V 1.25A, grounded 5 x 1.2V ni-cad battery pack
Battery Life:	8 to 10 hours. Recharging time 6-8 hours.
Electric Shock Classification:	Class 1
Degree of Electric Shock Protection:	Type B
Environmental conditions:	-10° to 35°C (14°F to 95°F) temperature, 90% max. humidity 750 to 1250 hPa pressure The device must remain in the operational environment a minimum of one hour prior to use.

Note: Equipment not suitable for use in the presence of flammable anaesthetic mixture with air or Nitrous Oxide.

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## Troubleshooting

<b>PROBLEM</b>	<b>PROBABLE CAUSE</b>	<b>SOLUTION</b>
Device oscillates back and forth at end of travel.	<ol style="list-style-type: none"><li>1. Switch is set at low load setting.</li><li>2. Obstruction is blocking movement of device.</li><li>3. Patient is resisting motion.</li><li>4. Electromechanical fault.</li></ol>	<ol style="list-style-type: none"><li>1. Switch device to high load setting.</li><li>2. Remove obstruction.</li><li>3. Check to ensure that patient is properly harnessed and comfortable. Proper motion will resume when patient tires.</li><li>4. Refer to Service Technician.</li></ol>
Device does not run.	<ol style="list-style-type: none"><li>1. Batteries discharged. Yellow light on CPM is very dim or off.</li><li>2. Power supply turned off/ batteries need to be recharged.</li><li>3. Fuse blown in power supply.</li><li>4. Electromechanical fault.</li><li>5. Broken cable.</li></ol>	<ol style="list-style-type: none"><li>1. Plug in power supply.</li><li>2. Turn power supply on and verify that Yellow LED on power supply is illuminated.</li><li>3. Refer to Service Technician.</li><li>4. Refer to Service Technician.</li><li>5. Refer to Service Technician.</li></ol>
Hand cuff does not supinate and pronate.	<ol style="list-style-type: none"><li>1. Hand cuff adjustment knob is loose.</li><li>2. Hand cuff adjustment is incorrect.</li></ol>	<ol style="list-style-type: none"><li>1. Tighten knob.</li><li>2. Readjust as per instructions on page 6.</li></ol>
Device is uncomfortable.	<ol style="list-style-type: none"><li>1. No absorbent liner around hand.</li><li>2. Device or pads are in direct contact with skin.</li></ol>	<ol style="list-style-type: none"><li>1. Put absorbent dressing or thin towel between hand and hand cuff.</li><li>2. Padding on CPM is not absorbent for sanitary reasons. Patient must wear clothing or gown to prevent contact perspiration.</li></ol>
Device is uncomfortable when patient is in bed.	<ol style="list-style-type: none"><li>1. Device not suspended.</li><li>2. Elbow is unsupported.</li></ol>	<ol style="list-style-type: none"><li>1. Suspend device from distal end loop to overhead frame with rope or string.</li><li>2. Place pillow or other support beneath elbow allowing upper arm and forearm freedom of movement.</li></ol>

## Warranty

### New Product Limited Warranty

To obtain warranty service, the product must be returned freight prepaid to the Company or the selling distributor with a clear indication as to the defect. Upon receipt of a product returned under warranty, the Company will inspect the product and will notify the buyer of the extent of repair or replacement which the Company will perform under warranty. If the product is received incomplete, missing parts will automatically be replaced at the buyer's expense. The Company also reserves the right, at its sole election and own cost, to upgrade or replace parts or sub-assemblies to the latest production standards. The Company will normally perform the repair and return the product, or provide a replacement, within (30) days from the day of receipt, freight collect.

THE COMPANY IS NOT RESPONSIBLE FOR LOSS OF USE, LOST PROFITS, OR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE BREACH OF THIS WARRANTY, THE FAILURE OF ANY PRODUCT OR THE NEGLIGENCE BY THE COMPANY IN THE PERFORMANCE OF ANY SERVICE, INCLUDING DAMAGES FOR PERSONAL INJURY. THE WARRANTY CONTAINED HEREIN IS IN LIEU OF ALL WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. NO STATEMENT OF ANY REPRESENTATIVE SHALL EXTEND THE COMPANY'S LIABILITY AS HEREIN ESTABLISHED OR LIMITED. THIS WARRANTY IS PROVIDED TO THE ORIGINAL PURCHASER OF THE PRODUCT AND IS NON-TRANSFERRABLE.

### Returning the Device for Service

Should the device require warranty repair, buyer must contact either the Customer Service department (outside the USA contact International Customer Service), or the authorized distributor from which the device was purchased for return instructions.

If any warranted product is found by the Company to have a defect covered by this warranty, the Company shall, at its option, either repair the defective item or install a replacement.

If the device needs to be returned for any repair, pack the components in the original shipping container and contact:

#### In the USA:

OrthoRehab, Inc.

Attn: Technical Service

1-800-225-1814

Website: [www.orthorehab.com](http://www.orthorehab.com)

#### International Customer Service:

OrthoRehab Inc.

Attn: Customer Service

901 Dillingham Road

Pickering, Ontario

L1W 2Y5 Canada

Tel: 1-905-420-3303 Fax: 1-905-420-3970

E-mail: [stephen.barnes@ottobock.com](mailto:stephen.barnes@ottobock.com)

#### Note: Please enclose the following information when returning the device:

- Return Authorization Number
- Ship-to Address
- Purchase order for non-warranty repairs
- Name and phone number of a person to contact
- Brief description of the problem



**CUSTOMER CONTACTS:**

**In the USA:**

**OrthoRehab, Inc.**

Website: [www.orthorehab.com](http://www.orthorehab.com)

1-800-225-1814

**International:**

**OrthoRehab Inc.**

901 Dillingham Road

Pickering, Ontario L1W 2Y5 Canada

1-905-420-3303 Fax 1-905-420-3970

E-mail: [stephen.barnes@ottobock.com](mailto:stephen.barnes@ottobock.com)



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In the event that European (EU) customers are unable to reach our International Office, please contact our Authorized Representative:  
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