

# T1 TOE CPM

# DIRECTIONS FOR USE

## Indications:

Arthroplasties; Bunionectomies; Tendon repair and reconstruction; Osteotomies; Joint replacements; and Neuroma excisions

## Contraindications:

Septic tenosynovitis, until infection is controlled. Diffuse cellulitis of infection of digit, until infection is controlled. Unstable fractures.

*Note:* If signs of infection such as hyperthermia, irritation, swelling, bleeding, or increased or persistent pain are observed, CPM should be avoided or discontinued until infection is controlled.






**NOTE:** Ensure that Preparation of the Device (Steps 1-4) are complete prior to connecting the device to the patient's toe.

## Preparation of the Device

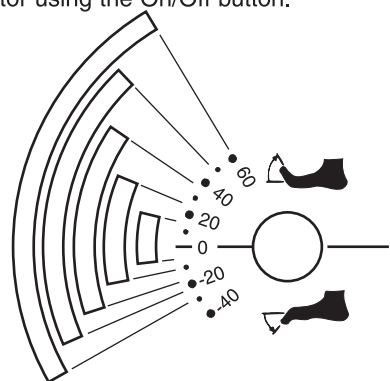
### Step 1: Range of Motion Selection

There are five Range of Motion settings available on the Toe CPM device. The table below shows the recommended settings.

- Loosen the Locking Knob. Using the Amplitude Dial, select the desired Range of Motion from the table below. Re-tighten the Locking Knob.

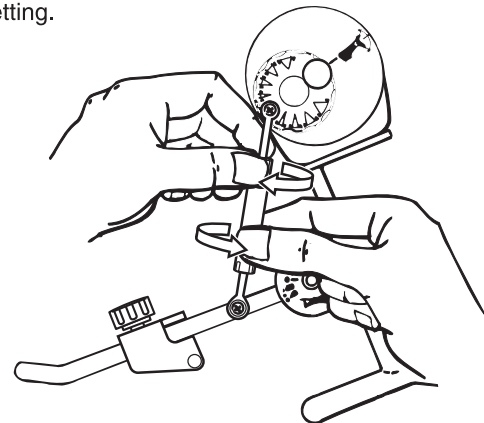
Range of Motion Setting	Dorsiflexion	Plantar Flexion
	+15°	-10°
	+25°	-15°
	+35°	-20°
	+45°	-25°
	+60°	-30°

- Using the ROM Endpoint Adjuster, set the maximum amount of dorsiflexion listed in the table. The device can be positioned at maximum dorsiflexion by running the actuator using the On/Off button.



\*under the Locking Knob

- Make sure to tighten the Adjuster Nut to maintain the setting.

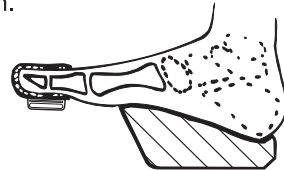


- With the device running, using the goniometer, verify that the dorsiflexion and plantar flexion settings are correct.

### Step 2: Softgoods Size Selection

Select the Metatarsal Head Isolator and Disposable Orthopaedic Shoe for the patient. Each is available in large and small sizes.

- Metatarsal Head Isolator - select the appropriate size to immobilize the great toe proximal/terminal phalangeal joint while allowing the free articulation of the metatarsophalangeal joint.
- Disposable Orthopaedic Shoe - select the size which provides maximum support of the foot while allowing full plantar flexion of the metatarsophalangeal without obstruction.



Shoe Size	Foot Length	
	centimeters	inches
small	22 - 25	8-5/8 - 9-7/8
large	25 - 29	9-7/8 - 11-3/8

### Step 3: Assembly of Softgoods and Toe CPM Device

The Disposable Orthopaedic Shoe is attached to the Toe CPM device using four mounting knobs.

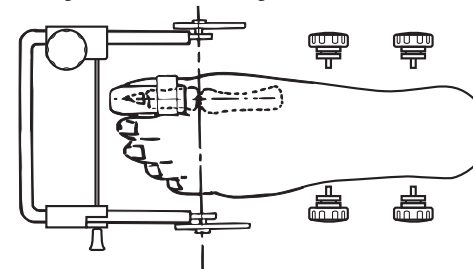
- Slide the shoe between the mounting plates of the Toe CPM.
- Align the Mounting Knobs with the shoe inserts which are visible on the sides of the shoe sole.
- Depress each knob and turn clockwise to tighten.

## Fitting the Device to the Patient

### Step 4: Alignment of the Metatarsal Head

Correct anatomical alignment of the Toe CPM with the patient is important for proper operation and comfort.

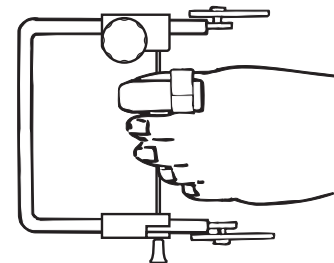
- Pull out the Drive Rod.
- Carefully fit the device to the patient's foot and secure with the two Velcro straps on the disposable shoe.
- Loosen the four Mounting Knobs sufficient to allow sliding of the device over the shoe.
- Align the Toe CPM Pivot Centre line with the MP joint.
- Re-tighten the Mounting Knobs.



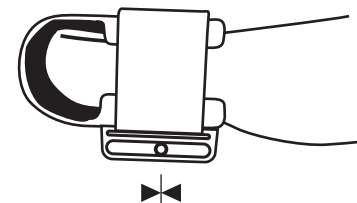
### Step 5: Attaching the Toe

Before attaching the toe, verify that the softgoods selection, MP joint alignment and Range of Motion are correct.

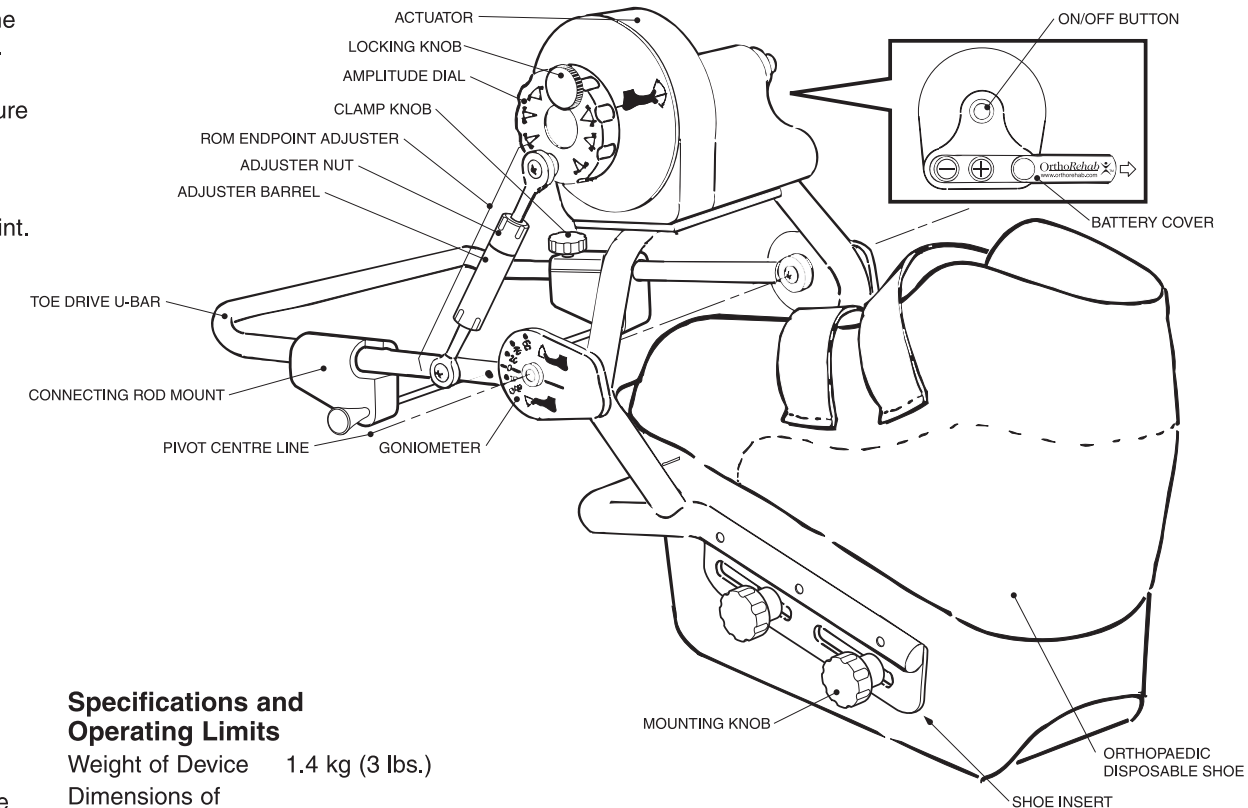
- Attach the Metatarsal Head Isolator to the toe with the Drive Clip beneath the toe.
- Loosen the Drive Rod Clamp Knob.
- Adjust the position of the Drive Rod Retainer such that the Drive Rod can be passed through the Drive Clip. Centre the Drive Rod as shown below.



- Adjust the position of the Drive Rod Clamp to receive the end of the Drive Rod and fully insert the Drive Rod.
- Re-tighten the Clamp Knob.
- Verify that the Drive Rod is centered in the Drive Rod Clamp.



- Turn the device on by pressing the On/Off button.
- Allow the patient to move through the established Range of Motion while monitoring patient comfort and tolerance. Adjust as required.



## Specifications and Operating Limits

Weight of Device 1.4 kg (3 lbs.)

Dimensions of Device 38cm x 20cm x 17cm (15" x 8" x 7")

Range of Motion:  
Dorsiflexion 0° to 60°  
Plantar Flexion 0° to 45°












Rate of Speed 1.5 minutes for a complete cycle of motion

Power requirement 2 AA (Alkaline) batteries, 3 volts  
Battery Life Up to 4 days for Alkaline batteries

## Ordering Information

T1-100 Toe CPM Kit  
T1-101A Disposable Orthopaedic Shoe - Small  
T1-101C Disposable Orthopaedic Shoe - Large  
T1-104A Metatarsal Head Isolator - Small  
T1-104C Metatarsal Head Isolator - Large

## SYMBOLS

	<b>Range of Motion: Dorsiflexion</b>		<b>Attention, Consult</b> ACCOMPANYING DOCUMENTS
	<b>Range of Motion: Plantarflexion</b>		<b>Danger Explosive Risk:</b> If used with flammable anaesthetic
	<b>Range of Motion: Dorsiflexion/Plantarflexion</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>Danger Electric Shock:</b> Service by qualified individual only		<b>Type B Applied Part</b>
			<b>This Way Up</b>
			<b>Fragile</b>
			<b>Keep Dry</b>

## WARNING

- Indoor use only. Do not immerse in liquid.
  - Do not reuse disposable components
  - Do not store device above 40°C (104°F).
  - Do not use rechargeable batteries.
  - Service should only be performed by a qualified technician.
- CAUTION: As with all portable objects, please store the device in a safe location when not in use to avoid a potential tripping hazard.**

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QUALITY FOR LIFE

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**CE 0120** ORTHOREHAB is registered to ISO13485 for Quality Assurance

**PLEASE REFER TO ENCLOSED INSERT FOR MAINTENANCE PROCEDURES, CAUTIONS AND WARNINGS, AND WARRANTY INFORMATION.**