

FLEX-MATE[®] *K500*



USER'S MANUAL

KLC Services, Inc.

4038 Weaver Court East
Hilliard, OH 43026
Ph: (614) 921-8866
Fx: (614) 921-8877
Toll Free: (866) 532-3534

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IMPORTANT SAFEGUARDS

When using electrical products, especially when children are present, basic safety precautions should always be followed, including the following:

READ ALL INSTRUCTIONS AND WARNINGS PRIOR TO OPERATION.

DANGER: TO REDUCE THE RISK OF ELECTROCUTION:

- Always unplug this product immediately after using.
- Do not use while bathing.
- Do not place or store product where it can fall or be pulled into a tub or sink.
- Do not place in or drop into water or other liquid.
- Do not reach for a product that has fallen into water. Unplug immediately.

WARNING: TO REDUCE THE RISK OF BURNS, ELECTROCUTION, FIRE, OR INJURY TO PERSONS:

- A product should never be left unattended when plugged in.
- Close supervision is necessary when this product is used by, on, or near children or invalids.
- Use this product only for its intended use as described in this manual. Do not use attachments not recommended by the manufacturer.
- Never operate this product if it has a damaged cord or plug. If it is not working properly, if it has been dropped or damaged, or dropped into water. Return this product to a service center for examination and repair.
- Keep the cord away from heated surfaces.
- Never use while sleeping or drowsy.
- Never drop or insert any object into any opening.
- Do not use outdoors or operate where aerosol (spray) products are being used or where oxygen is being administered.
- Connect this product to a properly grounded outlet only. See grounding instructions.

CAUTION: This equipment may cause electromagnetic or other interference between other devices. If this occurs, move the device away from the affected equipment.

CAUTION: Federal law restricts this device to sale by or on the order of a licensed health care practitioner.

CAUTION: Work in a range of motion as instructed by your healthcare practitioner.

CAUTION: If you experience increased pain, swelling, or any adverse reactions while using this product, immediately consult your health care practitioner.

WARNING: Set up and use of this equipment should be in a low traffic location and away from children and pets.

WARNING: Pinch points exist during assembly; use caution and assemble pursuant to the instructions.

WARNING: Make sure the hand control is accessible to the operator before starting this equipment. The stop button on the hand control is the only way of stopping the motion for disabled patients or children using the unit.

WARNING: Maximum rated load is 45 lbs.

CONTRAINDICATIONS:

USE OF CPM THERAPY IN GENERAL SHOULD BE AVOIDED OR DISCONTINUED, AT LEAST TEMPORARILY, IF SIGNS OF HYPERTHERMIA, IRRITATION, SWELLING, BLEEDING, OR INCREASED OR PERSISTENT PAIN ARE OBSERVED. ACUTE INFLAMMATORY CONDITIONS, SUCH AS ACUTE ARTHRITIS, OR DESTRUCTIVE BONE OR JOINT DISEASES, SHOULD NOT BE TREATED WITH CPM. PRODUCT IS LATEX FREE.

CAUTION: It is important to install and use this equipment in accordance with the instructions, to prevent harmful interference to other devices in the vicinity. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the other device(s).
- Increase the separation between the equipment.
- Connect this equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.



SAVE THESE INSTRUCTIONS



UL/C-UL Classification with respect to electric shock, fire, and mechanical hazards only in accordance with UL 60601-1/CAN/CSA C22.2 No. 601.1. Meets UL 1431 Standards for Personal Hygiene and Healthcare Appliances.

Product Description:

The purpose of the FLEX-MATE®K500 is to provide continuous passive motion to the knee or hip joint to increase circulation, range of motion, and to prevent scarring in the joint. The FLEX-MATE®K500 is an anatomically aligned CPM which mirrors the path of the knee as it goes through its range of motion from full—or hyper-extension through full flexion.

Safety Precautions:

- Use only manufacturer approved parts and maintenance procedures to service the unit. Refer to the FLEX-MATE®K500 Service Manual.
- Read and adhere to all warnings and instructions listed on the FLEX-MATE®K500 and this Users Manual.
- If you suspect the FLEX-MATE®K500 is not working properly, unplug the unit and refer to the Service Manual.
- If you detect a flaw of any type in the power cord, immediately unplug the transformer from wall.
- Use only the external power supply provided with the FLEX-MATE®K500 in order to meet the requirement of UL 60601-1.

Table 1. Symbols used on the FLEX-MATE® K500

Symbol	Description
	Direct Current
	Attention: Consult User's manual before use.
	Class I, Type B, Continuous Operation. Not suitable with flammable anesthetics.

Table 2. Physical and Electrical Specifications

Size Setup for Use:	
Length	39"
Width	13"
Height	22"
Weight:	
Without accessories	26 lbs.
With accessories	27 lbs.
Fully packaged	34 lbs.
Electrical Specifications:	
Input	120 VAC 60Hz 25 W
Environmental Requirements:	
Temperature:	
Operating	50°F to 95°F (10°C to 35°C)
Transport & Storage	-40°F to 158°F (-40°C to 70°C)
Humidity:	
Operating	30 – 75% R.H.
Transport & Storage	10 – 100% R.H., non-condensing
Atmospheric Pressure:	700 hPa to 1060 hPa
Standards Compliance	
Designed to conform to applicable requirements of: UL 60601-1, UL 1431 CSA C22.2 / No. 601.1	

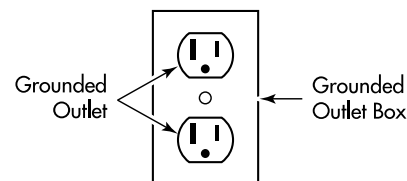
Grounding Instructions:

This product should be grounded. In the event of an electrical short circuit, grounding reduces the risk of electric shock by providing an escape wire for the electric current. This product is equipped with a cord having a grounding wire with a grounding plug. The plug must be plugged into an outlet that is properly installed and grounded.

DANGER—Improper use of the grounding plug can result in a risk of electric shock.

Check with a qualified electrician or serviceman if the grounding instructions are not completely understood, or if in doubt as to whether the product is properly grounded.

This product is factory equipped with a specific power supply to permit connection to a proper electric circuit. Make sure that the product is connected to an outlet having the same configuration as the plug. No adaptor should be used with this product. Do not modify the plug provided—if it will not fit the outlet, have the proper outlet installed by a qualified electrician.



Package Contents:

- 1 FLEX-MATE®K500
- 1 Users Manual
- 1 Service Manual
- 1 Package of soft goods
- 1 Tape measure

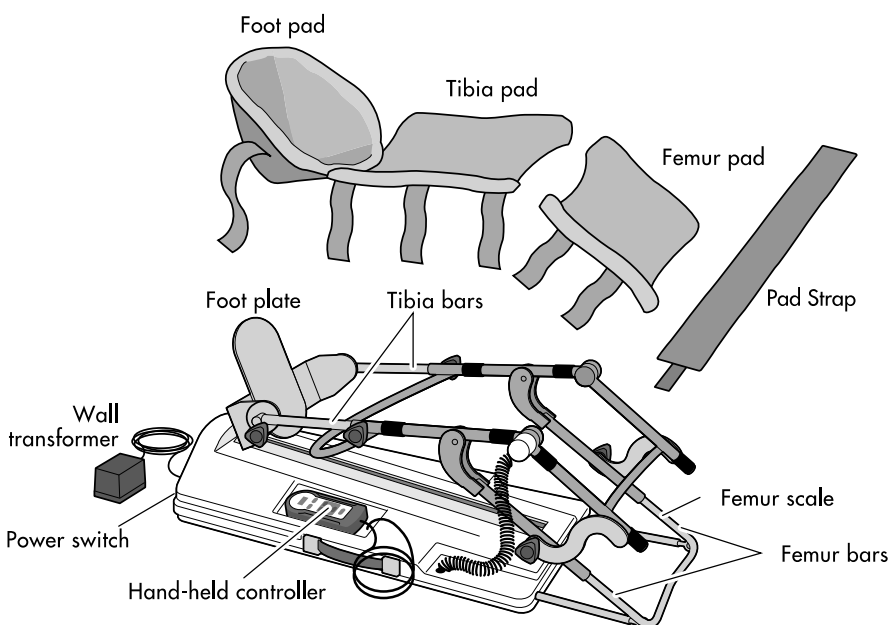


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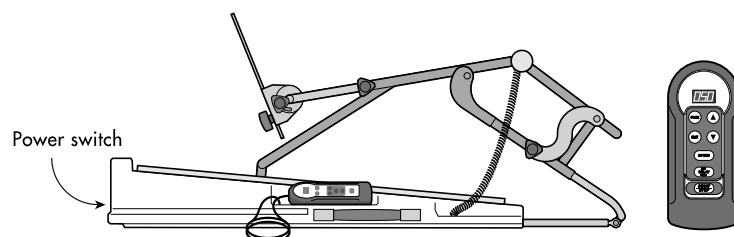
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Set Up Instructions

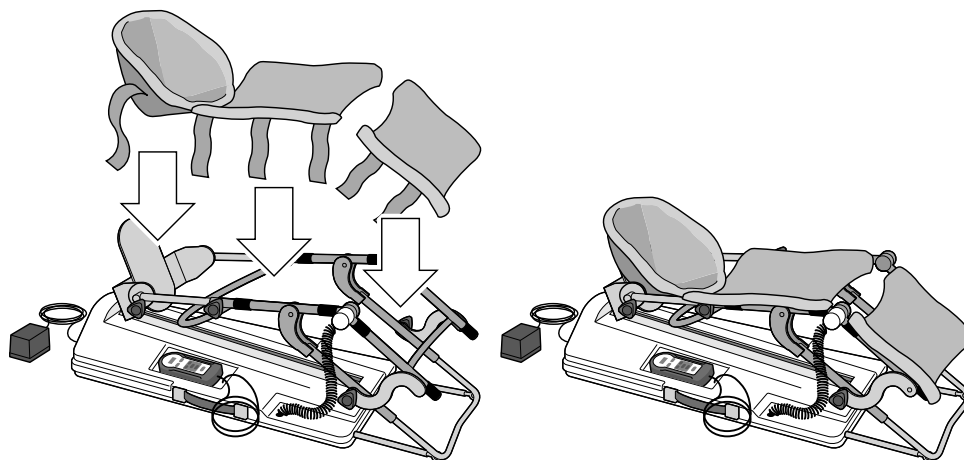
1. Open the shipping container and set aside the soft goods bag. Lift the FLEX-MATE® K500 from the box and place it where it is to be used.



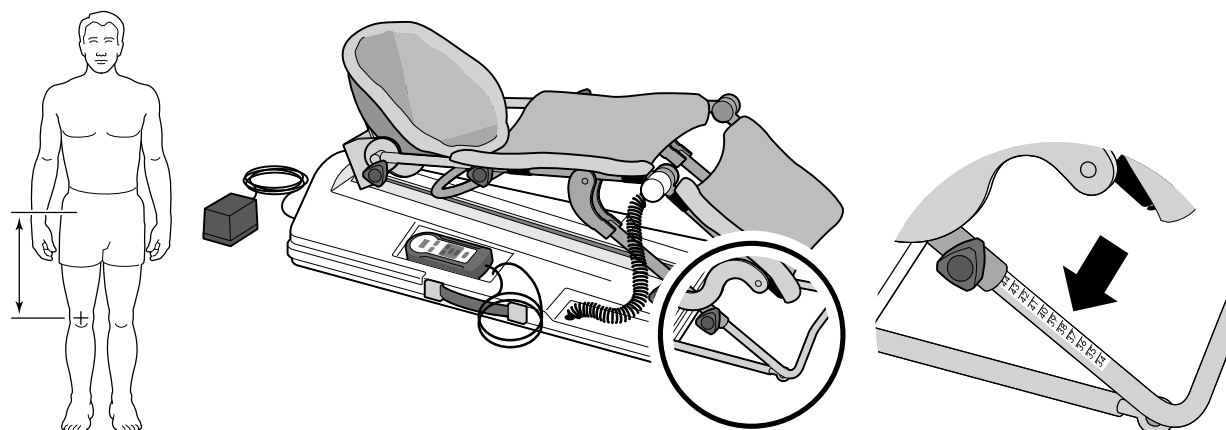
2. Plug the wall transformer into a 110/120V AC wall outlet close to the machine. Locate the power switch and press the "On" position. Using the hand-held controller, bring the machine to between 45° and 90°. See Hand-held Controller Operation instructions.



3. Secure the patient pads to the machine. The Foot Pad has a pocket that slips over the Foot Plate. The Tibia and Femur Pads have straps that secure to the black velcro pads.

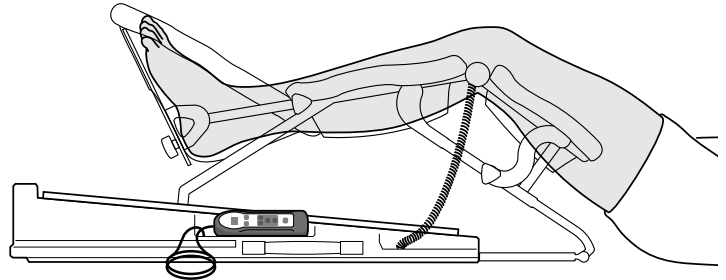


4. Measure the patient's involved leg in centimeters from the hip joint to the midline of the knee joint, set the femur scale to this measurement, and retighten knobs.

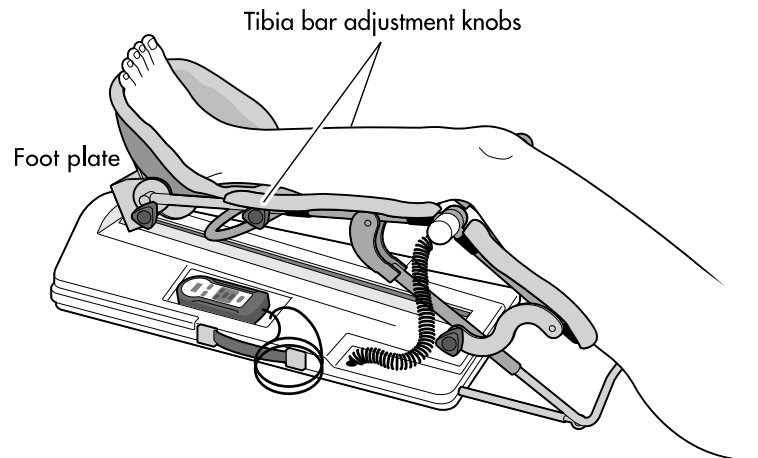


5. Loosen the adjustment knobs on the tibia bars and pull the foot plate out to a length greater than the patient's lower leg.
6. Use the hand-held controller to bring the machine to the desired start position.

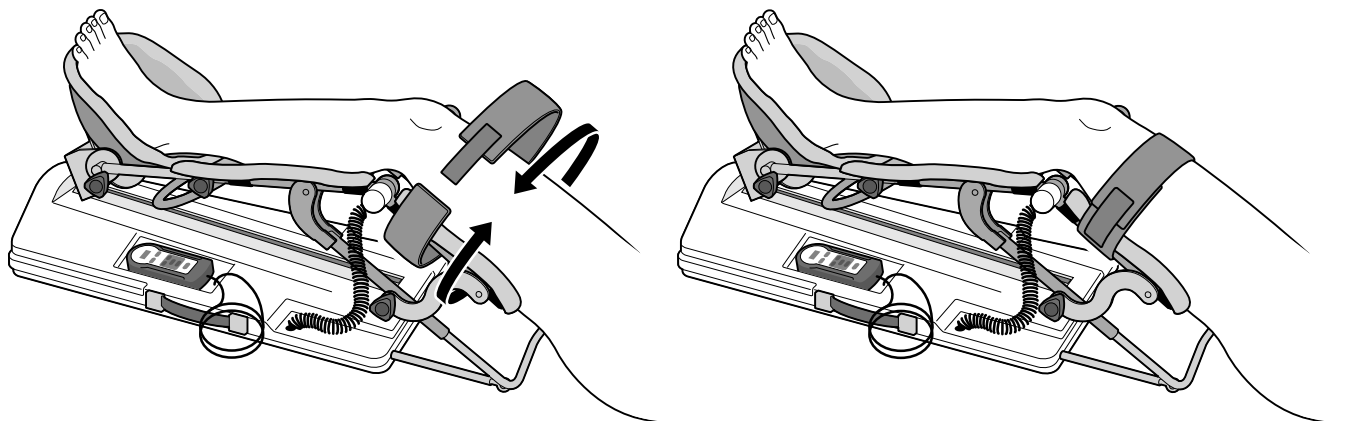
7. Place the patient's leg in the machine, making sure the patient's knee is aligned with the joint on the machine.



8. Adjust the foot plate so it just meets the patient's foot. Tighten the tibia bar knobs.

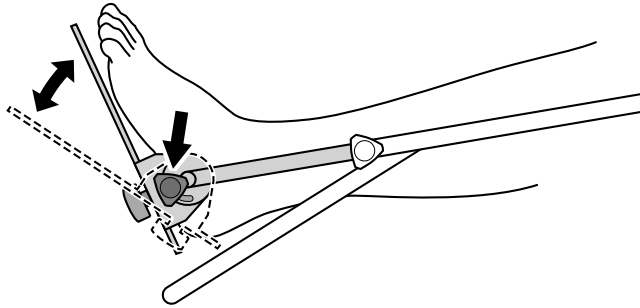


9. Wrap the Pad Strap around the thigh, femur bars and pad to secure the patient's leg to the FLEX-MATE K500.



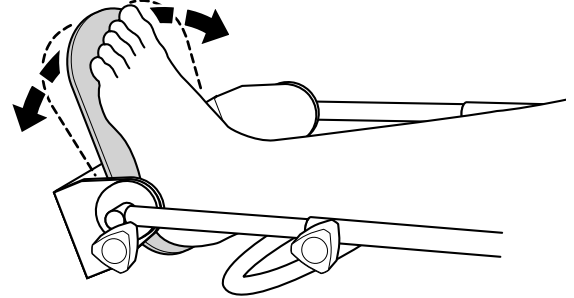
10. Before starting the machine, follow the Hand-held Controller Operation instructions to set flexion, extension, speed and pause duration. Run a complete cycle to ensure the knee is aligned correctly. The machine should now be fitted to begin the rehabilitation. If the knee joint does not mirror the movement of the machine joint, adjust the femur or tibia bars to keep the knee in the proper alignment.

Foot Plate Adjustment for Plantar/Dorsiflexion and External/Internal rotation



1. Plantar/Dorsiflexion

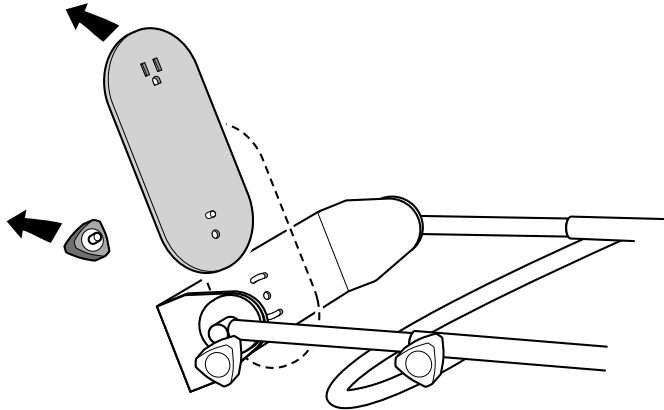
Loosen the adjustment knobs on each side of the foot plate. Adjust the foot plate to the desired degree of plantar or dorsiflexion. Retighten the knobs.



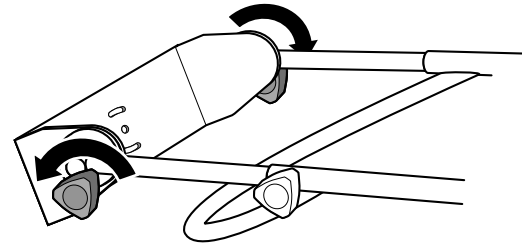
2. External/Internal Rotation

Loosen the adjustment knobs on the foot plate. Adjust the foot plate to the prescribed degree of external/internal rotation. Retighten the knobs.

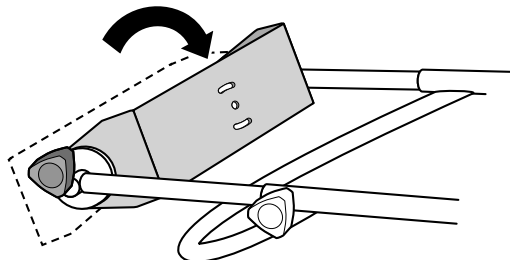
Foot Plate Adjustment for Pediatric Tibia Leg Length



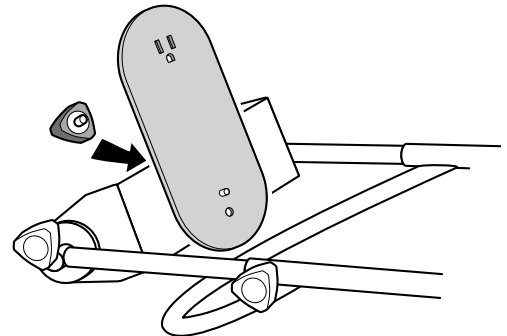
1. Remove the adjustment knob on the bottom of the foot plate. Remove the foot plate.



2. Loosen the adjustment knobs on each side of the foot plate.



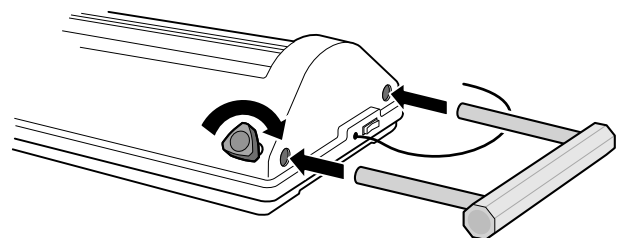
3. Rotate the foot plate bracket inward 180° as shown.



4. Reattach the foot plate to the foot plate bracket. Adjust for plantar/dorsiflexion and internal/external rotation as needed.

Hospital Bed Fixture

The FLEX-MATE® K500 Hospital Bed Fixture may be purchased optionally to attach the K500 to a hospital bed. Assemble the Hospital Bed Fixture to the K500 by sliding the fixture into the tubes at the end of K500 as shown. Screw in and tighten the knobs included with the fixture. Position the K500 on the bed in the appropriate position and attach to a bed mounted traction bar using standard traction fittings. The K500 is not to be carried by the Hospital Bed Fixture.

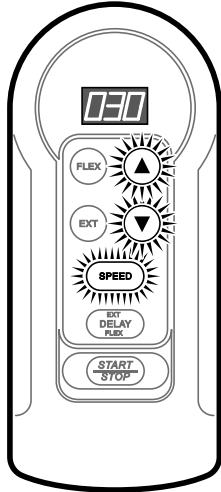


Hand-held Controller Operation

Turn on the power switch located at the foot of the machine.

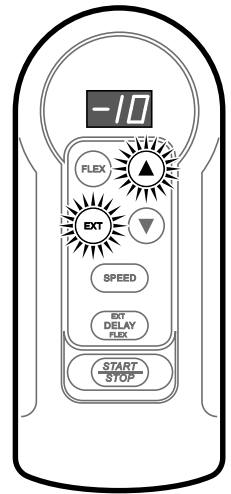
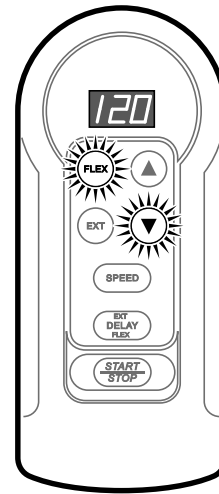
Range of Motion Set

Hold down “EXT” or “FLEX” and press “UP” or “DOWN” arrow to set the limits. Full range is from -10° extension to 120° flexion.



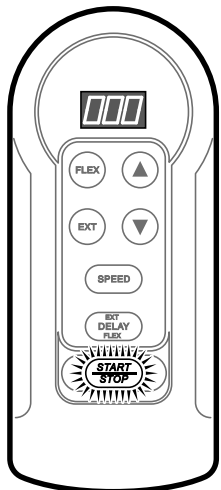
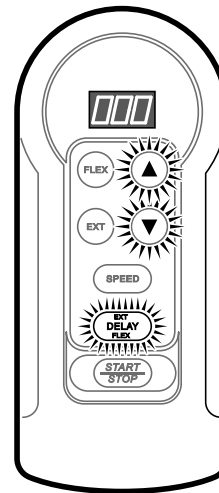
Speed Set

Hold down “SPEED” and press “UP” or “DOWN” arrow to set speed. Speed can be adjusted in 10 degree increments ranging from 30° per minute to 150° per minute.



Pause Set

Hold down “DELAY” and press “UP” or “DOWN” arrow to set the length of time the unit will pause at the flexion and extension limits. Delay range is from 0 seconds to 30 seconds.



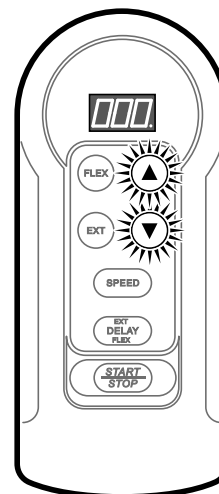
Press “START/STOP” to begin motion.

Press “START/STOP” again to stop motion.

Setting Lock

Press both “UP” and “DOWN” arrows at the same time to lock the setting, and again to unlock. When locked, a dot will show in the lower right corner of the display.

NOTE: Locking mode retained even when power is turned off.



Cleaning and Maintenance

With unit unplugged, clean housing and leg carriage with a mild soap solution and dry thoroughly. Refer to the Service Manual for recommended maintenance.

CAUTION: Avoid getting water inside the housing as it may damage the electrical components.

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