PS1 CPM — Forearm Pronation/Supination

DIRECTIONS FOR USE

Features

- Full range of motion (ROM)
- Bold goniometer with easy to set ROM limits
- Torque isolating technology
- Good anatomic alignment
- Two operational force settings
- Lightweight for maximum patient comfort
- User friendly design for easy setup and alignment
- Durable, compact and fully portable
- Rechargeable battery
- Reverse-on Load Safety Feature

ORDERING INFORMATION:

PS1-100U
PS1 Forearm Pronation/Supination CPM
(Includes: Actuator (Pronation/Supination device), Carrying Case, Motion Controller (Rechargeable Battery Pack), Power Supply and Disposable Patient Kit

PS1-101
PS1 Pronation/Supination Softgoods
(Single Patient Use)

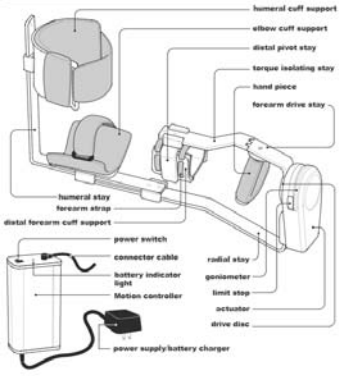
PS1-AC01
Humeral Cuff Strap Kit
(Adapts to smaller arm size with double-sided Velcro strap)

WARNING:
Indoor Use Only. Do not reuse disposable components. Do not store device above 40°C (104°F). Service by a qualified technician.

Specifications

Weight includes softgoods:	approx. 1.4 kg (3.0 lbs.)
Dimensions of Device:	56cm x 8cm x 28cm (22" x 3.0" x 11")
Dimensions of Motion Controller:	10cm x 18cm x 5cm (4" x 7" x 2")
Range of Motion:	Pronation: 0° to 90° Supination: 0° to 90°
Rate of Motion:	180° per minute
Force Settings:	Low: 2.8 Nm (25 in-lbs.) High: 4.0 Nm (35 in-lbs.)
Mode of Operation:	Continuous
Power Supply: Input	100-240 VAC, 50/60 Hz, 40 VA
Output	12 VDC, 1.25A
Battery Life:	Up to 100 hours
Electric Shock Classification:	Class II
Degree of Electric Shock Protection:	Type B
Environmental Conditions:	-10° to 35°C (14° to 95°F) temperature, 90% maximum humidity ATM pressure 750 to 1250 hPa pressure

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



Indications:
Immediate post-operative management after the following where indicated:
- Distal radius fractures (when stable);
- Fractures of the radius and ulna;
- Fractures of the radial head;
- Fractures associated with the humerus and ulna;
- Following surgical reduction or excision to treat radio-ulnar synostosis;
- Disruption of carpal and radio-ulna joints.

Contraindications:
- Septic tenosynovitis, until infection is controlled;
- Unstable fractures.

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

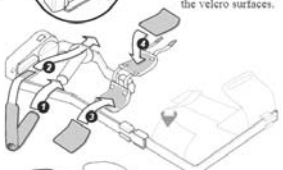
CAUTION: As with all portable objects, please store the device in a safe location when not in use to avoid a potential tripping hazard.

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

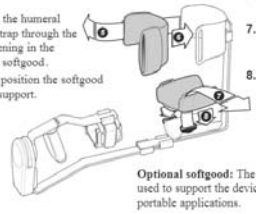
1 Softgoods Installation

1. Slide the hand softgood over the hand piece until the end of the hand piece protrudes out of the opening in the middle of the softgood.
2. Fold the pad as illustrated slipping the velcro strap through the hole in the ring.
2a. Attach the velcro strap to the hand softgood.

3. & 4. Apply the forearm pads to the forearm support cuffs securing the velcro surfaces.



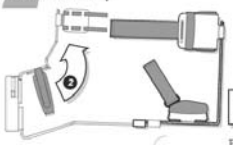
5. First pull the humeral support strap through the small opening in the humeral softgood.
6. Securely position the softgood over the support.



7. Pull the elbow support strap through the elbow softgood.
8. Position the softgood over the elbow support pad ensuring that the D-rings protrude through the openings on the softgood.

Optional softgood: The sling is used to support the device in portable applications.

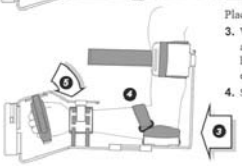
2 Patient Setup



Ensure the device hand piece is in the neutral position, i.e. goniometer is in 0° supination/pronation.

To facilitate patient setup:
1. Fully extend the humeral stay.
2. Lift the torque isolating stay.

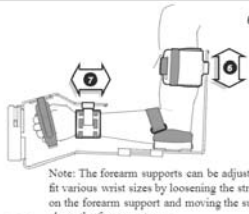
Place the patient's forearm in the device.
3. With the patient gripping the hand piece, and the elbow in 90° flexion, slide the humeral and elbow cuffs forward to engage the arm.
4. Secure the elbow strap.
5. Lower the torque isolating stay down onto the forearm ensuring that the distal pivot stay is on the back side of the forearm.



Symbols

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

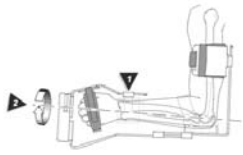
6. Slide the humeral cuff upwards as high as is comfortable for the patient and secure the strap.
7. Position the forearm support so that it engages the distal radius and ulna.



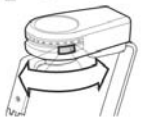
Note: The forearm supports can be adjusted to fit various wrist sizes by loosening the straps on the forearm support and moving the support along the forearm straps.

3 Alignment

1. Position the forearm cuff over the distal radius and ulna.
2. Ensure that the anatomical rotational axis is aligned with the centre of the drive disc.



4 Setting Range of Motion



To set the range of motion, depress and then slide the limit stops to the prescribed Range of Motion limits on the goniometer.

Note: To use the PS1 in ***Dynamic Traction Mode:***
1. Select the low force setting on the Motion Controller.
2. Place the limit stops just outside the patient's range of motion.

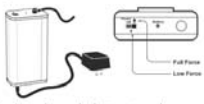
Caution: This feature should only be used as prescribed by a physician or therapist.

5 Initiating Treatment

Plug the connector cable from the Actuator into the Motion Controller.

The Motion Controller is equipped with two Operating Force Settings as indicated by the large and small graphics at the Power Switch.

To begin treatment, set the Power Switch on the Motion Controller to the required force.



Note: To recharge the battery, turn the power off. Plug the power supply into the Motion Controller. Then plug the power supply into the wall.

Charge the battery for six to eight hours. Charge once a month when not in use.

OrthoAgility™

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Printed In The United States PS1L005 Rev G