

S3S CPM

100U SHOULDER

For Shoulder Flexion/Extension and Abduction/Adduction –
Tripod and Ambulatory Use

Setup and Operating Manual



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CPM Device Information

Indications

The immediate post-operative management after the following where indicated:

Rotator cuff repair

After acromioplasty, particularly where the operation has been repeated and in cases where early physiotherapy cannot be assured

Capsulotomy and arthrolysis for post-traumatic arthritis with restriction of motion

Following total shoulder replacement

Synovectomy for rheumatoid arthritic and hemophilic arthropathy in the absence of acute inflammation, pain or bleeding

Arthrotomy and drainage for acute septic arthritis

In joint contracture after manipulation

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.

Prevention of negative effects of immobilization.

Note:

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

CPM Device Components

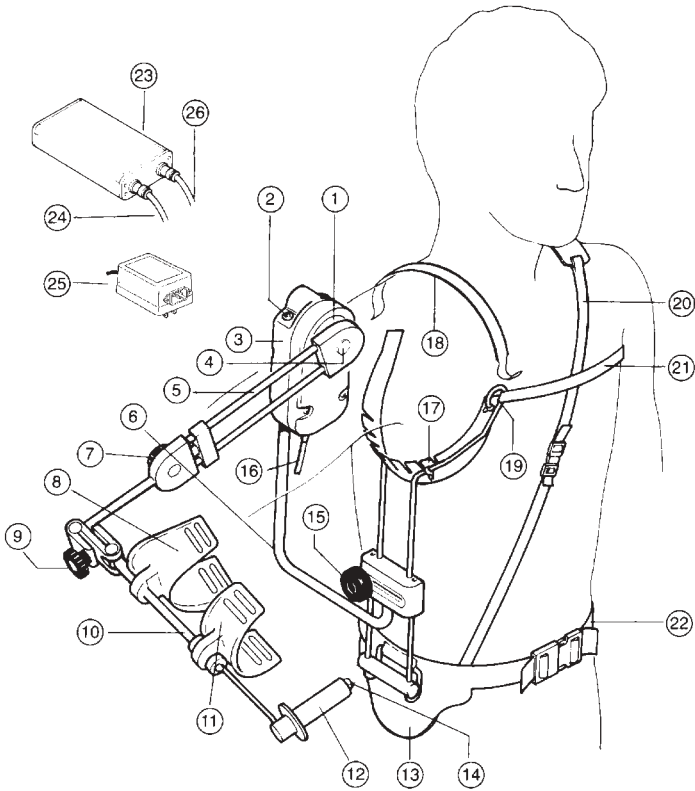


Figure 1

- | | |
|-----------------------------|--------------------------------|
| 1. Goniometer Label | 15. Main Locking Knob |
| 2. FWD/REV Buttons | 16. Cable to Motion Controller |
| 3. Actuator | 17. Underarm Pad |
| 4. Lock Button – Left/Right | 18. Shoulder Alignment Strap |
| 5. Upperarm Frame | 19. Chest Strap Rings |
| 6. Pivoting Support Frame | 20. Shoulder Strap |
| 7. Upperarm Locking Knob | 21. Chest Strap |
| 8. Forearm Cuff | 22. Waist Belt |
| 9. Elbow Flexion Knob | 23. Motion Controller |
| 10. Forearm Frame | 24. Cable to Actuator |
| 11. Wrist Cuff | 25. Power Supply |
| 12. Handle | 26. Cable to Power Supply |
| 13. Hip Support Pad | |
| 14. Patient Thumb Switch | |



WARNING. Device should only be used after the operator thoroughly reads and understands this manual. See Cautions and Warnings section.

Motion Controller

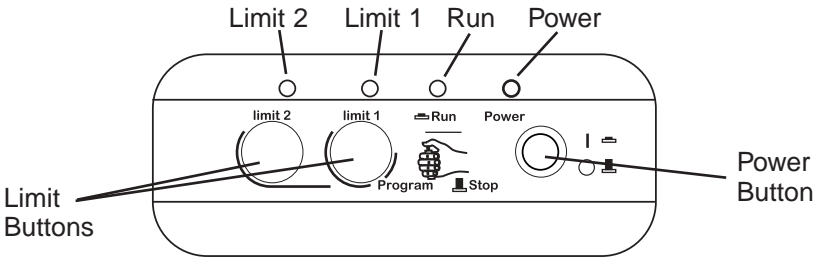


Figure 2

Indicator Lights (what each indicates)

- Power Indicator: **ON.** Indicates sufficient battery power
 Flashing. Indicates low battery power
- Run light: **ON.** Indicates operating between set ROM Limits
 OFF. Indicates controller is ready to accept new ROM programming
 Flashing. Indicates a malfunction; refer to Trouble Shooting Error Codes
- Limit 1/2 indicators: **ON.** Indicates CPM device has reached currently programmed Limit
 OFF. Indicates operating within programmed Limits.
 Flashing (rapidly). Indicates ready to accept new ROM programming
 Flashing (slowly). Indicates the last ROM Limit has been programmed successfully.
 Both ON. Indicates no ROM Limits programmed, or controller has not accepted programming.

Recharging the Motion Controller Battery

To recharge the Motion Controller, plug the Controller into the Power Supply. Recharging takes 6-8 hours and continues even while the CPM device is operating. Battery life is 8-10 hours.

Step 1: Assembling the Device – Ambulatory Use

- Remove all of the S3S components from the box, and review the parts illustration (see Figure 1) to identify the key device components.
- Loosen the black Main Locking Knob on the device's Main Lock. Insert the Hip Support Rails into the corresponding holes in the Main Lock (Figure 3).

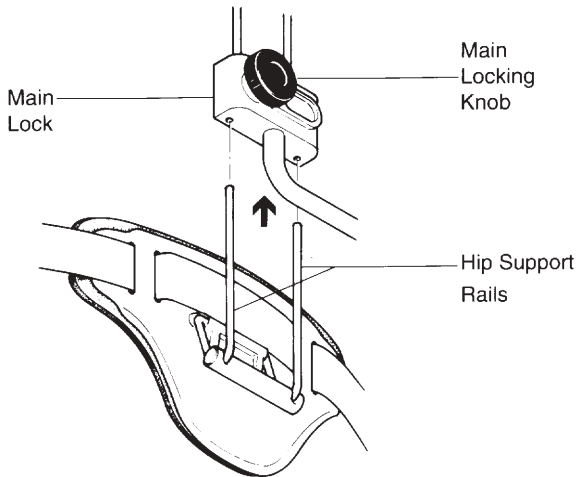


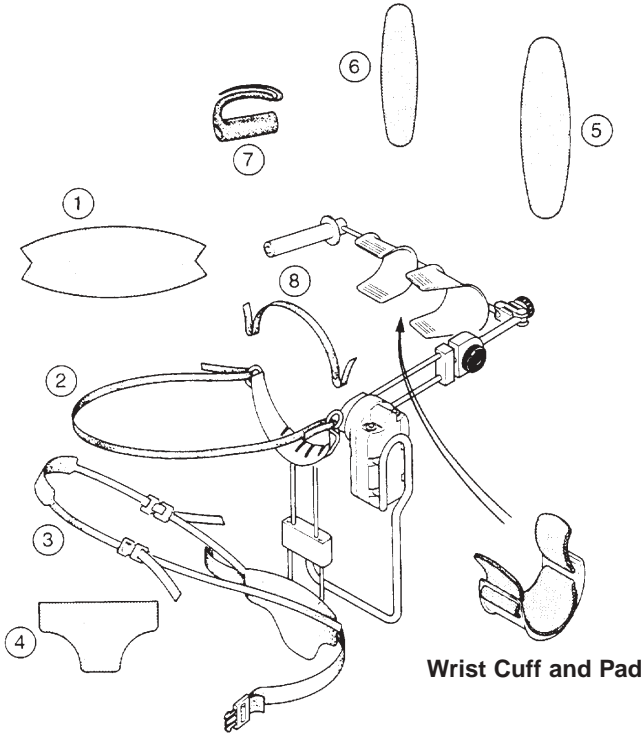
Figure 3

Step 2: Installing the Disposable Patient Kit (Softgoods)

- Install the Disposable Patient Kit as shown in Figure 4.
- Connect the Chest Strap to the Chest Strap Ring closest to the Shoulder Actuator.

Disposable Patient Kit (Softgoods)

Figure 4



Disposable Patient Kit (Softgoods)

Note: For reasons of hygiene, the following Disposable Kit has been supplied with your new S3S and is available to order separately. Soft goods are for single patient use only.

- | | | |
|-------------------|----------------|-----------------------------|
| 1. Underarm Pad | 4. Hip Pad | 7. Handle Pad |
| 2. Chest Strap | 5. Forearm Pad | 8. Shoulder Alignment Strap |
| 3. Shoulder Strap | 6. Wrist Pad | |

Ordering Information:

DESCRIPTION	PART NO.
S3S Shoulder CPM – <i>Requires a tripod, clamp and a steel, armless chair.</i>	S3S-100U
Portable Tripod Mount	S3-105
S3S Shoulder CPM – <i>Complete with portable CPM Chair</i>	S3S-200U
Portable CPM Chair for S3S-200U	GE-103
Portable Chair Adapter Kit – <i>Required for installation of S3S-100U or S3D-100U onto Portable CPM Chair</i>	S3-106
Disposable Patient Kit (Softgoods)	S3-101DS
Motion Controller	S3-104
Seat Clamp Assembly – <i>Use with S3-105</i>	S3-105D

Step 3: Preparing the Device for the Patient

- The S3S can be fitted to the left or right side of the body as treatment requires (Figure 5). To change the Device from the left or right shoulder application, depress the Lock Button on the inside of the Shoulder Actuator and rotate the Arm Assembly 180° until it locks in place.

- Loosen the Main Locking Knob and rotate the Hip Support Pad and Underarm Pad so that they are positioned to fit against the body on the side of the injured shoulder. Tighten the Main Locking Knob to secure this position.

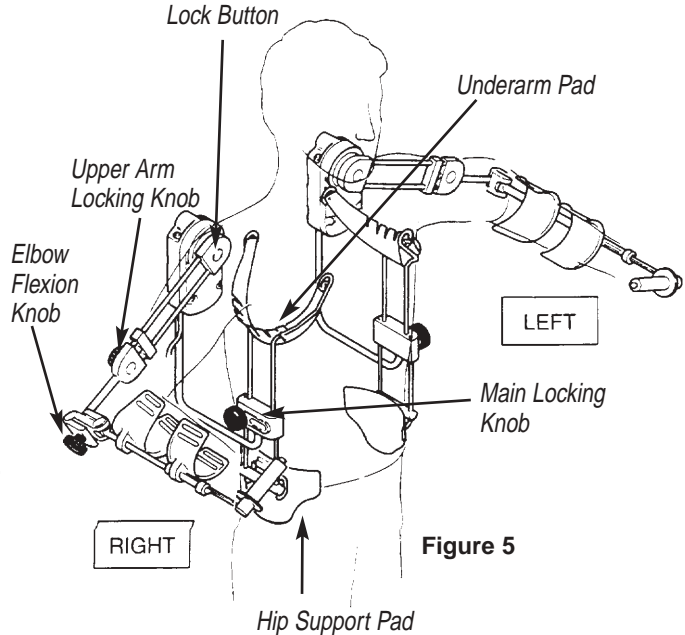


Figure 5

- Loosen the Upper Arm Locking Knob (Figure 6), located on the Upperarm Frame and extend the Upperarm Frame to its maximum length.
- Loosen the Elbow Flexion Knob and rotate the Forearm Frame to approximately 80° elbow flexion. Tighten the Elbow Flexion Knob.
- Pulling gently on the Handle, extend the Forearm Frame to its maximum length (Figure 6).

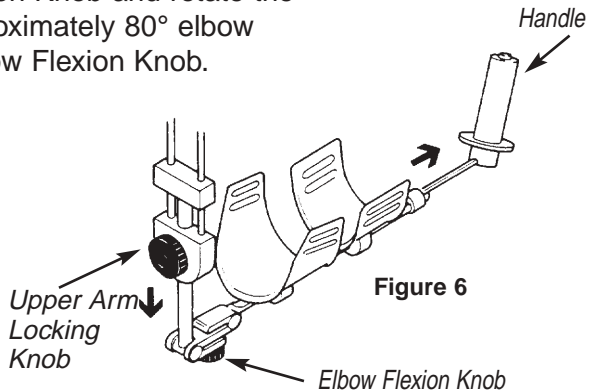
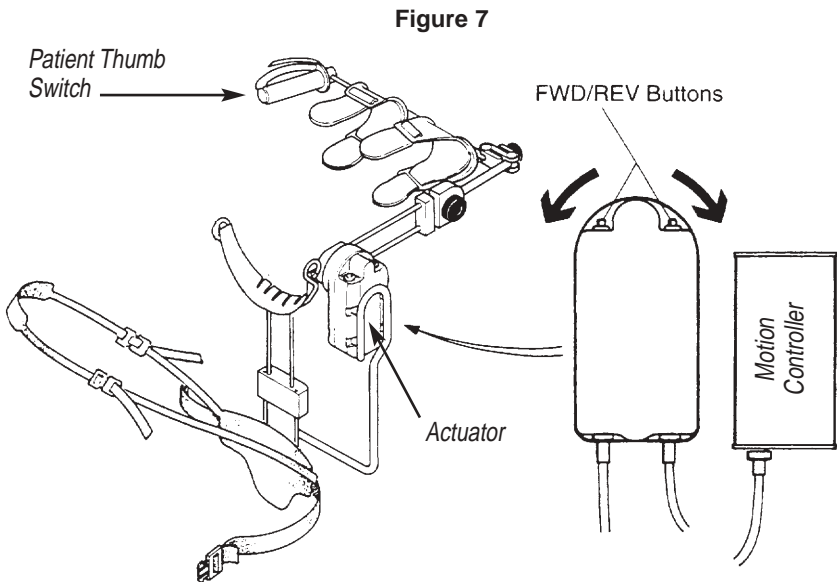


Figure 6

Patient Alignment

Step 4: Neutral Starting Position

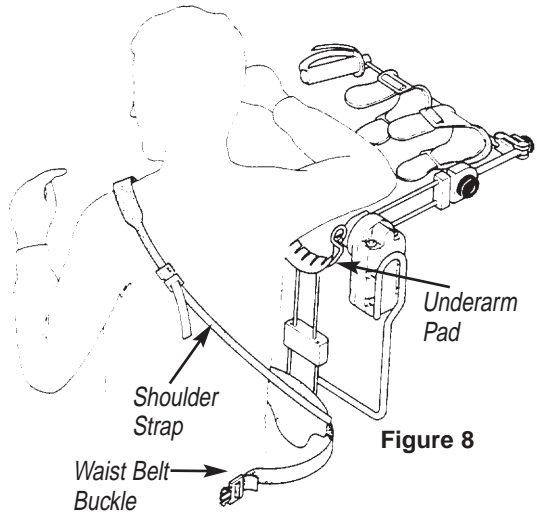
- With the Motion Controller turned off, plug the cable from the Shoulder Actuator into the Motion Controller.
- To turn the device on, depress the Power Button on the Motion Controller. (**Ensure Patient Thumb Switch is off**).
- For comfortable mounting onto the patient, move the S3S into a neutral starting position at approximately the midpoint of the physician's prescribed range of motion with the following steps:
 - 1) To achieve a neutral abduction position, use the FWD/REV Buttons on the Actuator (Figure 7) to move the Device into a mid-range of motion starting position for the patient. Refer to the Goniometer located on the Actuator for positioning.



Patient Alignment (cont'd.)

Step 5: Patient Setup

- Undo the Buckle on the black Waist Belt (Figure 8).
- Extend the black Shoulder Strap to its maximum length.
- Place the Device on the patient, lifting the Shoulder Strap over the patient's head so that it rests on the patient's healthy shoulder (Figure 8). Fit the Underarm Pad to the patient's underarm area.
- Fasten the Shoulder Strap Buckles and the Waist Belt Buckle.



Step 6: Hip/Shoulder Fitting

- While supporting the weight of the device, align the top of the Hip Support with the crest of the patient's ilium (Figure 9).
- Tighten the Waist Belt and Shoulder Strap to the patient's comfort.
- Thread the Chest Strap through the front Chest Strap Ring (under and over). Tighten the Chest Strap and then fold the Strap over the Chest Strap Ring and secure it with the velcro fastener.
- Refer to Figure 9. Loosen the black Main Locking Knob then slide the Underarm Pad up until it fits comfortably into the patient's underarm area. Tighten the Main Locking Knob.

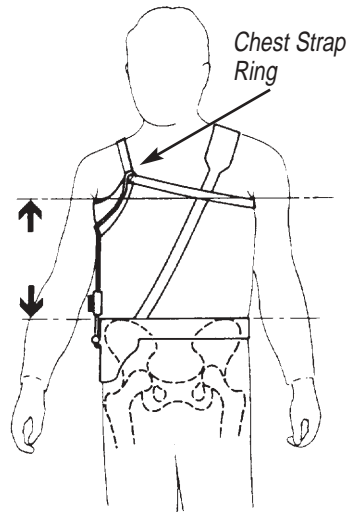


Figure 9

Patient Alignment (cont'd.)

Step 7: Adjusting Upperarm and Forearm Frames

- Loosen the Elbow Flexion Knob and position the Forearm Frame to comply with patient comfort. Tighten the knob.
- See Figure 10. Loosen the Upperarm Locking Knob located on the Upperarm Frame and adjust to position the patient's forearm comfortably in the Forearm Cuff. Tighten the Upperarm Locking Knob. Secure the Forearm Cuff with the Velcro fastener.
- Slide the Wrist Cuff along the Forearm Frame Rail until its front edge is positioned proximal to the patient's wrist. Secure the Wrist Cuff with the attached Velcro fastener.
- Slide the Handle with the Patient On/Off Thumb Switch into the patient's palm ensuring that the thumb has easy access to the Patient Thumb On/Off Switch.

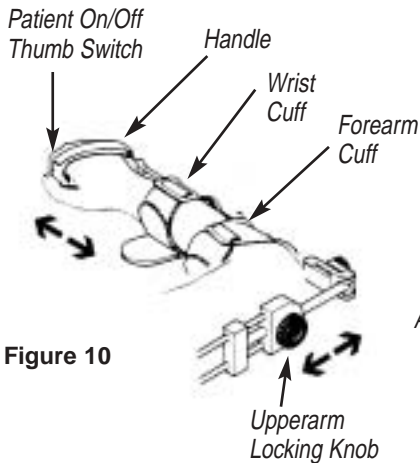


Figure 10

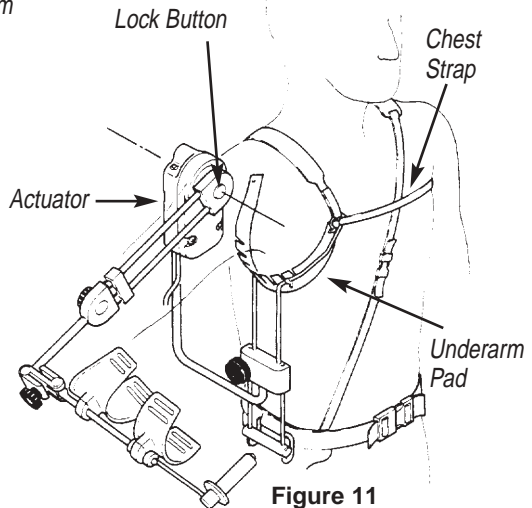


Figure 11

Step 8: Aligning the Shoulder

- The Lock Button located on the inside of the Actuator should align with the center of rotation of the patient's shoulder (Figure 11). This is achieved by adjusting the height of the Underarm Pad, the Chest Strap and the angle of the Actuator.

Range of Motion

Step 9: Setting the Range of Motion

The S3S can provide Abduction/Adduction, or Flexion/Extension, or any combination of the motions.

Figure 12

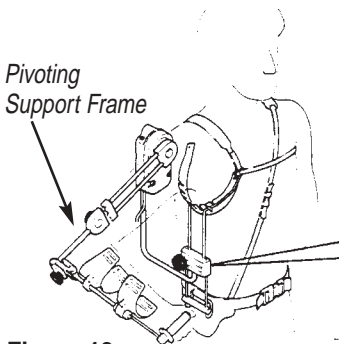
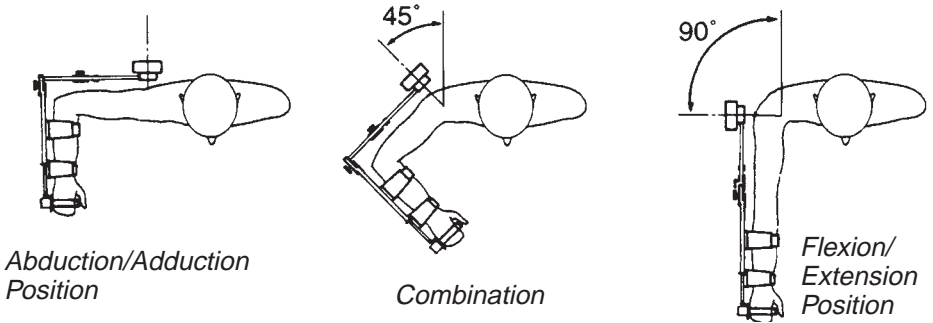


Figure 13

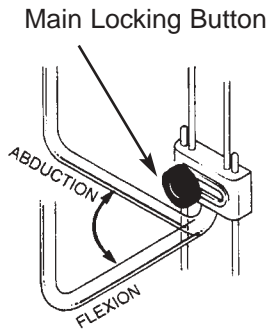


Figure 14

To change from Abduction (Figure 13) to Flexion (Figure 14):

- Loosen the Main Locking Knob.
- Rotate the Pivoting Support Frame 90°.
- Tighten the Main Locking Knob.
- The Pivoting Support Frame can be locked into any position between Abduction and Flexion.
- To ensure shoulder alignment and patient comfort readjust Elbow Flexion and Forearm Support (see step 7).

Range of Motion (cont'd.)

Step 10: Setting the Range of Motion

- Setting the range of motion for the S3S requires programming only two points, the beginning point of the range of motion, Limit 1, and the end point of the range of motion, Limit 2. The S3S's user friendly Motion Controller will memorize the motion path between the two set limits.
- Setting the range of motion is controlled by the FWD/REV Buttons on the Actuator.
- To set the range of motion as prescribed by the patient's physician, proceed by following the directions on the S3S Motion Controller Label (Figure 15), or see Programming on page 13.
- To begin treatment, start the Device by having the patient depress the On/Off Button on the Patient Thumb Switch located on the Handle.
- Take the patient through the full path of motion established by the range of motion limits, monitoring patient comfort and tolerance. Expand or reduce the range of motion as required for patient comfort using the following procedure:

Changing Range of Motion

- Run the device until a Blue LED turns on. Stop the device with the Patient Thumb Switch. Identify which LED is ON to indicate that Limit 1 (one) or Limit 2 (two) has been reached. Use the FWD/REV Buttons to change the Range of Motion. Press the same Limit Switch indicated by the previously lit Blue LED to store the new Limit. Press the Patient Thumb Switch to start the device.

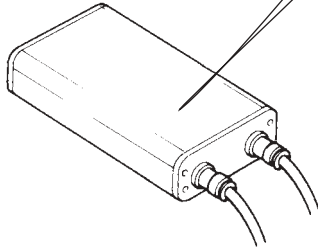
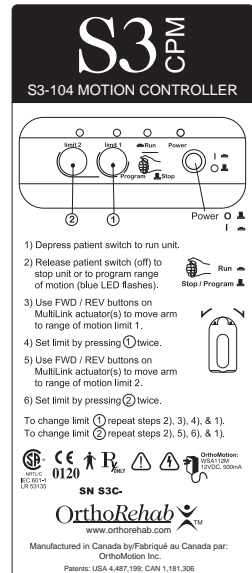


Figure 15



Range of Motion (cont'd.)

- When setting a new Limit, do not cross the Set Position of the other Limit or come within 5 (five) degrees of that limit. If this happens, the controller will not accept the program changes and will need to be re-programmed.
- To reset the controller, press both Limit Switches twice and start the programming procedure again beginning with Limit 1.
- The controller automatically erases the programmed ROM three minutes after the power switch has been turned off. This is done to prepare for a new patient and new program.
- To retain the programmed ROM in memory for treating the same patient at a later time, leave the power switch on continuously.

Programming Range of Motion

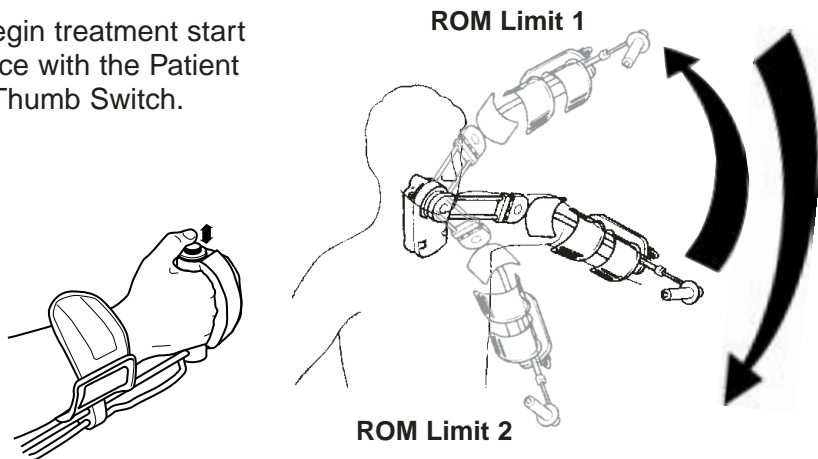
Before Starting: Ensure the device is turned on at the Power On/Off button on the Motion Controller, and the Patient On/Off Thumb Switch is turned off.

A: With the FWD/REV buttons run the Actuator Drive until the first desired ROM limit is reached. Then press the Limit 1 button twice. The light should go from flashing quickly to flashing slowly.

B: With the FWD/REV buttons run the Actuator Drive until the second desired ROM limit is reached. Then press the Limit 2 button twice.

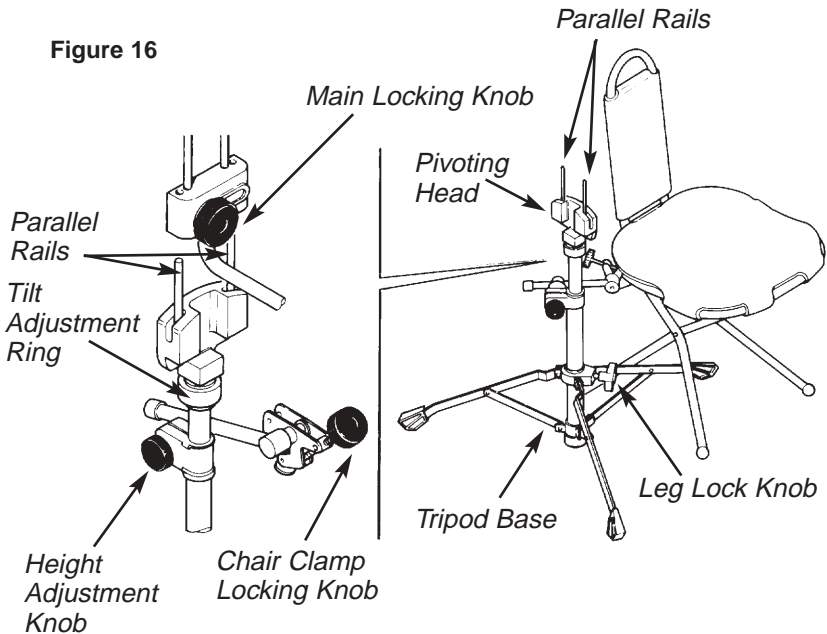
C: To begin treatment start the device with the Patient On/Off Thumb Switch.

Diagram
Setting Range of Motion



Chair Mount Configuration

Figure 16

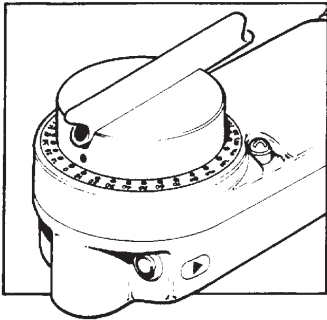


- Set up a steel, armless chair similar to the one shown.
- Set up the Tripod Mount next to the Chair, fully extending the legs of the Tripod Base. Lock these into position using the Leg Lock. Using the Chair Clamp, secure to the side of the chair corresponding to the involved shoulder.
- Select a left or right orientation by rotating the pivoting head and locking into position.
- Prepare the S3S as indicated in steps 1 and 2 on page 5, omitting mounting to the Hip Support.
- To mount the prepared Device, loosen the Main Locking Knob and slide the S3S onto the Pivoting Head Parallel Rails on the Tripod Mount (Figure 16). Tighten the Locking Knob.
- Move the Device into a neutral starting position (see Step 4, on page 8).

Chair Mount Configuration (cont'd.)

- Seat the patient on the chair and place the patient's arm in the device fitting the Underarm Pad to the patient's underarm area.
- Adjust the Upperarm and Forearm Frames (see Step 7, on page 10).
- The Lock Button located on the inside of the Shoulder Actuator should align with the center of rotation of the patient's shoulder. To align, adjust the following: (Refer to Figure 16)
 1. Tilt Adjustment Ring
 2. Height Adjustment Knob and Main Locking Knob
 3. Tripod Base Position
- Install the Chest Strap and the Alignment Strap and fit to the patient.
- Set range of motion, (see Step 10, on page 12).

Figure 17



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 light emitting diode (LED) just below the controller power switch. A flashing LED indicates that the battery needs to be recharged.
- The device can be operated independently by the battery for approximately 8-10 hours depending on the battery charge 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 the Reverse-On-Load function.

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 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
- 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.

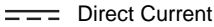
Symbols and Specifications



Off



On



Direct Current



Attention, Consult
Accompanying
Documents



Danger Electric Shock:
Service by a qualified
individual only.



Danger Explosive Risk:
If used with flammable anaesthetic



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)



**Use specified
power supply only.**



Type B applied part



Alternating Current



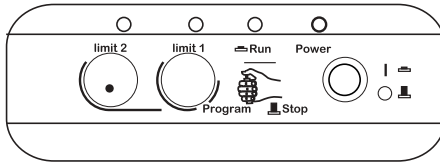
**This
Way Up**



Fragile



**Keep
Dry**



Weight:

CPM Device 5 kg (11 lbs.)

Range of Motion:

Forward Flexion 0° to 135°
Extension 0° to 135°
Abduction/Adduction 0° to 135°

Rate of Motion: 110° per min.

Power Supply: Input: 100-250 VAC, 50-60 Hz, 40VA
Output: 12VDC, 1.25A

Battery Life: 8-10 hours

Mode of Operation: Continuous

Electric Shock Classification: Class 1

Electric Shock Protection: Type B

Environmental Conditions: Temperature -10°C to 35°C, Humidity 90% Maximum.
The device must remain in the operational environment a minimum of one hour prior to use.

ATM pressure: 750 hPa to 1040 hPa

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

Trouble Shooting

Problem	Probable Cause	Solution
Power light does not light up	Fully discharged battery/blown fuse	Plug in power supply, recheck after charging.
Flashing run light	Malfunction	Switch off power, check all connectors. Reprogram & restart. If problem persists, check error codes.
Constant run light with device not running	Setup error	Switch off power. Reprogram & restart. If problem persists refer to service.
Device will not move with the setup button	Hitting safety stop	Depress opposite setup button.

Error Codes

Error codes are displayed using the indicators in the Motion Controller Front Panel. To display error codes, depress either Limit 1 or Limit 2 with the “Run” indicator flashing

a) Limit 1 Depressed

Indicator “ON”	Problem	Cause/Solution
Power	Reversed on load 3 times within the last 10 seconds	Check for obstruction, clear, reprogram and restart. If problem persists, refer to service.
Run	Out of range, reversed on load while driving towards range	Check for obstruction, clear, reprogram and restart. If problem persists, refer to service.
Limit 1	Out of range, driving in the wrong direction	Hardware error. Refer to service.
Limit 2	Not used	
None		Depressed Limit 2.

Trouble Shooting (cont'd.)

b) Limit 2 Depressed

Indicator "ON"	Problem	Cause/Solution
Power	Angle measurement out of range	Check all connectors reprogram and restart. If problem persists, refer to service.
Limit 1	Cable fault, controller to patient switch	Check all connectors, reprogram and restart. If problem persists, refer to service.
Limit 2	System over voltage Faulty battery/charger	Check all connectors, reprogram and restart. If problem persists refer to service.
None		Depressed Limit 1.

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

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

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



ORTHOREHAB

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