

A3^{CPM}

Setup and Operating Manual



QAL MedicalTM
OrthoAgilityTM

A3 CPM Setup and Operating Manual

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Device Setup

Indications

The immediate post-operative management of joints after the following types of surgical procedures:

Athrotomy

Stable fractures

Synovectomy

Arthroplasty

Reconstructive surgery on bone, cartilage, tendons, and ligaments

Prolonged joint immobilization

Surgical lengthening of the achilles tendon due to post trauma stiffness

Application

Continuous Passive Motion (CPM) is best applied immediately post-operative and continued, uninterrupted, for an average of four to six weeks or 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.



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Components

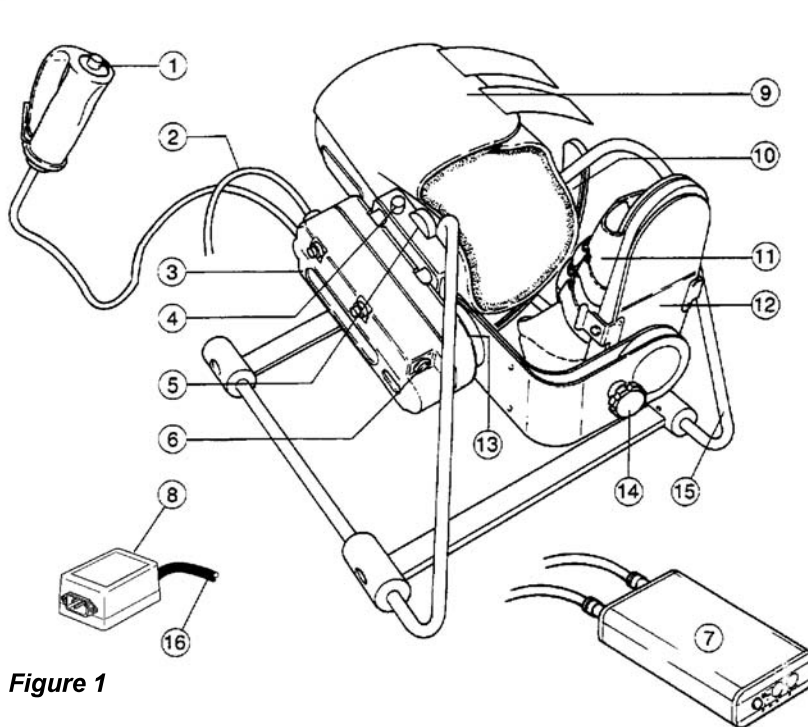
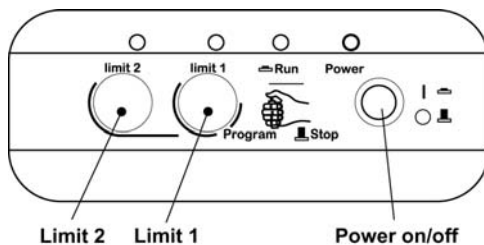


Figure 1

- 1 Patient Thumb Switch
- 2 Cable to Motion Controller
- 3 Actuator
- 4 Actuator Lock Button
- 5 Actuator Position Indicators
- 6 FWD/REV Buttons
- 7 Motion Controller
- 8 Power Supply
- 9 Lower Leg Softgoods
- 10 Actuator Ring
- 11 Patient Shoe
- 12 Footplate
- 13 Goniometer
- 14 Locking Knob
- 15 Support Frame
- 16 Cable to Motion Controller

Figure 2 Motion Controller



Control Buttons

- Power On/Off** – Power to entire device.
- Limits 1 & 2** – Set start and end points of Range of Motion.

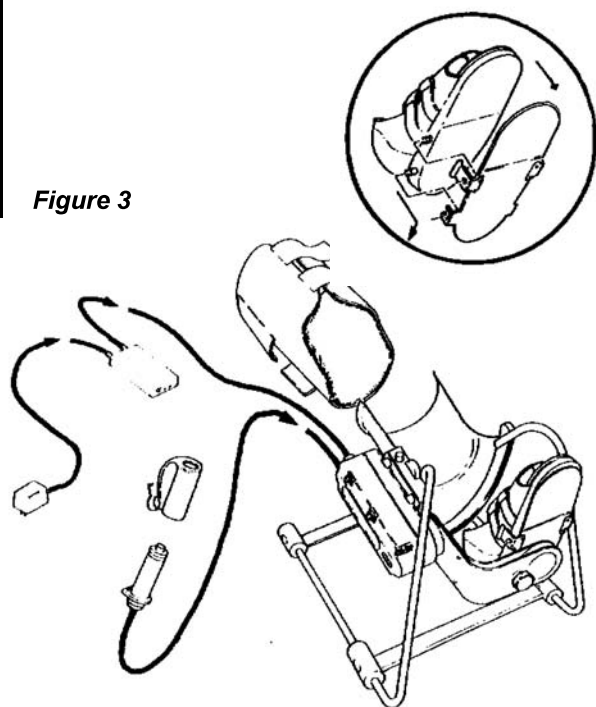
Indicators

- Power**
 - Green LED - On - indicates good battery.
 - Flashing - indicates low battery power.
- Run**
 - On - indicates operating between set limits.
 - Off - indicates it is ready to accept new limits.
 - Flashing - indicates a malfunction; refer to Trouble Shooting Error Codes.
- Limit 1/2**
 - On - indicates Actuator currently at set limit.
 - Off - indicates operating within set limit.
 - Flashing - ready to accept new limit; slower flashing rate indicates last limit set.

Both On – Indicates no limits are set.

Device Setup

Figure 3



Preparing the Device for the Patient

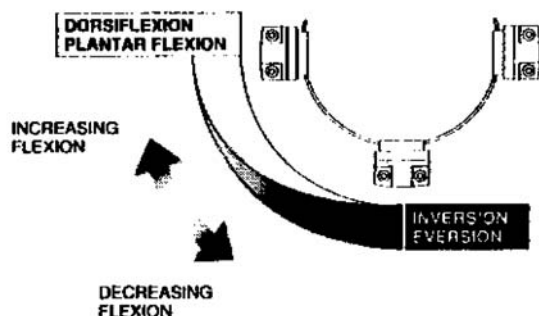
Step 1:

- Remove the A3 components from the box and review the parts illustration (see Figure 1) on page 2.
- Plug the cable from the Power Supply into the Motion Controller. **(Ensure that power is off).**
- Plug the cable from the Actuator into the Motion Controller. **(Ensure that power is off).**
- Plug the cable from the Patient Thumb Switch into the Actuator. **(Ensure that power is off).**
- Select appropriate shoe size. Install the patient shoe by positioning the rear shoe posts into the rear slots of the footplate (see Figure 3). Press the front shoe posts into the front slots securing the side spring tabs.
- Install the Disposable Patient Kit as shown (see Figure 3).
- Plug the power supply into the wall outlet.

Step 2: Selecting the Plane of Motion

Three setup options

1. Single Axis: Plantar Flexion (0° - 60°)
/ Dorsiflexion (0° - 60°)
2. Single Axis: Inversion (0° - 60°)
/ Eversion (0° - 60°)
3. Combined Axes Motion



Device Setup (cont'd.)

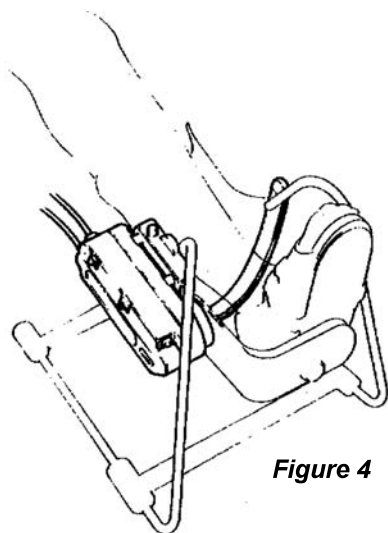


Figure 4

Single Axis Motion

Option 1:

Ankle Joint (Dorsiflexion/Plantar Flexion)

- Depress the Actuator Lock Button to permit the Actuator to slide around the Actuator Ring.
- Position the Actuator at the top (left or right) of the Actuator Ring, (see Figure 4) lining up the graphics on the Actuator Ring and the Actuator Position Button Block. Release the Locking Button.
- Align the goniometer to a neutral starting position (0°) using the Forward/Reverse Buttons on the Actuator. Adjust the angle of the Patient Shoe by loosening the Locking Knob below the Footplate. Position the shoe as required (typically vertically) and secure the Locking Knob.

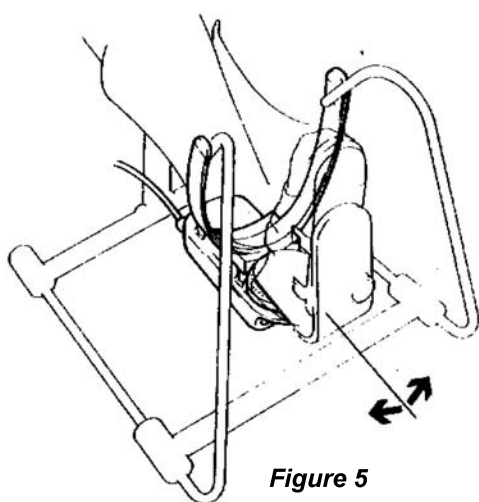
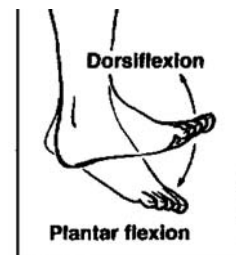


Figure 5

Option 2:

Subtalar Joint (Inversion/Eversion)

- Depress the Actuator Lock Button to permit the Actuator to slide around the Actuator Ring.
- Position the Actuator at the bottom of the Actuator Ring, (see Figure 5) lining up the graphics on the Actuator Ring and the Actuator Position Button Block. Release the Lock Button.
- Align the goniometer to a neutral starting position (0°) using the Forward/Reverse Buttons on the Actuator. Adjust the angle as in Option 1. Position the patient shoe in a vertical starting position (see Figure 5).

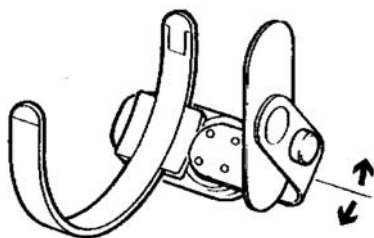
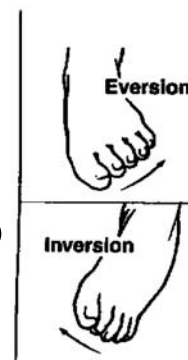


Figure 6

Combined Axes Motion

- Depress the Actuator Lock Button to permit the Actuator to slide around the Actuator Ring.
- For combined Ankle and Subtalar joint mobility, the Actuator may be positioned at any stop point located every 10° along the Actuator Ring by releasing the Lock Button. Align the Patient Shoe to a neutral starting position using the Forward/Reverse Buttons on the Actuator. Adjust the angle as in Option 1.

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Device Setup (cont'd.)

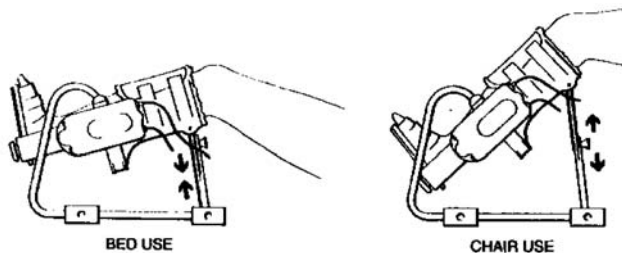
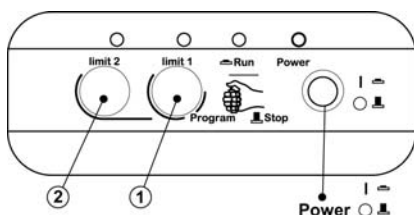


Figure 7



1) Depress patient thumb switch to run device.

2) Release patient thumb switch (off) to stop device or to program range of motion (blue LED flashes).

3) Use FWD / REV buttons on A3 actuator to move foot plate to range of motion limit 1.

4) Set limit by pressing ① twice.

5) Use FWD / REV buttons on A3 actuator to move foot plate to range of motion limit 2.

6) Set limit by pressing ② twice.

To change limit ① repeat steps 2), 3), 4), & 1).

To change limit ② repeat steps 2), 5), 6), & 1).

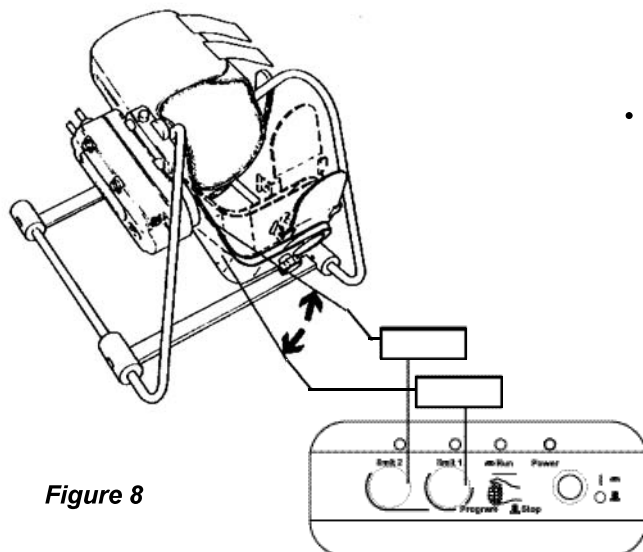


Figure 8

Step 3: Patient Setup

- The A3 can be used while the patient is sitting or lying down. To adjust for use, pull out the white locking knob located at the back of the device and position as shown in Figure 7 for bed or chair use. Secure the Locking Knob.
- Position the device next to the patient's lower leg and undo the Velcro straps to open the lower leg softgoods and the device's Patient Shoe.
- Gently place the patient's foot into the A3. Secure the Velcro fasteners on the shoe and around the lower leg softgoods.

Step 4: Setting the Range of Motion (ROM)

Setting the Range of Motion for the A3 CPM requires programming of only two points, the first end point of the Range of Motion (Limit 1) and the second end point of the Range of Motion (Limit 2). The A3's user friendly Motion Controller will memorize the two end points of the patient's ROM and provide a uniform motion between the two memorized limits.

(Note: See back of Motion Controller for instructions).

For Dorsiflexion/Plantar Flexion

- The Actuator is positioned at the upper side (left or right) of the Actuator Ring. **The Motion Controller power is turned on. The Patient Thumb Switch is turned off.**
- To set Dorsiflexion, press the Forward/Reverse Button on the Actuator until the required degrees of motion are achieved on the goniometer. This is the first end point. Press the Limit 1 Button on the Motion Controller.
 - To set Plantar Flexion, press the Forward/Reverse Button on the Actuator until the required degrees of motion are achieved on the goniometer. This is the second end point. Press the Limit 2 Button on the Motion Controller.

Device Setup (cont'd.)

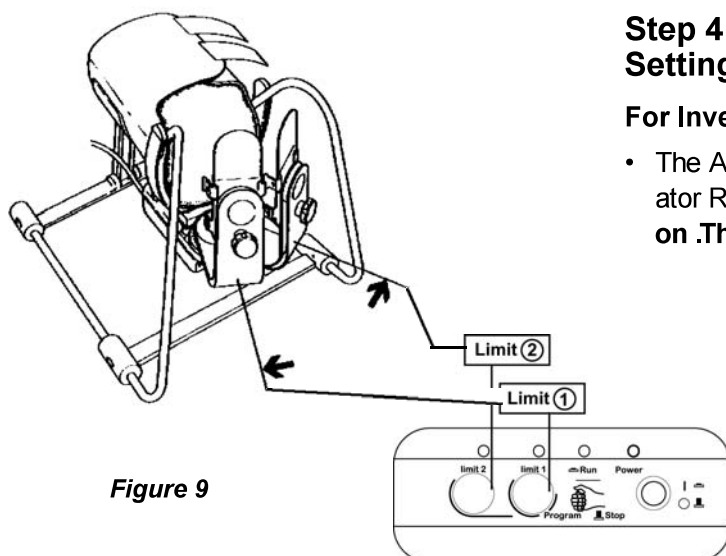


Figure 9

Step 4: Setting the Range of Motion (cont'd)

For Inversion/Eversion

- The Actuator is positioned at the bottom of the Actuator Ring. **The Motion Controller Power is turned on. The Patient Thumb Switch is turned off.**
 - To set Inversion, press the Forward/Reverse Button on the Actuator until the degrees of motion are achieved on the goniometer. Press the Limit 1 button on the Motion Controller.
 - To set Eversion, press the other Forward/Reverse Button on the Actuator until the required degrees of motion are achieved on the goniometer. Press the Limit 2 Button on the Motion Controller.

For Combined Planes of Motion

- To combine the above planes of motion, the Actuator may be positioned at any Stop Point located at 10° increments along the Actuator Ring. The combination of motion varies with the placement along the Actuator Ring.
- Position the Actuator: **The Motion Controller is turned on. The Patient Thumb Switch is turned off.** Press the first Forward/Reverse Button until the degrees of motion are achieved on the goniometer. Press Limit 1 on the Motion Controller.
- Press the other Forward/Reverse Button until the degrees of motion are achieved. Press Limit 2 on the Motion Controller.

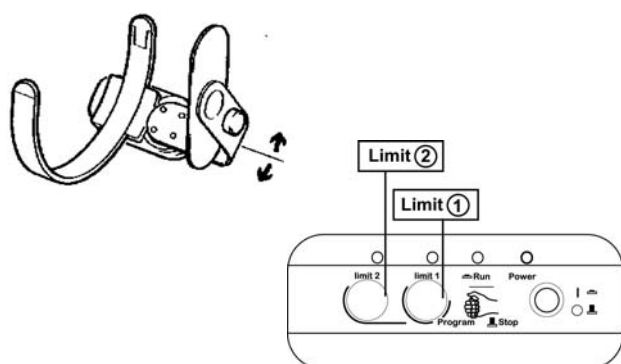


Figure 10

Step 5: To Begin Treatment

- Depress the On/Off Button on the Patient Thumb Switch.
- Take the patient through the full path of motion established by the Range of Motion limits, monitoring patient comfort and tolerance. Adjust as required to patient comfort.



Figure 11

Note: To retain ROM settings, leave the power on on the Motion Controller and interrupt therapy by using the Patient Thumb Switch.

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Device Setup (cont'd.)

Feature Notes

Memory

Retaining the Range of Motion Limits

- The Patient Thumb Switch is turned off and the Motion Controller remains on: **The Motion Controller will retain the Range of Motion Limits *indefinitely*.**
- The Patient Thumb Switch is turned off and the Motion Controller is turned off. The Motion Controller will retain the Range of Motion Limits for approximately three minutes. After three minutes, refer to Step 4 to reset the Limits .

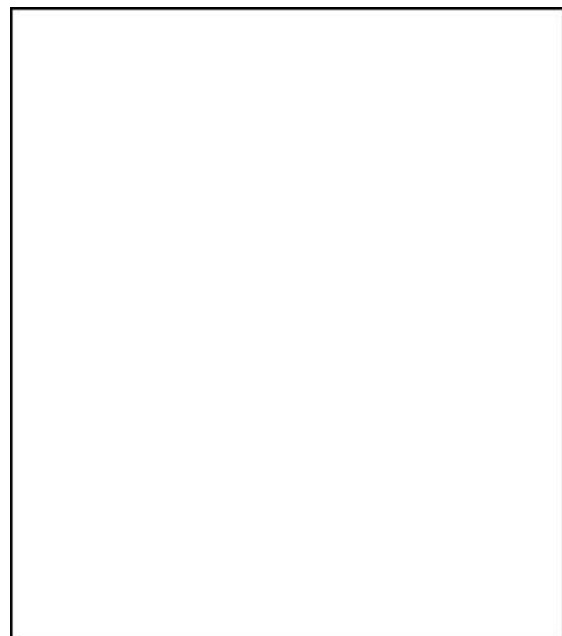
Changing the Range of Motion

- Using the Patient Thumb Switch, stop the device when the blue LED turns on at the Limit to be adjusted. Press the forward/reverse buttons until the ROM is increased or decreased. Press the Limit Switch for the same blue LED to enter the new ROM limit.

Note: When adjusting to the new limit, do not cross the other ROM limit or come within 5 degrees of that limit.

Reverse-on-Load Safety Feature

- The Reverse-on-Load Safety Feature enables the device to reverse its direction when resistance to motion is encountered.



Maintenance

Rechargeable Battery

- The controller is equipped with a rechargeable battery. Connecting the device's power supply to the controller recharges the battery.
- The battery requires 6-8 hours to fully recharge. Battery charging status is indicated by the light emitting diode (LED) beside the controller power supply connector. A steady LED indicates normal charging.
- The device can be operated independently by the batteries for approximately 10-12 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".

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.

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.
- Perform a complete check of the electronic and mechanical Reverse-On-Load safety function.
- Complete a final check of the device in accordance with QAL Medical Final Inspection criteria. (These are available through your QAL Medical representative, QAL Medical 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.

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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.
- 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 Specifications: Environmental 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

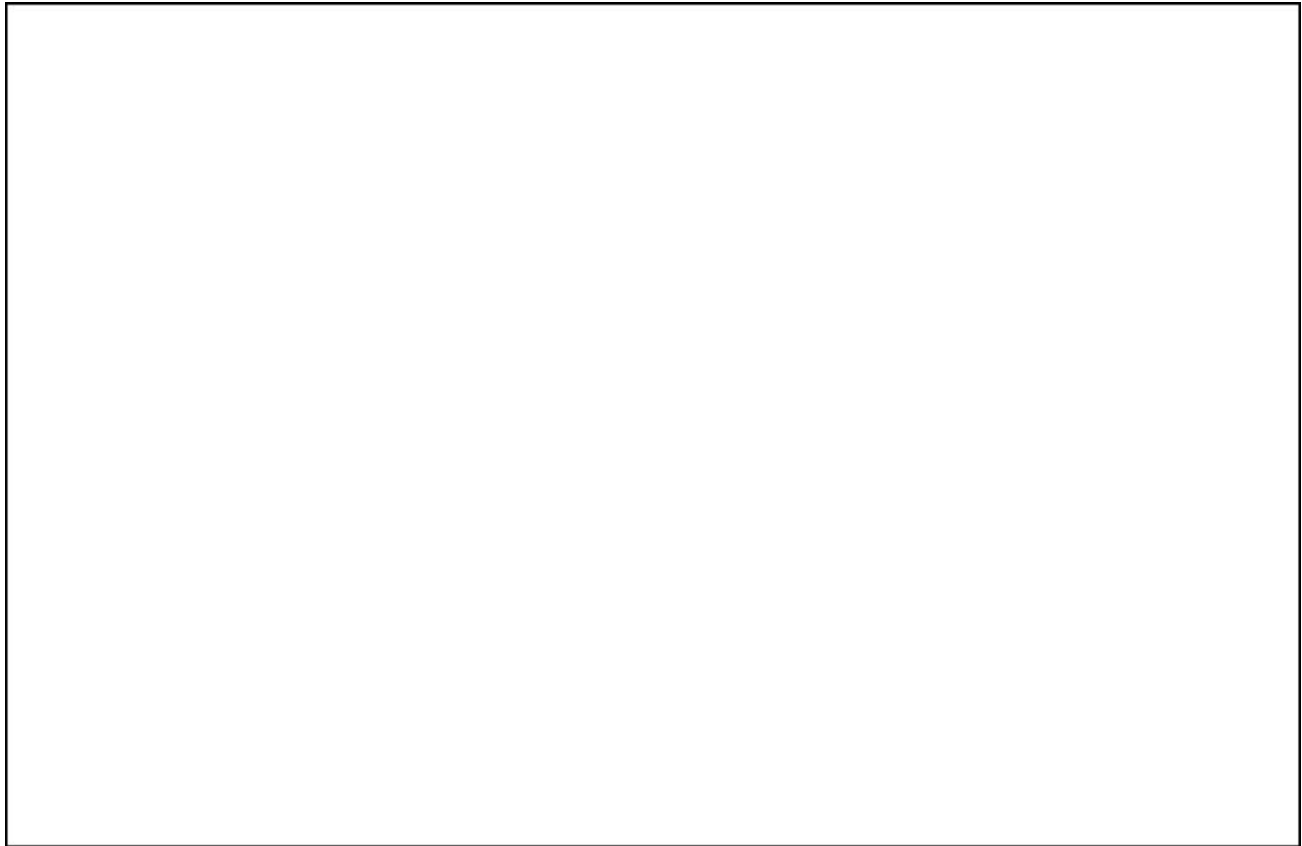
Do not use the device if any of the following are present:

- Untreated or uncontrolled infection
- Acute inflammatory arthrosis
- Spastic paralysis
- 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.

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Symbols and Specifications



Specifications

| | |
|--------------------------------------|--|
| Weight of Device: | 4.5 kg. (10 lbs.) |
| Dimensions of Device: | 42.3 cm x 48.3 cm x 33 cm (17" x 19" x 13") |
| Range of Motion: | Plantar Flexion: 0° - 60° Dorsiflexion: 0° - 60° Inversion: 0° - 60° Eversion: 0° - 60° |
| Rate of Speed: | 80° per minute |
| Mode of Operation: | Continuous |
| Power Supply: | Input: 100-240 VAC, 50-60Hz, 0.5A Output: 12 VDC, 1.25A |
| Battery Life: | 10 - 12 hours |
| Electric Shock Classification: | Class 1 |
| Degree of Electric Shock Protection: | Type B |

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

Environmental Conditions: Temperature -10° C to 35° C (14°F to 95°F), Humidity 90% Maximum.
ATM pressure: 750hPa to 1040 hPa
The device must remain in the operational environment a minimum of one hour prior to use .

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Trouble Shooting

| Problem | Probable Cause | Solution |
|---|--|---|
| Power light does not light up. | Fully discharged battery/ blown fuse. | Plug in power supply, recheck after charging. |
| Power light flashing. | Low battery power. | Connect power supply. |
| Flashing Run light. | Malfunction. | Switch off power, check all connectors. Reprogram and restart. If problem persists check error codes. |
| Constant Run light with machine not running. | Patient thumb switch pressed. | Release patient thumb switch and program the device. |
| | Setup error. | Switch off power. Reprogram and restart. If problem persists refer to service. |
| Device will not move with setup button. | Reached safety stop. | Depress opposite setup button. |

Error Codes

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

TABLE 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 | | Depress and hold Limit 2 and check Table B. |

TABLE B – Limit 2 Depressed

| Indicator "On" | Problem | Cause/Solution |
|----------------|---|---|
| Power | FLEX/EXT angle measurement out of range. | Check all connectors, reprogram and restart. If problem persists, refer to service. |
| Run | Not used. | |
| Limit 1 | Cable fault, controller to patient thumb 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 | | Depress and hold Limit 1 |

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:

QAL Medical, LLC

A division of Quality Assembly & Logistics, LLC

Attn: Customer Service

3000 Woleske Road

Marinette, Wisconsin, 54143 USA

Tel: 1-715-735-4727 Fax: 1-715-732-6402

Website: www.qalmedical.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:

QAL Medical, LLC

A Division of Quality Assembly and Logistics, LLC

Website: www.qalmedical.com

Tel: 1.715.735.4727; 1.888.430.1625 Fax: 1.715.732.6402

International:

QAL Medical, LLC

A Division of Quality Assembly and Logistics, LLC

3000 Woleske Road, Marinette, Wisconsin 54143 USA

Tel: 1.715.735.4727 Fax: 1.715.732.6402



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