

E3^{CPM}

Instructions for Use

Patent 6,743,187



QAL Medical.
OrthoAgility™
www.QALMedical.com

NOTICE

- 1. Before each use, run the E3 for a minimum of 5 complete cycles at force 5 and speed 5 before making the final selection of force and ROM.**
- 2. If it is required to use the device in its portable mode and the device has been out of use for a week or longer, it is recommended that the battery be charged by connecting the power supply to either the actuator or the controller and the controller switched on, for a minimum of 2 hours (full charge may take 12 hours). The device can be used in its stationary mode while the battery is being charged.**

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WARNING

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

1 DEVICE DESCRIPTION AND DIAGRAMS

Glossary of Terms:

ROM – Range of Motion, the arc in degrees that a joint moves through.

Distal – Moving down the arm towards the wrist.

Proximal – Moving up the arm towards the shoulder.

Lateral – Further from the middle of the body.

Medial – Closer to the middle of the body.

Elbow Flexion – Bending the elbow.

Elbow Extension – Straightening the elbow.

Supination – Rotation of the forearm with the palm facing up.

Pronation – Rotation of the forearm with the palm facing down.

THIS CPM DEVICE MAY BE USED FOR EITHER THE LEFT OR RIGHT ARM AND MAY BE SETUP ON A CHAIR, A BED OR A SOFA.

1.1 Introduction

The E3 Elbow CPM device is prescribed and used under the supervision of a physician or other licensed healthcare provider.

This manual has been written for the owners and operators of the device. It contains general instructions on the operation, precautionary practice and maintenance of the device. To maximize the use, efficiency and life of your E3 Elbow device, please read this manual thoroughly and become familiar with the controls and accessories before operating the device.

1.2 Health Care Provider Orientation Instructions for New Patients

- Before any setup begins, establish communication with the patient, family, etc.
- Introduce yourself.
- Explain why you are there and what you will be doing.
- Explain the purpose and function of the device and demonstrate its use. Outline the patient safety features and refer to the cautions and warnings in Section 11.
- Explain what the patient should expect when the device is turned on and how to contact their local representative for customer service.

1.3 Indications

- Post-operative management of:
- Joint arthroplasty.
- Stable fractures of radius, ulna, humerus.
- Reconstructive surgery on bone, cartilage, tendons and ligaments.
- Prolonged joint immobilization.

1.4 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.

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Fig. 1.1 Device Components
Lateral View of CPM Right Arm Setup

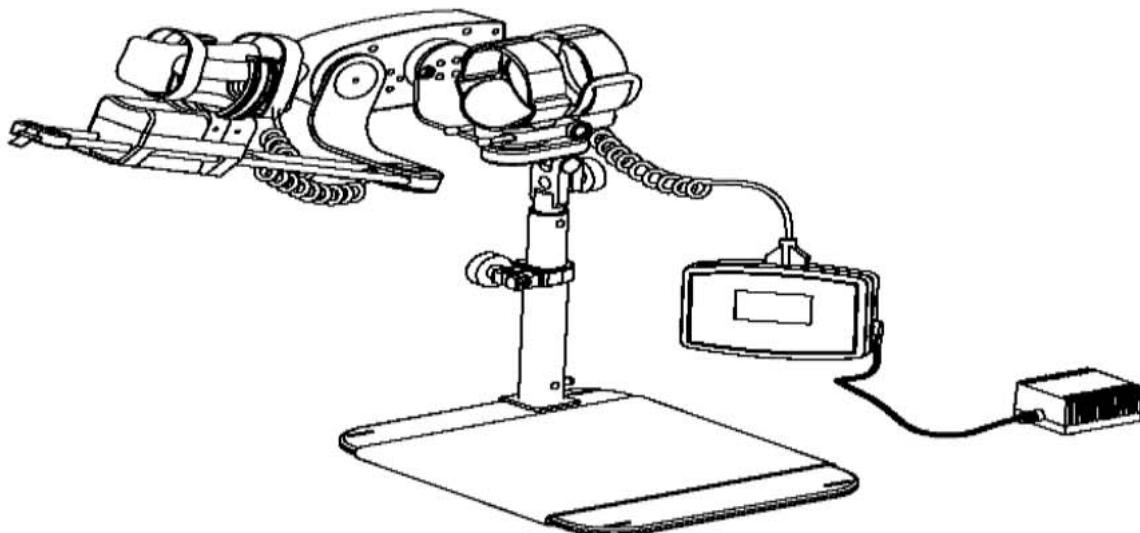
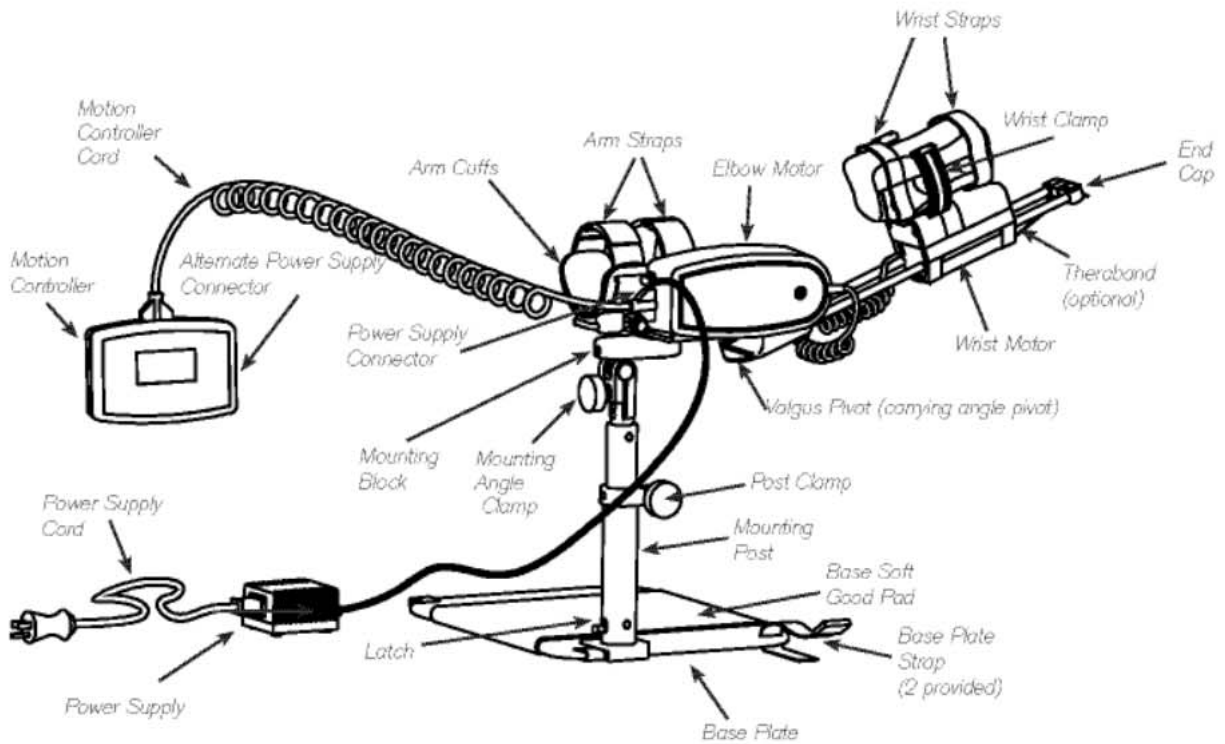


Fig. 1.2 Medial View of CPM Right Arm Setup

2 Device Configuration and Setup

2.1 The device is stored and transported in a custom carrying case. (See Fig. 2.1)

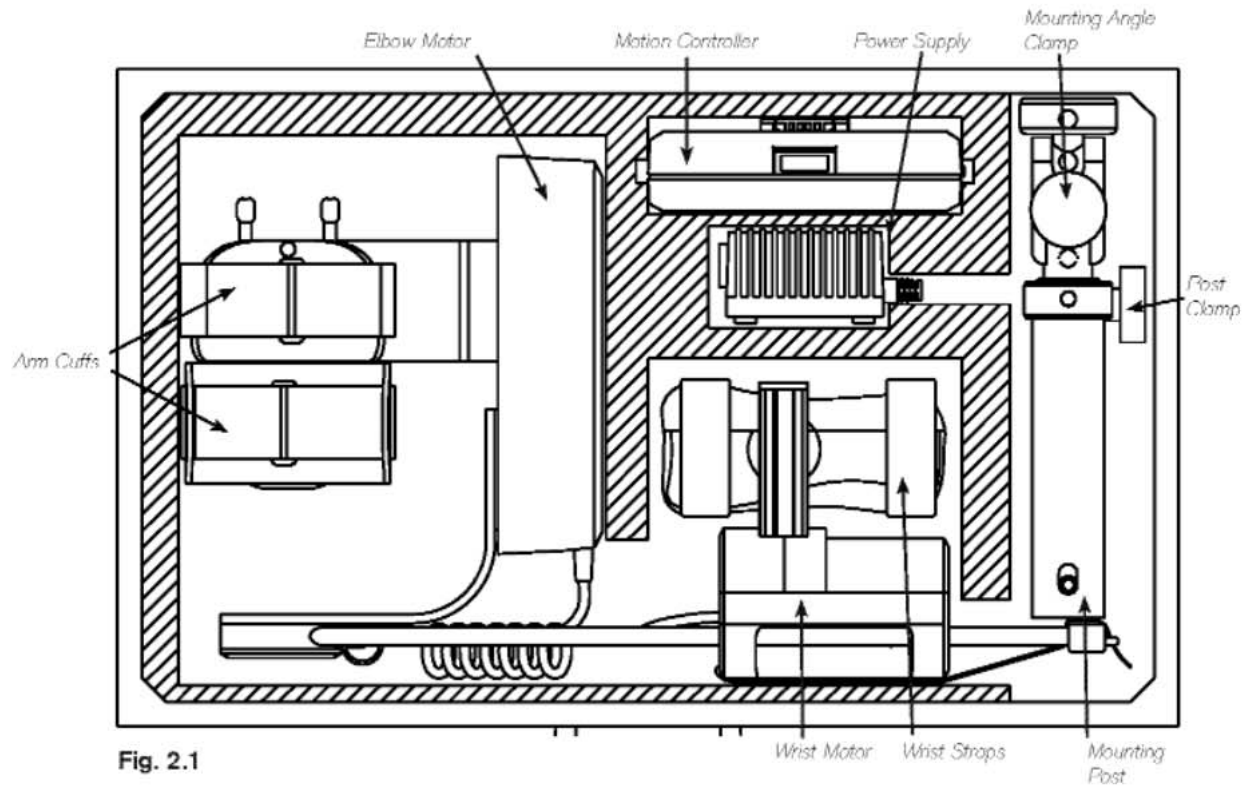


Fig. 2.1

NOTE:

Base Plate not shown for clarity.

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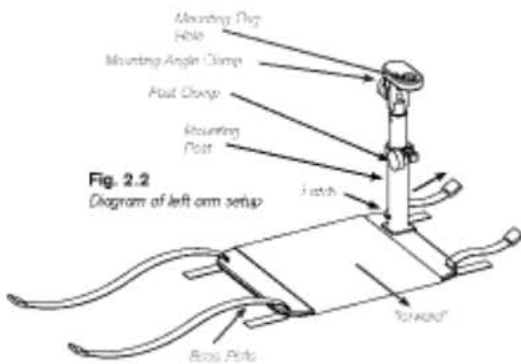


Fig. 2.2
Diagram of left arm setup

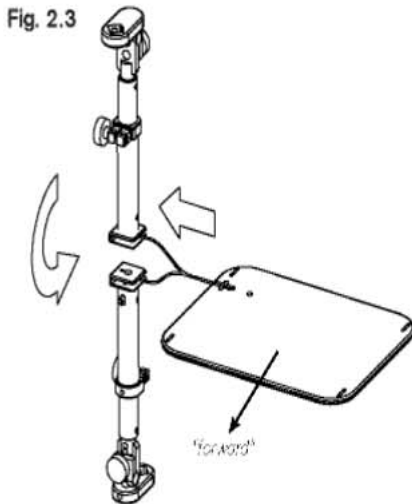
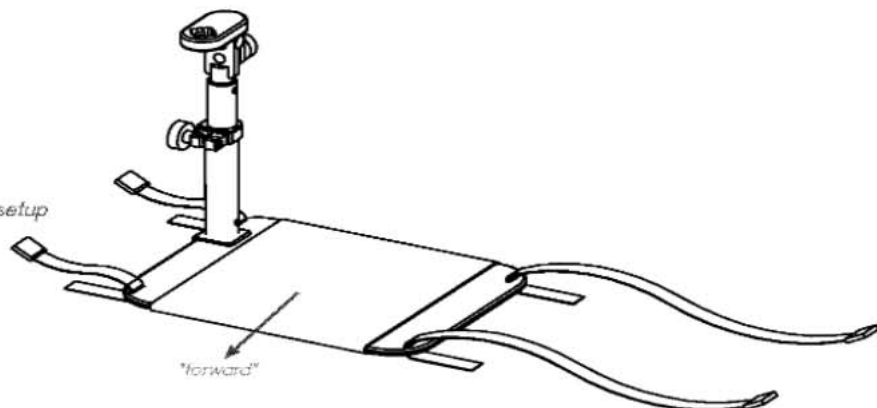


Fig. 2.3

Fig. 2.4
Diagram of right arm setup



2.2 Determine left or right arm setup.

2.3 Configure mounting accessory for left or right application.

- To change from left to right arm application, lift the latch and slide the mounting post off of the base plate. (See Fig. 2.2)
- Flip the mounting post to the opposite side of the base plate, lift the latch, and slide the mounting post back onto the base plate. (See Fig. 2.3)
- Turn the base plate so that the mounting post is upright. (See Fig. 2.4)

Note: Ensure that the mounting post latches onto the base plate.

- Loosen the post clamp and rotate the mounting block so that the mounting peg hole points forward.
- Thread the base plate straps top-down through the base plate and secure the Velcro. (See Fig. 2.4)
- Clasp the buckles under the chair (bed, sofa) and pull the straps tight so that the base does not move on the surface.

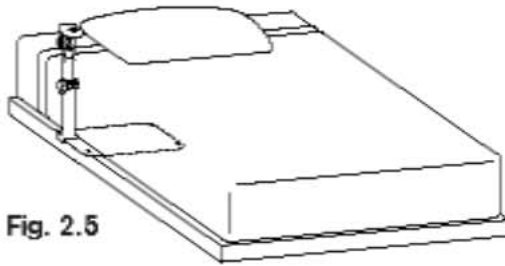


Fig. 2.5

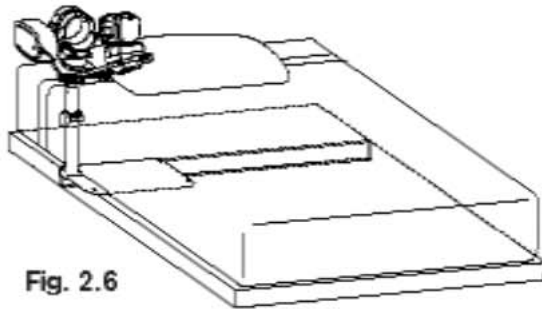


Fig. 2.6

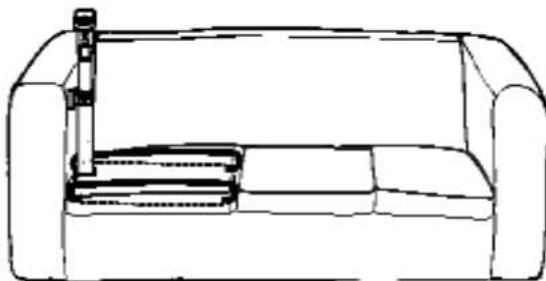
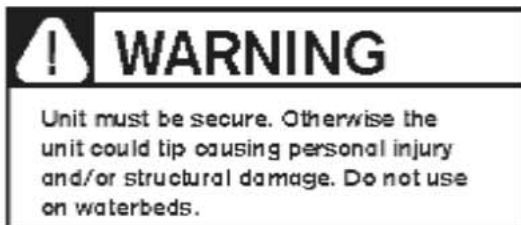


Fig. 2.8

2.4 Bed application

- Position the base plate of the mounting accessory between the mattress and frame or box-spring. The mounting post should be positioned towards the head of the bed. (See Fig. 2.5)
- Remove one (1) set of long and short straps from the base plate and buckle together. Connect the Velcro ends of the long straps together, secure one end to the mounting accessory base plate and the other to the opposite side of the bed around the bed frame. If the mattress is small enough both straps may go completely around the mattress. (See Fig. 2.6)

2.5 Chair application

- Position the base plate under the cushion of the chair if possible. Secure straps around seat base or cushion. (See Fig. 2.7)



Right arm setup



Left arm setup

Fig. 2.7

2.6 Sofa/Couch

- Position the device at the end of the sofa/couch and install base plate under seat cushion.
- Secure mounting accessory straps around frame or cushion if possible. (See Fig. 2.8)

2.7 Stability and Clearance Check

- Ensure the device is stable to support patient use.
- Verify that the mounting accessory straps are secure and that the extra strap length is stowed to prevent a hazard.

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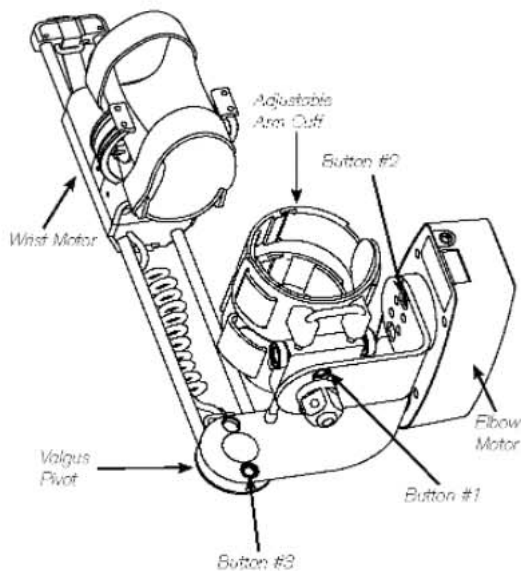


Fig. 2.9
Right Arm Setup

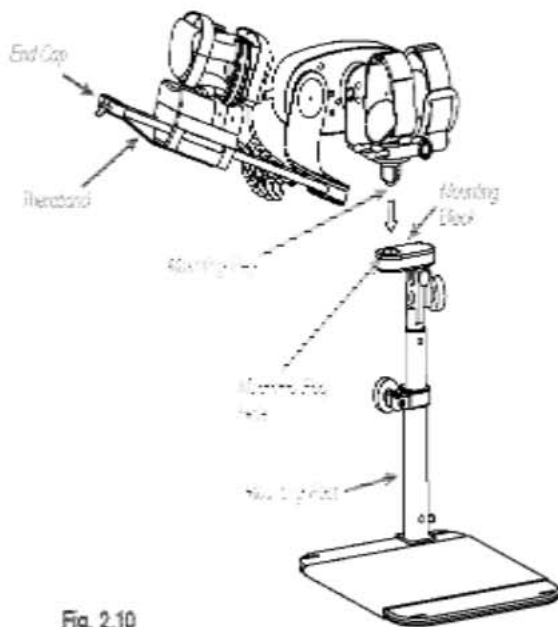


Fig. 2.10
Right Arm Setup

2.8 CPM Device Setup

- Configure the CPM device for left or right arm use.
- **Note:** For proper setup the Elbow Motor is positioned on the outside of the arm.
 - Depress blue buttons and rotate 180° as required in the following order. (See Fig. 2.9)
 - 1) Arm Cuffs – Button #1
 - 2) Elbow Motor – Button #2
 - 3) Valgus Pivot (carrying angle pivot) – Button #3
 - Ensure the adjustable cuff is uppermost
 - Ensure each button locks into position at the end of rotation.

Note: The wrist motor assembly pivots through a small angle to accommodate for the natural motion of the elbow.

- Attach the CPM device to the mounting post. (See Fig. 2.10)
 - Insert the mounting peg on the back side of the arm cuffs into the mounting peg hole on the mounting block. The button on the end of the mounting peg unlocks the frame assembly from the mounting block.
 - Make sure the frame locks into place on the mounting post.

2.9 Theraband (optional)

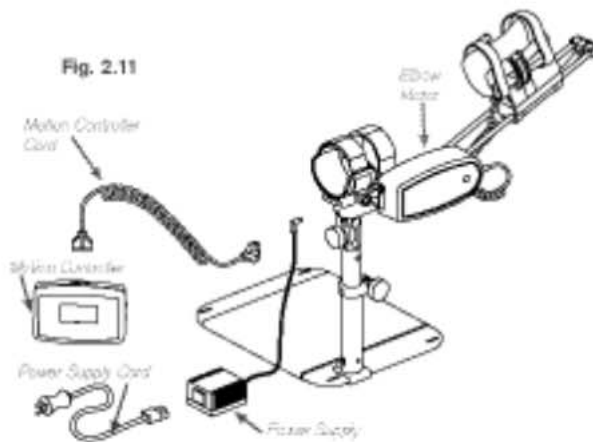
- A thin piece of elastic, latex-free Theraband may be connected from the end cap to the wrist motor to compensate for the mass of the wrist motor. If there is no Theraband, it may be installed. See wrist motor label for instructions.

Note: For Left Arm Setup

- Rotate Items 1), 2) and 3) through 180° from that shown in Fig. 2.9.

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Fig. 2.11



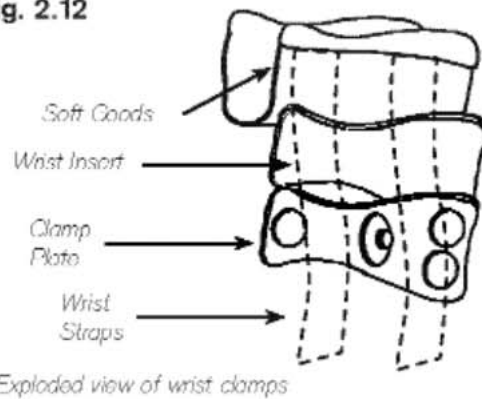
2.10 Motion Controller

- Plug the motion controller cord into the elbow motor and then into the CPM motion controller. (See Fig. 2.11)

2.11 Power Supply

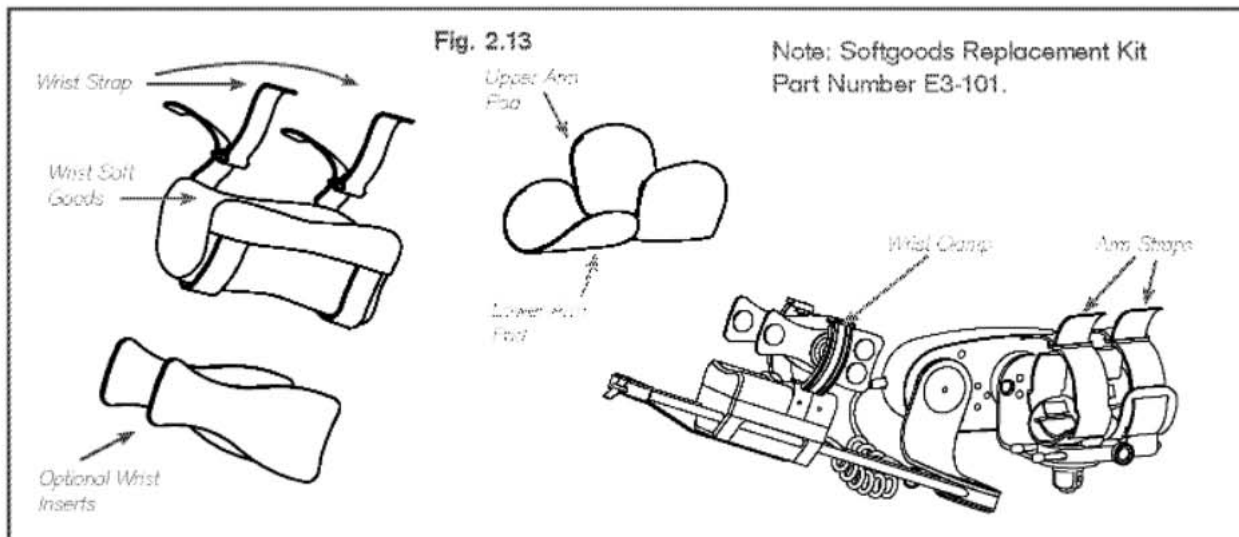
- Connect the AC cord to the power supply then plug the AC cord into an AC power outlet.
- Connect the power supply output plug into the elbow motor as shown (alternatively it may be plugged into the motion controller).

Fig. 2.12



2.12 Apply Softgoods

- Open up the arm and wrist straps and the wrist clamping plates. (See Fig. 2.12)
- Attach softgoods to upper arm cuffs, base plate and wrist clamp. Use additional pads in the wrist clamps to suit narrower wrists. (See Fig. 2.13)



3 Programming the Motion Controller

Note: See back of Motion Controller for programming summary.

3.1 Programming Operating Features

- Turn the motion controller on by moving the On button at the right side of the unit down. (See Fig. 3.1)
- If setting up a new patient, select the "New Patient, Y" key.
 - This ensures the previous patient programmed settings are erased and the Compliance Monitoring feature is reset.
- For a previous patient or ongoing use, select the "New Patient, N" key and the previous session's settings will re-established.

3.2 Setting the ROM

- Select the elbow or wrist axis by depressing the appropriate variable function key to set ROM.

Note: Both axes can be programmed while in CPM mode if desired.

- Elbow, Flexion/Extension.
 - Depress + or - keys to increase or decrease the ROM settings.
 - Depress the variable function key underneath "Exit" to return to previous screen.
- Repeat the above instructions for wrist Pronation/Supination.
- Depress the Set key to save the ROM settings or program the Force, Pause or Speed for the axis of motion. The yellow light shuts off and treatment can begin.

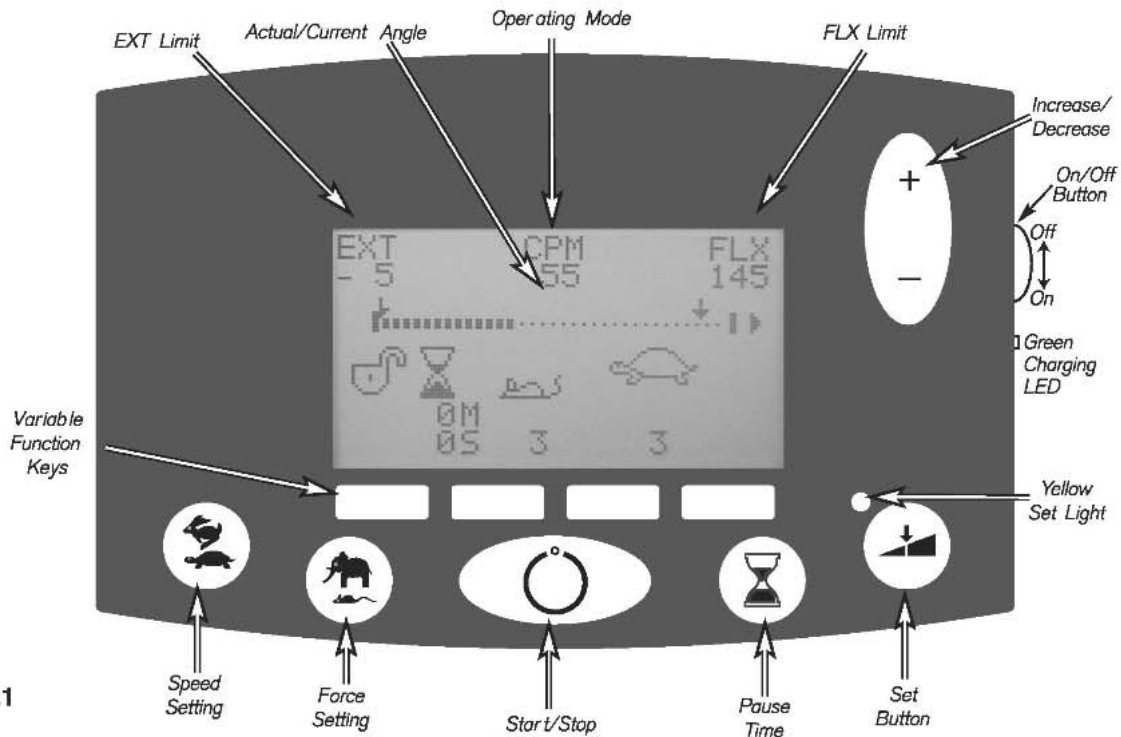


Fig. 3.1

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3.3 Setting the Force, Pause and Speed Functions.

- Stop the unit by depressing the Start/Stop key.
- Depress the Set key (a yellow light illuminates to indicate the key has been depressed).
- Select the desired function to be set (Force, Speed or Pause keys).
- Adjust the function by depressing the + or – keys to increase or decrease.
- Press “Exit” and repeat setting for each function.
- Depress the Set key (the light will go off) to store the settings and go to run mode. You will be prompted for “select mode”, “sync”, “ser” for synchronous or serial mode; press appropriate variable function key.

3.4 Test Cycle: Do NOT Skip This Procedure.

- Before placing the patient in the device, press the yellow start button to run the device through a complete cycle to ensure the operational settings are correct.
- Explain to the patient what the device is doing throughout the test cycle.



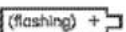

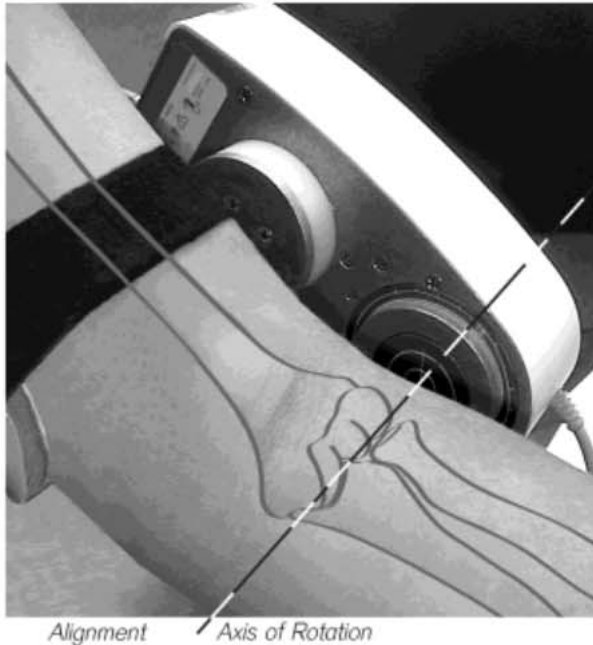
Operating Feature and Display Icon	Description
FLX	Elbow Flexion Range of Motion - Displayed at the top of the LCD display when elbow is being manipulated. Range is set when "Set" key is pressed and elbow is selected.
EXT	Elbow Extension Range of Motion - Displayed at the top of the LCD display when elbow is being manipulated. Range is set when "Set" key is pressed and elbow is selected.
PRO	Forearm Pronation Range of Motion - Displayed at the top of the LCD display when wrist is being manipulated. Range is set when "Set" key is pressed and wrist is selected.
SUP	Forearm Supination Range of Motion - Displayed at the top of the LCD display when wrist is being manipulated. Range is set when "Set" key is pressed and wrist is selected.
	Warm Up Mode - Warm Up is available in CPM mode. Treatment starts at 50% of the set range and gradually increases.
	Battery - Device is operating from battery.
	Low Battery - Low battery power. Insert power jack.
	Lock / Unlock - The "+" and "-" buttons are depressed during power up to lock or unlock settings.
SYNC/SER	Synchronized Motion Feature The SYNC feature synchronizes the maximum programmed flexion with the maximum programmed supination. If synchronized motion is not selected the programmed pro/supination motion will be completed at 90° flexion or as close to 90° as programmed.
Compliance Monitor	The Compliance Monitor logs the daily total running hours and maximum range of motion for the last 48 days. To display the stored information, depress the "Pause" key and switch on the power.

Table 3.1

4 PATIENT SETUP

Fig. 4.1



4.1 Setting Up the Patient in the Device.

- Do this only after completion of the Test Cycle.
- Raise or lower the CPM device by supporting the device and then loosening the post clamp on the mounting post to adjust for patient's comfort. (See Fig. 1.1)
- Position the patient's arm in the device, aligning the lateral bony prominence of the elbow with the elbow motor axis of rotation. The patient's shoulders should be level. (See Fig. 4.1)
- Adjust the position of the upper arm cuff by turning the silver and brass knobs on the back of the cuff to loosen and permit sliding the cuff up or down the arm. Retighten the knobs.
- Adjust and fasten the straps on the arm cuffs.
- Align the center of the wrist clamp approximately 1" (25 mm) proximal to the wrist crease and tighten the clamp knobs. (See Fig. 4.2)
- Ensure the forearm is centered in the Pronation/Supination drive ring and fasten the Velcro straps.

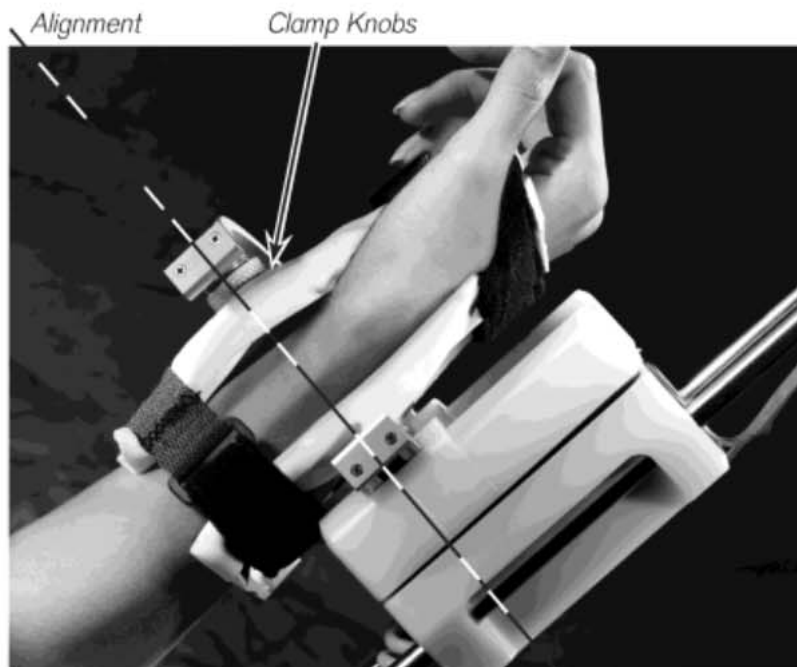


Fig. 4.2

5 TREATMENT GUIDELINES

5.1 The First Treatment.

- Start treatment by depressing the Start/Stop key at the center of the motion controller unit.
- Observe the patient for 2-3 cycles to verify for comfort and alignment. See contraindications under Section 1.4.

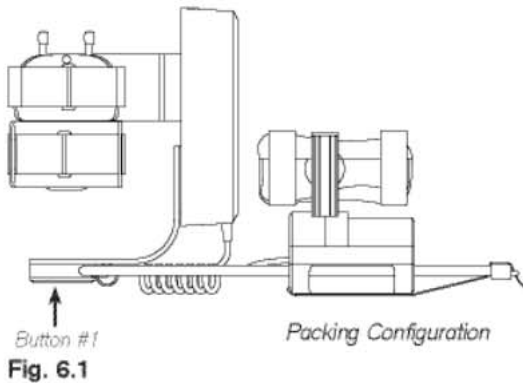
5.2 Patient Protocol

- Describe the physician prescribed protocol to the patient.
- If the patient is required to adjust the device during the prescribed protocol, instruct the patient on the features to be adjusted.
- Have the patient repeat the instruction and adjust the device accordingly.
- **Note: If the patient is at risk of injury by incorrectly adjusting the device or is not allowed to adjust the settings, lock the programmed settings on the motion controller or discontinue use and contact the patient's physician.**

5.3 Applying and Removing the Device.

- Describe to the patient how to enter and exit the device.
- Describe the alignment landmarks of the elbow and wrist clamp and how they should align with rotation axes.
- Demonstrate how to secure the arm and wrist straps and clamping mechanisms and remind the patient of the danger of using the device in improper alignment.

6 PACKAGING



Package the device in the carrying case in the following order.

6.1 Elbow and Wrist Motor Positions

- Position elbow motor drive at 90° of flexion and the wrist motor in 0° (neutral). (See Fig. 6.1)
- **Note:** The device will automatically position the motors for packaging if both Speed and Force keys are depressed while turning power on.
- Disconnect all cable connections and remove E3 from the mounting accessory.

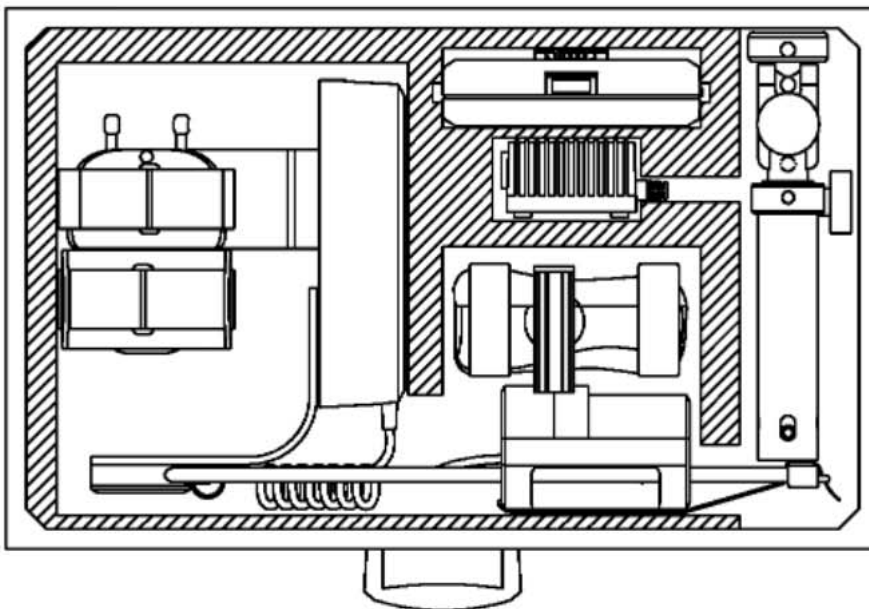
6.2 Pronation/Supination Actuator Assembly

- Depress button #1 (See Fig. 6.1) and position forearm assembly at 90° to the elbow motor.
- Place frame in carrying case as shown in Fig. 6.2.

6.3 Base Plate and Mounting Accessory

- Remove the mounting post from the base plate and place in compartment containing power cord. The base plate is laid across the top of the frame. (See Fig. 6.2)

Fig. 6.2
E3 in carrying case



7 MAINTENANCE

7.1 Rechargeable Battery

- The motion controller is equipped with a rechargeable battery which provides backup power during power outages, or patient transport. (typical duration 1 hour.)
- The battery requires 10-12 hours to charge fully, if completely discharged. The battery recharges whenever the controller **On/Off** button is set to "**On**" and the device's power supply is connected to either the controller or to the elbow motor power connector.
- If the unit has been out of service for lengthy periods, it is recommended to charge the battery as above, with the machine plugged in, turned on, but not running.
- Battery charging status is indicated by the green light emitting diode (LED) located just below the motion controller power switch. A flashing LED indicates normal charging.

7.2 Maintenance by Patients

- Patients are responsible for using the device according to the Operating Instructions. Do not wash softgoods.

7.3 Maintenance Between Patients

- Softgoods for the device are for single patient use only.
- Check the entire unit 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 unit 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 smooth.
- Gently wipe clean all exposed surfaces with a soft cloth dampened with a mild soap solution or alcohol. Wipe soap deposits from the equipment using a clean damp cloth. For stubborn areas, use a household spray cleaner applied to a soft cloth. After cleaning, wipe off residue immediately with a water-dampened cloth. Do not use abrasive cleansers. To disinfect, wipe all exposed surfaces with a 10% solution of bleach and water, or other suitable disinfectant. Do not pour cleaning solution directly onto the machine. This may allow fluids to enter the machine and cause electrical problems, or wash lubricants away from running components reducing the life span of the device. NEVER IMMERSE THE DEVICE IN FLUIDS.

- Ensure that all labels are present.
- Replace the patient softgoods kit.
- Verify that the device operates to its set limits over several complete cycles.
- For Range Of Motion (ROM) settings verify device calibration by observing the ROM of the device while taking a visual reading using a goniometer at the device's anatomic pivot points.

7.4 Maintenance Every Six Months

- Repeat steps under 7.3 "Maintenance Between Patients".

7.5 Sterilization

- The device does not require sterilization for use.
- Exposing the device to sterilization condition will damage the device and may result in a potential hazard.

7.6 Device Handling and Storage

- Do not submerge the device or any of its components in any liquid.
- Do not store the device or any of its components in a vehicle in extremely cold or hot conditions. The temperature inside a vehicle in extreme climates can exceed the recommended operating and storage temperature ranges.
- Do not sterilize the device or any of its components.
- Do not bend, twist or drop the device or controller. These actions may damage the electronics and/or device structural components.
- It is recommended that the unit be stored in the carrying case provided with the device. The carrying case is designed to protect the unit when not in use.

8 DEVICE SPECIFICATIONS

Table 8.1 Operational Environment

Temperature	57°F to 104°F (14°C to 40°C)
Maximum Relative Humidity	85% Non condensing
Pressure	25.1 in. Hg to 31.0 in. Hg (850-1050 hPa)

Table 8.2 Storage Environment

Temperature	5°F to 140°F (-15°C to 60°C)
Maximum Relative Humidity	85% Non condensing
Pressure	25.1 in. Hg to 31.0 in. Hg (850-1050 hPa)

Note: The device must remain in operational environment a minimum of 1 hour prior to use.

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Table 8.3 Operating Features and Default Settings

Operating Feature	Setting Range	Motion Controller Setting	Default Setting
Force Flexion/Extension	CPM: 2 ft. lbs. - 20 ft. lbs.	1 (lowest) - 5 (highest)	1
Force Pronation/Supination	CPM: 0.3 ft. lbs. - 4 ft. lbs.	1 (lowest) - 5 (highest)	1
Range of Motion Flexion/Extension	Flx 145° Ext -5°	Flx 145° Ext -5°	current angle
Range of Motion Pronation/Supination	Pro 80° Sup 80°	Pro 80° Sup 80°	current angle
Pause	CPM: 60 minutes - 59 seconds	0 min - 0 sec	0
Warm Up	On or Off	Icon present when On	Off
Settings Locked	unlocked or locked	Icon locked or unlocked	unlocked
CPM Motion	Synchronous or Serial	Sync	Serial
Speed	40 - 270°/minute (CPM)	1 (slow) - 5 (fast)	1

Table 8.4 Mass and Size

Description	Size and Mass
Frame Assembly	7.5 lbs. (3.2 kg)
Frame Assembly at 0° Flexion	24" x 8.5" x 7" (60cm x 21cm x 18cm)
Controller Module Dimensions	6.5" x 4.5" x 1.5" (16cm x 11cm x 4cm)
Controller Module Mass	1.2 lbs. (0.5 kg)
Shipping Configuration	10" x 17" x 21" (25cm x 42cm x 52cm)
Shipping Weight	27 lbs. (12 Kg)
Wrist Motor Mass	2.2 lbs. (1 Kg)

8.5 Power Supply

Power Supply Input:	100 to 240 VAC, 50/60 Hz., 40VA
Power Supply Output:	12 VDC, 1.25 A
Mode of Operation	Continuous
Electric Shock Classification	Class 1
Electric Shock Protection	Type B



9 TROUBLE SHOOTING

Error Codes

- Error codes are displayed on the motion controller.
- To clear an error code press the start/stop button or turn the power off for 5 seconds and back on.
- Note: If an error code does not clear, the device needs technical service. Contact customer service or your local representative.

Symptom	Solution
Display is blank	Ensure that the power supply connector is plugged into the controller or elbow motor, and that the power supply cord is connected to AC power.
Unit does not run from battery	Charge battery. See 7.1.
Error Codes E31, E32, E33:	Make sure that the curly grey Motion Controller Cord is plugged into both the E3 and the Motion Controller.
Error Code E40:	Do not switch to left- or right-hand mode with the power on. Make sure that the blue button at the Arm Cuff is locked in position and turn the power off and on.

10 SYMBOLS USED



Alternating Current



Direct Current



Attention, Consult Accompanying Documents



Off (Power: Disconnection from the mains)



On (Power: Connection to the mains)



Indicates certification to CSA and UL standards



Indicates compliance to safety and quality standards throughout all member states in the EC



Protective Earth (Ground)



Danger Electric Shock:
Service by a qualified individual only.



Use specified power supply only.



Type B applied part



Dispose of through your Registered Waste Carrier or Take-back Facility



Prescription Symbol:
Federal law restricts this device or sale by or on the order of a physician.

11 CAUTIONS AND WARNINGS

11.1 Read this manual before assembling using the E3 Elbow CPM (device). Use device only as described in this manual.

- Use the device only in accordance with the Physician prescription and Setup and Operating Instructions. 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 supplier 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 condition 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 temperature. Do not use the device on waterbeds. See Section 7.6 for the 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 motion controller if it appears damaged or if there are exposed wires.
- Store the device and component parts in the carrying case 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 (motion controller, straps, cables and power supply) to prevent a tripping hazard during use.

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.

Note: Refer to the E3 Technical Service Manual for further specifications or contact your local distributor.

12 WARRANTY / SERVICE

New Product Limited Warranty

The Manufacturer warrants the product to be free from defects in material and workmanship for a period of two (2) years for all major components (motor, power transmission parts and circuit boards) and for a period of ninety (90) days for all housing parts, knobs, hardware and sub-assemblies (excluding disposables). The warranty takes effect from the date of the original purchase from the Manufacturer, or it's Authorized Distributor, and provided the product is new and unused. No warranty shall apply if the product has been lost, or damaged by accident, abuse, misuse, or misapplication, or as a result of service or modification by other than a person authorized by the Manufacturer. This warranty shall only apply to the original buyer of the product and is non-transferable. The Manufacturer's liability under this warranty and the original buyer's exclusive remedy, is limited to the cost of materials and labor to repair the defective product, or to its replacement, and in no event shall exceed the purchase price.

To obtain Warranty service the product must be returned freight prepaid to the Manufacturer or the selling distributor, with a clear indication as to the defect. Upon receipt of a product returned under warranty, the Manufacturer will inspect the product and will notify the buyer of the extent of repair or replacement which the Manufacturer will perform under warranty. If the product is received incomplete, missing parts will automatically be replaced at the buyer's expense. The Manufacturer also reserves the right, at its own cost, to upgrade or replace parts or sub-assemblies to the latest production standards. The Manufacturer will normally perform the repair and return the product, or provide a replacement, within thirty (30) days from the day of receipt, freight collect.

THE MANUFACTURER IS NOT RESPONSIBLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE BREACH OF ANY EXPRESSED OR IMPLIED WARRANTY, INCLUDING DAMAGE 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 MANUFACTURER'S LIABILITY AS HEREIN ESTABLISHED OR LIMITED.

Returning the Device for Service

Should the device require warranty repair, the buyer must contact either the Customer Service department or the authorized distributor from which the device was purchased for return instructions.

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 and Logistics, LLC)
Attn: Customer Service
3000 Woleske Road
Marinette, Wisconsin 54143 USA
Tel: 1-888-430-1625; 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 CONTACT:

QAL Medical, LLC

3000 Woleske Road, Marinette, Wisconsin 54143 USA
Tel: 1-715-735-4727; 1-888-430-1625 Fax: 1715-732-6402
Website: www.qalmedical.com



QAL Medical, LLC®

3000 Woleske Road, Marinette, Wisconsin 54143 USA
Tel: 1-715-735-4727; 1-888-430-1625 Fax: 1-715-732-6402



Russell Square Quality Representatives, Ltd.

Ludgate House, 107-111 Fleet Street, London EC4A 2AB
info@rsqr.co.uk www.rsqa.co.uk



QAL Medical is registered to ISO 13485 for Quality Assurance