480E Family – Lower Limb CPMs CE Marked 3rd Edition

Instructions for Use

QAL Medical®

OrthoAgility®

Customer Contact:
QAL Medical®, LLC
(A division of Quality Assembly and Logistics, LLC)
3000 Woleske Road
Marinette, Wisconsin 54143 USA
Tel: 1-888-430-1625
Email: cpm-csr@qualityal.com
Website: www.qalmedical.com

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1 Intended Use

1.1 Introduction

The 480E family of Continuous Passive Motion (CPM) system is designed for the rehabilitation of the lower limbs. The 480E family of CPMs offers interchangeable foot cradle components allowing standard and pediatric patient usage.

1.2 Application

Continuous Passive Motion (CPM) is best applied immediately post-operative for up to six weeks as per physician's prescription.

1.3 Clinical Advantages/Indications

- Maintenance of range of motion.
- Prevention of negative effects of immobilization.

1.4 Use (Past and Present)

Physicians have prescribed immediate post-operative CPM use for the following:

- Total knee surgery
- General knee surgery
- Fracture rehabilitation
- Reconstructive surgery on bone, cartilage, tendons and ligaments
- Prolonged joint immobilization

1.5 Contraindications/Residual Risks

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

- Untreated or uncontrolled infection
- Unstable fractures
- Hemorrhage
- Nickel allergy/sensitivity
- Indoor use only
- Do not immerse in liquid

♦ ***Caution:*** **If signs of infection such as fever, redness, irritation, warmth, swelling, bleeding and/or increased pain are present, discontinue use of the CPM device and contact the patient's physician. Do not continue using the device until the physician has approved continuing use of the device.**

1.6 Safety Features

Read manual before use and operating the device. We recommend that all clinicians and others responsible for the operation of this device become thoroughly familiar with its capabilities and proper operation procedures prior to actual patient use. Skill at measuring the patient and adjusting the device accordingly will come with experience and practice.

Reverse-On-Load

The device is designed to automatically reverse direction if an obstruction occurs.

Safety Considerations

Please make the patient aware of the following considerations:

- Use the device only according to the physician's prescription and instructions for use. Failure to do so may result in damage to the device and/or personal injury.
- Soft goods are for single patient use only. (Not to be reused).
- The device should not be used near flammable materials like anesthetics.
- Use only manufacturer's supplied replacement parts.
- Do not use the device if there are mental or physical conditions that prohibit 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 prohibit the safe use of the device.
- Position the device in a comfortable position. Make sure the device is stable through its full range of motion.
- Keep hair and loose clothing, fingers and all parts of the body away from moving parts of the device.
- Do not expose the device to water or extreme temperatures.
- Do not use the device near exposed flames, while smoking or near excessive heat.
- Turn the device off when not in use.
- 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.
- Do not store device above 40˚C (104˚F).
- Only a Qualified Service Technician should service the medical device.
- The device will produce minimal electromagnetic fields and has been tested to pass IEC 60601-1:2005 and collateral standard for EMC 60601-1-2:2007.
- Use specified power supply only.
- Do not store device under a bed, which has less than 19 inches of clearance at all times.
- 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, turn the device off and unplug from the power supply.
- The power supply delivers less than 20 volts DC to the device. The family of CPM devices will tolerate electrical supply variations which may be found in the home or hospital environments.

Specific Device Safety Features

- The Start/Stop Button on the controller gives the patient the ability to stop or interrupt the action of the device should he/she experience discomfort. The patient can restart the device (in the opposite direction) upon pressing the Start/Stop button a second time.
- The 480E family of CPM devices are equipped with a warmup feature that when selected

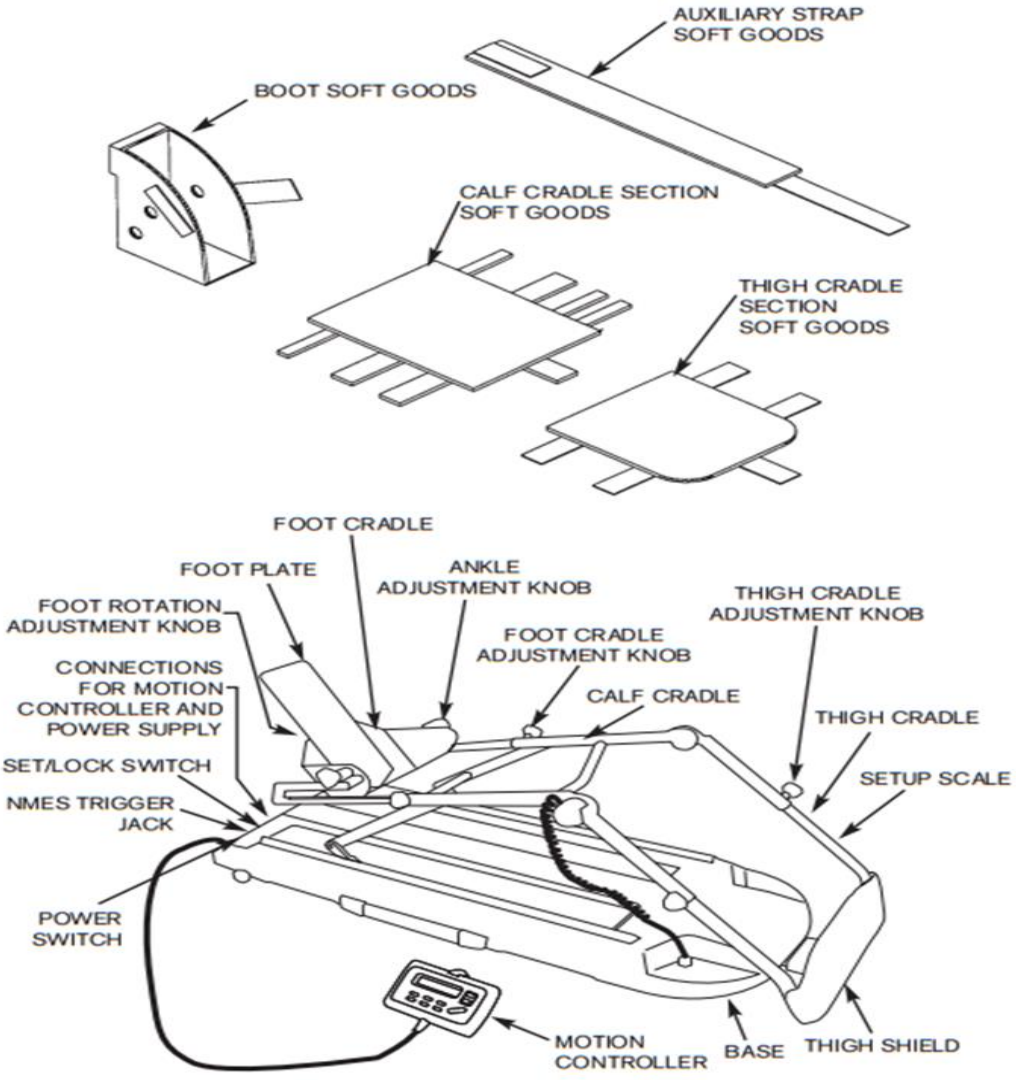
cycles the device through a much smaller range of motion than programmed and slowly increases the range over a series of cycles until the full range of motion is reached.

- ***Caution:*** **The power supply is part of the device. The supplied power supply MUST be used at all times.**

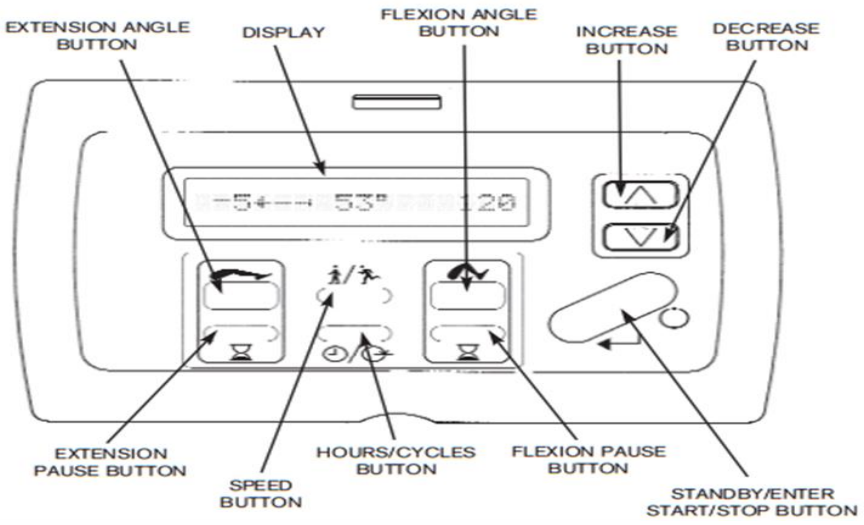
- ***Caution:*** **Make sure placement of device allows plug to be disconnected from power source.**

2 Components Overview

2.1 480E Family



2.2 Motion Controller



3 Setting up a 480E Device

3.1 Unpacking a 480E CPM Device

Remove all of the 480E CPM device system components from the carton. During unpacking, check for external damage. Report any substantial damage to the distributor or QAL Medical ®, LLC Customer Service.

- ***Note:*** **Save packaging for storage when the device is not in use. Additionally, it if is ever necessary to return for service, this packaging provides all the protection that is required under warranty.**

Make sure that both the Power Cord and Motion Controller Cord are uncoiled from the device.

3.2 Attaching the Soft goods to a 480E Device

Coverings for a 480E device are made of a synthetic material. They are easily adjusted, offer the necessary limb support, and provide a comfortable surface for prolonged contact with body surfaces.

- ***Note:*** **Soft goods are for single patient use only.**

1. Beginning with the Thigh Cradle Section (Make sure thigh shield is in place) place matching hook and loop fasteners.

- ***Note:*** **One strap will attach on the underside of the Thigh Pivot Block. Be sure coverings are adjusted for both support and comfort.**

2. Next, working on the Calf Cradle Section, attach Boot by placing the elastic flap over the Foot Plate (sole of Boot adheres to Velcro on the Foot plate).
3. After placing the patient's foot in the Boot, fold the sides inward and attach the straps tightly to hold the foot securely.

- ***Note:*** **An Auxiliary Strap is provided and may be used to securely hold the thigh or calf to the device.**

3.3 Power Supply and Motion Controller for a 480E Device

3.3.1 Motion Controller

Connect the Motion Controller to the connector on the end of the device and tighten the plug's lock nut.

3.3.2 Power Supply

1. Connect the Power Supply to the connector on the end of the device and tighten the plug's lock nut.
2. Plug the power cord into the power supply. Plug the other end of the power cord into a standard (grounded) wall outlet.

3.4 Measuring Patient and Adjusting the Length of the Device

- ***Note:*** **Make sure the leg carriage is in extension when fitting the patient to the device.**

3.4.1 Thigh Measurement and Adjustment

1. Using a measuring tape, determine the length of the patient's thigh.
2. Loosen Thigh Cradle Adjustment Knobs on both sides of the thigh tubes (Section 2.1, Overview of a 480E Device).
3. Fit thigh shield to gluteal crease of patient (the bottom of the buttocks).

- ***Note:*** **The knee pivot on the CPM should align with the approximated center of the patient's knee joint.**

4. Lengthen or shorten both sides equally.
5. Tighten both adjustment knobs securely.

- ***Note:*** **If readjustment is necessary, do not attempt to adjust only one side as this can cause damage to the device.**

3.4.2 Calf Measurement and Adjustment

1. Using a measuring tape, determine the length of the patient's calf and foot.

- ***Note:*** **Measure from the center of the patient's knee joint to 1/4 inch beyond the heel of the patient's foot to accommodate Boot padding.**

2. Loosen adjustment knobs on both sides of the Calf Cradle and adjust both sides equally.
3. Tighten both knobs securely.

3.4.3 Setup Scale

The letters on the setup scale may be recorded to recall a patient's adjustment from one treatment session to the next.

3.4.4 Ankle Setup

1. 1.To allow free movement of the ankle, loosen ankle adjustment knobs located on the Foot Cradle.
2. For rotation of the foot, loosen the adjuster knob located on the back of the Foot Cradle and reset to the right or left side as required (Figures 1 & 2).

Figure 1

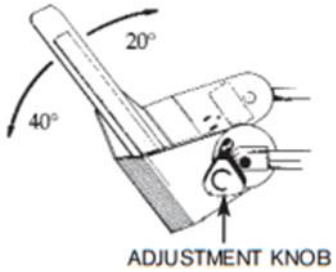
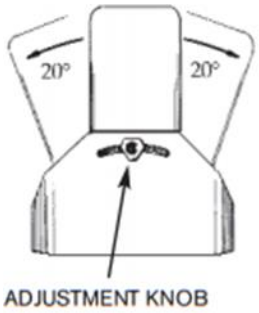


Figure 2



3.5 Attaching a 480E Device to the Bed

3.5.1 Home Bed Mount Kit

(Part Number 12200)

A Home Bed Mount is available for the 480E family of CPM devices. This kit secures the CPM to the bed for home use. The Home Bed Mount attaches to the base via 2 tubes, which are secured with set screws. The CPM is secured to the bed with the "L" brackets that can attach to the mattress or the bed frame.

3.5.2 Hospital Bed Mount Kit

(Part Number 12138)

A Standard Hospital Bed Mount is available for the 480E family of CPM devices. This lightweight clamp provides stability and permits maximum flexibility for positioning the device on the bed.

The Standard Hospital Bed Mount will fit on either side of the CPM base. To adjust the position of the bed mount, loosen set screws, position the device at any angle, and secure the set screws. (If the bed is raised or lowered, readjust bed mount to proper position.)

3.5.3 Traction Bed Mount Kit

(Part Number 10363)

A Traction Hospital Bed Mount is available for the 480E family of CPM devices. This kit provides maximum stability for the CPM.

- ***Note:*** **The Traction Bed Mount differs from the Standard Bed Mount in that the Traction Bed Mount attaches to the CPM at two points thus forming a stable triangulated attachment.**

3.6 Changing Modular Components

The 480E family of CPM devices offers a unique design, accommodating standard and pediatric patients by simply changing modular components on the device.

3.6.1 Standard Pediatric Foot Cradle

1. Loosen the Foot Cradle Adjustment Knobs (Section 2.1, Components Overview).
2. Remove Foot Cradle from the Calf Cradle.
3. Install desired Standard/Pediatric Foot Cradle, making sure the Foot Plate is in the upright position.
4. Select appropriate length for the Foot Cradle and tighten Foot Cradle Adjustment Knobs.

4 Operating a 480E Device

- ***Notes:*** **Tighten all knobs and fasteners before use.**

  Verify Range of Motion (ROM) settings by operating the CPM through one full cycle before use.

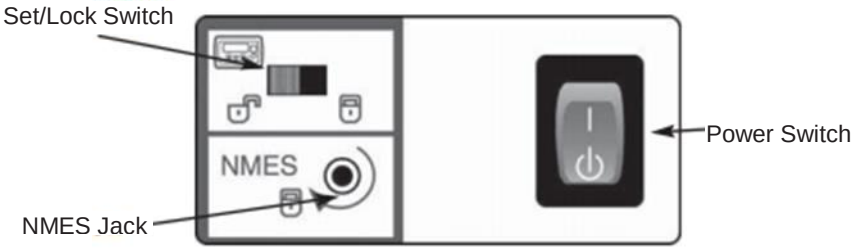
  A complete calibration is required if:
  - **Any components have been replaced**
  - **Any visual damage is noticed**
  - **Erratic motion occurs during operation**
  - **Any of the covers have been removed**

  Only qualified technicians should perform Service. Training is available through the manufacturer.

4.1 Turning on a 480E device

Turn device on via the Power Switch located on the end of the device (Figure 3).

Figure 3



- ***Note:*** **Each time a 480E device is powered up, the motion controller's display will prompt the user to choose Warm up and Timer features. The Extension, Flexion, Speed and Pause settings will be the same as when the device was last run.**

4.2 Start/Stop Control Button

The patient may stop and restart the CPM at any time by depressing the Start/Stop button on the Motion Controller (Section 2.2).

The device will proceed in the opposite direction upon restarting.

4.3 Warm up Feature

The 480E family of CPM devices are equipped with a warm up feature that when selected cycles the device through a much smaller range of motion than programmed and slowly increases the range over a series of cycles until the full range of motion is reached.

4.3.1 Selecting Warm Up Feature

1. Turn on the device from the power switch located on the end of the device.
2. In the motion controller display window, the operator is prompted with the choice of whether to initiate the Warm up feature or not. The operator must choose 'Yes' or 'No' to proceed. To select the Warm up feature, choose 'Yes' by pressing the extension on the Motion Controller (Section 2.2, Motion Controller Overview).

- ***Notes:*** **Upon pressing the Start/Stop button the device will run through the full range of motion that was last programmed into the Motion Controller.**

  If the device is stopped by depressing the start button on the Motion Controller and then restarted, the warm up cycle will be repeated.

4.3.2 Unselecting Warm Up Feature

1. Turn the device off and on again at the power switch.
2. Select 'No' to 'Warmup' feature prompt.

4.4 Timer Feature

The 480E family of CPM devices are equipped with a Timer feature that when selected allows the operator to preset the duration of the treatment session (Figure 5).

Figure 5

Time can be set in 10-minute increments up to 480 minutes (eight hours). Once the treatment session is over, a 480E device will run to the middle of the set range of motion and stop. The motion controller will display a flashing timer symbol. The operator must turn the device off and on again at the power switch to proceed (Section 2.1, Overview of Family of 480E Devices).

When Timer has been selected, the operator may view the time remaining by pressing the increase or decrease buttons (Section 2.2, Motion Controller Overview).

Once the timer has been set, the operator cannot adjust the time without turning the device off and on, then reselecting 'Timer'.

4.4.1 Selecting Timer Feature

1. Turn on the device from the power switch located at the base of the device.
2. Following the prompt for warm up, the operator will be prompted for the Timer. The operator must choose 'Yes' or 'No' to proceed.
3. To select the Timer feature, choose 'Yes' by repressing the Extension button on the Motion Controller (Section 2.2, Motion Controller Overview).
4. The operator can then set the treatment session time in 10-minute increments using the ∆ Increase or ∇ Decrease arrow buttons.

- ***Notes:*** **Pressing the Start/Stop button will save the time and advance to the run screen.**

  The Timer will not function if a time of 0 minutes is set.

4.4.2 Unselecting the Timer Feature

To avoid the Timer feature, choose 'No' by pressing the Flexion button.

- ***Note:*** **The Timer will not count time while the device has been stopped by depressing the button on the Motion Controller. It will count time that passes during set pause times at the ends of the Flexion and Extension cycles.**

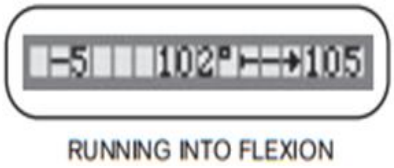
4.5 Setting Range of Motion (ROM)

Using the Motion Controller, set the Range of Motion (ROM) parameters by pressing and holding the Extension or Flexion buttons while simultaneously depressing the desired ∆ Increase or ∇ Decrease arrow buttons. The Extension and Flexion angles will change slowly for the initial 5° (allowing for precise adjustment), after 5° the parameters will change rapidly (allowing for quicker adjustment).

- ***Notes:*** **The device has been designed for a 5° minimum ROM and will not allow limits to be set less than 5° from each other.**

During normal operation, the large center display area of the Motion Controller continuously displays the Knee Pivot angle of the CPM device (Figures 6 & 7).

Figure 6



RUNNING INTO FLEXION

Figure 7

RUNNING INTO EXTENSION

4.6 Speed Setting

The 480E family of CPM devices operates at speed cycles from 16° to 160° per minute. To check speed setting, depress and hold the Speed button. The center of the display window will indicate the present speed of the CPM by displaying a simple bar graph. Minimum speed is represented by a single bar. Maximum speed is represented by all bars being displayed (Figure 8).

Figure 8

SPEED

4.6.1 Adjusting Speed

To adjust Speed, depress and hold the Speed button while simultaneously depressing either the Δ Increase arrow to increase speed or ∇ Decrease arrow to decrease speed (Section 2.2, Motion Controller Overview).

4.7 Pause Setting

A pause of 0 to 30 seconds may be selected at the end of the Extension and/or Flexion cycles. The Pause setting can be checked by depressing the Pause button located under the Extension or Flexion buttons. The number of seconds will appear in the center of the display window upon depressing each Pause button.

4.7.1 Setting Pause

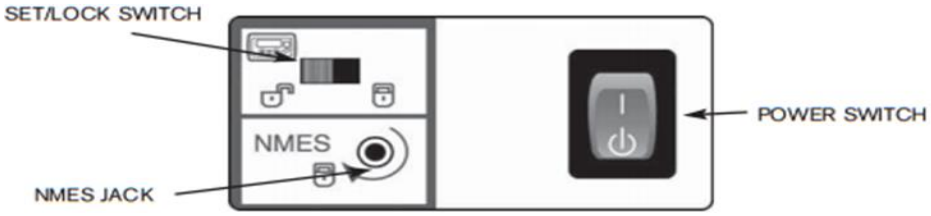
To change Pause settings, depress and hold either Pause button and adjust with the Δ Increase or ∇ Decrease arrow buttons.

- ***Note:*** **When changing both Pause functions (Extension and Flexion), repeat the above steps for setup of each Pause function separately.**

4.8 Neuro-Muscular Electrical Stimulation

Neuro-Muscular Electrical Stimulation (NMES) may be used during the Extension Pause mode only. Simply set the desired pause interval and connect a Muscle Stimulation Device to the NMES trigger jack located at the base of the device (Figure 9).

Figure 9

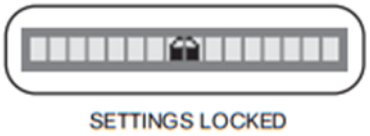


- ***Note:*** **To prevent inadvertent loss of synchronism between the CPM and the chosen muscle stimulator, use only medical grade link cables with locking plugs. The NMES trigger jack will deactivate the muscle stimulator one second before the end of the Extension Pause Mode. Refer to the muscle stimulator instruction manual for proper set-up.**

4.9 Lockout Settings

Motion Controller settings (ROM, Speed, Pause) can be locked out to prevent inadvertent changes by the patient (Figure 10).

Figure 10



- ***Note:*** **Attempting to change settings while the Lockout feature is engaged will result in the lock symbol appearing in the center display window.**

4.9.1 Setting Lockout

To set the Lockout feature place the Set/Lock switch located on the end of the device in the LOCK position.

4.9.2 Unlocking the Lockout Feature

To unlock the Lockout feature, place the Set/Lock switch in the  Set position.

4.10 Hours/Cycles Meter

To check the number of User Cycles since the last reset, simply depress the Hours/Cycles button. User hours and cycles will appear in the display window (Figures 11 & 12).

Figure 11

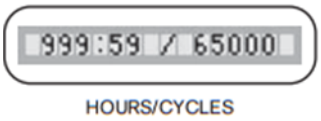
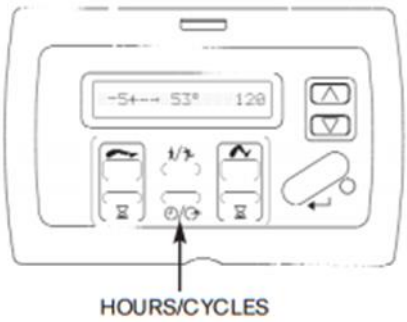


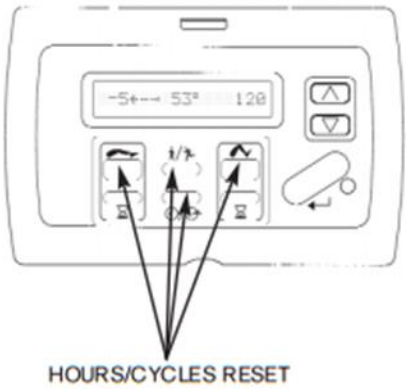
Figure 12



4.10.1 Resetting Hours/Cycles Meter

To reset the User Hours and Cycles, depress ‘Extension’, ‘Speed’, ‘Hours/Cycles’, and ‘Flexion’ simultaneously. “HRS & CYC RESET” will appear in the display window (Figure 13).

Figure 13



5 Technical Data

5.1 Specifications and Operating Limits

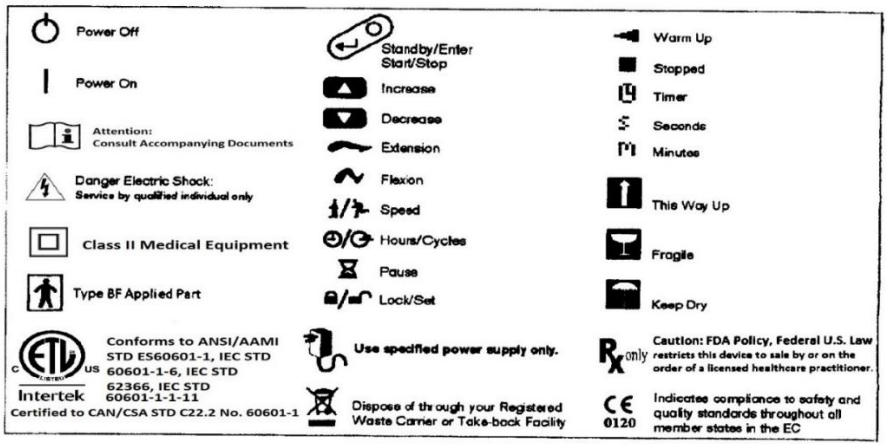
Unit Weight	11 kg	(24 lbs.)
Configuration Limb Length Calf Length Thigh	**Standard** 28.5 – 41 in. (73 – 104 cm) 16.5 – 24 in. (43 – 61 cm) 12 – 17 in. (30 – 43 cm)	**Pediatric** 21.5 – 35.5 in. (53 – 90 cm) 9.5 – 18.5 in. (24 – 47 cm) 12 – 17 in. (30 – 43 cm)
Maximum Patient Weight	300 lbs. (136 kg)	
Range of Motion (ROM):	-5° extension to 120° flexion	
Flexion Speed	16 to 160° per minute	
Pause	0-30 seconds at maximum extension/flexion	
Timer	10 – 480 minutes	
Mode of Operation	Continuous	
Power Supply		

Input	100-240 VAC, 1.5A, 50-60 Hz
Output	12 VDC, 5.0A
NMES	Compatible with various NMES devices
Safety	CE Marked
Device Protection Classification	Class II Medical Equipment
Degree of Shock Protection	Type BF
Environmental, Storage and Transport Conditions	-10° to 35° C (14° to 95° F) temperature, 90% maximum humidity, ATM pressure 750 hPa to 1040 hPa
IP Rating *	IP 21 Device, IP 22 Controller

***IP Rating is a rating code that identifies the amount of protection a given product has against dust and fluid.**

- ***Notes:*** **Allow device to reach room temperature for a minimum of one hour prior to use. Equipment not suitable for use in the presence of flammable anesthetic mixture with air or Nitrous Oxide.**

5.2 Symbols



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consult instructions for use manual

consult technical manual before servicing

6 Maintenance

- Information needed for service personnel can be found in the Technical and Service Manual, Final Inspection and Product Test criteria available through QAL Medical®, LLC Customer Service or your local distributor.
- **Expected Service Life:** The device's expected service life is 2 years, which is limited to the life of the motor. With proper maintenance, the device can last longer.

Maintenance Between Patients

Immediately following each patient use:
The CPM Patient Kit should be removed and discarded and the unit cleaned**.** CPM devices are constructed with components made from aluminum (silver), stainless steel (silver), polycarbonate plastic (blue), modified polyphenylene oxide plastic (light blue, trade name Noryl), acetyl plastic (white), polypropylene plastic (translucent white), polyethylene plastic (translucent white), nylon web straps (black). These materials offer excellent resistant to common cleaning materials such as soaps and mild cleaning agents when used as recommended.

- Use a cloth and a mild soap solution to remove dirt and deposits.
- 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 pour cleaning solutions directly onto the machine. This may allow fluids to enter the machine and cause electrical problems, or wash lubricants away from the running components reducing the life span of the device.
- Never immerse the device in fluids.
- Soft goods 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.
- Make sure that all knobs and/or levers are usable and in place.
- Make sure 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.
- Make sure that all labels are present.
- Replace the patient soft goods 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. Compare the ROM settings of the device with the goniometer readings. ROM readings should be within +/- 5° of the set parameters. If the readings do not fall within the set parameters, the device needs to be checked and recalibrated by a properly trained Service Technician using the Final Inspection and Product Test criteria available through QAL Medical®, LLC Customer Service or your local distributor.

Maintenance Every Six Months

Repeat steps under “Maintenance Between Patients.”

Maintenance Every Twelve Months

Repeat steps under “Maintenance Between Patients.”

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 drive components, and repair or replace as necessary.
- Perform a complete recalibration and subsequent check of electronic and mechanical safety systems including Reverse-on-Load function and Range of Motion controls.
- Complete a final check of the device in accordance with QAL Medical Final Inspection and Product Test criteria. (These are available through QAL Medical®, LLC 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.

7 Troubleshooting

Problem	Possible Cause	Fix
Device will not power up. Device does not beep.	No Power to device. Main PCB Failure. Motion controller cable disconnected.	Replace power cord, power supply or switch. Replace PCB. Check motion controller cable at both ends. Return for service.
Motion controller, erratic display.	Motion controller cable break. Motion controller PCB failure. Main PCB failure.	Replace cable. Replace PCB. Return for service.
Error codes: E1, 2, 3, 4, 6, 7, 8, 12, 13, 14, 15, 16, 18	Out of calibration. Main PCB failure. Motion controller cable break. Motion controller PCB failure.	Re-calibrate device following calibration procedures. Replace PCB. Replace motion controller cable. Replace motion controller. Return for service.
Error code E9	Calibration error. Motion controller cable break. Motion controller PCB failure.	Re-calibrate following calibration procedures. Replace motion controller cable. Replace motion controller. (kit #L480SA033E) Return for service.

Error codes: E10, 11, 21	Kneepot cable break. Kneepot. Main PCB failure.	Replace kneepot cable. Replace kneepot. Replace main PCB. Return for service.
Error code E20	Main PCB failure	Replace PCB Return for service
Mechanical binding/jerking.	Insufficient lubrication on track, ballscrew and track seals. Bearing bracket assembly failure. Ballscrew failure. U-bracket/slider assembly failure. Motor failure.	Use a Light Lithium based lubricant, Lubricate #105 on the ballscrews and a silicone spray on track seals and tracks. Replace bearing bracket assembly. Replace ballscrew assembly. Replace bracket/slider assembly. Replace motor. Return for service.
Insufficient lifting power.	Motor failure. Bearing bracket assembly failure.	Replace motor. Replace bearing bracket assembly. Return for service.

8 Ordering Information and Accessories

480EPK	Soft goods Kit
11261	Knob Kit
12200	Home Bed Mount
12138	Standard Hospital Bed Mount
10363	Traction Bed Mount
11329	Kit, Kneepot Cover with Fasteners
11274	Kit, Fasteners for Bottom Cover
WP480PK	480 Series Reusable Plastic Patient Kit, White
WP480EPK	480E Series Reusable Plastic Patient Kit, White
Modular Components:	
12604	Pediatric Foot Cradle
L480SA016	Standard Foot Cradle

9 New Product Warranty

QAL Medical®, LLC a Division of Quality Assembly & Logistics, LLC warrants the product to be free from defects in materials and workmanship for a period of two (2) years for all critical components (motor, power supply and circuit boards) and for a period of ninety (90) days for all other components, such as housing parts, knobs, hardware and sub-assemblies (excluding disposables). The warranty takes effect from the date of the original purchase from QAL Medical®, LLC or its Authorized Distributor or the original activation date into the QAL Medical®, LLC rental pool, and provided the product is new and unused. No warranty will be recognized or honored unless all applicable service records can be supplied with the service request.

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 someone other than a person authorized by QAL Medical®, LLC. This warranty shall only apply to the original buyer of the product and is nontransferable. QAL Medical®, LLC liability under this warranty, and the original buyer's exclusive remedy is limited to the cost of the materials and labor to repair the defective products, 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 QAL Medical®, LLC or the selling distributor with a clear indication as to the defect. Upon receipt of a product returned under warranty, QAL Medical®, LLC will inspect the product and will notify the buyer of the extent of repair or replacement that QAL Medical®, LLC will perform under warranty. If the product is received incomplete, missing parts will automatically be replaced at the buyer's expense. QAL Medical®, LLC also reserves the right, at its own cost, to upgrade or replace parts or sub-assemblies to the latest production standards. QAL Medical®, LLC will normally perform the repair and return the product, or provide a replacement, within thirty (30) days from the day of receipt, freight collect.

QAL MEDICAL®, LLC 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 PARTICULAR PURPOSE. NO STATEMENT OF ANY REPRESENTATIVE SHALL EXTEND QAL MEDICAL®, LLC'S LIABILITY AS HEREIN ESTABLISHED OR LIMITED.

Returning the Device for Service
Should the device require warranty repair, buyer must contact either the Customer Service Department or the Authorized Distributor from which the device was purchased for return instructions.

If any warranted product is found by QAL Medical®, LLC to have a defect covered by this warranty, QAL Medical®, LLC 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:

Customer Service:
QAL Medical®, LLC
Attn: Customer Service
3000 Woleske Road
Marinette, Wisconsin 54143 USA
Tel: 1-888-430-1625
Fax: 1-715-735-6402
Email: cpm-csr@qualityal.com
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

Disposal of Device
For proper disposal of the device, contact your distributor or the listed manufacturer.

QAL Medical®, LLC
3000 Woleske Road, Marinette, Wisconsin 54143
Tel: 1-888-430-1625 Fax 1-715-732-6402

EC REP
Emergo Europe
Prinsessegracht 20, 2514 AP
The Hague, The Netherlands
www.emergogroup.com

CE 0120

QAL Medical®, LLC is registered to ISO 13485 for Quality Assurance