QAL Medical™

OrthoAgility™

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480E

(GB) **Instructions for Use**
(F) **Mode d'emploi**
(S) **Inpassningsanvisningar**

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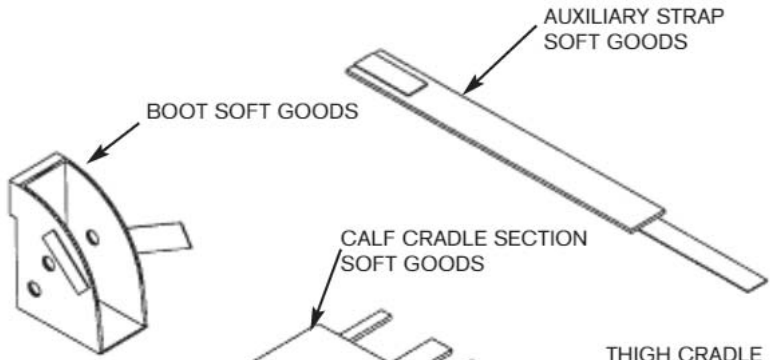


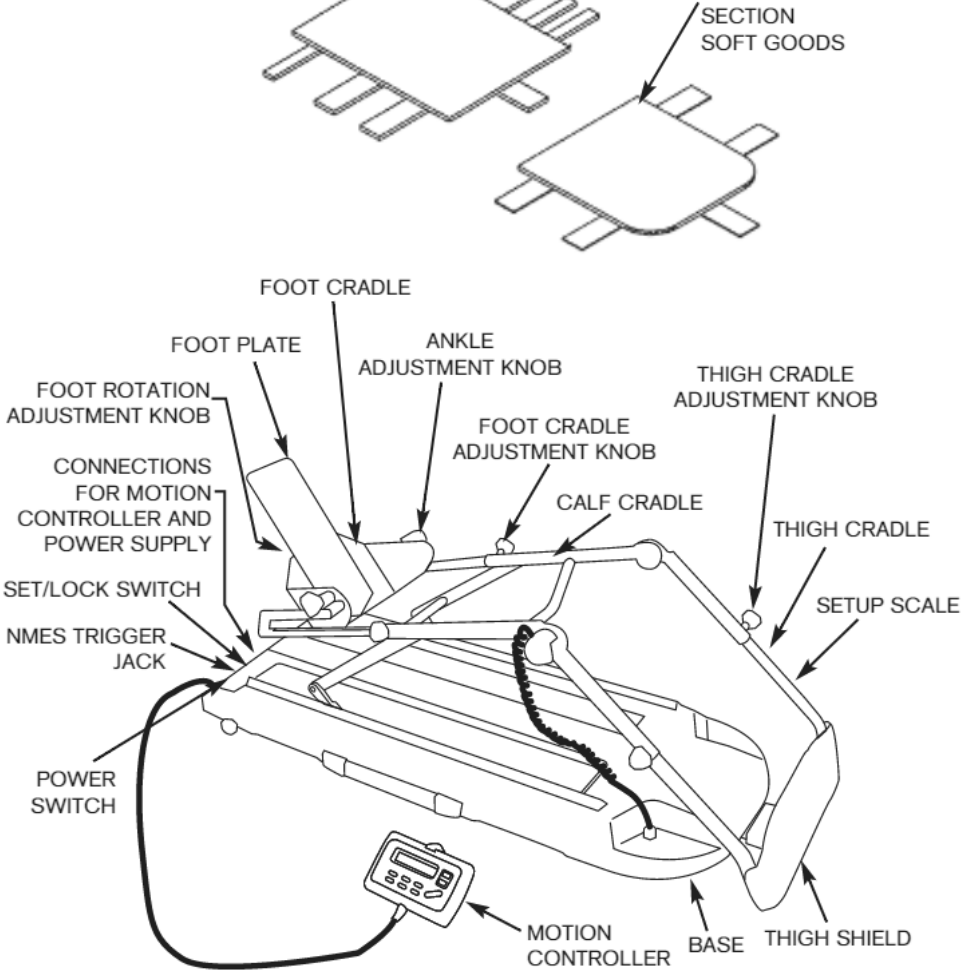


Fig. 1 – 480E CPM Device

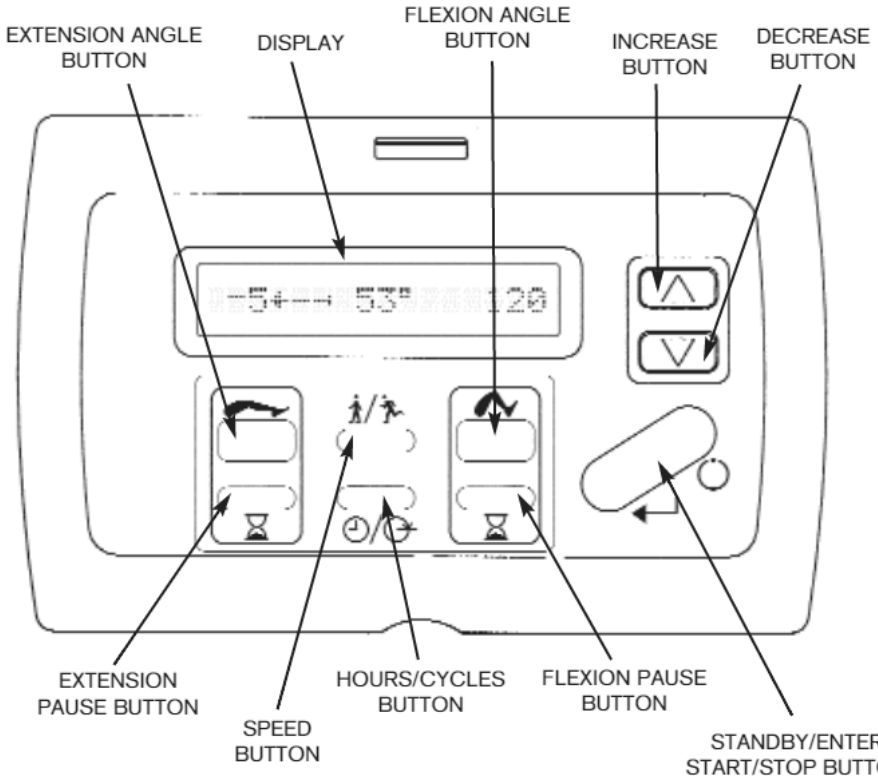


Fig. 2 – 480E Motion Controller

SET/LOCK SWITCH

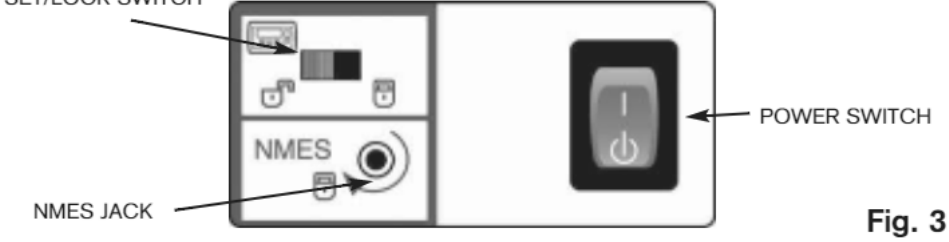


Fig. 3

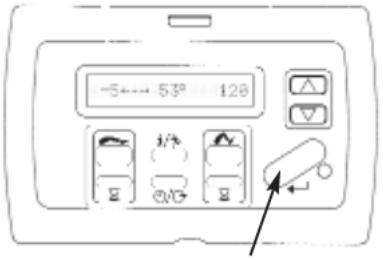
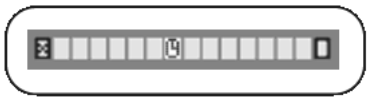


Fig. 4

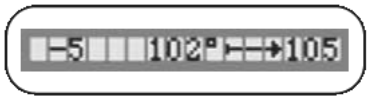
WARM UP

Fig. 5



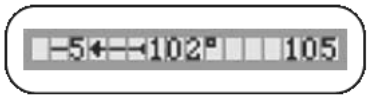
TIMER

Fig. 6



RUNNING INTO FLEXION

Fig. 7



RUNNING INTO EXTENSION

Fig. 8

SPEED

Fig. 9

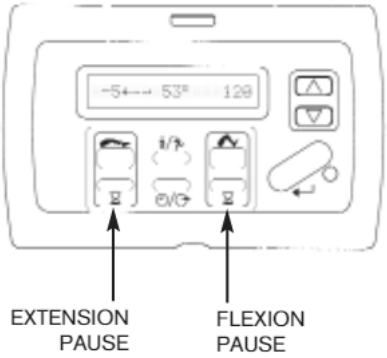
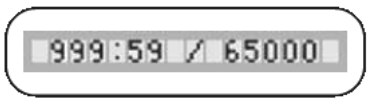


Fig. 10

SETTINGS LOCKED



HOURS/CYCLES

SETTINGS LOCKED

HOURS/CYCLES

Fig. 11

Fig. 12

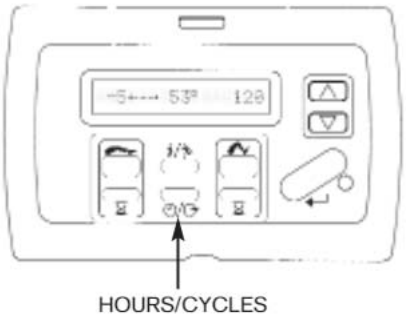


Fig. 13

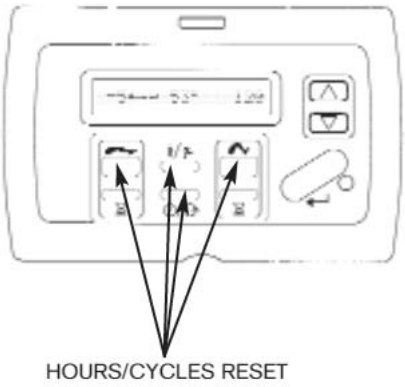


Fig. 14

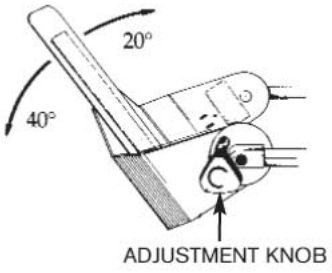


Fig. 15

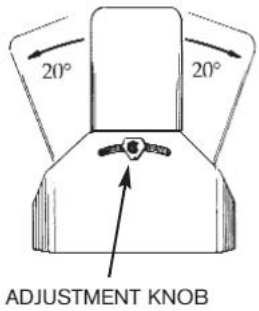


Fig. 16

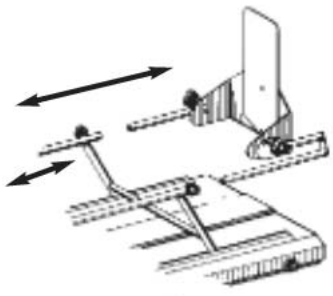


Fig. 17

Power Off
Power On
Attention:
Consult Accompanying Documents
Danger Electric Shock:
Service by qualified individual only
Danger Explosive Risk:
If used with flammable anaesthetic
Type B Applied Part
Prescription Symbol:
Federal law restricts this device or sale by
or on the order of a physician.
Rx ONLY
Standby/Enter
Start/Stop
Increase
Decrease
Extension
Flexion
Speed
Hours/Cycles
Pause
Lock/Set
Warm Up
Stopped
Timer
Seconds
Minutes
This Way Up
Fragile
Keep Dry

Fig. 18

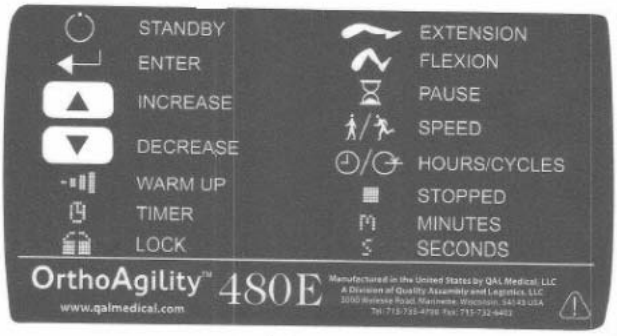


Fig. 19

1.0 Intended Use

1.1 Introduction

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

1.2 Application

Continuous Passive Motion (CPM) is best applied immediately post-operative and continued, uninterrupted, for up to six weeks as per physicians prescription.

1.3 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.

1.4 Indications

Immediate post-operative management after the following where indicated: ACL reconstruction; open reduction and rigid internal fixation of intra-articular, diaphyseal and metaphyseal fractures; capsulotomy and arthrolysis for post-traumatic arthritis with restriction of motion; synovectomy for rheumatoid arthritis and hemophilic arthropathy; Arthrotomy and drainage of acute septic arthritis; surgical release of extra-articular contractures or adhesions (quadricepsplasty); Metaphyseal osteotomy with rigid internal fixation of tibia and femur; prosthetic replacement (arthroplasty); reconstruction of medial collateral ligament tears of the knee using a semitendinosus tenodesis; reconstructive surgery on bone, cartilage, tendons and ligaments; prolonged joint immobilization.

1.5 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.

1.6 Safety Considerations

1. Do not use in a volatile atmosphere.
2. Do not store device under a bed which has less than 19 inches of clearance at all times.
3. 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.

SAFETY FEATURES

Low Voltage

The power supply delivers less than 20 volts DC to the device. The 480E will tolerate electrical supply variations which may be found in the home or hospital environments.

Reverse-On-Load

The device is designed to automatically reverse direction in the event that an obstruction occurs.

Motion Controller

The 480E provides immediate patient access to all operating controls via the Motion Controller (see Fig. 2). Restricted access is also possible by means of a SET/LOCK switch (see Fig. 3).

Start/Stop Button

The START/STOP button 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 (see Fig. 4).

- Use the device only in accordance with the Physician prescription and Setup

Use the device only in accordance with the Physician prescription and Setup and Operating Manual. Failure to do so may result in damage to the device and/or personal injury.

- Softgoods are for single patient use only.
- The device must not be used in the presence of flammable materials including 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.
- 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, 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.
- 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, if applicable), to prevent a tripping hazard during use.

2.0 Components

2.0 Components

2.1 Overview

1. Instructions for Use Manual
2. 480E Device with Motion Controller, Power Supply, and Power Cord
3. Thigh Shield
4. Patient Kit (Softgoods)

Foot Cradle and Thigh Assembly

2.2 Technical Data

Weight of Device.....Approximately 24 lbs. (11 kg)

Standard Configuration .....pediatric Configuration

Limb Length 28.5 - 41 in.....21.5 - 35.5 in.
(73 - 104 cm).....(53 - 90 cm)

Calf Length 16.5 - 24 in.....9.5 - 18.5 in.
(43 - 61 cm) .....(24 - 47 cm)

Thigh Length 12 - 17 in. .....12 - 17 in.

(30 - 43 cm).....(30 - 43 cm)

Range of Motion.....-5 degrees extension to 120 degrees flexion Speed

16 to 160 degrees per minute

Pause 0-30 seconds at maximum extension/flexion

Timer 10 to 480 minutes

Mode of Operation .....Continuous

Power Supply
Input 100 - 240 VAC 1.6A 50 - 60 Hz
Output 15 VDC 2.0A

NMES Compatible with various NMES devices

Safety CSA approved, CE marked

Electric Shock Classification.....Type B

Classification Class 1 Medical Device

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

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

2.3 Ordering Info

480E Replacement Parts Ordering Information

Description .....Part No.

Softgoods Kit 400PK

Knob Kit 11261

Bed Mount:

Standard.....12138

Traction 10363

Home 12200

Kit, Kneepot Cover with Fasteners.....11329

Kit, Fasteners for Bottom Cover.....11274

480E Modular Components

Replacement Parts Ordering Information

Description	*Part No.*
pediatric Foot Cradle	12604
Standard Foot Cradle	L480SA016

3.0 Using the 480E

3.1 Setting Up the 480E

Remove all the 480E CPM system components from the carton. During unpacking, check for external damage. Report any substantial damage.

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

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

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

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

BEFORE USE

1. Allow device to reach room temperature for a minimum of one hour prior to use.
2. Tighten all knobs and fasteners.
3. Before patient use, verify the Range Of Motion (ROM) settings by operating the CPM through one full cycle.

Note: A complete calibration is required if:

a. Any components have been replaced

b. Any visual damage is noticed

c. Erratic motion occurs during operation

d. Any of the covers have been removed

Note: Service should be performed only by qualified technicians. Training is available through the manufacturer.

3.2 Operating the 480E

(Read: "Before Use" above)

TURNING ON THE DEVICE

Turn device on via the **POWER** switch located on the end of the device (see Fig. 3). **Note:** Each time the 480E is powered up, the motion controller's display will prompt the user to choose the **WARM UP** and **TIMER** features. The extension, flexion, speed and pause settings will be the same as when the device was last run.

PATIENT STOP/START CONTROL BUTTON

The patient may stop and restart the CPM at any time by depressing the **[↵ ○]** (START/STOP) (see Fig. 4) button on the Motion Controller. The device will proceed in the opposite direction upon restarting.

WARM UP FEATURE

The 480E is 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.

Selecting and De-selecting Warm-Up feature:

Turn on the device from the **POWER** Switch located on the end of the device. 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.

Selecting the Warm Up feature:

To select the Warm Up feature, choose ☒ (YES) by pressing the (EXTENSION) button on the Motion Controller (see Fig. 2). Upon pressing the **[↵ ○]** (START/STOP) button the device will begin to cycle through a much smaller range of motion than programmed and slowly increase over a series of cycles until the full range of motion is reached. Once the device has reached the full range of motion, it will continue to cycle at that range.

De-selecting the Warm Up Feature:

To avoid the warm up feature choose ☐ (NO) by pressing the (FLEXION) button (see Fig. 2). Upon pressing the **[↵ ○]** (START/STOP) button the device will run through the full range of motion that was last programmed into the Motion Controller.

Note: If the device is stopped by depressing the **[↵ ○]** (START/STOP) button on the Motion Controller and then restarted, the Warm Up cycle will be repeated. To turn off the **WARM UP** feature, turn the device off, then on again at the **POWER** Switch (see Fig. 1). Then select ☐ (NO) to the Warm Up feature prompt.

TIMER FEATURE

The 480E is equipped with a **TIMER** feature that, when selected, allows the operator to preset the duration of the treatment session (see Fig. 6). The time can be set in 10 minute increments up to 480 minutes (eight hours). Once the treatment session is over, the 480E will run to the middle of the set range of motion and stop and 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 (see Fig. 1). When the TIMER has been selected, the operator may view the time remaining by pressing the Increase or Decrease buttons in Fig. 2.

Once the time has been set, the operator cannot adjust the time without turning the device off and on and reselecting the **TIMER**.

Selecting and De-selecting Timer feature:

Turn on the device from the **POWER** Switch located at the base of the device. Following the prompt for **WARM UP**, the operator will be prompted for the **TIMER**. The operator must choose ☒ (YES) or ☐ (NO) to proceed.

Selecting the Timer feature:

To select the Timer feature, choose ☒ (YES) by pressing the (EXTENSION) button on the Motion Controller (see Fig. 2). The operator can then set the treatment session time in 10 minute increments using the △ (INCREASE) arrow or ▽ (DECREASE) arrow buttons. Pressing the **[↵ ○]** (STOP/START) button will save the time and advance to the run screen.

Note: The **TIMER** will not function if a time of 0 minutes is set.

De-selecting 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 **[↵ ○]** (STOP/START) button on the Motion Controller. It **will** count time that passes during set pause times at the ends of the flexion and extension cycles.

SETTING RANGE OF MOTION (ROM)

The 480E achieves a maximum Range of Motion (ROM) of -5° extension to 120° flexion. The ROM settings are continuously displayed in the Motion Controller display window during operation.

Setting ROM Parameters:

Using the Motion Controller, set the ROM parameters by pressing and holding the (EXTENSION) or (FLEXION) button while simultaneously depressing the desired △ (INCREASE) arrow or ▽ (DECREASE) arrow buttons. The Extension and Flexion angles will change slowly for the initial 5 degrees (allowing for precise adjustment); following this, the parameters will change rapidly (allowing for quicker adjustment).

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.

SPEED SETTING

The 480E operates at speed cycles from 16 to 160 degrees per minute. To check the 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.

Adjusting Speed:

To adjust speed, depress and hold the (SPEED) (see Fig. 2) button while simultaneously depressing either the △ (INCREASE) arrow to increase speed or ▽ (DECREASE) arrow keys to decrease speed.

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 under the (EXTENSION) or (FLEXION) buttons. The number of seconds selected will appear in the center of the display window upon depressing each ⧖ (PAUSE) button.

Setting PAUSE

To change **PAUSE** settings, depress and hold either ⧖ (PAUSE) button and adjust with the △ (INCREASE) arrow or ▽ (DECREASE) arrow keys. When changing both **PAUSE** functions, repeat the above steps for setup of each **PAUSE** function separately.

Neuro-Muscular Electrical Stimulation

Neuro-Muscular Electrical Stimulation (NMES) may be utilized 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 (see Fig. 3). 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.

LOCK-OUT SETTINGS

Motion Controller settings (ROM, Speed, Pause) can be locked out to prevent inadvertent changes (see Fig. 11). Attempting to change settings while the **LOCK OUT** feature is engaged will result in the lock symbol appearing in the centre display window.

Locking out settings:

To lock out settings place the **SET/LOCK** switch located on the end of the device in the (LOCK) position (see Fig. 11).

To disengage lock out, place the **SET/LOCK** switch in the (SET) position.

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 (see Figs. 12 & 13).

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 (see Fig. 14).

3.3 Attaching the Patient Kit to the 480E (Softgoods) (see Fig. 1)

Coverings for the 480E 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. The Patient Kit (Soft-goods) is for **SINGLE PATIENT USE ONLY.**

Begin with the Thigh Cradle Section (see Fig. 1). Place on the thigh section of the device (ensure thigh shield is in place), matching hook and loop fasteners.

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

Next, attach the Calf Cradle Section.

To attach the Boot, place the elastic flap over the Foot Plate (sole of Boot adheres to velcro on the Foot plate). After placing the patient's foot in the Boot, fold the sides inward and attach the straps tightly to hold the foot securely.

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

3.4 Measuring Patient and Adjusting the Length of the Device

Important: Make sure the leg carriage is in extension when fitting the patient to the device.

Thigh Measurement (use a measuring tape)

Determine the length of the patient's thigh. Loosen Thigh Cradle Adjustment knobs on both sides of thigh tubes (see Fig. 1). Fit thigh shield to gluteal crease of patient (the bottom of the buttocks). The knee pivot on the CPM should align with the approximated center of the patient's knee joint. Lengthen or shorten both sides equally. Tighten both adjustment knobs securely. If readjustment is necessary, do not attempt to adjust only one side as this can cause damage to the device.

Calf Measurement (use a measuring tape)

Determine the length of the patient's calf and foot. 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. Loosen adjustment knobs on both sides of the Calf Cradle and adjust both sides equally. Tighten both knobs securely.

Setup Scale

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

Ankle Setup

To allow free movement of the ankle, loosen ankle adjustment knobs located on the Foot Cradle. 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 (see Figs. 15 & 16).

3.5 Attaching the 480E to the Bed

Home Bed Mount Kit (part number 12200):

A Home Bed Mount is available for the 480E. 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.

Hospital Bed Mount Kit
(Part number 12138):

A Standard Hospital Bed Mount is available for the 480E CPM device. 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.)

Traction Bed Mount Kit
(Part number 10363):

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

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

(Standard Pediatric Foot Cradle)

The 480E offers a unique design, accommodating standard and pediatric patients by simply changing modular components on the device. This is accomplished by following these step-by-step instructions:

1. Loosen the Foot Cradle Adjustment Knobs (see Fig. 1)
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. Select appropriate length for the Foot Cradle and tighten Foot Cradle Adjustment Knobs.

4.0 Maintenance

Patient Maintenance

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

Operator 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.
- 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.

Maintenance Every Six Months

- Repeat steps under "Maintenance Between Patients".

Maintenance Every Twelve Months

- 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 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 OrthoAgility Final inspection criteria. (These are available through your Sales Representative, OrthoAgility 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.

5.0 Troubleshooting Guide

PROBLEM	POSSIBLE CAUSE	FIX
Device will not power up Device does not beep	No Power to device	Replace power cord, Power Supply or replace switch
	Main PCB Failure	Replace PCB
	Motion controller cable disconnected	Check motion controller cable connections at both ends
		Return for service
Motion controller, erratic display	Motion controller cable break	Replace cable
	Motion controller PCB failure	
	Main PCB failure	Replace PCB
		Return for service
Error codes: E1,2,3,4,6,7,8, 12,13,14,15,16,18	Out of calibration	Re-calibrate device following calibration procedures
	Main PCB failure	Replace PCB
	Motion controller cable break	Replace motion controller cable
	Motion controller PCB failure	Replace motion controller
		Return for service

Error code E9	Calibration error	Re-calibrate following calibration procedures
	Motion controller cable break	Replace motion controller cable
	Motion controller PCB failure	Replace motion controller kit # L480SA033E
		Return for service
Error codes E10,11,21	Knee pot cable break	Replace knee pot cable
	Knee pot	Replace knee pot
	Main PCB failure	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	Use a Light Lithium based lubricant, Lubriplate #105 on the ballscrews, and a Silicone spray on track seals and tracks
	Bearing bracket assembly failure	Replace bearing bracket assembly
	Ballscrew failure	Replace ball screw assembly
	U-bracket/slider assembly failure	Replace bracket/slider assembly
	Motor failure	Replace motor Return for service
Insufficient lifting power	Motor failure	Replace motor
	Bearing bracket assembly failure	Replace bearing bracket assembly Return for service

6.0 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:

International Customer Service:

QAL Medical
Attn: Customer Service
3000 Woleske Road
Marinette, WI 54143
Tel: 1-715-735-4700 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

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1.0 Utilisation prévue

1.1 Introduction

Le système de mouvement passif continu (MPC) 480E est conçu pour la réadaptation des membres inférieurs. Le MPC 480E offre des berceaux de pied interchangeables tout en permettant une utilisation standard et pédiatrique par le patient.

1.2 Application

Le mouvement passif continu (MPC) est plus efficace lorsqu'il est utilisé immédiatement après la chirurgie et, par la suite, sans interruption pendant une

période pouvant atteindre six semaines, selon les directives du médecin.

1.3 Avantages cliniques

Maintien d'une bonne amplitude articulaire

Prévention d'adhésions intra-articulaires

Prévention de contractures extra-articulaires

Réduction de la douleur post-opératoire

Prévention des effets négatifs de l'immobilisation.

1.4 Indications

Une gestion post-opératoire immédiate après les interventions suivantes, lorsque prescrite : reconstruction du LCA; réduction ouverte et fixation interne rigide de fractures intra-articulaires, diaphysaires et métaphysaires; capsulotomie et arthrolyse pour arthrite post-traumatique avec restriction de mouvement; synovectomie pour l'arthrite rhumatoïde et l'arthropathie hémophilique; arthrotomie et drainage de l'arthrite septique aiguë; libération chirurgicale de contractures ou d'adhésions extra-articulaires (myoplastie du quadriceps); ostéotomie métaphysaire avec fixation interne rigide du tibia et du fémur; remplacement prosthétique (arthroplastie); reconstruction des déchirures du ligament latéral interne du genou au moyen d'une ténodèse semi-tendineuse; reconstruction chirurgicale sur l'os, le cartilage, les tendons et les ligaments; immobilisation prolongée du joint.

1.5 Contre-indications

Ne pas utiliser l'appareil en présence de l'un des éléments suivants :

- infection non traitée ou non contrôlée;
- fractures instables;
- hémorragie;

Remarque : lors de l'utilisation de l'appareil, si des signes d'infection tels que de l'hypothermie, de la fièvre, des rougeurs, de l'irritation, de la chaleur, de l'enflure, des saignements et/ou une augmentation persistante de la douleur apparaissent, cesser l'utilisation de l'appareil et communiquer avec le médecin du patient. Ne pas continuer le traitement jusqu'à ce que le médecin ait approuvé l'utilisation de l'appareil.

1.6 Considérations de sécurité

1. Ne pas utiliser dans une atmosphère volatile.
2. Ne pas ranger l'appareil sous un lit dont la hauteur est inférieure à 48 cm en tout temps.
3. Lire le manuel avant d'utiliser et de faire fonctionner l'appareil. Nous recommandons à tous les cliniciens et toutes les autres personnes responsables de l'opération de cet appareil de bien se familiariser avec ses capacités et ses procédures de fonctionnement avant l'utilisation par le patient. L'habileté à mesurer le patient et à régler l'appareil en conséquence augmentera avec l'expérience et la pratique.

DISPOSITIFS DE SÉCURITÉ

Basse tension

L'alimentation fournit moins de 20 volts de CC à l'appareil. Le 480E tolérera les variations d'alimentation électrique qui peuvent se produire dans les hôpitaux ou les domiciles.

Inversion sur charge

Cet appareil est conçu pour changer automatiquement de direction en cas

d'obstruction.

Contrôleur de mouvement

Le 480E offre au patient un accès immédiat à toutes les commandes d'opération par l'entremise du contrôleur de mouvement (se reporter à la figure 2). Un accès restreint est aussi possible par l'entremise d'un interrupteur RÉGLER/VERROUILLER (se reporter à la figure 3).

Bouton marche/arrêt

Le bouton MARCHE/ARRÊT donne au patient la capacité d'arrêter ou d'interrompre l'action de l'appareil en cas de malaise. Le patient peut faire redémarrer l'appareil (en direction opposée) en appuyant sur le bouton MARCHE/ARRÊT une seconde fois (se reporter à la figure 4).

- Utiliser cet appareil conformément à l'ordonnance du médecin et au manuel d'utilisation et d'installation seulement. Sinon, il y a des risques de dommages à l'appareil et/ou de blessures.
- Les produits doux ne doivent être utilisés que par un seul patient.

- L'appareil ne doit pas être utilisé en présence de matériaux inflammables, y compris des anesthésiques inflammables.
- Utiliser seulement les composants de rechange fournis par le fabricant.
- Ne pas utiliser cet appareil s'il y a des conditions mentales ou physiques qui empêchent le patient de respecter les directives.
- Pour éviter le risque de blessures, telles que les dangers d'étranglement ou de suffocation, garder l'appareil hors de la portée des enfants ou des personnes souffrant de problèmes mentaux ou physiques qui empêcheraient l'utilisation sécuritaire de l'appareil.
- Placer l'appareil dans une position confortable et sécuritaire. S'assurer que l'appareil est stable tout au long du mouvement.
- Garder les cheveux, les vêtements amples, les doigts et toutes les parties du corps loin des composants mobiles de l'appareil.
- Ne pas exposer l'appareil à l'eau ou à des températures extrêmes.
- Ne pas utiliser l'appareil près de flammes nues, de cigarettes ou d'une source de chaleur excessive.
- Couper l'alimentation électrique avant de réparer ou nettoyer. Le non-respect de cette consigne peut causer un choc électrique ou des blessures.
- Éteindre l'appareil avant de le débrancher.
- Couper l'alimentation en tirant sur la fiche, non sur le cordon.
- Si l'appareil n'est pas utilisé, l'éteindre et le débrancher de son alimentation en électricité.
- Ne pas utiliser l'appareil, la source d'alimentation ou le contrôleur s'ils semblent endommagés ou si des fils sont exposés.
- Ne pas verser de solution nettoyante directement sur l'appareil. Ceci peut permettre aux liquides de s'infiltrer dans l'appareil et de causer des problèmes électriques ou d'éliminer les lubrifiants des composants mobiles, réduisant ainsi la durée de vie de l'appareil.
- Sélectionner un endroit pour l'appareil et ses composants (contrôleur, courroies, câbles et source d'alimentation, s'il y a lieu), afin d'éviter la création d'un danger de trébuchement pendant l'utilisation.

2.0 Composants

2.1 Aperçu

1. (1) Manuel d'utilisation et d'installation
2. (1) Appareil 480E avec contrôleur de mouvement, source d'alimentation et cordon d'alimentation

3. (1) Protecteur de cuisse
4. (1) Trousse de patient (produits doux)
5. Berceau de pied avec montage de cuisse

2.2 Données techniques

Poids de l'appareil .....Approximativement 11 kg (24 lb).

	Configuration standard	**Configuration pédiatrique**
Longueur du membre	73 à 104 cm (28,5 à 41 po)	53 à 90 cm (21,5 à 35,5 po)
Longueur du mollet	43 à 61 cm (16,5 à 24 po)	24 à 47 cm (9,5 à 18,5 po)
Longueur de la cuisse	30 à 43 cm (12 à 17 po)	30 à 43 cm (12 à 17 po)

Amplitude articulaire 5 degrés d'extension jusqu'à 120 degrés de flexion

Vitesse 16 à 160 degrés par minute

Pause 0 à 30 secondes à l'extension/flexion maximum

Minuterie 10 à 480 minutes

Mode de fonctionnement .....Continu

Source d'alimentation

Entrée	100 à 240 V CA 1,6 A 50 à 60 Hz
Sortie	15 V CA 2,0 A

SENM Compatible avec divers appareils SENM

Sécurité Homologué CSA, marque CE

Classification de choc électrique .....Type B

Classification .....Appareil médical de catégorie 1

Conditions ambiantes empérature de -10 °C à 35 °C (14 °F à 95 °F), humidité maximale de 90 %, pression atmosphérique de 750 hPa à 1040 hPa. L'appareil doit demeurer dans un environnement fonctionnel pendant au moins une heure avant son utilisation.

Remarque : l'appareil ne doit pas être utilisé en présence d'un mélange d'anesthésiques inflammables avec de l'air ou avec de l'oxyde nitreux.

2.3 Renseignements de commande

Renseignements de commande des pièces de rechange du 480E

Description .....N° de pièce

Trousse de produits doux 400PK

Trousse de bouton 11261

Monture sur lit :

Standard 12138

Traction 10363

Domicile 12200

Trousse, revêtement de potentiomètre de genoux avec attaches ...11329

Trousse, attaches pour le revêtement inférieur 11274

Composants modulaires du 480E
Renseignements de commande des pièces de rechange

Description .....N° de pièce

Berceau de pied pédiatrique.....12604

Berceau de pied standard.....L480SA016

3.0 Utiliser le 480E

3.1 Installer le 480E

Retirer tous les composants du système MPC 480E de la boîte. Pendant le déballage, s'assurer qu'il n'y ait aucun dommage externe. Signaler tout dommage important.

IMPORTANT : conserver l'emballage afin de pouvoir ranger l'appareil lorsqu'il n'est pas utilisé. De plus, s'il s'avère nécessaire de le retourner pour toute réparation, cet emballage fournit toute la protection requise en vertu de la garantie.

S'assurer que le cordon d'alimentation et le cordon du contrôleur de mouvement soient déroulés de l'appareil.

Relier le contrôleur de mouvement au connecteur situé à l'extrémité de l'appareil et serrer le contre-écrou de la fiche.

Relier la source d'alimentation au connecteur situé à l'extrémité de l'appareil et serrer le contre-écrou de la fiche. Brancher le cordon d'alimentation dans la source d'alimentation et dans une prise de courant murale standard (mise à la terre).

AVANT L'UTILISATION

1. Laisser l'appareil atteindre la température de la pièce pendant au moins une heure avant l'utilisation.
2. Serrer tous les boutons et attaches.
3. Avant l'utilisation, vérifier les réglages de l'amplitude articulaire (AA) en faisant fonctionner le MPC pendant un cycle complet.

Remarque : un étalonnage complet est requis si :

a. un des composants a été remplacé;

b. tout dommage visuel est évident;

c. un mouvement erratique se produit pendant le fonctionnement;

d. un des revêtements a été enlevé.

Remarque : l'entretien doit être effectué par des techniciens qualifiés seulement. Une formation est offerte par l'entremise du fabricant.

3.2 Faire fonctionner le 480E

(Veuillez lire la section « Avant l'utilisation » ci-dessus.)

ALLUMER L'APPAREIL