

Otto Bock®

QUALITY FOR LIFE



480E PRO Knee CPM

 **Instructions for Use**

NOTE: To protect the patient, settings may be locked to allow only medical/clinical professionals to make changes to the CPM device settings. Locking the settings will require a Special Key Sequence. Please contact your Authorized Service Representative, Dealer, or Distributor for this or answers to any other questions you may have.



Alternating Current



Direct Current



Attention, Consult Accompanying Documents



Off (Power: Disconnection from the mains)



On (Power: Connection to the mains)



Indicates CSA certification to North American standards



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



Danger Explosive Risk: If used with flammable anaesthetic



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



This Way Up



Fragile



Keep Dry

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1.0 Intended Use

1.1 Introduction

The 480E PRO Continuous Passive Motion (CPM) Device is designed for the rehabilitation of the lower limbs. The 480E PRO CPM Device offers interchangeable foot cradle components allowing standard and pediatric patient usage. The 480E PRO is controlled with the Pro Controller pendant.

1.2 Application

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



Danger!

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 Declaration of Conformity

Otto Bock as manufacturer with sole responsibility declares that the 480E PRO Knee CPM Device conforms to the requirements of European Directive for medical products 93/42/EEC.

2.0 Safety Considerations

2.1 Symbol Legend

**Danger!**

Warning messages regarding possible risks of accident or injury.

**Attention!**

Warning messages regarding possible technical damages.

**Note!**

Information regarding operation of the device.

**Note!**

Information for service staff.

**Attention!**

Please read the Instructions for Use first.

2.2 General Safety Considerations

**Attention!**

Read manual before operating the device. Clinicians and others responsible for the operation of this device should become thoroughly familiar with its capabilities and proper operation procedures prior to actual patient use.

**Danger!**

Do not use in a volatile atmosphere. Equipment not suitable for use in the presence of flammable anaesthetic mixture with air or Nitrous Oxide.

**Danger!**

Do not use CPM device in operating rooms. This CPM device is only to be used outside the operating room.

**Danger!**

Disconnect the electrical supply before servicing or cleaning. Failure to do so could result in electrical shock or personal injury.

**Danger!**

Do not use the device, power supply or controller if it appears damaged or if there are exposed wires.

**Danger!**

To prevent potential physical injury, such as strangulation and choking, keep the device away from children or individuals with mental or physical conditions that preclude the safe use of the device.

**Danger!**

Unplug the power supply by grasping the plug, not the cord.

**Danger!**

Unless using the device, turn the device off and unplug from the power supply.

**Danger!**

The controller must be positioned so that patients and medical personnel can reach the START/STOP button during use.

**Danger!**

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.

**Danger!**

Position the device in a comfortable and secure position. Ensure that the device is stable through its full range of motion.

**Danger!**

Keep hair, loose clothing, fingers, etc., away from moving components of the device.

**Attention!**

Use the device only in accordance with the Physician prescription and these Instructions for Use. Failure to do so may result in damage to the device and/or personal injury.

NOTE: Patient Kits are for single patient use only.

**Attention!**

The use of accessories and cables other than those specified, with the exception of accessories and cables qualified and sold by the manufacturer of the equipment, may result in increased emissions or decreased immunity of the equipment and may cause the system to be non-compliant with the requirements of IEC 60601-1-2:2004.

**Attention!**

The equipment should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, verify operation in that configuration.

**Attention!**

Portable and mobile RF communications equipment can affect *Medical Electrical Equipment*.

**Attention!**

Use only manufacturer's supplied replacement components.

**Attention!**

Do not use the device if there are mental or physical conditions that preclude patient compliance.

**Attention!**

Do not expose the device to water or extreme temperatures.

**Attention!**

Do not use the device near exposed flames, while smoking or near excessive heat. Turn the power off before unplugging.

**Attention!**

Select a location for the device and device components (controller, straps, cables and power supply, if applicable), to prevent a tripping hazard during use.

**Attention!**

Device must be stored in a location that has a least 19 inches of clearance at all times.

2.3 Safety Features

Low Voltage

The power supply delivers less than 20 volts DC to the device. The 480E PRO 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.

Restricted Patient Access

The 480E PRO provides immediate patient access to all operating controls via the Pro Controller pendant. Restricted access is also possible by means of the controller settings.

Start/Stop Button

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.

3.0 480E PRO Components and Technical Data

3.1 Components and Ordering Information

Description.	Part No.
Pro Controller Pendant	NG-104
Pro Controller Pendant Cable	NG-103
Pro Controller Memory Card	PMC-256
Pro Controller Protective Cover	NG-105
Power Supply	L480SA031
Power Cord (to wall outlet) NORTH AMERICA	14157.5
Power Cord (to wall outlet) ELSEWHERE	please consult Customer Service for the correct Power Cord for your region
Patient Kit	480EPK
Pediatric Foot Cradle	12604
Standard Foot Cradle	L480SA016
Thigh Shield	L480SA019
Replacement Knob Kit	11261
Kit, Knee pot Cover with Fasteners	11329
Kit, Fasteners for Bottom Cover	11274
480E PRO Instructions For Use	MM480EP0M1

3.2 Technical Data

Weight of Device Approximately 24 lbs. (11 kg)
Standard Configuration Pediatric Configuration
Limb Length . .28.5 - 41 in (73 - 104 cm) 21.5 - 35.5 in. (53 - 90 cm)
Calf Length . . 16.5 - 24 in (43 - 61 cm) 9.5 - 18.5 in. (24 - 47 cm)
Thigh Length .12 - 17 in. (30 - 43 cm) 12 - 17 in. (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
Mode of Operation Continuous
Power Supply
Input 100 - 240 VAC 1.6A 50 - 60 Hz
Output 15 VDC 2.0A



Electric Shock Classification Type B
Classification Class 1 Medical Device (USA)
Class IIa (93/42/EEC)
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.

3.3 Electromagnetic Compliance

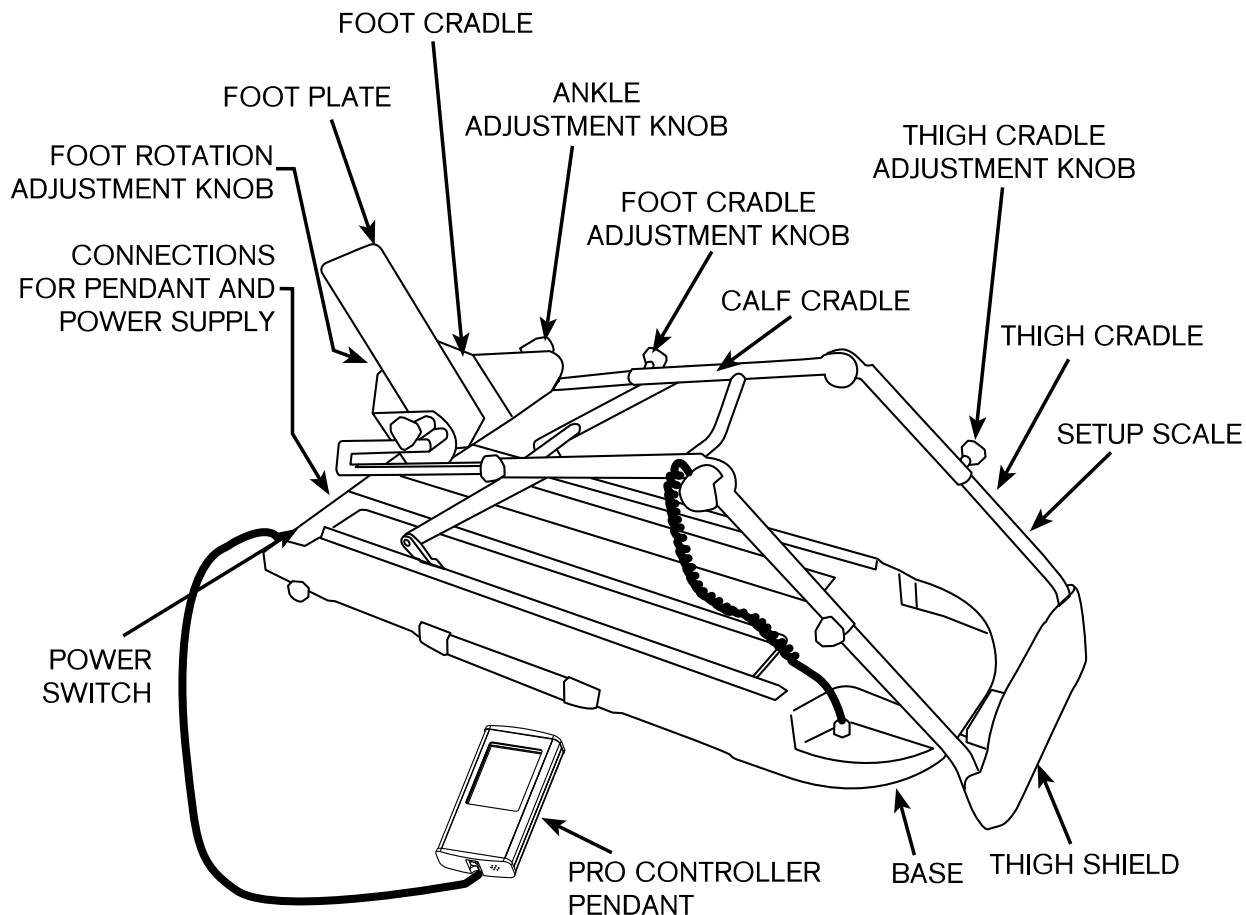


Attention!

Medical Electrical Equipment needs special precautions regarding electromagnetic compliance and needs to be installed and put into service according to the electromagnetic compliance information provided in the Appendix in section 12.

4.0 Setting up the 480E PRO

Fig. 1



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

In the carton, you will find:

- 480E PRO base unit
- pendant ("Pro Controller")
- pendant cable
- power supply
- power cable
- patient kit
- IFU manual, warranty card, product registration card

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 Pro Controller Cable are uncoiled from the device.

Connect the Pro 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. Review Section 5.0 to become familiar with operating the Pro Controller pendant.
3. Tighten all knobs and fasteners.
4. Before patient use, verify the Range Of Motion (ROM) settings by operating the CPM device through one full cycle.

- Note:** 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

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

5.0 Operating the 480E PRO

5.1 Pro Controller Overview

The Pro Controller is connected to the 480E PRO CPM Device via a pendant cable, which plugs into the bottom of the CPM Base Unit.

Fig. 2

SD Memory Card
being inserted into
Pro Controller.



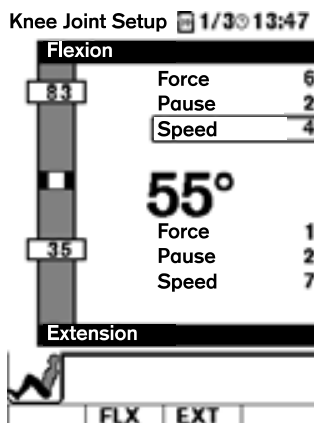
Each Pro Series CPM Base Unit controls one or more motors and ancillary equipment according to commands received from the Pro Controller pendant. The firmware in the Pro Controller and base unit can be upgraded. (Fig. 2) The SD Memory Card can also store and download patient therapy profiles and doctor's prescriptions.

Pro Controller Overview Modes and Screens

The Pro Controller has two main modes: Operating Mode, with 1 or more Joint Operator screens available, and Settings Mode, which contains multiple settings screens. All screens are controlled with the buttons and keys located on the lower half of the Pro Controller pendant.

Fig. 3

Operating Mode Screen with
all settings made available
to patient.



The Operating Mode Screen (Fig. 3) is normally the first screen displayed. The Operating Mode Screen displays current settings and also allows limited access of patient operational controls, including Force, Pause Time, Speed, and Range of Motion settings. In order to avoid unintended changes to the settings we have created a special Key Sequence that allows a Clinical Professional to exit the Operating Mode and enter the Setting Mode. The Key Sequence* must be input via the Direction and Select Keys and can be obtained from your account representative.

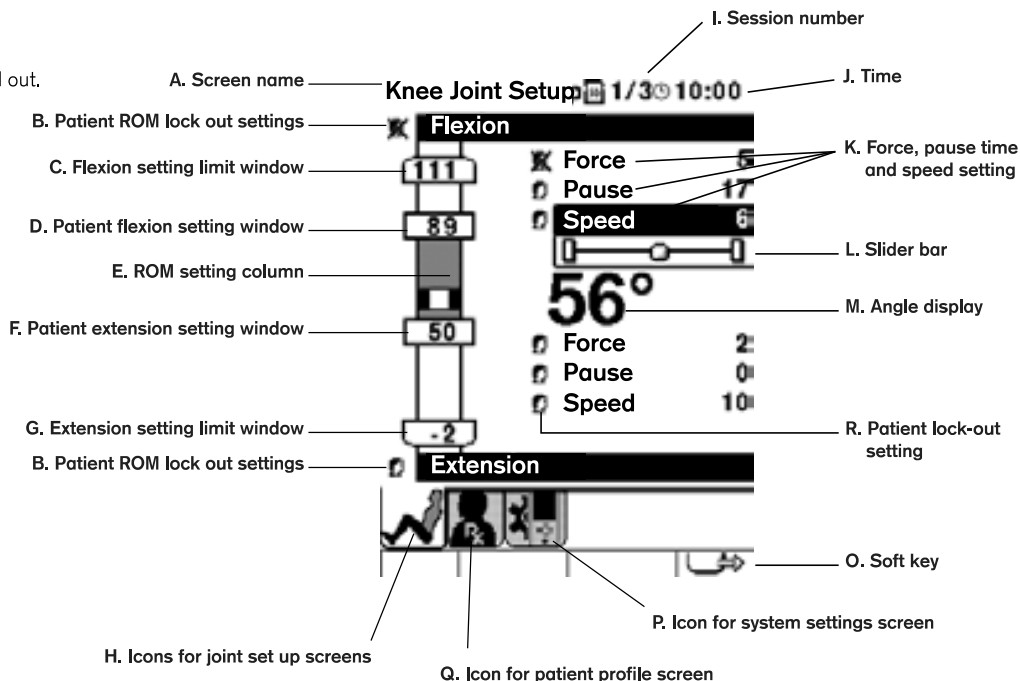
* NOTE: To protect the patient, settings may be locked to allow only medical/clinical professionals to make changes to the CPM device settings. Locking the settings will require a Special Key Sequence. Please contact your Authorized Service Representative, Dealer, or Distributor for this or answers to any other questions you may have.

Setting Mode Information, settings and operation concerning the CPM Device are presented on a series of setting and operating screens in the Pro Controller. The Setting Screens include Joint Set-up Screens, the Patient Profile Screen, and the System Settings Screen, and are intended to permit only qualified professionals to make changes to the CPM device setting parameters.

Once the functional parameters are set, the Pro Controller can be put into **Operating Mode**.

Fig. 4

Joint Set-up Screen with functional elements called out.

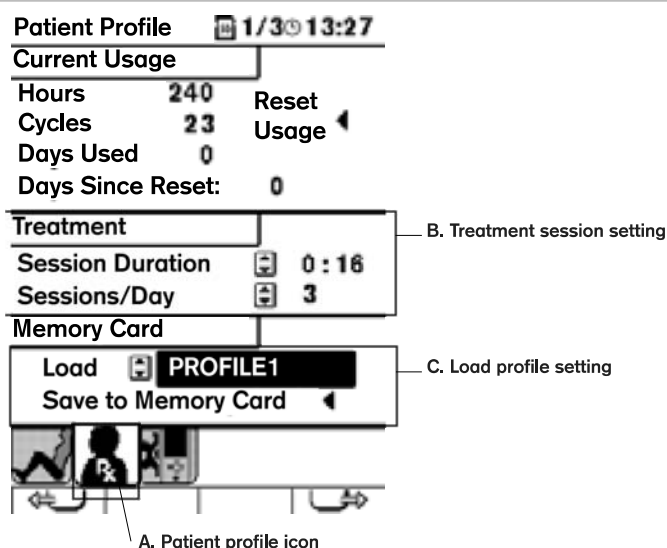


Screen Orientation (Fig. 4) The top of all screens (Fig. 4, Pos. A, I, J) contains the name of the screen as well as session number and session time remaining. The central portion of each screen (Fig. 4, Pos. B, C, D, E, F, L) contains relevant CPM Device and setting information. The bottom of each screen (Fig. 4, Pos. H, Q, P, O) contains a row of icons that are representative of the various screens. Icons are selected with the Soft Keys and are highlighted when selected.

The Joint Set-up Screen (Fig. 4), allows for the setting of Force, Speed, Pause Time and Range of Motion of all involved CPM Device joints.

Fig. 5

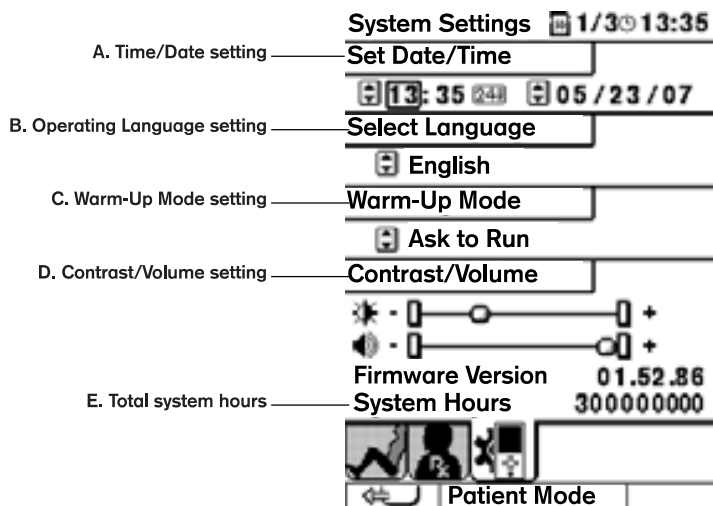
Patient Profile Screen



The Patient Profile Screen (Fig. 5), presents patient information concerning patient session duration and CPM Device use, and allows for the setting of Patient Profiles. Patient Profiles can be stored on the SD Memory Card, and can be named and retrieved. The card can then be used in other similar Pro Series CPM Devices.

Fig. 6

System Settings
Screen



The System Settings Screen (Fig. 6), allows Time, Date, Operating Language, Warm-Up Mode and Contrast/Volume to be changed.

Fig. 7

Pro Controller Key Pad

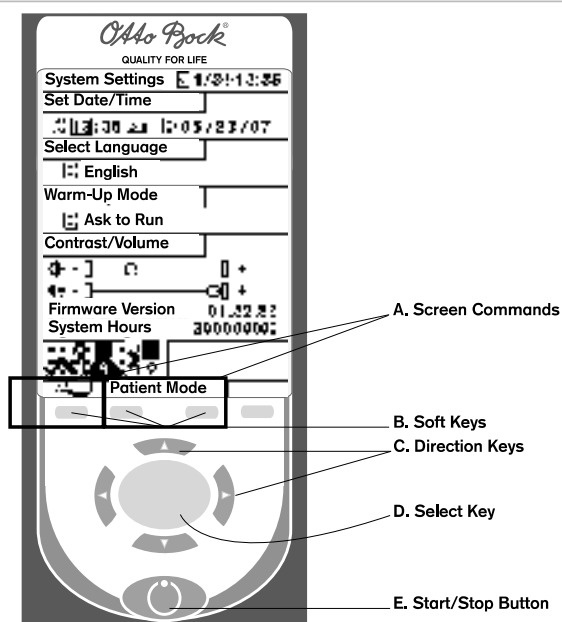


Fig. 8

The Cursor selects a
functional setting.

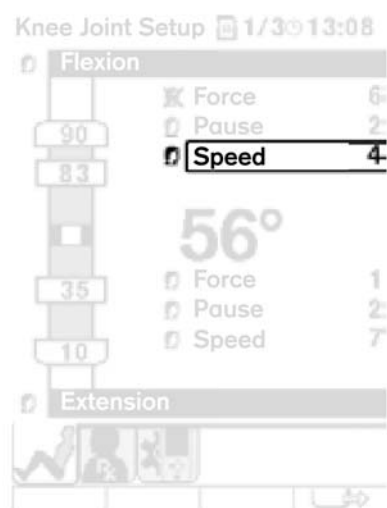
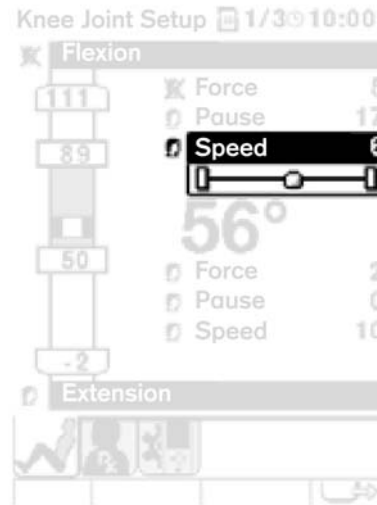


Fig. 9

By selecting a functional setting highlighted by the cursor, the slider bar will appear.



Pro Controller Keypad

Soft Keys are used to navigate between the Pro Controller Setting and Operating Screens. Pressing the leftmost and rightmost keys (Fig. 7, Pos. B) moves between the various Setting Screens. Pressing the central two keys moves to the Operating Screen. A Special Key Sequence is required to get out of the Operating Screen and back to the Setting Screens.

Direction Keys (Fig. 7, Pos. C) allow the user to move a Cursor (Fig. 8), up, down, left and right to various sections of the screen. The Cursor places a box or otherwise highlights the functions over which it is placed. The Direction Keys are also used to input a Key Sequence to take the Pro Controller out of Operating Mode and into Settings Mode.

The Select Key (Fig. 7, Pos. D) selects or deselects a setting function (Fig. 8) and opens up a setting window or slider bar so that changes can be made (Fig. 9).

The Start/Stop Button starts and stops the CPM Device when in Setting or Operating Mode (Fig. 7, Pos. E).

Fig. 10

Connecting the Pendant Cable to the pendant.



5.2 Connecting the Pro Controller to the CPM Device

Note: Make sure the CPM system is unplugged and turned off when connecting the Pendant Cable.

If it is not already connected, plug the small connector side of the Cable into the bottom of the ProController (Fig. 11). To disconnect the Pendant cable from the Pro Controller, place a small flat screwdriver into the end of the Pro Controller, between the connector lever and the Pendant chassis, and gently depress the lever to release the cable lock while pulling on the cable.

Fig. 11

Connecting the Pendant Cable to a CPM device.



To connect the Pro Controller to the CPM device, simply attach the cable with three prong connector to the socket located on the base of the CPM Device (Fig. 11). The cable can only be plugged in one way. Screw the locking collar in place . If it is not already attached, connect the power adaptor cable to the socket located in the base unit. Connect the other end to the power adaptor and plug the adaptor into the wall socket. Turn on the system via the power switch located on the base unit.

Fig. 12

Start-up Screen

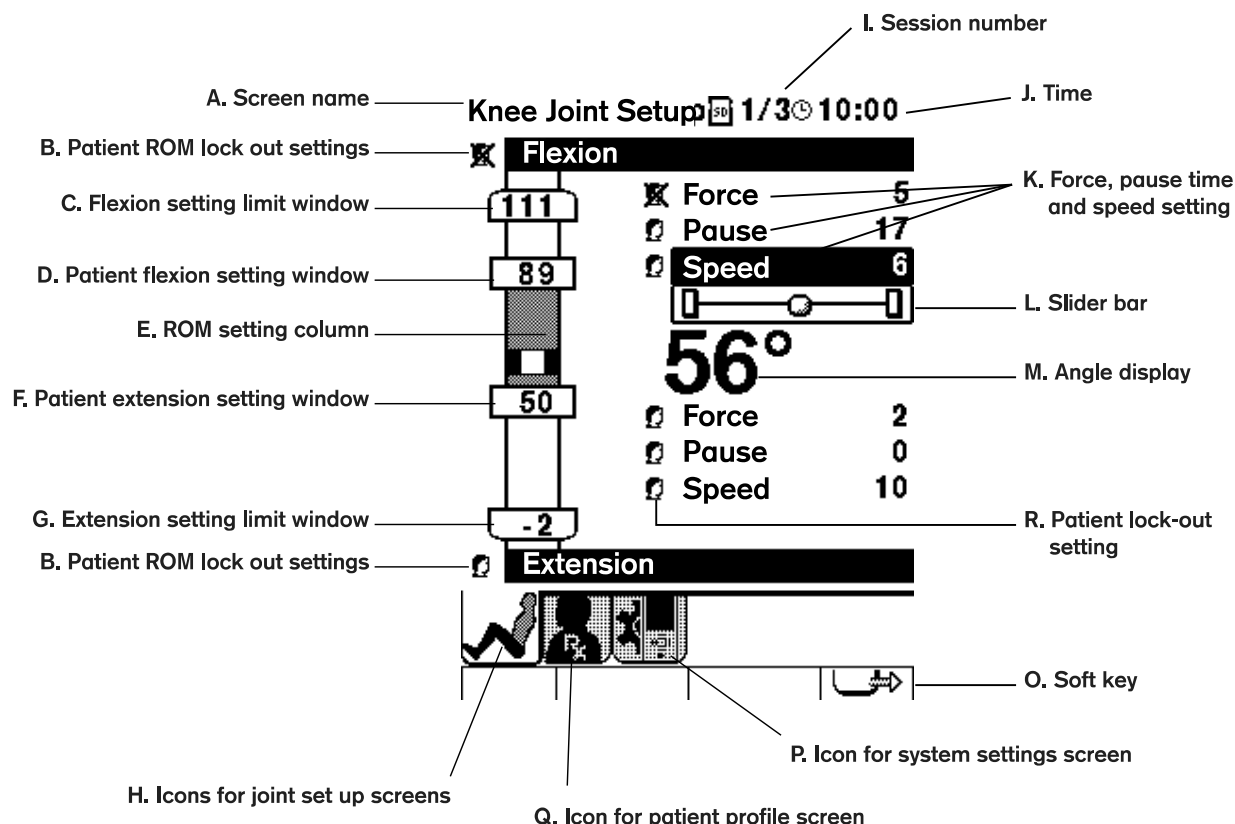


The Pro Controller will automatically recognize which Pro Series CPM Device it is connected to, and will flash a Start up Screen (Fig. 12). for about 10 seconds to indicate that it has been properly connected. It will then progress to standby mode and start up in the Operating Mode.

* NOTE: To protect the patient, settings may be locked to allow only medical/clinical professionals to make changes to the CPM device settings. Locking the settings will require a Special Key Sequence. Please contact your Authorized Service Representative, Dealer, or Distributor for this or answers to any other questions you may have.

5.3 CPM Device Parameters: Overview

Fig. 13 Joint Set-Up Screen



The Pro Controller has several screens available in the Setting Mode, including the Joint Set-up Screens (one or more, depending on the CPM device being controlled), the Patient Profile Screen, and the System Set-up Screen. Each screen has the title of the screen listed in the upper left corner (Fig. 13, Pos. A). Each screen also has its own icon at the bottom of the Screen. Icon for Joint Set-up Screen, (Fig. 13, Pos. H). Icon for Patient Profile Screen (Fig. 13, Pos. Q). Icon for System Settings Screen (Fig. 13, Pos. P).

All CPM Devices will automatically default to the Operating Mode (Fig. 3) when powered up.

After entering the Key Sequence*, the Joint Set-up Screen will appear (Fig. 13).

* NOTE: To protect the patient, settings may be locked to allow only medical/clinical professionals to make changes to the CPM device settings. Locking the settings will require a Special Key Sequence. Please contact your Authorized Service Representative, Dealer, or Distributor for this or answers to any other questions you may have.

5.4 Joint Set-up Screen: Setting CPM Device Parameters

Force, Pause, Pause Time and Speed Parameters for the specific joints in a CPM device are set in the Joint Set-up Screen (Fig. 14). To set these parameters, use the Soft Keys to navigate to the desired Joint Set-up Screen if there is more than one joint involved.

Fig. 14

Selection Cursor selected

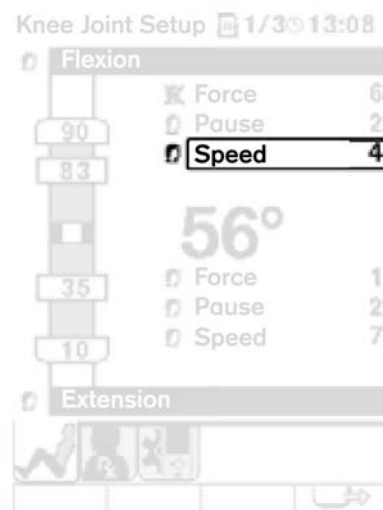
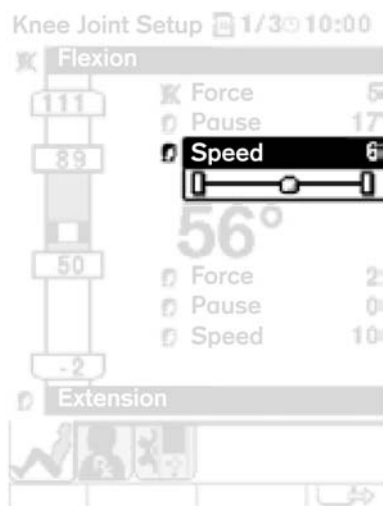


Fig. 15

Slider Bar selected



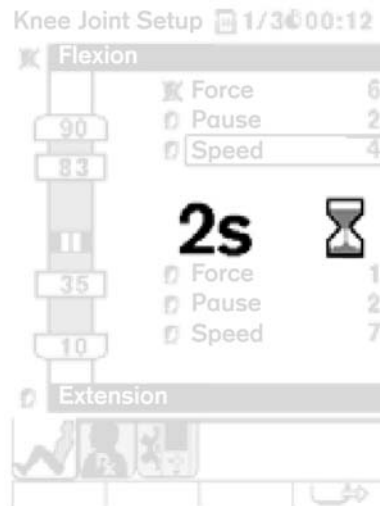
Next, use the Direction Keys to move the Cursor to the desired parameter (Fig. 14), and press the Select Key to select that parameter. A **Setting Slider Bar** will appear (Fig. 15) that will allow you to change the setting with the left and right Direction Keys. Once you have chosen your setting, press the Select Key to set, and scroll to the next parameter setting.

Range of Motion (ROM) parameters Use the left and right Direction Keys to navigate to the ROM Setting Column (Fig. 13, Pos. E). When the Pro Controller is first connected to a CPM device it will display the CPM device's ROM limits in the Setting Limit windows (Fig. 13, Pos. C, G). Both these and the Patient Controlled ROMs (Fig. 13, Pos. D, F) can be set using the keypad. Simply scroll to the desired setting and select, then use the up and down Direction Keys to raise or lower the slider bar to the desired degree.

A **Status Window** in the center (Fig. 13, Pos. M) will show the CPM's current angle or a countdown timer when it is in the Pause portion (Fig. 16) of its cycle.

Fig. 16

Countdown Timer displayed

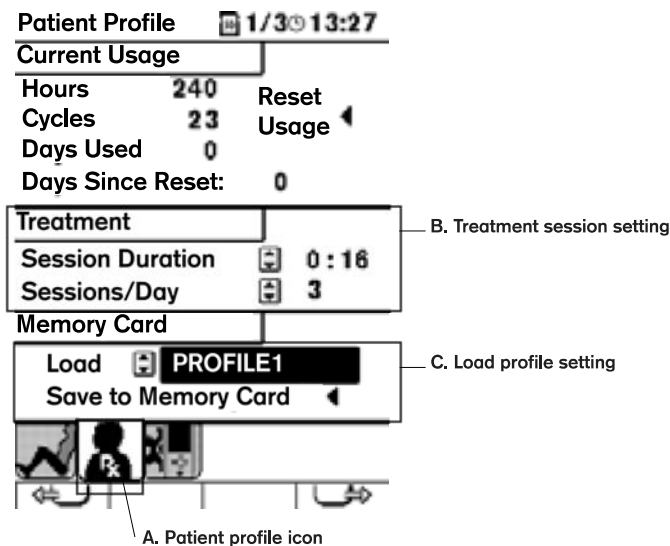


A **Lock out** option (Fig. 13, Pos. B) is available to prevent patients from making any changes to Patient Controlled ROMs as well as Pause Time, Speed, and Force. This is available in the leftmost column by scrolling to the Patient Flexion or Extension Icon (Fig. 13, Pos. B) and selecting or deselecting the icon. An X indicates that the patient is locked out from control of that parameter.

5.5 Patient Profile Screen: Settings and Patient Profiles

Fig. 17

Patient Profile Screen



The Clinical Professional can set other parameters and also view information about patient use of a CPM Device on the Patient Profile Screen, indicated by the Patient Profile Screen Icon (Fig. 17, Pos. A). To navigate to the Patient Profile Screen, use the Soft Keys. Time can be set for each session as well as number of sessions per day (Fig. 17, Pos. B). (Note: if either the Session Duration or the Sessions/Day is at zero, the session feature will be disabled.) This information can be reset or saved to the memory card.

A **Patient Profile** stores therapy settings for Force, Time, Speed, Pause, and ROM goals. It also includes lock-out and treatment session information. These profiles make it easy to apply therapy settings to the patient at a later time, or to another patient with similar therapy needs. Profiles beyond the one in use must be stored on the removable memory card, which is located under the cover on top of the device and can be removed by simply pressing in the card to disengage (Fig. 2, Page 8). To access and create profiles, scroll to the Load Profile Function (Fig. 17, Pos. C) and select either "Load" or "Save".

To use a previously stored Patient Profile on the memory card scroll through the Patient Profile window and select the desired profile.

Fig. 18

Naming a patient profile

Patient Profile 1/3 13:28

Current Usage

Hours	240	Reset
Cycles	23	Usage
Days Used	0	
Days Since Reset:	0	

Treatment

Session Duration	0:16
Sessions/Day	3

Memory Card

P R _ _ _ _ _ Save Cancel

To create a new Patient Profile, which will be stored on the unit's removable SD Memory Card, it is important that you first make all desired settings in the Setting Screens. Once you have created your settings, select "Save to Memory Card" in the Patient Profile Screen (Fig. 17, Pos. C). You can name the profile with up to eight alphanumeric characters. The characters are selected by scrolling up or down through each character position (Fig. 18) with the Direction Keys, moving right to the next character position and repeating. Choose Save and press the Select Key to save profile.

5.6 System Settings Screen

Fig. 19

System Settings Screen

System Settings 50 1/3 13:35

A. Time/Date setting — Set Date/Time

13:35 24h 05/23/07

B. Operating Language setting — Select Language

English

C. Warm-Up Mode setting — Warm-Up Mode

Ask to Run

D. Contrast/Volume setting — Contrast/Volume

Contrast: [Sun icon] - [Slider] +

Volume: [Speaker icon] - [Slider] +

Firmware Version 01.52.86

E. Total system hours — System Hours 30000000

← Patient Mode →

Time, Date, Operating Language, Screen Brightness, Volume and Warm-up Mode can be changed within the System Settings Screen (Fig. 19). To make changes, scroll to the desired setting and select. Scroll within the selection boxes to select the desired settings.

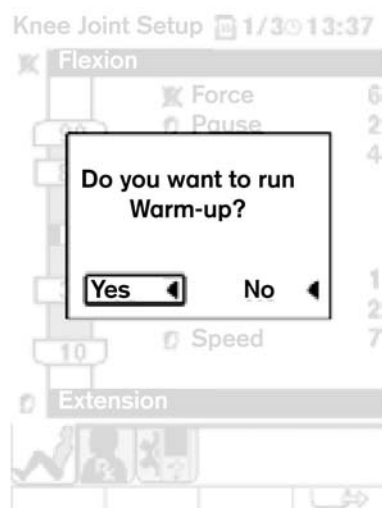
The Warm-Up Mode (Fig 19, Pos. C) offers several options. "Always run" begins any session with the Warm-Up Mode. "Never run" eliminates the Warm-Up Mode. "Ask to run" asks the users at the beginning of each session if the Warm-Up Mode is desired. See section 5.7 for more information about the Warm-Up Mode.

The System Settings Screen also provides information on Total System Cycles (Fig. 19, Pos. E) and which version of Firmware version it is using.

5.7 Warm-Up Mode

Fig. 20

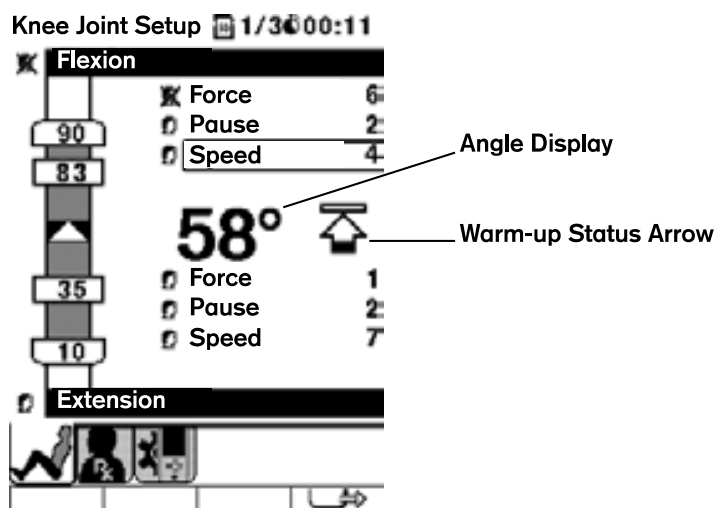
Warm-up Mode
Pop-up Window



The **Warm-Up** Mode has several settings which are set by the Clinical Professional: **“Ask to run,” “Always run,”** and **“Never Run.”** If the Clinical Professional has selected **“Ask to run,”** a pop-up window will appear whenever the device is run for the first time after being powered on (Fig. 20). The patient can select yes or no using the Pro Controller right or left Direction Keys and then select it with the Select Key.

Fig. 21

Warm-up Mode
indicator arrow



Warm-Up Mode begins at 25% less than the patient's set limits for both flexion and extension, and expands to 100% of the patient's set limits over a period of 10 cycles. The patient can view an arrow (Fig. 21), which slowly fills up with black as the cycles progress. The patient can disable the Warm-Up Mode by stopping the device and then immediately starting it again.

6.0 Patient Operation of the 480E PRO

Note: Please make sure that the patient is educated concerning the operation of the Pro Controller and CPM device.

SAFETY CONSIDERATIONS



Danger!

The controller must be positioned so that patients and medical personnel can reach the START/STOP button during use.



Attention!

Keep hair, loose clothing, fingers, etc., away from moving components of the device.



Attention!

Do not expose the device to water, including ice bags. Do not expose to extreme temperatures.



Attention!

Turn the power off before unplugging.



Attention!

Do not use the device, power supply or controller if it appears damaged or if there are exposed wires.



Attention!

Do not pour cleaning solution directly onto the device. This may allow fluids to damage the device.



Note!

When the device is not in use, turn it off and unplug the power supply.



Note!

If you have pain, discomfort or treatment questions, contact your physician.



Danger!

Patients are responsible for using the device according to these Instructions for Use.

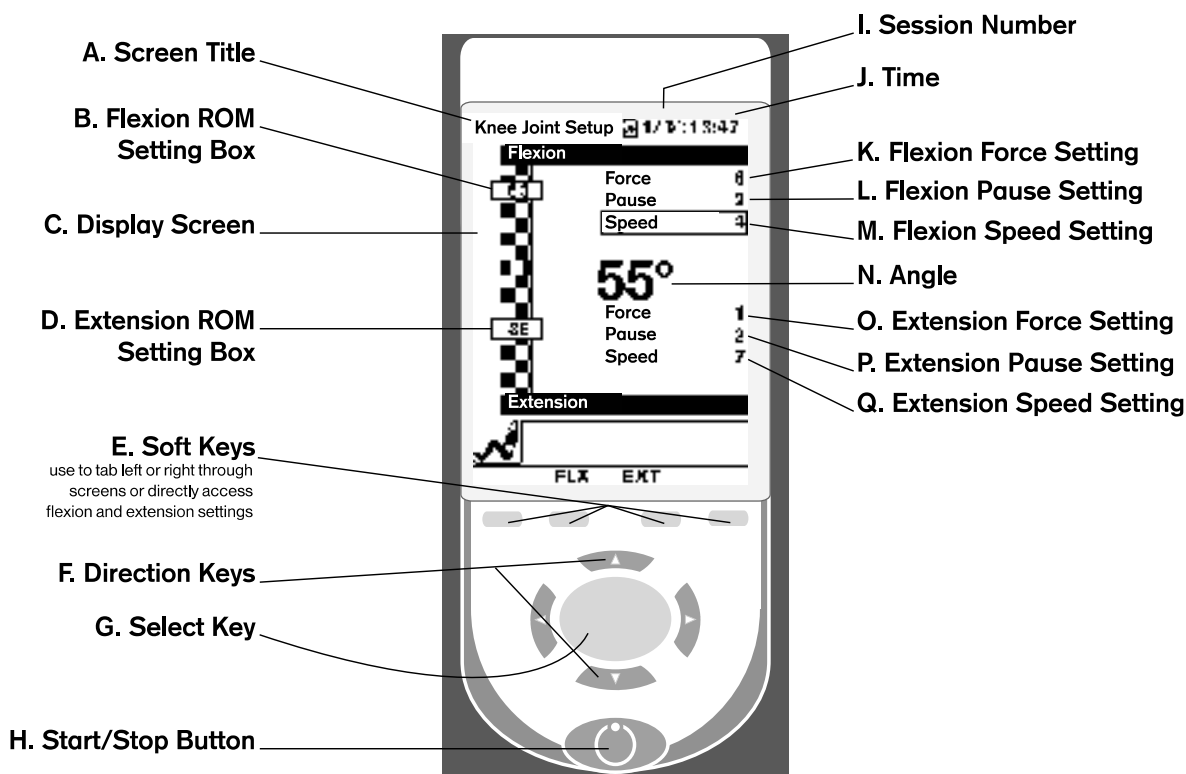
Patient Instructions

The 480E PRO Knee CPM Device is designed to offer continuous passive motion for your knee after surgery. The 480E PRO is operated via a Pendant controller, which allows you to start, pause and stop the activity of the device. The Pendant also allows you to make changes to certain functional settings, depending on your Physician's prescription.

Turning on the 480E PRO CPM Device

Turn on the 480E PRO at the base of the device. A Start-up Screen will appear in the Pendant which will be replaced after a moment with the Operating Screen.

Fig. 22 Operating Screen with functional elements called out.



The Operating Screen (Fig. 22) gives you information about the status of the 480E PRO, and may display setting options depending on your prescription. Keys located in the lower half of the Pendant are used to start, stop, and choose various function in the Pendant.

How to Start and Stop the CPM Device

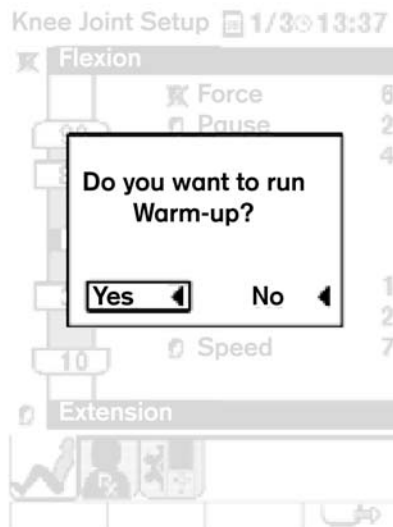
Simply press the Start/Stop Button once to begin your session (Fig. 22). To stop the device at any time, press the Start/Stop Button again. When restarted the device will begin by moving in the opposite direction.

Warm-up Feature

The 480E PRO has a Warm-up feature which moves slowly through your flexion and extension range. It begins at 25% of your maximum settings, then increases to 100% over 10 cycles.

Fig. 23

Warm-up Mode
Pop-up Window

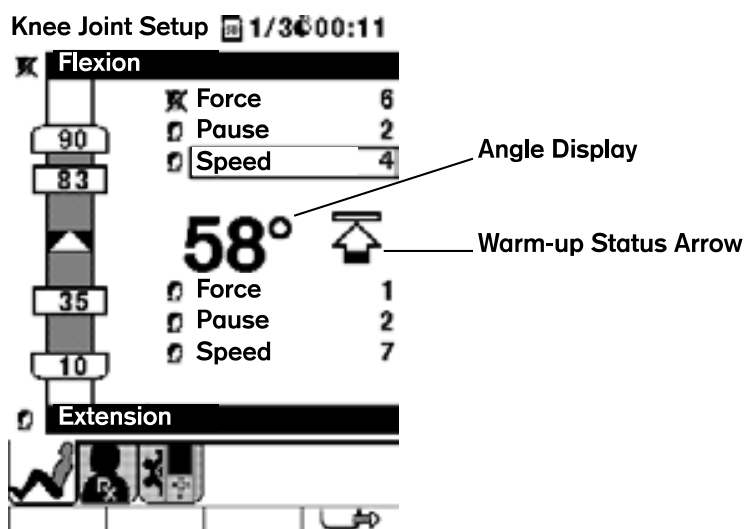


If the automatic Warm-up feature is enabled, it will automatically begin with the warm-up. It may also provide a pop-up window (Fig. 23) to ask if you'd like to do the warm-up or not.

To select yes or no, simply use the Direction Keys (Fig. 22), to move the Cursor Box over the desired selection, then press the Select Key (Fig. 22).

Fig. 24

Warm-up Mode
indicator arrow

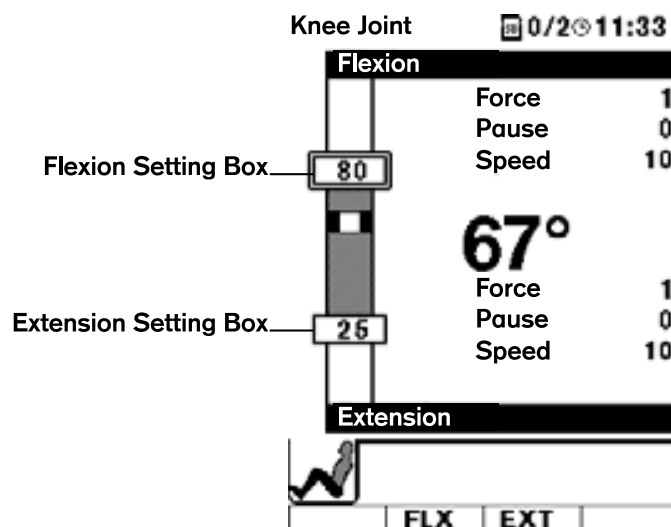


During warm-up an indicator arrow will appear alongside the Angle Display (Fig. 24). It will 'fill up' to indicate warm-up status.

Changing Functional Parameters

Depending on your Physician's prescription, you may be able to make changes to flexion and extension Ranges of Motion, to the Force, to the amount of time the device Pauses between flexion and extension, and to the Speed at which the device operates.

Fig. 25
ROM Settings



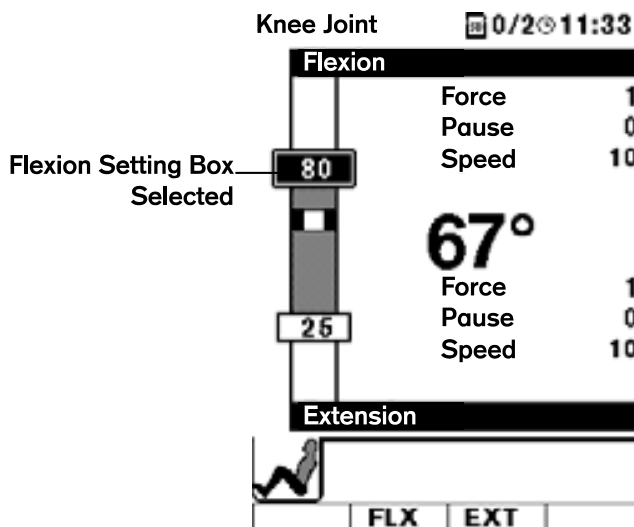
Range of Motion Settings

Range of Motion refers to the amount of flexion (bending) and extension (straightening) your leg will experience while on the 480E PRO.

Your doctor may set up the 480E PRO so that you can adjust these angle settings. You'll know you can make such changes if you see a box on the left side column that has numbers in it (Fig. 25). To make changes, simply use the Direction Keys (Fig. 22, Page 19) to navigate to the desired Flexion or Extension box in the left hand column.

Press the Select Key to open the settings box and press the Up or Down Direction Keys to attain the desired angle.

Fig. 26
ROM Settings with
Box Selected



Once you've made your adjustment, press Select again to confirm the setting.

Force, Pause and Speed Settings

Fig. 27

Selection Cursor selected

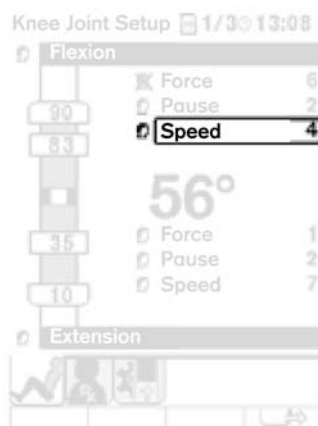
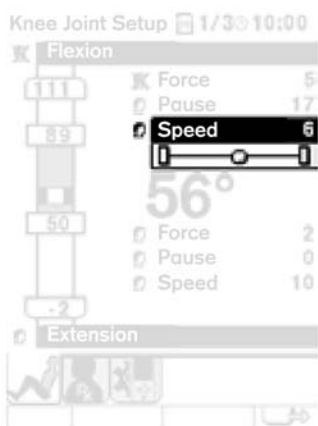


Fig. 28

Slider Bar selected



Force, Pause and Speed Settings can also be changed with the Direction and Select Keys. (Fig. 27)

- Force is set on a scale from 1 to 5
- Pause time can be set from 0 to 30 seconds
- Speed can be set on a scale from 1 to 10

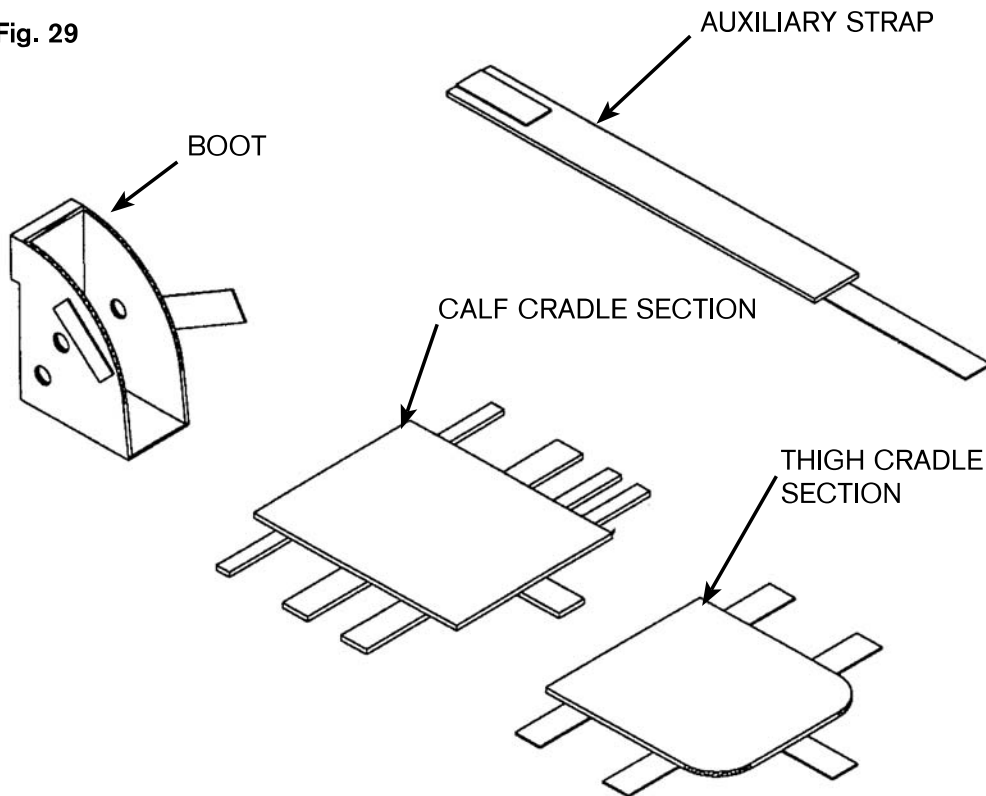
To make a change, simply use the Direction Keys to navigate the Cursor Box over the desired function, (Fig. 27) then press the Select Key.

A Slider Bar will appear (Fig. 28) which can be adjusted with the Left and Right Direction Keys.

- Adjusting the Slider bar to the left=weaker, shorter, slower
- Moving it to the right=stronger, longer, faster

7.0 Attaching the 400PK Patient Kit to the Pro Series 480E PRO

Fig. 29



Coverings for the 480E PRO 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 is for **SINGLE PATIENT USE ONLY**.

Begin with the Thigh Cradle Section (see Fig. 29), and place on the thigh section of the device. Make sure the thigh shield is in place and connect the hook and loop fasteners.

Next, attach the Calf Cradle Section.

To attach the Boot, place the elastic flap over the Foot Plate (Fig. 1, Page 7) (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.

8.0 Measuring Patient and Adjusting Device Length

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 (Fig. 1, Page 7). Fit thigh shield to gluteal crease of patient (the bottom of the buttocks). The knee pivot on the CPM device 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 (6 mm) 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

Fig. 30

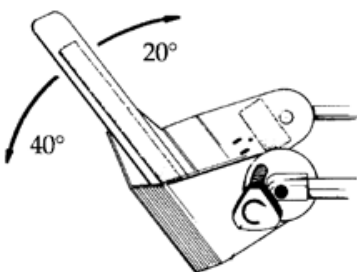
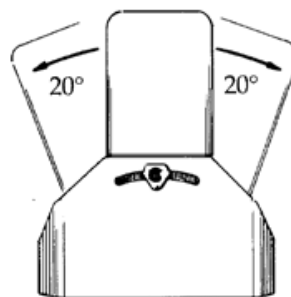


Fig. 31



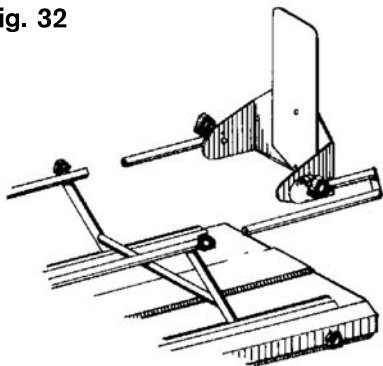
To allow free movement of the ankle, loosen ankle adjustment knobs located on the Foot Cradle. For rotation of the foot, loosen the adjustment knob located on the back of the Foot Cradle and reset to the right or left side as required (see Figs. 30, 31).

9.0 Changing Modular Components (Foot Cradle)

The 480E PRO 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. 32).
2. Remove Foot Cradle from the Calf Cradle
3. Install desired Standard or 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.

Fig. 32



10.0 Maintenance and care



Attention!

DO NOT IMMERSE THE PRO CONTROLLER IN ANY FLUIDS.

Immediately following each patient use, the CPM Pro Controller should be cleaned with a soft cloth and mild disinfectant. Do not wash soft goods.

Maintenance Between Patients

- Patient Kits 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 disinfectant.
- 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 $\pm 5^\circ$ 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 from "Maintenance Between Patients".
- 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 Final Inspection criteria. (These are available through your Sales representative, Customer Service, or your local distributor.)

Sterilization

- This device does not require sterilization for use.



Attention!

Exposing the device to sterilization conditions will damage the device and may result in a potential hazard.

11.0 Troubleshooting Guide

PROBLEM	POSSIBLE CAUSE	FIX
Device will not power up	No power to base unit	Check Power Cord and Power Supply connections and ensure lock nut is tight (the Power Supply's green light glows when it is connected to the mains AC power), ensure Power Switch is in the On position
	No connection to Pro Controller	Check Pendant Cable connections at both ends, ensure the lock nut is tight
	Internal electrical malfunction	Return for service
Insufficient lifting power	Force setting too low	Increase force setting
	Internal malfunction	Return for service
Mechanical binding or jerking motion	Internal mechanical malfunction	Return for service
	Obstruction	Remove obstruction
Pro Controller shows Error Codes	Self-detected malfunction	Follow prompts on Pro Controller display

12.0 Appendix for Electromagnetic Compliance


IEC 60601-1-2:2004 Table 201 Requirements

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions		
CISPR 11	Class B	The equipment is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions		
IEC 61000-3-3	Complies	

IEC 60601-1-2:2004 Table 202 Requirements:

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the Equipment should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air with documented necessary	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 UT = 230 Vac	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles No anomalies 95% dip meets requirements.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

IEC 60601-1-2:2004 Table 204 Requirements:

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the equipment including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a should be less than the compliance level in each frequency</p> <div></div> <p>Interference may occur in the vicinity of known RF transmitting devices and equipment marked with the following symbol:</p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment</p> <p>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

13.0 Limited Warranty

New Product Limited Warranty

The Manufacturer warrants the product to be free from defects in material and workmanship for a period of (2) two years for all major components (motor, power transmission parts and circuit boards) and for a period of 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 its 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 (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 (outside the USA contact International Customer Service), 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 your local dealer/distributor or the manufacturer (*see last page of this manual*).

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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Registered to ISO 13485 Quality Assurance

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