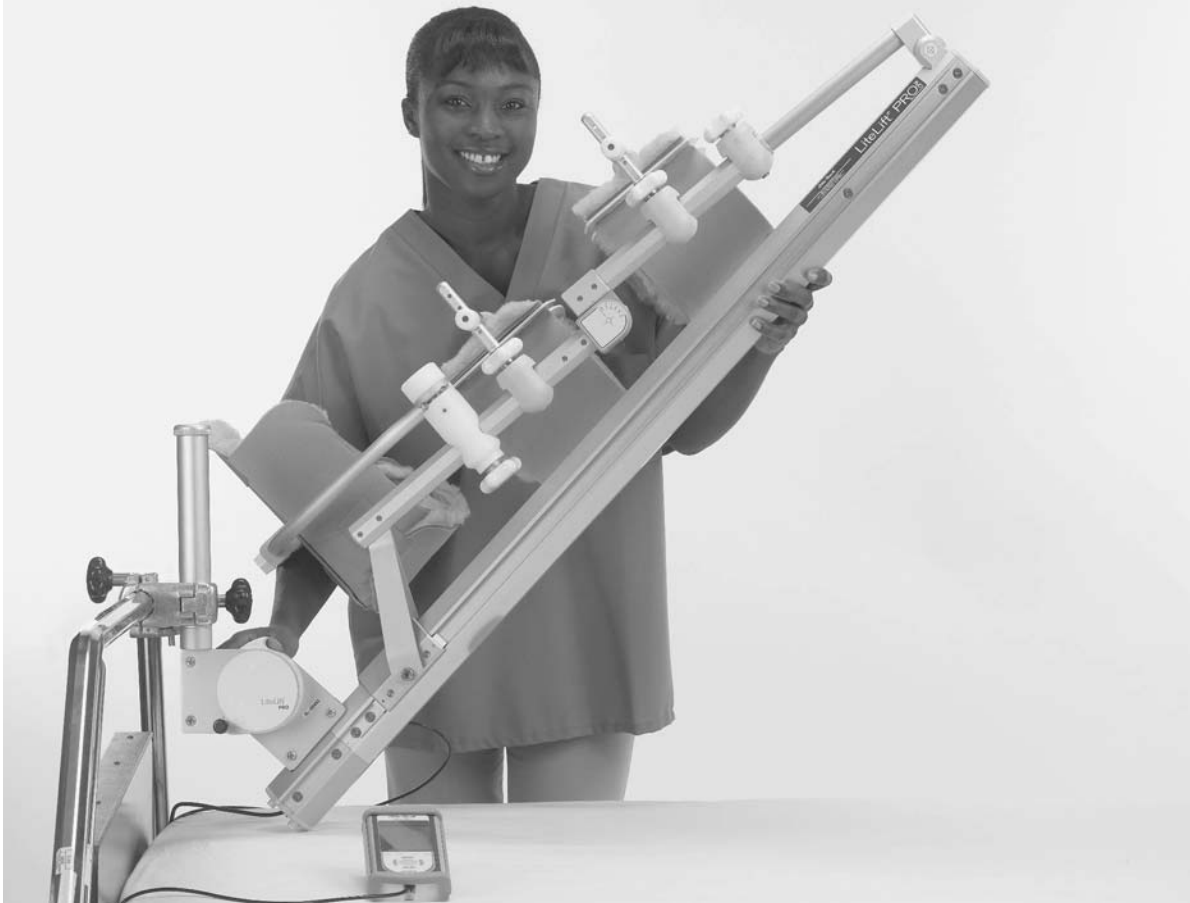


QAL Medical™

OrthoAgility™



LiteLift PRO CPM Device

Model 7000P

Ⓞ 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



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



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 LiteLift® PRO Continuous Passive Motion (CPM) system is designed for the rehabilitation of the lower limbs following knee or hip surgery, and is designed primarily for use in the hospital environment and works only with the PRO Series Pendant Controller.

The LiteLift® PRO has a lifting mechanism which allows it to be attached directly to a standard hospital bed frame. It conveniently stores out of the way when not in use. A clutch mechanism locks at any angle and also reduces the functional lifting weight of the LiteLift® PRO by almost half.

The patient's leg is suspended from the device rather than being supported by it.

The foot, calf and thigh supports along with the patient kit attachments are all independently adjustable to ensure that the LiteLift® PRO can be anatomically aligned for a wider range of patient sizes.

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. following
- Prevention of negative effects of immobilization.

1.4 Indications

Immediate post-operative management after the following where indicated:

- ACL reconstruction
- Total Knee Replacement
- Ligament reconstruction
- Manipulation under anesthesia
- Meniscal repair
- Stabilized intra- or extra-articular fractures of the femur and tibia

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.

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!**

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.

**Danger!**

Before raising the CPM upright for storage, place the CPM into full flexion to avoid foot plate interference with mounting bar or bed frame.

**Danger!**

When applying the CPM to patient, make sure that the CPM is fully supported on the bed: the CPM should NOT be supported by lift mechanism while applied to patient.

**Danger!**

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

**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 LiteLift 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 LiteLift 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 LiteLift® PRO Components and Technical Data

3.1 LiteLift® PRO Replacement Parts Ordering Information

Description	Part No.
Power Adaptor (GlobTek GTM21097-5015).	L480SA031
Power Cord (North America)	14157.5
Power Cord (elsewhere).please consult Customer Service for the correct Power Cord for your region
Pro Pendent Cable	NG-103
Pro Controller Pendant	NG-104
Long Footbar	221476-1
Short Footbar	221476-2
White Foam Pads	221970
Patient Kit	7100
Customized Double Clamp	13504
Post Tube Extension	DL009
Post Tube Extension Joint (required with Post Tube Extension)	DL011

3.2 Technical Data

Model 7000P

Specifications	min (imp)	max (imp)	min (si)	max (si)
Packing Length	48 in		122 cm	
Length, Traction Frame to Hip Pivot	48 1/2 in		123 cm	
Weight of Device	26 lbs.		12 kg	
Thigh Adjustment	12 in.	20 in.	30 cm	51 cm
Calf Adjustment				
Short Foot Bar	11 in	20 in	28 cm	51 cm
Long Foot Bar	14 in	23 in	36 cm	58 cm
Leg Length				
Short Foot Bar	23 in	40 in	58 cm	102 cm
Long Foot Bar	26 in	43 in	66 cm	109 cm
Range Of Motion (ROM)	0°	110°		
Speed	30 degrees/minute	80 degrees/minute		
Pause	0 seconds	30 seconds		
Timer	0 minutes	24 hours		
Mode of Operation	Continuous			

Power Supply

Input 100-240 VAC 1.6A 50-60Hz

Output 15 VDC 2.0A

Class II

Electric Shock Classification

Type B

Medical Device Classification

Class 1 (USA)

Class IIa (93/42/EEC)

3.3 Electromagnetic Compliance



Danger!

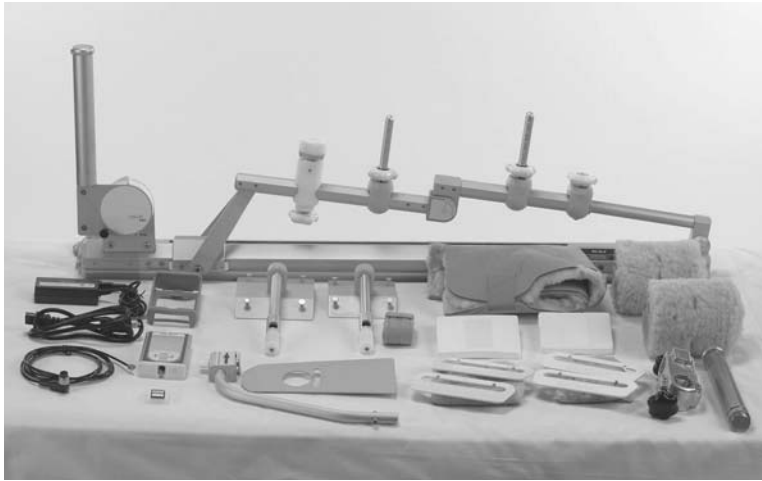
Equipment not suitable for use in the presence of flammable anesthetic mixture with air or Nitrous Oxide.

4.0 Setting Up the LiteLift® PRO

4.1 Unpacking the LiteLift® PRO

Remove all the LiteLift® PRO CPM system components from the carton. During unpacking, check for all components and any external damage. Report any substantial damage.

Fig. 1
LiteLift®
PRO Device
with all
components



4.1.1 Included in your Kit

- 1 Motion unit
- 1 Power Adaptor
- 1 Power cord
- 1 PRO Pendant Controller
- 1 Pendant Cable
- 1 Long Footbar
- 2 White Foam Pads
- 1 Patient Kit
- 1 Foot Plate
- 1 Thigh Support Bar
- 1 Calf Support Bar
- Instructions for Use



Note!

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.

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.
4. Ensure that both Power Cord and PRO Controller Cable are uncoiled from the device.



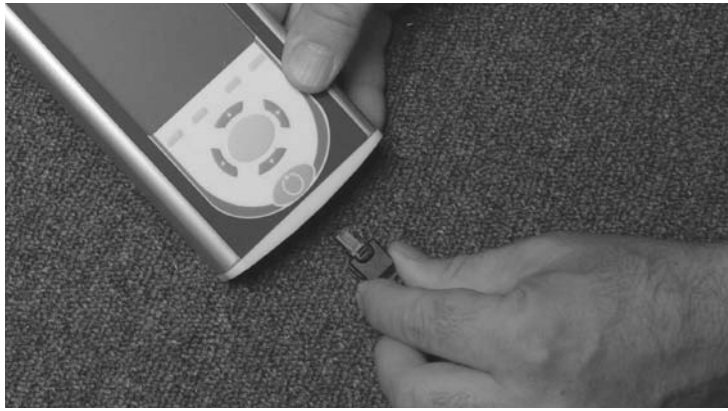
Attention!

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

4.2 Connecting your Components

Fig. 2

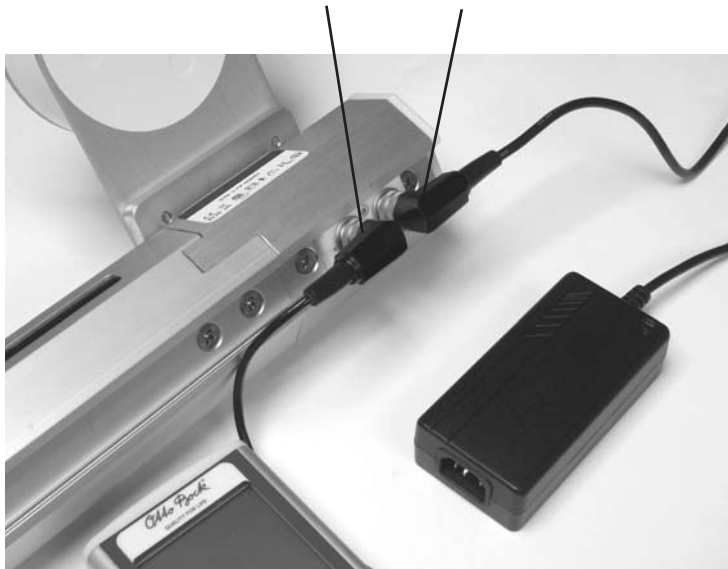
Connecting the Pendant Cable to the pendant.



1. Connect the appropriate end of the PRO Controller cable to the PRO Controller (Fig. 2), and the other end to the CPM Device (Fig. 3, Pos. 1), and tighten the lock nut.

Fig. 3

Connecting the Pendant Cable to a CPM device.



2. Connect the Power Adaptor connector on the end of the Motion Unit and tighten the plug's lock nut (Fig. 3, Pos. 2).
3. Connect the Power cord to the Power Adaptor. Plug the other end of the Power cord into a standard (grounded) wall outlet.

4.3 Bed Setup

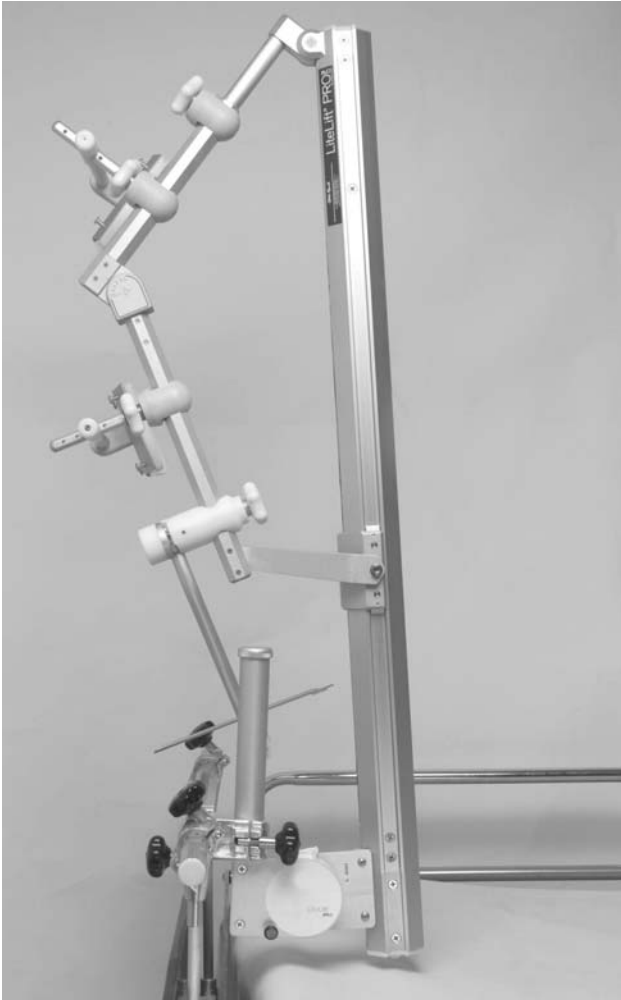
**Danger!**

LiteLift PRO must be securely fastened to the hospital bed.

**Danger!**

Never release the mounting knob while there is a patient in the bed.

Fig. 4



The LiteLift® PRO mounts to hospital beds with a standard bed mount, and comes with a self-storing Wrap Spring Clutch, which makes it easier for hospital staff to apply and store the LiteLift PRO while avoiding contamination. The Wrap Spring Clutch conveniently locks at any angle and reduces the functional lifting weight of the CPM by almost half. It also stores the CPM out of the way when not in use (Fig. 4).

4.3.1 Attaching LiteLift® PRO to bed

Fig. 5



To attach the LiteLift® PRO to bed, first attach the smooth, round side of the Double Clamp to the Post Tube (Fig. 5). Then attach the octagonal side of Double Clamp to bed's horizontal Traction Bar. The Traction Bar must have a flat surface facing up. Securely tighten both sides of the clamp.

Fig. 6



The post tubes should be long enough to allow the unit to rest above the mattress a minimum of 8" (20cm) (Fig. 6). Because the Traction Bars on different hospital beds are not all the same height above the mattress, it may be necessary to add extensions to the Post Tube to obtain enough height. To add an extension, unscrew the Post Cap and replace it with a Post Tube Extension Joint. Screw the Post Tube Extension onto the Joint and screw the Post Cap into the top of the Post Tube Extension.

4.3.2 Raising and Storing LiteLift PRO while attached to bed



Danger!

Failure to observe the following safety instructions can lead to injury of patient or hospital staff.



Danger!

DO NOT engage the Clutch Release if the CPM Device is not fully supported.



Danger!

Hospital staff must support the CPM Device with at least one hand when lowering the device to the bed.



Danger!

Always store the CPM Device in a vertical position.

**Danger!**

The Clutch Release Lock must be engaged in the locked position when the CPM Device is stored and when it is in position for patient use.

**Attention!**

Before raising the CPM Device upright for storage, place it into full flexion to avoid foot plate interference with mounting bar or bed frame.

**Attention!**

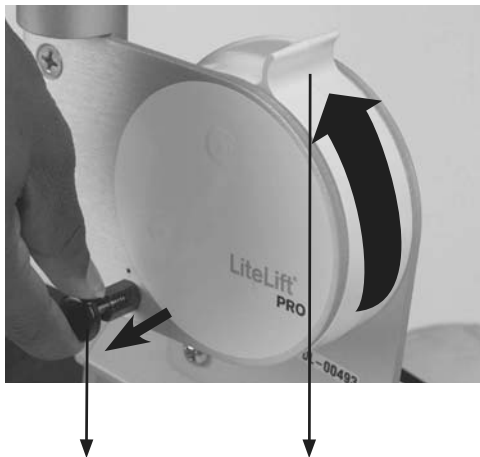
When applying the CPM to patient, make sure that the CPM is fully supported on the bed: the CPM should NOT be supported by Lift Mechanism while applied to patient.

Fig. 7**Fig. 8****Fig. 9**

To raise the CPM Device from patients between treatments, make sure Clutch Release Lock is correctly engaged (Figs. 7, 8, 9), and simply lift the CPM Device/Wrap Spring Clutch Assembly away from the patient. The Wrap Spring Clutch will automatically lock in place at any angle unless the Clutch Release is pressed (Fig. 10).

Fig. 10

1. Clutch release lock
2. Clutch release

**Fig. 11**

Make sure the CPM is in a fully upright (Fig. 4, page 9) position and that the Clutch Release Lock is in the locked position. If the Clutch Release Lock does not fully engage it may be necessary to push/pull the Clutch Release slightly.

4.3.3 Lowering LiteLift PRO for adjustments and Patient Use

**Danger!**

Always fully support CPM and Wrap Spring Clutch when lowering device to bed.

**Danger!**

Always reengage Clutch Release Lock after lowering device to bed.

Fully support the CPM Device with at least one hand (Fig. 11) before disengaging the Clutch Release Lock. (Fig. 10, Pos. 2)

Fig. 12



Fig. 13



Next, still supporting the CPM Device with one hand, press the Clutch Release (Fig. 12) and lower device to the bed. (Fig. 13) The Wrap Spring Clutch will automatically lock in place if the Clutch Release is released.

Once the CPM Device is lowered to the bed (Fig. 14), make sure the Clutch Release Lock is correctly engaged. (Fig. 15)

Fig. 14



Fig. 15



Finally, adjust the Double Clamp so that the CPM device rests flat on the mattress.

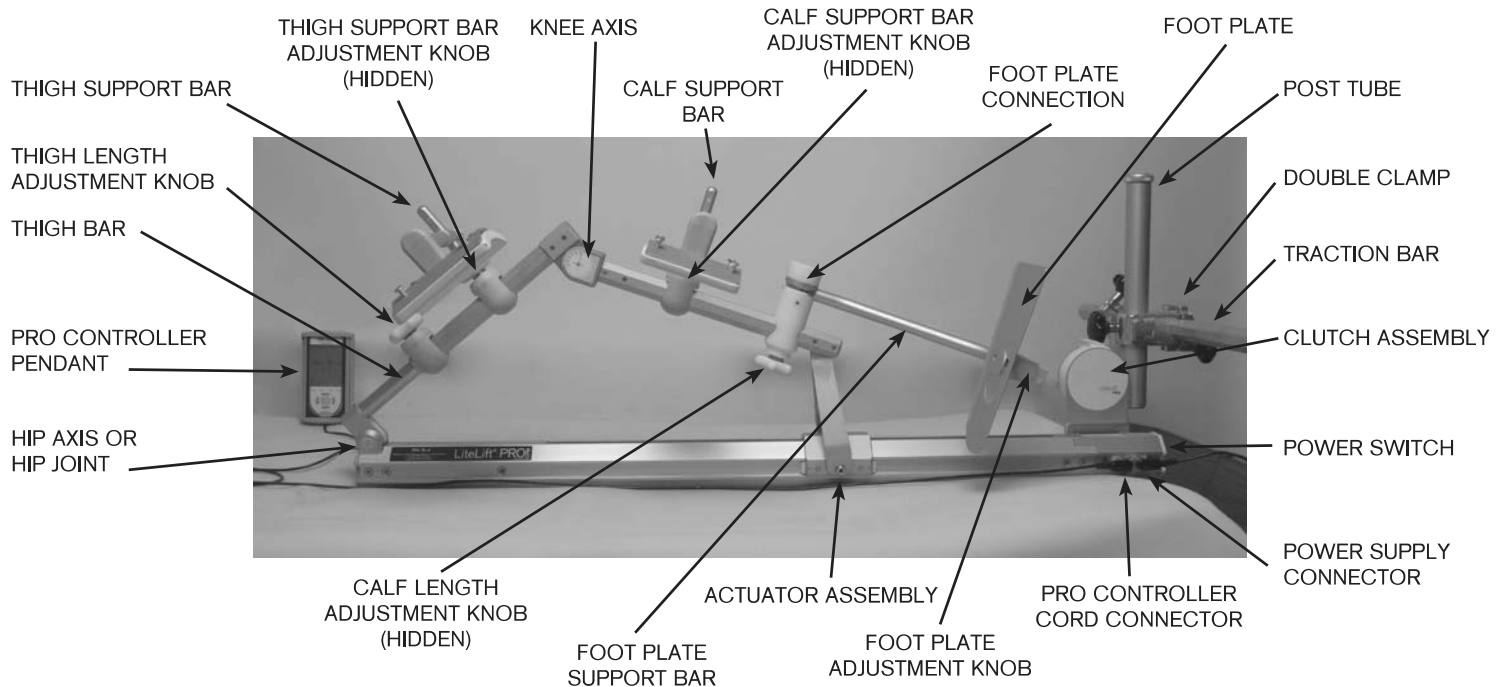


Attention!

The Wrap Spring Clutch is designed to only support the CPM device. It is NOT designed to support both the CPM and the user's leg.

5.0 Patient Alignment and Set Up

Fig. 16



Danger!

Always fully support CPM when lowering device to bed.



Danger!

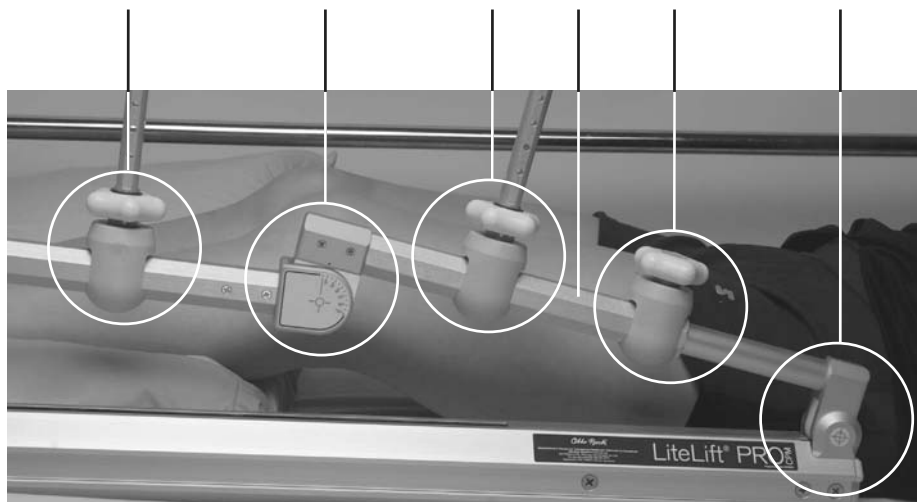
Always reengage Clutch Release Lock after lowering device to bed.

With the patient in the supine position, release the safety strap (if attached) and gently lower the LiteLift® PRO over the patient's limb according to directions in section 4.3.3. Make sure that the LiftLift is completely supported by the bed (you may have to adjust the double clamp to do so). Also make sure that the Clutch Release Lock is correctly engaged.

5.1 Aligning the Knee and Hip Axes

Fig. 17

1. Calf Support Bar Adjustment Knob
2. Knee Axis
3. Thigh Support Bar Adjustment Knob
4. Thigh Bar
5. Thigh Length Adjustment Knob
6. Hip Axis



Step 1: Measure the distance between the patient's greater trochanter to knee center.

Step 2: With the patient supine (lying down) and the LiteLift PRO lateral to the involved leg, align the patient's greater trochanter to the + symbol of the LiteLift PRO's hip axis (Fig. 17, Pos. 6).

Step 3: Loosen and push down on the Thigh Length Adjustment Knob (Fig. 17, Pos. 5) while pulling up on the Thigh Bar (Fig. 17, Pos. 4) to set the distance between the device knee axis and the device hip axis EQUAL to the distance measured between the patient's greater trochanter and knee center in Step 1.

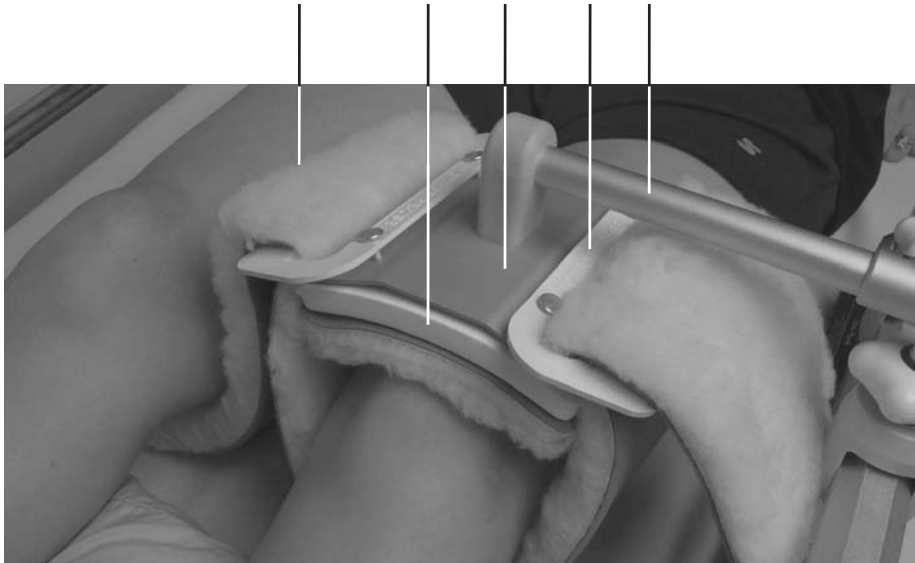
Step 4: Re-tighten the Thigh Length Adjustment Knob.

IMPORTANT NOTE: The device will not operate if the Thigh Length Adjustment Knob is not tightened securing alignment. An error code will occur requiring you to turn the device off and on again to re-set.

5.2 Attaching the Thigh and Calf Support Bars

Fig. 18

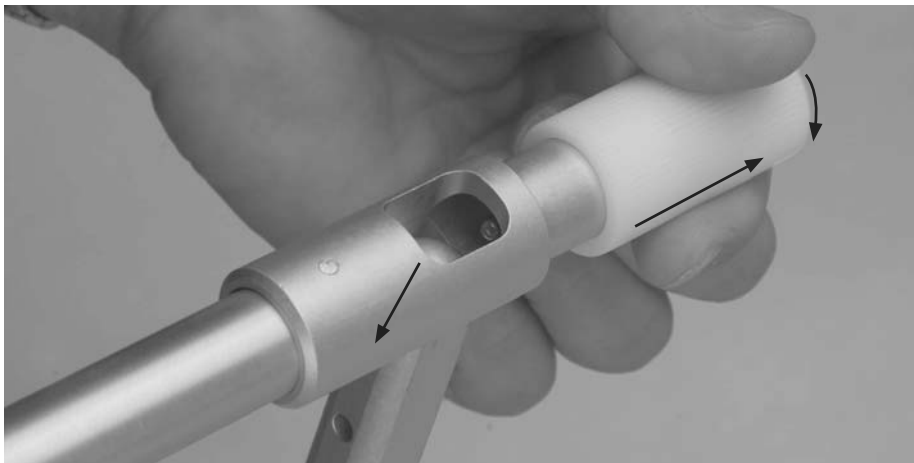
1. Sling
2. Pad
3. Paddle
4. Sling Clip
5. Support Bar



The Thigh and Calf Support Bars and Paddles, in conjunction with pads and slings, support the patient's leg during CPM use and can be used on both left and right legs (Fig. 18).

Fig. 19

1. Loosen Knob
2. Retract Knob
3. Apply or Remove Paddle



Attach Paddles to the Thigh and Calf Support Bars by loosening and pulling ridged knob on Support Bar (Fig. 19). Retighten once Support Bar is positioned properly.

There are two sizes of White Foam Spacer Pads, a larger one for the Thigh Paddle, and a smaller one for the Calf Paddle. Apply these first (Fig. 20) and then apply the appropriate Patient Kit Soft Squares (Fig. 21). Next, loosen Thigh and Calf Support Bar Adjustment Knobs (Fig. 17, Pos. 1, 3, page 13) and position Paddles where appropriate (generally centered on the thigh and calf).

Fig. 20



Fig. 21



5.3 Attaching Thigh and Support Slings

First, position the Thigh Sling beneath the patient's leg, then slide Sling through the Thigh Paddle Clips (Velcro® side down) (Fig. 22), making sure that the split side of the Sling is on the same side as the Paddle Arm. Next, snap the clips into place on the Clip Posts (Fig. 23) and adjust Sling to patient's thigh.

Fig. 22



Fig. 23



Equally adjust both sides of the Thigh Sling until there is a finger's width distance between the patient's leg and the paddle. Repeat this procedure with the Calf Sling.

5.4 Attaching Soft Boot

Attach Soft Boot to Foot Plate by sliding over top of Plate (Fig. 24). Secure bottom with Velcro® tab.

Fig. 24



5.5 Attaching the Foot Bar and Plate

To adjust Foot Plate to patient, first loosen the Calf Length Adjustment Knob (Fig. 25, Pos. 3) and slide distally. With the Soft Boot already attached to Foot Plate, attach Foot Plate to Foot Plate Support Bar (Fig. 25, Pos. 4; Fig. 26), making sure that the lateral wings of the bar fit correctly into Fitting (the bar should not be able to rotate).

Next, slide the Calf Length Adjustment Bar proximally until the patient's foot rests comfortably against plate. Tighten knob and secure boot around patient's foot with Velcro® tabs.

Fig. 25

1. Foot Plate Adjustment Knob
2. Soft Boot
3. Calf Length Adjustment Knob
4. Foot Plate

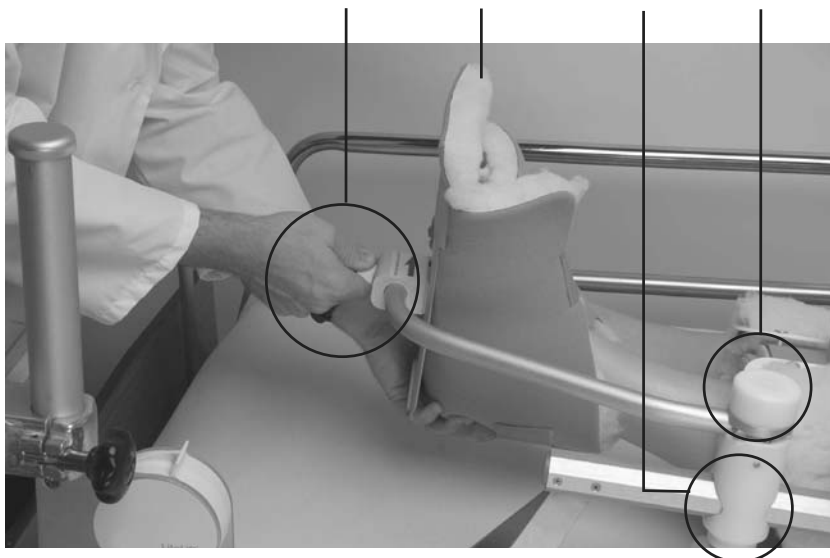
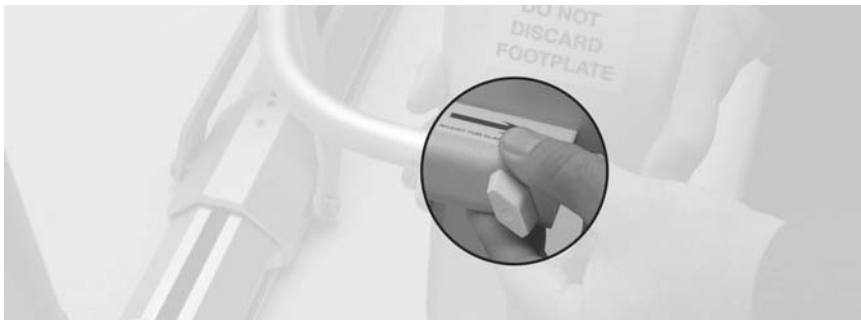


Fig. 26



Fig. 27



Adjust Foot Plate position by pulling on Foot Plate Adjustment Knob (Fig. 25, Pos. 1, page 16; Fig. 27) so that the ankle is flexed appropriately and the toes are pointing at the ceiling.

Tighten all knobs and then run the LiteLift PRO through several cycles to ensure proper alignment and patient comfort.

Finally, make sure the PRO Controller is in Patient Mode and show patient how to operate LiteLift PRO with the PRO Controller (see section 7.0).



Note!

We recommend that patients using the LiteLift PRO are checked at least once every shift—or anytime the patient removes and reapplies device—to ensure that they are properly aligned and secured.

5.6 Changing Orientation of Foot Plate

The Foot Plate is designed to work on both left and right sides, with the Support Bar lateral to the patient's leg when in use. To switch sides, first loosen Foot Plate Knob and remove Plate (Fig. 28). Next, loosen Support Bar Connection Knob (Fig. 29) just enough to slide Support Bar out. Flip Bar over, making sure to correctly engage lateral wings within Support Bar Connection (Fig. 30). Finally, reattach Foot Plate.

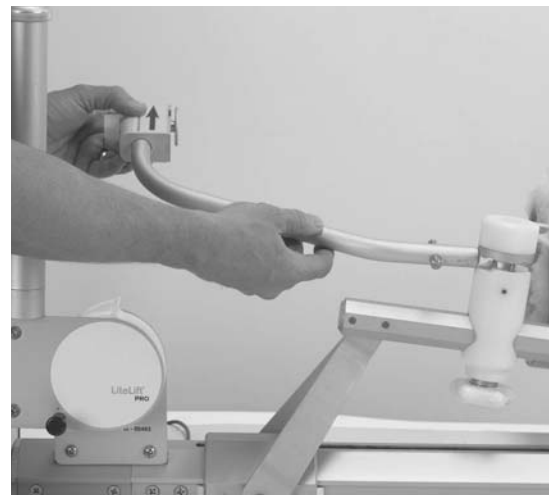
Fig. 28



Fig. 29



Fig. 30



6.0 Operating the LITELIFT® PRO-for Medical Personnel



Attention!

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

6.1 Setting up the LiteLift PRO Controller

Fig. 31

SD Memory Card being inserted into Pro Controller.



6.2 Operating the LiteLift PRO

6.1 PRO Controller Overview

The PRO Controller is connected to the LiteLift PRO CPM Device via a pendant cable, which plugs into the bottom of the CPM Base Unit (Fig. 31).

Fig. 32

SD Memory Card being inserted into Pro Controller.



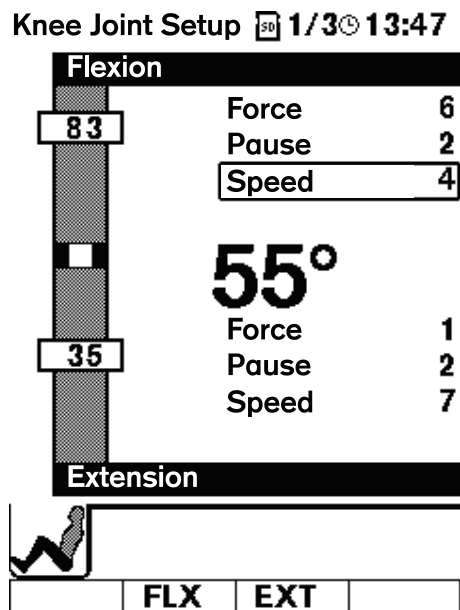
Each PRO Series CPM Base Unit controls one or more motors and ancillary equipment according to commands received from the PRO Controller pendant. The firmware in the PRO Controller and base unit can be upgraded (Fig. 32). The SD Memory Card can also store and download patient therapy profiles and doctor's 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. 33

Operating Mode Screen
with all settings made
available to patient.



The Operating Mode Screen (Fig. 33) 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.

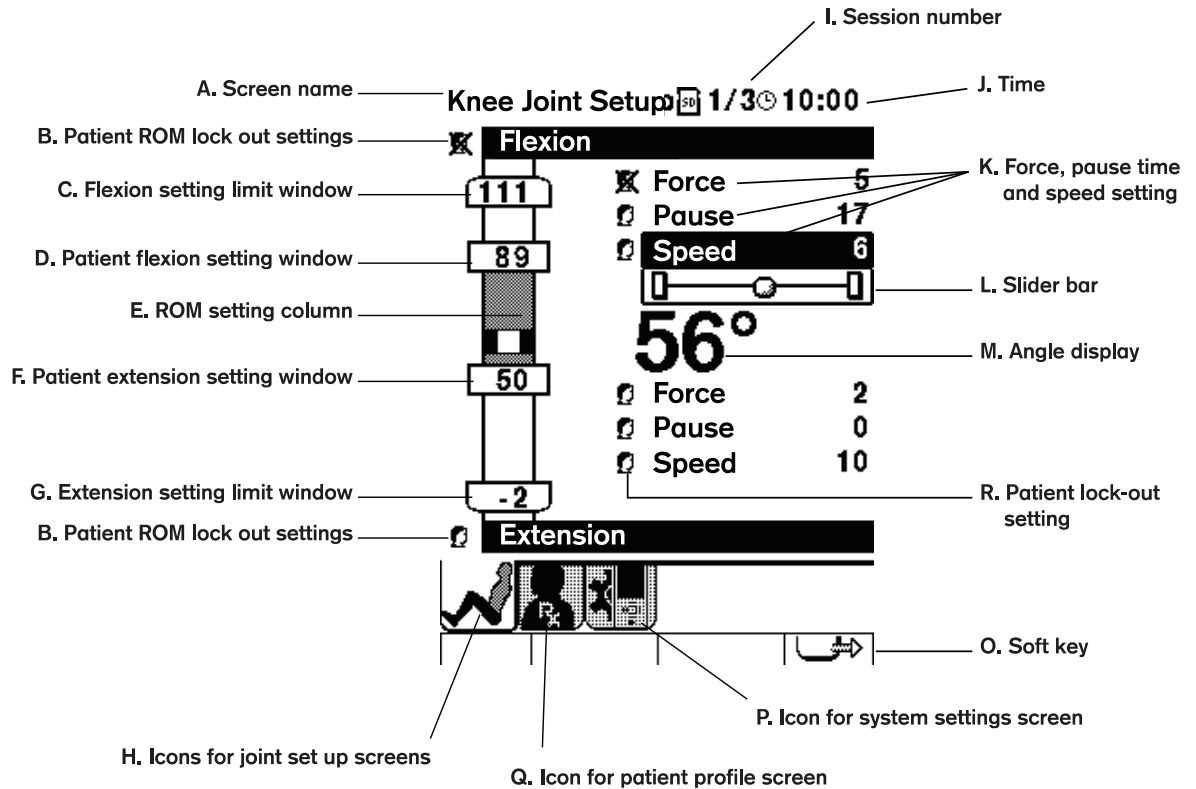
* NOTE: To protect the patient, settings may be locked to allow only medical/clinical professionals to make changes to the CPM device settings. Locking the settings will require a Special Key Sequence. Please contact your Authorized Service Representative, Dealer, or Distributor for this or answers to 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. 34

Joint Set-up Screen
with functional
elements called out.

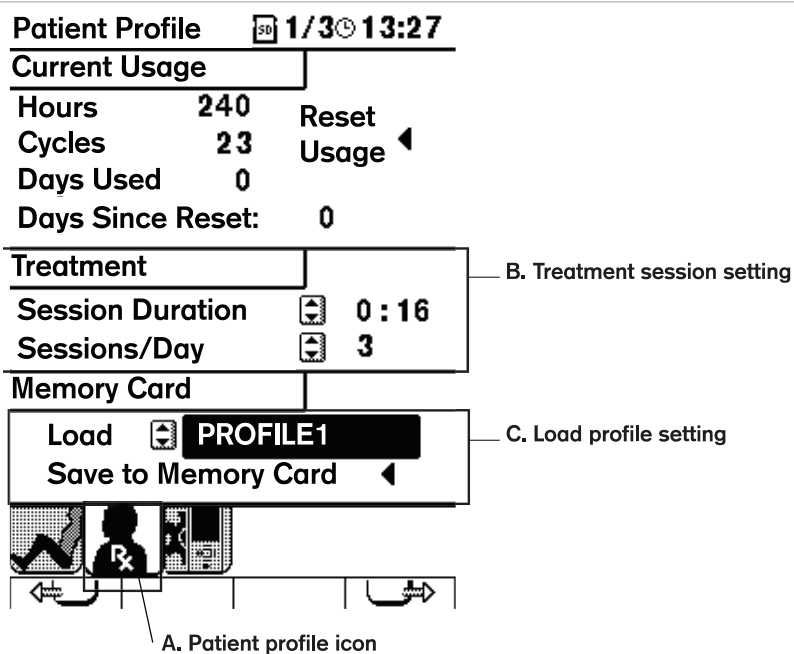


Screen Orientation (Fig. 34) The top of all screens (Fig. 34, Pos. A, I, J) contains the name of the screen as well as session number and session time remaining. The central portion of each screen (Fig. 34, Pos. B, C, D, E, F, L) contains relevant CPM Device and setting information. The bottom of each screen (Fig. 34, 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. 34), allows for the setting of Force, Speed, Pause Time and Range of Motion of all involved CPM Device joints.

Fig. 35

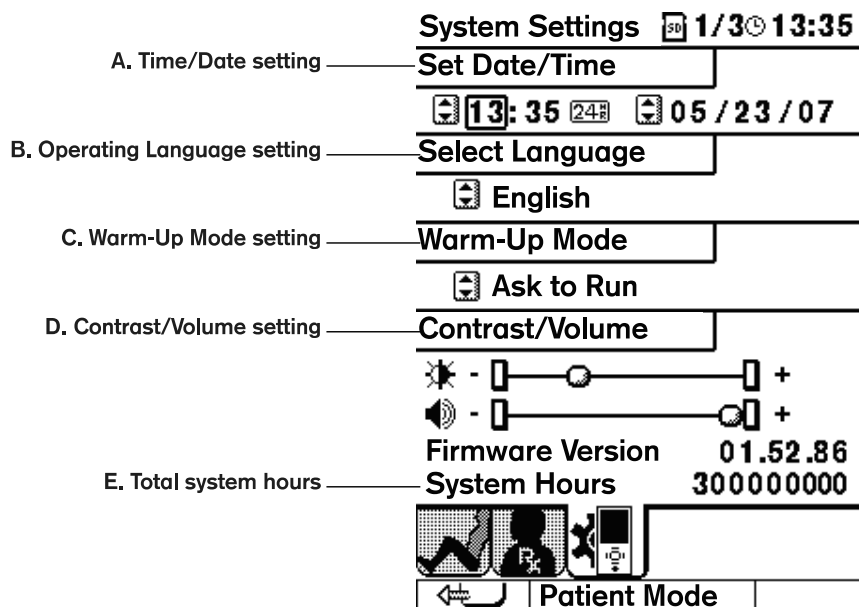
Patient Profile Screen



The Patient Profile Screen (Fig. 35), 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. 36

System
Settings
Screen



The System Settings Screen (Fig. 36), allows Time, Date, Operating Language, Warm-Up Mode and Contrast/Volume to be changed.

Fig. 37

PRO Controller Key Pad

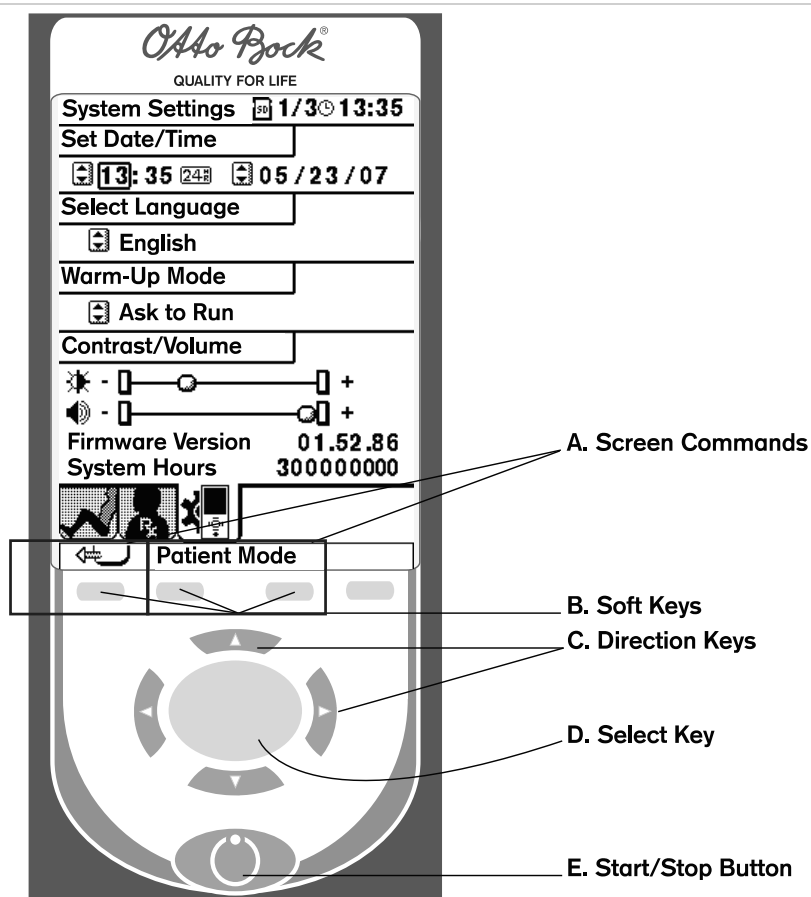


Fig. 38

The Cursor selects a functional setting.

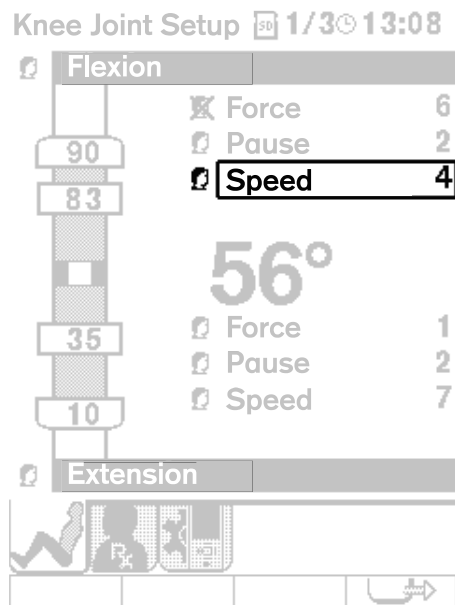
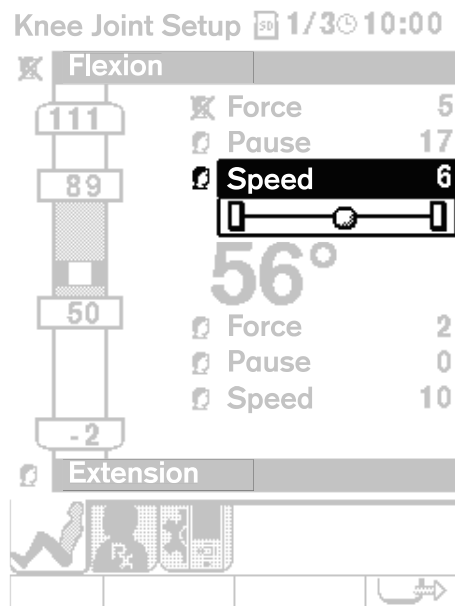


Fig. 39

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. 37, Pos. B, page 21) 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. 37, Pos. C, page 21) allow the user to move a Cursor (Fig. 38, page 22), 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. 37, Pos. D, page 21) selects or deselects a setting function (Fig. 38, page 22) and opens up a setting window or slider bar so that changes can be made (Fig. 39, page 22).

The Start/Stop Button starts and stops the CPM Device when in Setting or Operating Mode (Fig. 37, Pos. E, page 21).

Fig. 40

Connecting the Pendant Cable to the pendant.



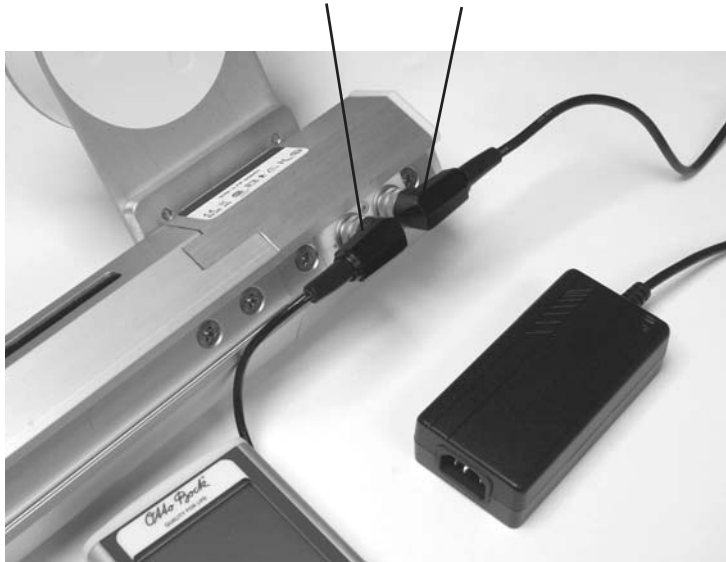
6.2.2 Connecting the PRO Controller to the CPM Device

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. 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. 41

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. 41, Pos. 1). 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 (Fig. 41, Pos. 2). 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. 42
Start-up Screen

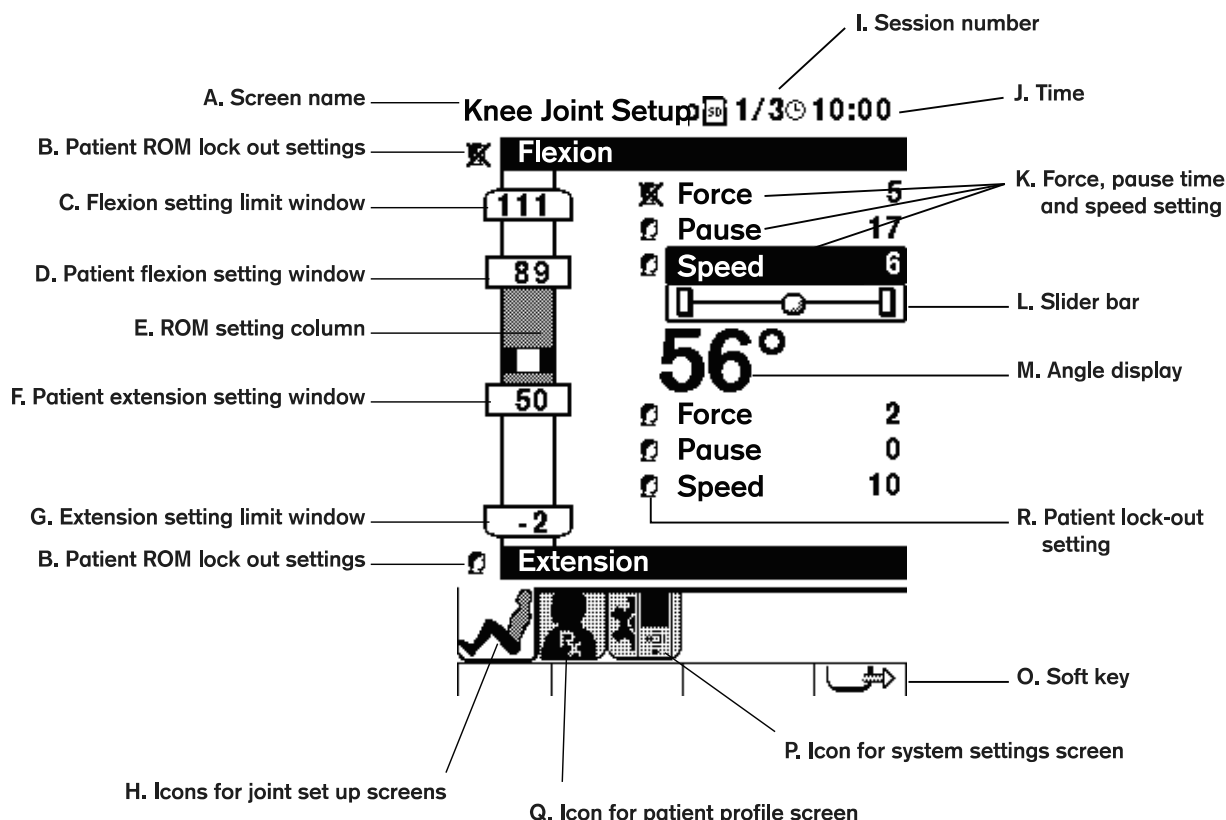


The PRO Controller will automatically recognize which PRO Series CPM Device it is connected to, and will flash a Start up Screen (Fig. 42). for about 10 seconds to indicate that it has been properly connected. It will then progress to standby mode and start up in the Operating Mode.

* 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.

6.2.3 CPM Device Parameters: Overview

Fig. 43 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. 43, Pos. A). Each screen also has its own icon at the bottom of the Screen. Icon for Joint Set-up Screen, (Fig. 43, Pos. H). Icon for Patient Profile Screen (Fig. 43, Pos. Q). Icon for System Settings Screen (Fig. 43, Pos. P).

All CPM Devices will automatically default to the Operating Mode (Fig. 33, page 19) when powered up.

After entering the Key Sequence*, the Joint Set-up Screen will appear (Fig. 43).

* 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.

6.2.4 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. 44). 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. 44
Selection Cursor
selected

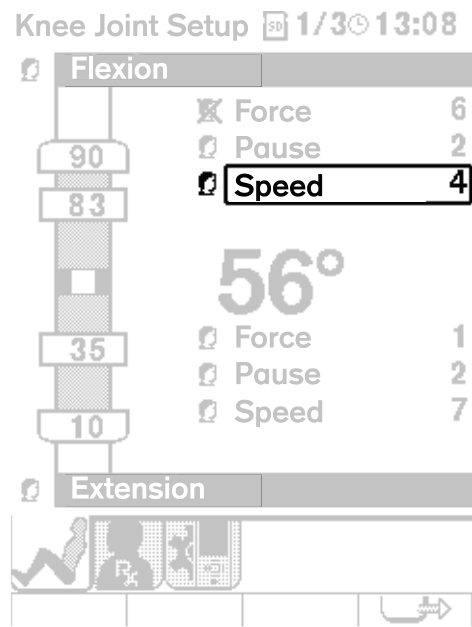
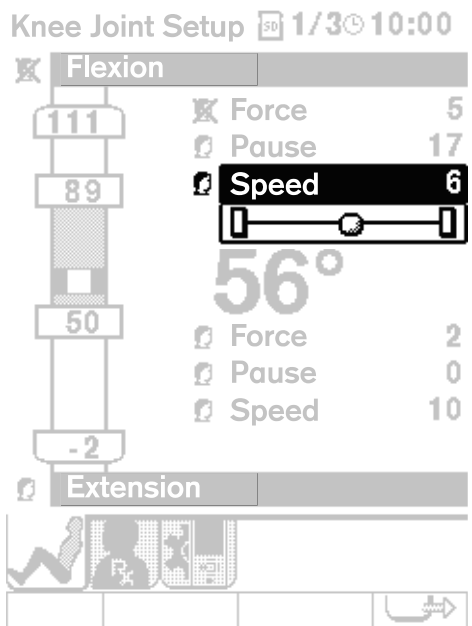


Fig. 45
Slider Bar selected



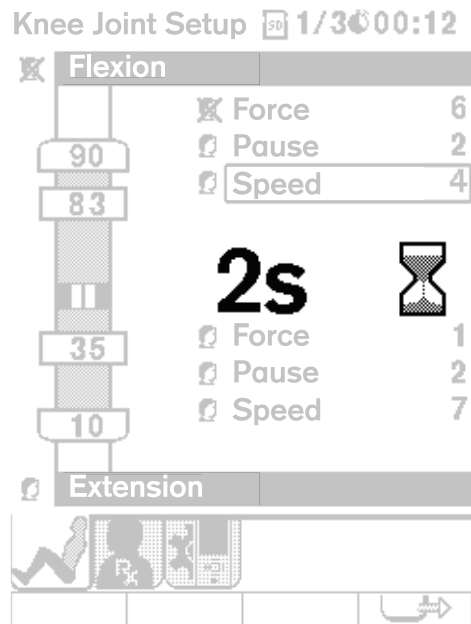
Next, use the Direction Keys to move the Cursor to the desired parameter (Fig. 44), and press the Select Key to select that parameter. A **Setting Slider Bar** will appear (Fig. 45) that will allow you to change the setting with the left and right Direction Keys. Once you have chosen your setting, press 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. 43, Pos. E, page 24). 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. 43, Pos. C, G, page 24). Both these and the Patient Controlled ROMs (Fig. 43, Pos. D, F, page 24) 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. 43, Pos. M, page 24) will show the CPM device's current angle or a countdown timer when it is in the Pause portion (Fig. 16) of its cycle.

Fig. 46

Countdown Timer displayed

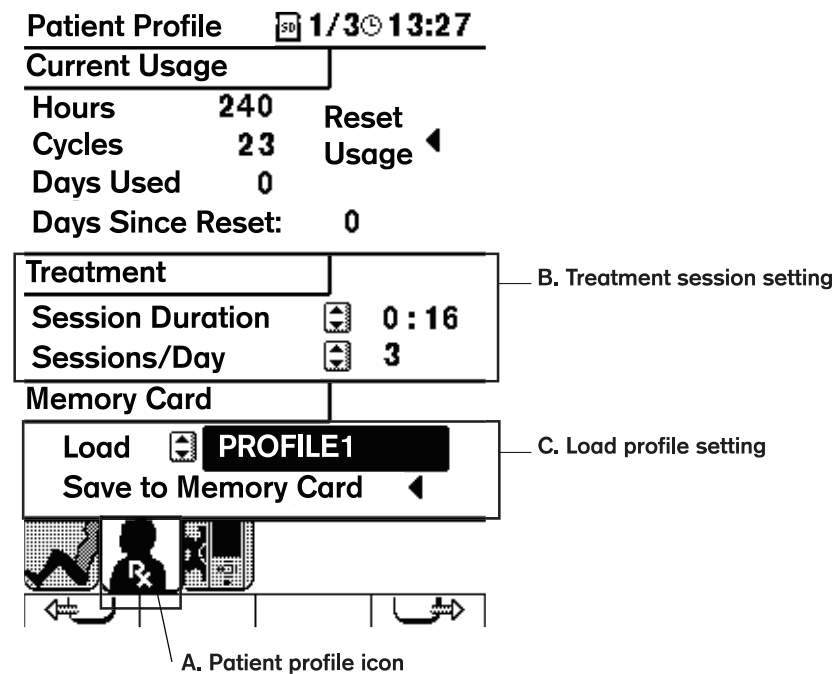


A **Lock out** option (Fig. 43, Pos. B, page 24) is available to prevent patients from making any changes to Patient Controlled ROMs as well as Force, Pause Time, and Speed. This is available in the leftmost column by scrolling to the Patient Flexion or Extension Icon (Fig. 43, Pos. B, page 24) and selecting or deselecting the icon. An X indicates that the patient is locked out from control of that parameter.

6.2.5 Patient Profile Screen: Settings and Patient Profiles

Fig. 47

Patient Profile Screen



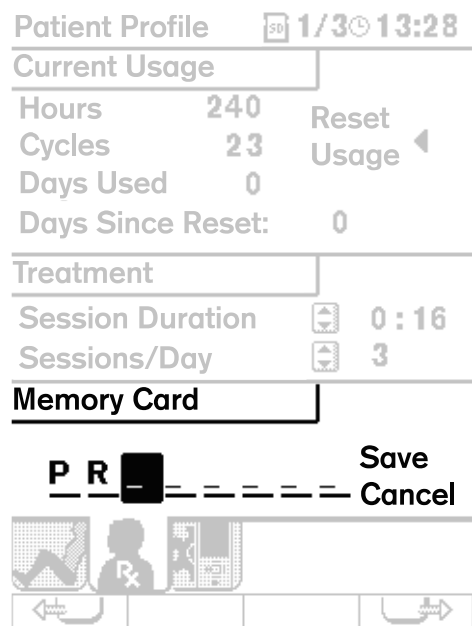
The Clinical Professional can set other parameters and also view information about patient use of a CPM Device on the Patient Profile Screen, indicated by the Patient Profile Screen Icon (Fig. 47, Pos. A). To navigate to the Patient Profile Screen, use the Soft Keys. Time can be set for each session as well as number of sessions per day (Fig. 47, 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 savedf 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. 32, Page 18). To access and create profiles, scroll to the Load Profile Function (Fig. 47, Pos. C, page 26) 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. 48

Naming a patient profile

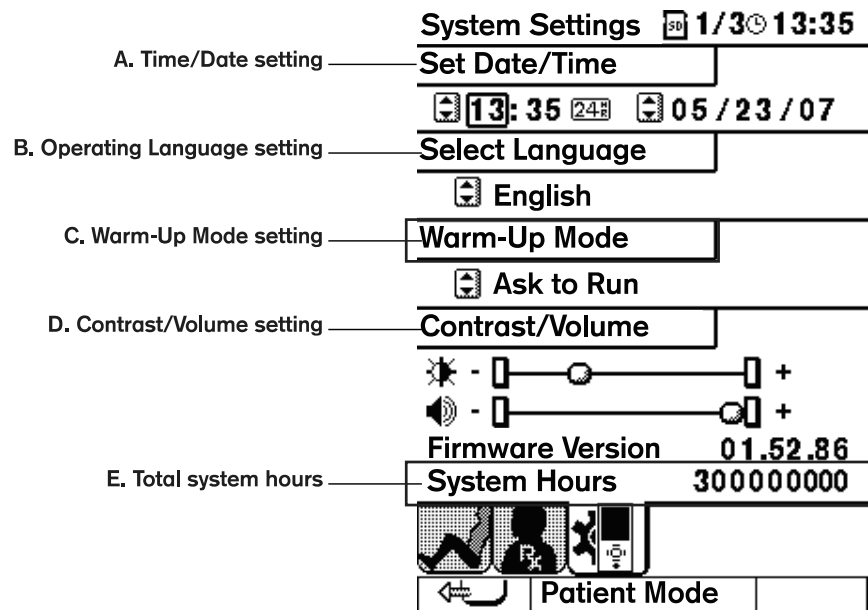


To create a new Patient Profile, which will be stored on the unit’s removable SD Memory Card, it is important that you first make all desired settings in the Setting Screens. Once you have created your settings, select “Save to Memory Card” in the Patient Profile Screen (Fig. 47, Pos. C, page 26). You can name the profile with up to eight alphanumeric characters. The characters are selected by scrolling up or down through each character position (Fig. 48) with the Direction Keys, moving right to the next character position and repeating. Choose Save and press the Select Key to save profile.

6.2.6 System Settings Screen

Fig. 49

System Settings Screen



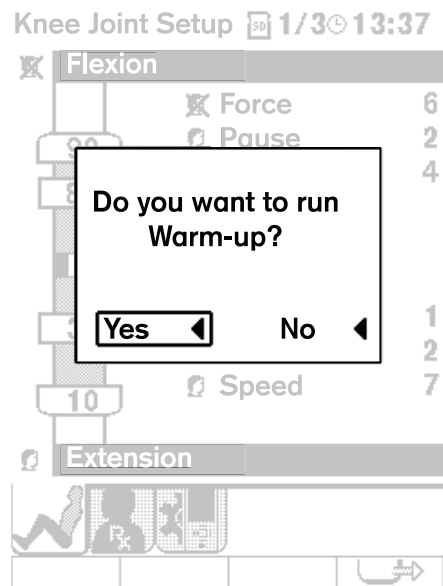
Time, Date, Operating Language, Screen Brightness, Volume and Warm-up Mode can be changed within the System Settings Screen (Fig. 49, page 27). To make changes, scroll to the desired setting and select. Scroll within the selection boxes to select the desired settings.

The Warm-Up Mode (Fig 49, Pos. C, page 27) 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. 49, Pos. E, page 27) and which version of Firmware version it is using.

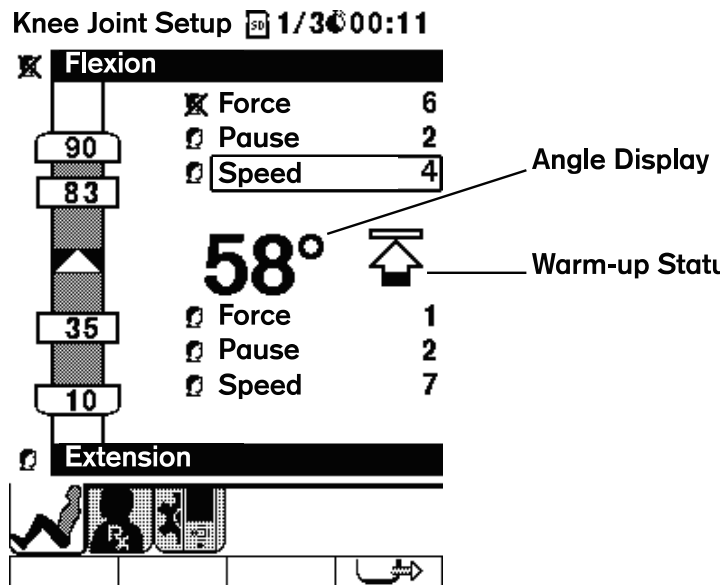
6.2.7 Warm-Up Mode

Fig. 50
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. 50). 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. 51
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. 51), 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.

7.0 Patient Operation of the LiteLift Pro

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

SAFETY CONSIDERATIONS



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.

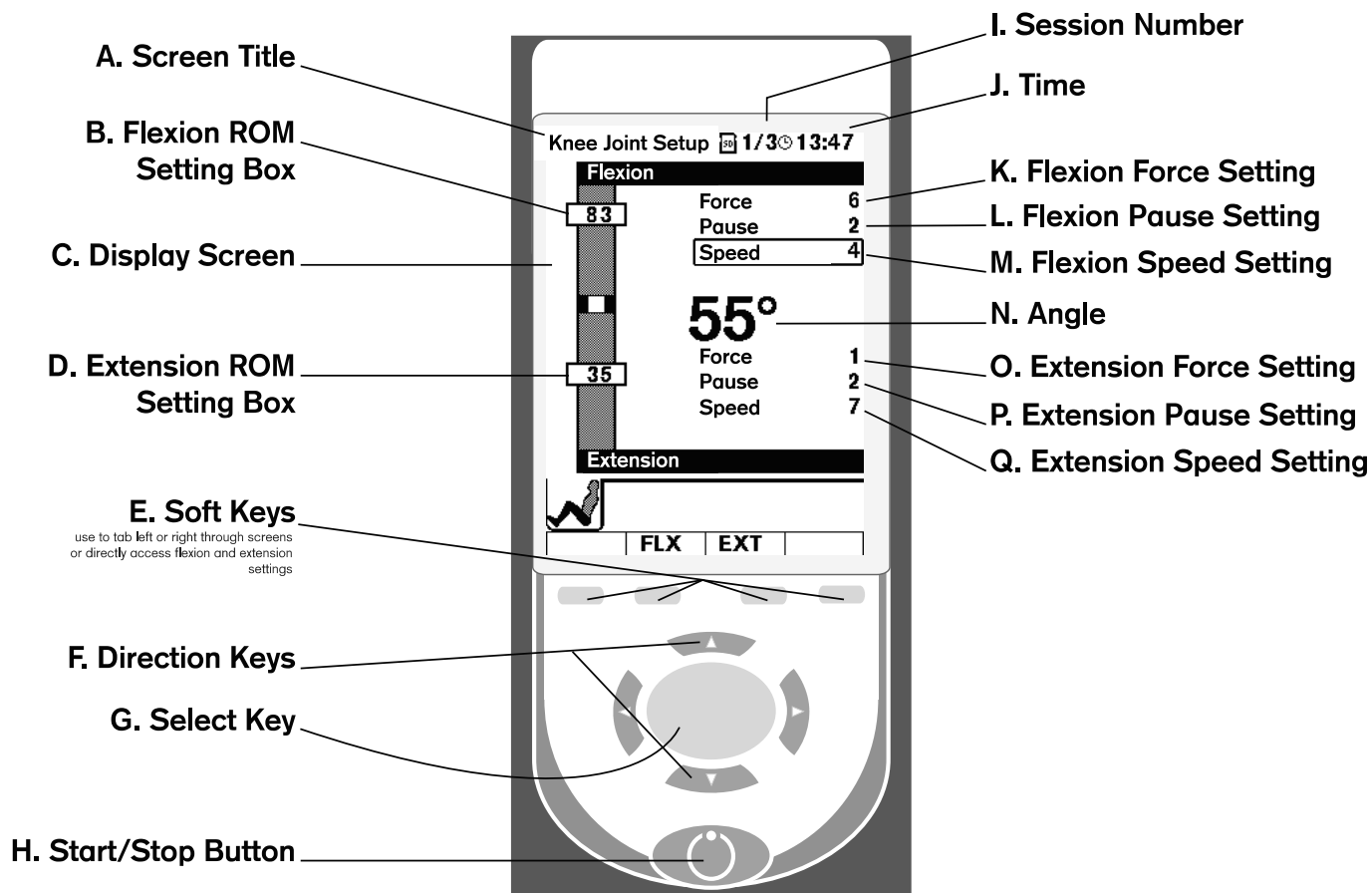
Patient Instructions

The LiteLift PRO Knee CPM Device is designed to offer continuous passive motion for your knee after surgery. The LiteLift 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 LiteLift PRO CPM Device

Turn on the LiteLift 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. 52 Operating Screen with functional elements called out.



The Operating Screen (Fig. 52) gives you information about the status of the LiteLift 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.

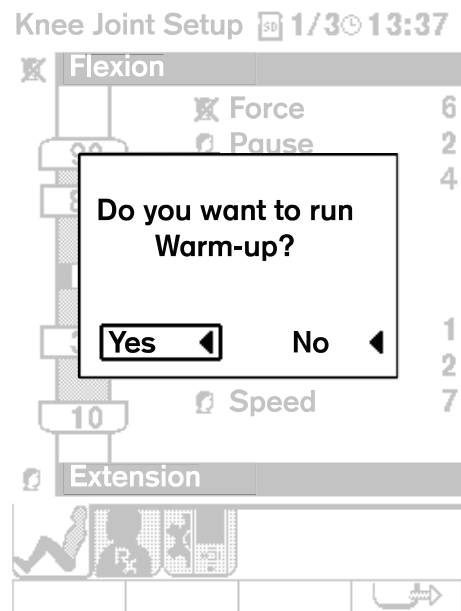
How to Start and Stop the CPM Device

Simply press the Start/Stop Button once to begin your session (Fig. 52, page 30). 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

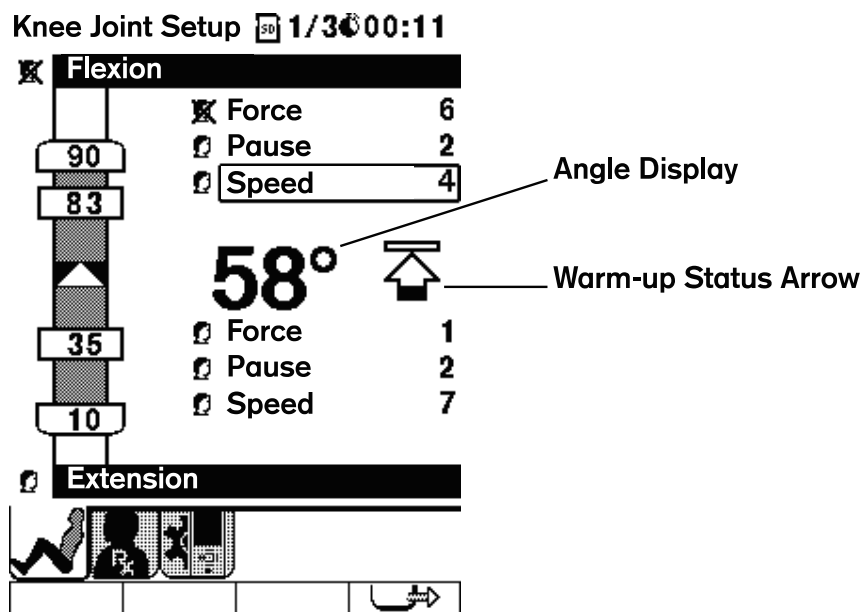
The LiteLift PRO has a Warm-up feature which moves slowly through your flexion and extension range. It begins at 25% of your maximum settings, then increases to 100% over 10 cycles.

Fig. 53
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. 53) to ask if you'd like to do the warm-up or not. To select yes or no, simply use the Direction Keys (Fig. 52, page 30), to move the Cursor Box over the desired selection, then press the Select Key (Fig. 52, page 30).

Fig. 54
Warm-up Mode
indicator arrow

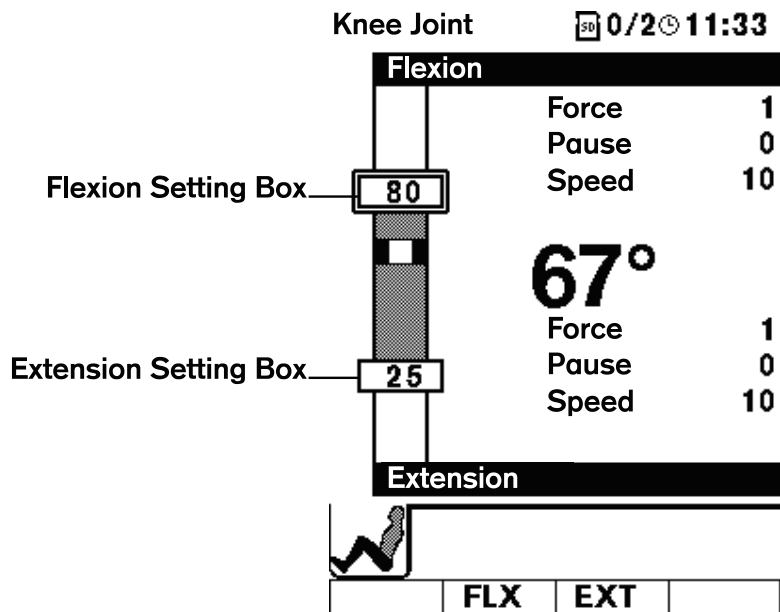


During warm-up an indicator arrow will appear alongside the Angle Display (Fig. 54). It will 'fill up' to indicate warm-up status.

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. 55
ROM Settings



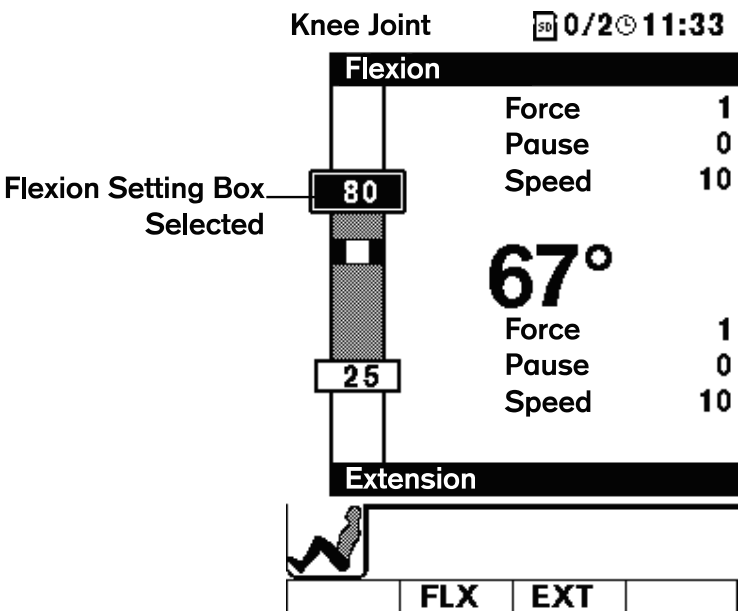
Range of Motion Settings

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

Your doctor may set up the LiteLift 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. 55). To make changes, simply use the Direction Keys (Fig. 52, Page 30) to navigate to the desired Flexion or Extension box in the left hand column.

Press the Select Key to open the settings box (Fig. 56) and press the Up or Down Direction Keys to attain the desired angle.

Fig. 56
ROM Settings with
Box Selected



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

Force, Pause and Speed Settings

Fig. 57

Selection Cursor
selected

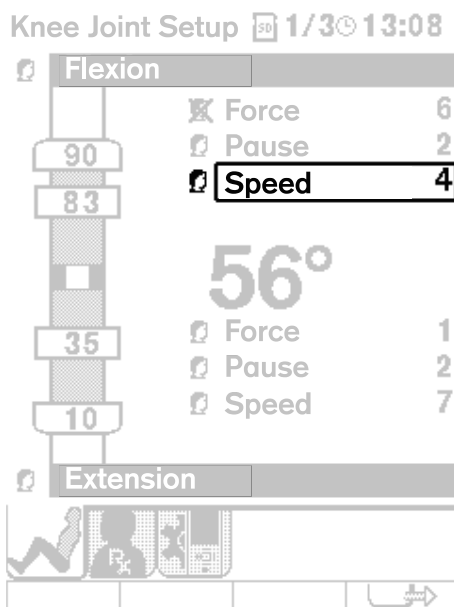
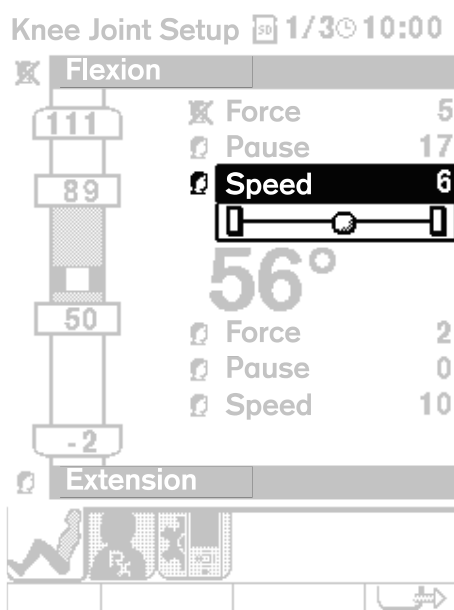


Fig. 58

Slider Bar selected



Force, Pause and Speed Settings can also be changed with the Direction and Select Keys. (Fig. 57)

- 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. 57) then press the Select Key.

A Slider Bar will appear (Fig. 58) 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

8.0 Maintenance—for Medical Personnel



Attention!

Do not immerse the PRO Controller in any fluids.

Cleaning

Gently clean all exposed surfaces with a mild soap 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. Do not immerse the device in liquids. Store the CPM device in its box when not attached to the bed.

Operator 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 disinfectants.
- Ensure that all labels are present.
- Replace the Patient 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 "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 OthroAgility 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.

9.0 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

10.0 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> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	<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 range^b</p>  <p>Interference may occur in the vicinity of known RF transmitting devices and equipment marked with the following symbol:</p>

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

11.0 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

CUSTOMER CONTACTS:

In the USA:

QAL Medical, LLC

A Division of Quality Assembly and Logistics, LLC

Website: www.qalmedical.com

Tel: 1.715.735.4727; 1.888.430.1625 Fax: 1.715.732.6402

International:

QAL Medical, LLC

A Division of Quality Assembly and Logistics, LLC

3000 Woleske Road, Marinette, Wisconsin 54143 USA

Tel: 1.715.735.4727 Fax: 1.715.732.6402



QAL Medical, LLC

A Division of Quality Assembly and Logistics, LLC

3000 Woleske Road, Marinette, Wisconsin 54143 USA

Tel: 1.715.735.4727; 1.888.430.1625 Fax: 1.715.732.6402



Russell Square Quality Representatives, Ltd.

Ludgate House, 107-111 Fleet Street, London EC4A 2AB

info@rsqr.co.uk www.rsqa.co.uk



QAL Medical is registered to ISO 13485 for Quality Assurance