L4D/L4KD CPM

Instructions for Use

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Table of Contents

Illustrations. ................................................................. 4

1.0 Intended Use ................................................................... 12
  1.1 Introduction .................................................................. 12
  1.2 Application .................................................................. 12
  1.3 Clinical Advantages.................................................... 12
  1.4 Indications .................................................................. 12
  1.5 Contraindications ....................................................... 13
  1.6 Safety Considerations ............................................... 13

2.0 Components ..................................................................... 14
  2.1 Overview ..................................................................... 14
  2.2 Digital Motion Controller ........................................... 15
  2.3 Control Panel ............................................................. 15
  2.4 Technical Data ............................................................ 16
  2.5 Ordering Information and Accessories........................... 18

3.0 Setting Up the L4D .......................................................... 18
  3.1 Attaching the Softgoods to the L4D ................................ 18
  3.2 Power Supply and Motion Controller for the L4D ............ 18
  3.3 Adjustment Locations for the L4D ................................. 19
  3.4 Patient’s Knee Alignment for the L4D ............................ 19

4.0 Setting Up the L4KD ......................................................... 19
  4.1 Carrying the L4KD ..................................................... 19
  4.2 Opening the L4KD .................................................... 19
  4.3 Attaching the Softgoods to the L4KD ............................ 20
  4.4 Adjustment Locations to the L4KD ............................. 20
  4.5 Power Supply and Motion Controller for the L4KD ......... 20
  4.6 Patient’s Knee Alignment for the L4KD ....................... 20

5.0 Digital Motion Controller ............................................... 21
  5.1 Using the Digital Motion Controller ............................ 21
  5.2 Patient Memory Key ................................................ 23

6.0 Maintenance .................................................................... 24

7.0 Troubleshooting ............................................................. 25

8.0 Warranty ........................................................................ 27

WARNING
The L4D/L4KD device should only be used after the operator thoroughly reads and understands this manual. See Safety Considerations section.
L4D/L4KD CPM Instructions for Use

For Customer Service: 1-888-430-1625; 1-715-735-4727
Fig. 9

Fig. 10

Fig. 11

Fig. 12
Initialization Screen

Stopped Screen

Speed Setting

Force Setting

Pause Setting

Warm Up Selection

Timer Selection

Hours/Cycles

Run Screen

Lock Symbol
Fig. 26

Fig. 27

Start/Stop | Set | Knee Position Left | Service Light
---|---|---|---
Increase | Speed | Knee Position Right | Connection Port
Decrease | Force | Range of Ankle Motion | Use Specified Power Supply Only
Extension | Pause | Attention, Consult Accompanying Documents | 
Flexion | Menu | Danger Electric Shock: Service by qualified individual only | 
Warm Up | Stopped | Electrostatic Sensitive Devices | 
Timer | Minutes | Type B Applied Part | 
Lock | Seconds | Caution: FDA Policy, Federal U.S. Law restricts this device to sale by or on the order of a licensed healthcare practitioner. | 
Alternating Current | Direct Current | R |
1.0 Intended Use

1.1 Introduction
The L4D/L4KD CPM Device provides Continuous Passive Motion (CPM) therapy for the joints of the leg.

A range of motion can be programmed for the knee using the Digital Motion Controller. The hip is mobilized as the knee is flexed and extended.

In addition to range of motion, the Digital Motion Controller allows users to program settings for Speed, Reverse on Load Force, end of range Pause time, Warm Up mode, and a Session Timer. The Digital Motion Controller will maintain a count of the number of user hours and cycles.

The L4D/L4KD also allows users to save program settings to an optional Patient Memory Key.

1.2 Application
Continuous passive motion (CPM) is best applied immediately post-operatively and continued, uninterrupted, for up to 6 weeks, or as prescribed by the physician.

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.

NOTE:
Allow the device a minimum of one hour to reach room temperature prior to use.

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 hemophiliac arthropathy;
- Arthrolysis and drainage of acute septic arthritis;
- Surgical release of extra-articular contractures or adhesions (quadricepsplasty);
- Metaphyseal osteotomy with rigid internal fixation of tibia and femur;
- Prosthetic replacement (arthroplasty);
- Reconstruction of medial collateral ligament tears of the knee using a semitendinosus tenodesis;
- Reconstructive surgery on bone, cartilage, tendons and ligaments;
- Prolonged joint immobilization.
1.5 Contraindications
Do not use the device if any of the following are present:

- Untreated or uncontrolled infection;
- Unstable fractures;
- Hemorrhage;

Note: Upon using the device, if signs of infection such as hyperthermia, fever, redness, irritation, warmth, swelling, bleeding, and/or increased persistent pain are present, discontinue operation of the device and contact the patient’s physician. Do not proceed with treatment until the physician has approved continued use of the device.

1.6 Safety Considerations
Please make patient aware of the following safety considerations.

- Use the device only in accordance with the Physician’s prescription and Instructions for Use. Failure to do so may result in damage to the device and/or personal injury.
- Softgoods are for single patient use only.
- The device should not be used in the presence of flammable materials like anesthetics.
- Use only manufacturer’s supplied replacement components.
- Do not use the device if there are mental or physical conditions that preclude patient compliance.
- To prevent potential physical injury, such as strangulation and choking hazards, keep the device away from children or individuals with mental or physical conditions that preclude the safe use of the device.
- Position the device in a comfortable and secure position. Ensure that the device is stable through its full range of motion.
- Keep hair, loose clothing, fingers and all parts of body away from moving components of the device.
- Do not expose the device to water or extreme temperatures.
- Do not use the device near exposed flames, while smoking or near excessive heat.
- Disconnect the electrical supply before servicing or cleaning. Failure to do so could result in electrical shock or personal injury.
- Turn the device off before unplugging.
- Unplug the power supply by grasping the plug not the cord.
- Unless using the device, turn the device off and unplug from the power supply.
- Do not use the device, power supply or controller if it appears damaged or if there are exposed wires.
- Store the device in its carrying case (if applicable) when not in use.
- Do not pour cleaning solution directly onto the device. This may allow fluids to enter the device and cause electrical problems, or wash lubricants away from running components, reducing the life span of the device.
- Select a location for the device and device components (controller, straps, cables and power supply) to prevent a tripping hazard during use.
2.0 Components

2.1.1 Overview L4D (see Fig. 1A)

1. Thigh Support Pad
2. Gluteal Pad
3. Gluteal Bar
4. Calf Pad
5. Foot Support Pad
6. Pad Attachment Loops
7. Power Supply
8. Digital Motion Controller (see Section 2.2)
9. Control Panel (see Section 2.3)
10. Locking Levers (four)
11. Ankle Locking Lever
12. Foot Plate Handle
13. Accessory Attachment Points (four)
14. Motion Controller Connection Port
15. Power Supply Connection Port
16. Controller Cable
17. Power Supply Cable

2.1.2 Overview L4KD (see Fig. 1B)

1. Thigh Support Pad
2. Gluteal Pad
3. Gluteal Bar
4. Calf Pad
5. Foot Support Pad
6. Pad Attachment Loops
7. Power Supply
8. Digital Motion Controller (see Section 2.2)
9. Control Panel (see Section 2.3)
10. Locking Levers (four)
11. Ankle Locking Lever
12. Foot Plate Handle
13. Accessory Attachment Points (four)
14. Motion Controller Connection Port
15. Power Supply Connection Port
16. Controller Cable
17. Power Supply Cable
2.2 Digital Motion Controller

The L4D/L4KD’s Digital Motion Controller is used to program the treatment settings and stop and start the device (see Fig. 2). The Controller Cable connects the Motion Controller to the device at the Motion Controller Connection Port on either side of the machine.

1. Controller Power On/Off
2. Controller Power Indicator Light
3. Start/Stop Button
4. Display Screen
5. Set Button
6. Set Mode Indicator Light
7. Extension Button
8. Flexion Button
9. Speed Button
10. Force Button
11. Pause Button
12. Menu Button
13. Increase Button
14. Decrease Button
15. Connector
   (for Symbols see Fig. 27)

2.3 Control Panel (see Fig. 3)

1. Manual Forward/Reverse Buttons
2. Service Light
3. Knee Goniometer
4. Motion Controller Connection Port
5. Power Supply Connection Port
6. Knee Alignment Target
   (for Symbols see Fig. 27)
2.4 Technical Data

2.4.1 Technical Data L4D

Specifications and Operating Limits

<table>
<thead>
<tr>
<th>Specification</th>
<th>L4D-100U</th>
<th>L4D-300U</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight of Device</td>
<td>10.9 kg (24 lbs.)</td>
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<tr>
<td>Length L4D-100U</td>
<td>110 cm (44&quot;)</td>
<td>100 cm (39&quot;)</td>
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<tr>
<td>Length L4D-300U</td>
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<td>100 cm (39&quot;)</td>
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<tr>
<td>Width</td>
<td>33 cm (13&quot;)</td>
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<tr>
<td>Patient Size L4D-100U</td>
<td>123 cm to 195 cm (4’1” to 6’6”</td>
<td>123 cm to 178 cm (4’1” to 5’10”</td>
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<td>Patient Size L4D-300U</td>
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<td>123 cm to 178 cm (4’1” to 5’10”</td>
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<tr>
<td>Range of Motion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hip</td>
<td>4° to 100°</td>
<td></td>
</tr>
<tr>
<td>Knee</td>
<td>-10° to 135°</td>
<td></td>
</tr>
<tr>
<td>Ankle</td>
<td>-25° to 45°</td>
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<tr>
<td>Speed</td>
<td>30° to 210° per minute</td>
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</tr>
<tr>
<td>Force (ROL)</td>
<td>1 (least) to 5 (greatest)</td>
<td></td>
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<tr>
<td>Pause</td>
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<td>Mode of Operation</td>
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<td>Power Supply</td>
<td>External Power Supply</td>
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<tr>
<td>Input</td>
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<td>Output</td>
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<td>Electric Shock Classification</td>
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<tr>
<td>Degree of Electric Shock Protection</td>
<td>Type B</td>
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<td>Environmental Conditions</td>
<td>-10° to 35°C (14° to 95°F) temperature,</td>
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<td></td>
<td>90% max. humidity</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ATM pressure 750 hPa to 1040 hPa</td>
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</table>

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

Note: Equipment not suitable for use in the presence of flammable anaesthetic mixture with air or Nitrous Oxide.
# 2.4.2 Technical Data L4KD

## Specifications and Operating Limits

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight of Device:</td>
<td>9.8 kg (21.5 lbs.)</td>
</tr>
<tr>
<td>Length (extended):</td>
<td>64 - 99 cm (25 - 39&quot;)</td>
</tr>
<tr>
<td>Length (folded):</td>
<td>41 cm (16&quot;)</td>
</tr>
<tr>
<td>Width:</td>
<td>33 cm (13&quot;)</td>
</tr>
<tr>
<td>Patient Size:</td>
<td>123 cm to 195 cm (4'1&quot; to 6'6&quot;)</td>
</tr>
<tr>
<td>Range of Motion:</td>
<td></td>
</tr>
<tr>
<td>Hip</td>
<td>4° to 100°</td>
</tr>
<tr>
<td>Knee</td>
<td>-10° to 135°</td>
</tr>
<tr>
<td>Speed:</td>
<td>30° to 210° per minute</td>
</tr>
<tr>
<td>Force (ROL):</td>
<td>1 (least) to 5 (greatest)</td>
</tr>
<tr>
<td>Pause:</td>
<td>0 to 30 seconds</td>
</tr>
<tr>
<td>Mode of Operation:</td>
<td>Continuous</td>
</tr>
<tr>
<td>Power Supply:</td>
<td>External Power Supply</td>
</tr>
<tr>
<td>Input:</td>
<td>100-240 VAC 50-60 Hz 40 VA</td>
</tr>
<tr>
<td>Output:</td>
<td>12 VDC 1.25 A</td>
</tr>
<tr>
<td>Electric Shock Classification:</td>
<td>Class 1</td>
</tr>
<tr>
<td>Degree of Electric Shock Protection:</td>
<td>Type B</td>
</tr>
<tr>
<td>Environmental Conditions:</td>
<td>-10° to 35°C (14° to 95°F) temperature,</td>
</tr>
<tr>
<td></td>
<td>90% max. humidity</td>
</tr>
<tr>
<td></td>
<td>ATM pressure 750 hPa to 1040 hPa</td>
</tr>
</tbody>
</table>

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

**Note:** Equipment not suitable for use in the presence of flammable anaesthetic mixture with air or Nitrous Oxide.
2.5 Ordering Information and Accessories

L4KD-100U  CPM device complete with patient kit, Digital Motion Controller, power supply and Setup and Operating Manual.

L4D-100U  CPM device complete with patient kit, Digital Motion Controller, power supply and Setup and Operating Manual.

GE-107-10  Patient Memory Key (set of 10).

AC-100  Stabilizer Pad.

L4K-101  Disposable Patient Kit (softgoods).

L4-120  Hospital Bed Clamp.

L4-130  Bed Strap Kit.

L4-140  Accessory Thigh Strap. To help ensure full knee extension.

L4-150  Transporter Carriage.

L4-180  Mattress Clamp Accessory. Stabilizes L4D or L4KD to a home or hospital mattress.

3.0 Setting up the L4D

3.1 Attaching the Softgoods to the L4D

1. Slide the foot support pad over the foot plate and secure to the Velcro patch on the foot plate (see Fig. 4A).

2. Slide the smaller pad onto the calf support plate and secure to the Velcro patch (see Fig. 4B).

3. Attach the gluteal pad to the gluteal bar with the two Velcro straps (see Fig. 4C).

4. To fasten the thigh support pad, thread the four elastic straps through the pad attachment loops located on the inner side of the thigh side rails (see Fig. 4D), and secure the Velcro to the back of the thigh support pad. Fasten the lower edges of the thigh support pad to the thigh side rails using the two Velcro straps (see Fig. 4E).

3.2 Power Supply and Motion Controller for the L4D

1. Plug the Power Supply into a grounded wall receptacle (see Fig. 5).

2. Plug the Power Supply into the Power Connection Port on the CPM device (left or right side).

3. Connect the Controller cable to the same side of the L4D (see Fig. 3, 4) as the Power Supply and then connect it to the Motion Controller (see Fig. 2.15).
3.3 Adjustment Locations for the L4D
1. Side rails adjust to thigh and calf lengths (see Fig. 6A).
2. The four locking levers release by lifting (see Fig. 6B) (two of the levers are hidden under the thigh pad).
3. The swivel foot plate adjusts for patient comfort (see Fig. 6C).

3.4 Patient’s Knee Alignment for the L4D
1. Ensure that the device is in the 0° position (Extension).
2. Lay the device next to the patient’s leg, lining up the knee with the blue knee alignment target on the inside of the thigh slider (see Fig. 7).
3. To adjust thigh length, release the two blue locking levers on the thigh sliders and pull the gluteal bar out to approximate patient size and secure the locking levers. To adjust calf length, release the two blue locking levers on the calf sliders and pull the handle on the foot plate to approximate patient size and secure the locking levers.
4. Place the device under the patient’s leg.
5. Align the gluteal bar with the patient’s gluteal crease. Adjust the thigh rails to align the knee with the blue knee alignment target. Secure the locking levers.
6. Adjust the calf sliders so that the patient’s heel is resting comfortably against the foot plate. Secure the locking levers.
7. The footplate can be swiveled to adjust to patient comfort.

4.0 Setting up the L4KD

4.1 Carrying the L4KD
1. The L4KD device should be carried only by the Gluteal Bar (see Fig. 8).

4.2 Opening the L4KD
1. Remove the L4KD, Motion Controller, Controller Cable and Power Supply from the case.
2. Place the device on the floor or a long, flat surface, with the foot plate handle facing up (see Fig. 9).
3. Connect the power supply and motion controller to the side of the device (see Fig. 9).
4. Press the blue extension button on the control panel, allowing the device to slowly unfold until the blue dot rotates to 80° on the goniometer.
5. Holding the foot plate handle, pull the device over onto its wheels and unfold the Gluteal Plate (see Fig. 10).
6. Press the blue extension button, bringing the device to a 0° position (see Fig. 11).
7. To adjust the ankle pivot angle, pull out the white ankle pivot lock knob, set pivot angle for motion comfort and release the ankle pivot lock knob (see Fig. 12).
4.3 Attaching the Softgoods to the L4KD

1. Slide the foot support pad over the foot plate and secure to the Velcro patch on the foot plate (see Fig. 13A).
2. Slide the smaller pad onto the calf support plate and secure to the Velcro patch (see Fig. 13B).
3. Attach the gluteal pad to the gluteal bar with the two Velcro straps (see Fig. 13C).
4. To fasten the thigh support pad, thread the four elastic straps through the pad attachment loops located on the inner side of the thigh side rails (see Fig. 13D), and secure the Velcro to the back of the thigh support pad. Fasten the lower edges of the thigh support pad to the thigh side rails using the two Velcro straps (see Fig. 13E).

4.4 Adjustment Locations for the L4KD

1. Side rails adjust to thigh and calf lengths (see Fig. 14X).
2. The four locking levers release by lifting (see Fig. 14Y) (two of the levers are hidden under the thigh pad).
3. The swivel foot plate adjusts for patient comfort (see Fig. 14Z).

4.5 Power Supply and Motion Controller for the L4KD

1. Plug the Power Supply into a grounded wall receptacle (see Fig. 5).
2. Plug the Power Supply into the Power Connection Port on the CPM device (left or right side).
3. Connect the Controller cable to the same side of the L4KD (see Fig. 3, 4) as the Power Supply and then connect it to the Motion Controller (see Fig. 2, 15).

4.6 Patient’s Knee Alignment for the L4KD

1. Ensure that the device is in the 0° position (Extension).
2. Lay the device next to the patient’s leg, lining up the knee with the blue knee alignment target on the inside of the thigh slider (see Fig. 15).
3. To adjust thigh length, release the two blue locking levers on the thigh sliders and pull the gluteal bar out to approximate patient size and secure the locking levers. To adjust calf length, release the two blue locking levers on the calf sliders and pull the handle on the foot plate to approximate patient size and secure the locking levers.
4. Place the device under the patient’s leg.
5. Align the gluteal bar with the patient’s gluteal crease. Adjust the thigh rails to align the knee with the blue knee alignment target. Secure the locking levers.
6. Adjust the calf sliders so that the patient’s heel is resting comfortably against the foot plate. Secure the locking levers.
7. The footplate can be swiveled to adjust to patient comfort.
5.0 Digital Motion Controller

5.1 Using the Digital Motion Controller for the L4D/L4KD

To turn the Digital Motion Controller on, press the Power On/Off button on the top of the controller. The green Power Indicator Light on the keypad will be illuminated and the screen will display the “L4D CPM” initialization screen (see Fig. 16).

After a few seconds, the controller will display the stopped screen (see Fig. 17). A square-ended direction arrow will indicate that the unit is stopped and the settings will be the same as for the previous treatment session, unless a Patient Memory Key is used (see Section 5.2).

Changing Settings (Set Mode)

Before changing any of the settings, the L4D/L4KD must be in Set mode. To enter Set mode, the L4D/L4KD must be stopped; then, the Set button must be pressed. The amber Set light will illuminate to indicate that the controller is in Set mode and that the settings may be changed.

Setting Range of Motion (Knee)

The knee range of motion (ROM) may be set from –10° extension to 135° flexion.

To set the extension limit, press the Extension button. To set the flexion limit, press the Flexion button. The selected limit on the controller’s display will flash, indicating which limit may be changed.

Use the Increase or Decrease buttons to change the limit. Pressing and holding the Increase or Decrease buttons will cause the limit to change more quickly.

When the first limit has been set, the other limit may be selected by pressing its button and set using the Increase and Decrease buttons.

Setting Speed

To set the speed, press the Speed button. Use the Increase or Decrease buttons to set the speed. The speed is adjustable in 10 increments, from 30 to 210 degrees per minute (see Fig. 18).

Setting Force

The Force controls the amount of resistance required to cause the L4D/L4KD to reverse direction (Reverse on Load or ROL). Resistance may come from the stiffness or weight of the patient’s leg or the CPM unit encountering an obstruction. Generally, it is best to use the lowest force setting that will move the patient’s leg through the set range of motion.

To set the force, press the Force button. Use the Increase or Decrease buttons to set the force. The force is adjustable in 5 increments, from 1 (least) to 5 (greatest) (see Fig. 19).
Setting Pause Time

The Pause time is the length of time the L4D/L4KD will stop when it reaches the set extension and flexion limits. When the unit is pausing, it will show a pause countdown on the controller display (see Fig. 20).

To set the pause, press the Pause button. Use the Increase or Decrease buttons to set the pause time. The pause is adjustable from 0 to 30 seconds.

Selecting Warm Up

When the Warm Up feature is selected, the L4D/L4KD will begin at 50% of its set range of motion and then gradually increase to the full range of motion over ten cycles. When Warm Up is selected, the Warm Up symbol will appear on the controller display, opposite to the direction arrow, until the full range of motion has been reached.

To set the Warm Up, press the Menu button (see Fig. 21). Use the Extension button under the “[X]” to select or the Flexion button under the “[ ]” to deselect Warm Up or the Menu button to proceed to the Timer function.

Selecting Session Timer

The Timer allows the user to preset a treatment session time. When the Timer is selected, the Timer symbol will appear on the controller display, opposite to the direction arrow. Users may view the time remaining by pressing the Increase or Decrease buttons.

Once the treatment time has expired, the unit will stop at mid-range and display the Timer symbol. The L4D/L4KD’s controller will then have to be powered OFF the ON before the unit can be reactivated.

To set the Timer, press the Menu button and go through the Warm Up selection screen. Use the Extension button under the “[X]” to select or the Flexion button under the “[ ]” to deselect Timer or the Menu button to proceed to the Hours/Cycles display (see Fig. 22).

Once the Timer has been selected, use the Increase or Decrease buttons to set the treatment session time. The session time may be set in 10-minute increments up to 480 minutes (8 hours).

Displaying Hours/Cycles

To view the number of running hours or cycles, press the Menu button and go through the Warm Up and Timer selection screens. The Hours are displayed on the top line and the number of Cycles are displayed on the bottom line (see Fig. 23). To reset the Hours and Cycles, press the Speed, Force, and Increase buttons at the same time.

Press the Menu button to return to the main Set mode screen.
Beginning Treatment

When all of the settings have been made, press the Set button to exit from Set mode. The Set light will be extinguished.

To begin treatment, press the Start/Stop button. Press the Start/Stop button again to stop the L4D/L4KD at any time. When the Start/Stop button is pressed again to restart the L4D/L4KD, the L4D/L4KD will begin moving opposite to the last direction of travel (see Fig. 24). When the unit is running, the direction arrow will indicate towards which limit the unit is travelling.

Settings Lock

To prevent patients from making programming changes, the settings may be locked. When the settings are locked, any attempt to make changes will be ineffective and cause the Lock symbol to be displayed (see Fig. 25).

To lock the settings, press the Pause, Increase, and Decrease buttons at the same time from the stopped screen. Pressing the three buttons again will unlock the settings.

5.2 Patient Memory Key

The L4KD allows the user to save a patient’s settings to an optional Patient Memory Key. For example, settings programmed in a therapy clinic can be saved to the Patient Memory Key and then transferred to a different L4KD in the patient’s hospital room or home. The Patient Memory Key can also be used to save an individual patient’s settings if the same L4KD is being shared among several users.

To save existing settings to the Patient Memory Key, turn the L4KD’s controller on without the Patient Memory Key installed. Remove the plug on the bottom of the controller and insert the Key (see Fig. 26). Press the Set button twice to enter and exit Set mode: exiting from the Set mode downloads the controller’s settings to the Patient Memory Key. The Key’s light will flash three times to indicate that it is saving the settings. The existing settings will now be saved to both the Key and the controller’s internal memory.

To use a program that has already been saved to a Patient Memory Key, install the Key before turning the controller’s power on. When the controller is powered on, the settings will be taken from the Key and loaded into the controller’s internal memory.

To change the program on a Patient Memory Key, see section 5.1 “Changing Settings.” Changes will be saved to the both the Key and the controller’s internal memory upon exiting from Set mode.

If the Patient Memory Key is removed, the controller will continue using its settings.

Once the Patient Memory Key has been programmed, the patient or program identification can be written on its key tag.
6.0 Maintenance

Maintenance Between Patients

- Softgoods for the device are for single patient use only and cannot be washed for reuse.
- Check the entire device for any visible evidence of damage such as bent components, cracked or broken covers, frayed or damaged wires, etc. If any signs of damage are found, the device must be repaired before use.
- Ensure that all knobs and/or levers are usable and in place.
- Ensure that all moving components move freely as required.
- Check all displays and electronic controls for proper operation.
- Check all mechanical pivot and linkage points for smooth operation and secure mechanical connection. Make sure all screws, nuts, bolts, rivets, pivot pins, and other fasteners are secure.
- Gently wipe clean all exposed surfaces with a soft cloth dampened with a mild soap solution or alcohol. Do not use abrasive cleansers. To disinfect, wipe all exposed surfaces with a 10% solution of bleach and water, or other suitable disinfectants.
- Ensure that all labels are present.
- Replace the patient softgoods kit.
- Verify that the device operates to its set limits over several complete cycles.
- For Range of Motion (ROM) settings verify device calibration by observing the ROM of the device while taking a visual reading using a goniometer at the device’s anatomic pivot points. Compare the ROM settings of the device with the goniometer readings. ROM readings should be within +/- 5° of the set parameters. If the readings do not fall within the set parameters, the device needs to be checked and recalibrated by a properly trained Service Technician.

Maintenance Every Six Months

- Repeat steps under “Maintenance Between Patients.”

Maintenance Every Twelve Months

- Verify electrical ground continuity where applicable from the device frame to ground pin of the power supply, if so equipped, using a Safety Analyzer or appropriate device.
- 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 drive components, and repair or replace as necessary.
- Perform a complete recalibration and subsequent check of electronic and mechanical safety systems including Reverse-On-Load function and Range of Motion controls.
- Complete a final check of the device in accordance with QAL Medical Final Inspection criteria. (These are available through QAL Medical Customer Service or your local distributor.)

Sterilization

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

7.0 Troubleshooting

<table>
<thead>
<tr>
<th>Condition</th>
<th>Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controller does not power on.</td>
<td>1. Ensure that power is available at the wall outlet.</td>
</tr>
<tr>
<td></td>
<td>2. Ensure that the power supply and controller are connected to the same side of the base unit.</td>
</tr>
<tr>
<td></td>
<td>3. Ensure the cables are undamaged.</td>
</tr>
<tr>
<td>Device does not run.</td>
<td>1. Ensure that the controller is not in Set mode and that the Set light is off. The device will only run from the stopped screen.</td>
</tr>
<tr>
<td></td>
<td>2. If the display only shows the Timer symbol, the controller will have to be powered off and on before resuming treatment.</td>
</tr>
<tr>
<td></td>
<td>3. If the Service Light is on or an alarm is audible, the device will need to be returned for service.</td>
</tr>
<tr>
<td>Condition</td>
<td>Solutions</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Device will not reach set limits.</td>
<td>1. Check for and remove any physical obstructions.</td>
</tr>
<tr>
<td></td>
<td>2. Increase the Force setting.</td>
</tr>
<tr>
<td></td>
<td><strong>Note:</strong> Due to its geometry, the device will not reach full flexion when set to its smallest calf and thigh adjustments.</td>
</tr>
<tr>
<td>Error E17 appears on the display.</td>
<td>1. The controller has detected too many ROLs. Check for and remove any physical obstructions.</td>
</tr>
<tr>
<td></td>
<td>2. Increase the Force setting.</td>
</tr>
<tr>
<td>Other Errors appear on display.</td>
<td>1. Check for obvious signs of damage or obstruction.</td>
</tr>
<tr>
<td></td>
<td>2. Turn the controller power off and on and restart the device.</td>
</tr>
<tr>
<td></td>
<td>3. If the error code persists, return the device for service.</td>
</tr>
<tr>
<td>Patient is uncomfortable.</td>
<td>1. See Sections 3.4 and 3.5 for correct adjustment and alignment.</td>
</tr>
<tr>
<td></td>
<td>2. Position patient with gluteal crease just resting on the gluteal bar and knee centre aligned with blue knee alignment indicator.</td>
</tr>
<tr>
<td>Hip angle is too great in flexion.</td>
<td>1. Lengthen the thigh adjustment and shorten the calf adjustment.</td>
</tr>
</tbody>
</table>
8.0 Warranty

New Product Limited Warranty

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

THE COMPANY IS NOT RESPONSIBLE FOR LOSS OF USE, LOST PROFITS, OR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE BREACH OF THIS WARRANTY, THE FAILURE OF ANY PRODUCT OR THE NEGLIGENCE BY THE COMPANY IN THE PERFORMANCE OF ANY SERVICE, INCLUDING DAMAGES FOR PERSONAL INJURY. THE WARRANTY CONTAINED HEREIN IS IN LIEU OF ALL WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. NO STATEMENT OF ANY REPRESENTATIVE SHALL EXTEND THE COMPANY'S LIABILITY AS HEREIN ESTABLISHED OR LIMITED. THIS WARRANTY IS PROVIDED TO THE ORIGINAL PURCHASER OF THE PRODUCT AND IS NON-TRANSFERRABLE.
Returning the Device for Service

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

If any warranted product is found by the Company to have a defect covered by this warranty, the Company shall, at its option, either repair the defective item or install a replacement.

If the device needs to be returned for any repair, pack the components in the original shipping container and contact:

Customer Service:
QAL Medical, LLC
Attn: Customer Service
3000 Woleske Road
Marinette, Wisconsin 54143 USA
Tel: 1-715-735-4727 Fax: 1-715-732-6402
Website: www.qualityal.com

Note: Please enclose the following information when returning the device:

- Return Authorization Number
- Ship-to Address
- Purchase order for non-warranty repairs
- Name and phone number of a person to contact
- Brief description of the problem
CUSTOMER CONTACT:

QAL Medical, LLC
3000 Woleske Road, Marinette, Wisconsin 54143 USA
Tel: 1.715.735.4727; 1.888.430.1625  Fax: 1.715.732.6402
Website: www.qalmedical.com

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