J·A·C·E™
SYSTEMS
SUPERIOR BY DESIGN

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J·A·C·E Universal

CPM — K100-A

OPERATING MANUAL

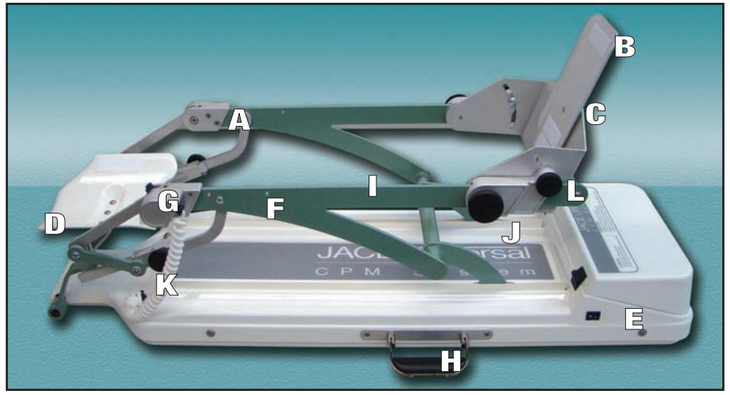
SUPERIOR BY DESIGN

Symbol	Reference	Description
	IEC 60417-5032	AC
	IEC 60417-5021	Earth (Ground)
	IEC 60417-5008	Off (Power)
	IEC 60417-5010	On (Power)
	IEC 60417-5840	Type B Applied Part
	ISO 7010-W001	General Warning Sign
	ISO 7000-1641	Follow Operating Instructions or Consult instructions for use

JACE Universal

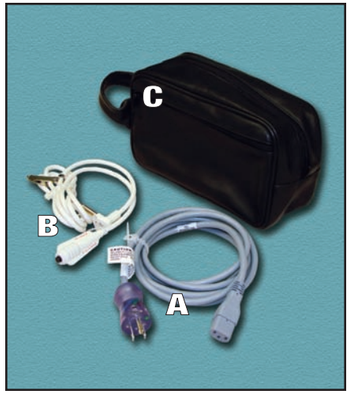
CPM — K100-A

CONTENTS



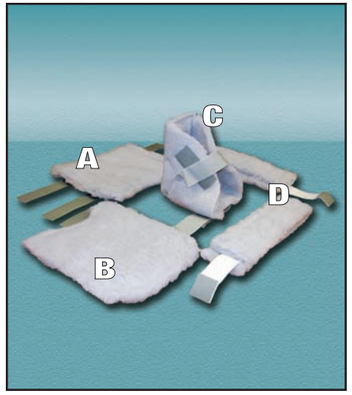
BASE UNIT

- **A** KNEE PIVOT
- **B** FOOT PLATE
- **C** FOOT PLATE PIVOT
- **D** THIGH SUPPORT PLATE
- **E** POWER SWITCH (ON/OFF)
- **F** FRAME ANGLE INDICATOR
- **G** JACK FOR PATIENT OVERRIDE SWITCH
- **H** CARRYING HANDLE
- **I** CARRIAGE FRAME
- **J** CALF LEG LENGTH ADJUSTMENT KNOB(S)
- **K** THIGH LENGTH ADJUSTMENT KNOB(S)
- **L** ANKLE ANGLE ADJUSTMENT KNOB(S)



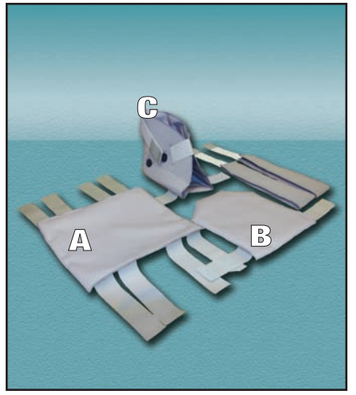
ACCESSORIES

- **A** POWER CORD
- **B** PATIENT OVERRIDE SWITCH
- **C** ACCESSORY BAG



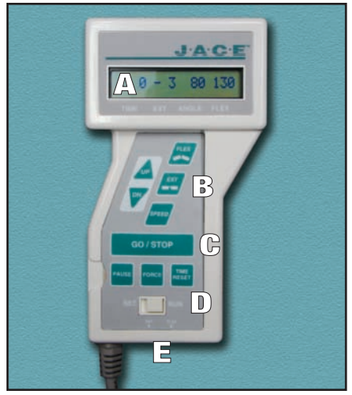
SOFTGOODS (USA)

- **A** CALF SUPPORT PAD
- **B** THIGH SUPPORT PAD
- **C** ANKLE BOOT
- **D** KNEE EXTENSION STRAPS (2)



SOFTGOODS (International)

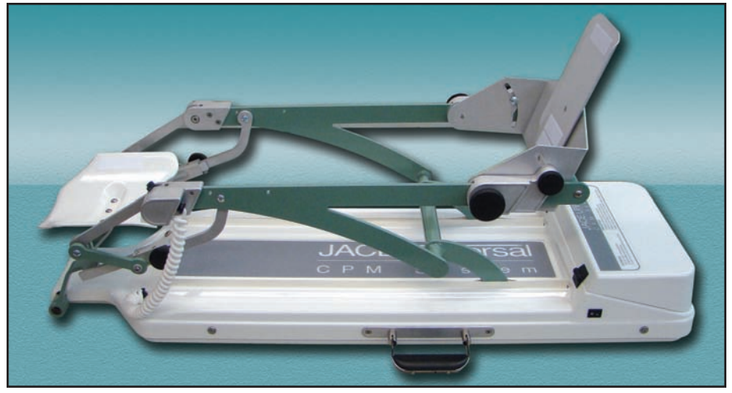
- **A** CALF SUPPORT PAD
- **B** THIGH SUPPORT PAD
- **C** ANKLE BOOT



CONTROLLER

- **A** LCD (LIQUID CRYSTAL DISPLAY) WINDOW
- **B** CONTROL BUTTONS
- **C** GO/START BUTTON
- **D** SET/RUN SWITCH
- **E** EXTERNAL DEVICE JACKS (2) (FOR NEUROMUSCULAR ELECTRICAL STIMULATOR)

COMPONENTS



JACE Universal

CPM — K100-A

THE JACE UNIVERSAL K100-A is a lower extremity CPM (Continuous Passive Motion) system for rehabilitation therapy. The K100-A integrates a 4 bar link hinge system that extends the Flexion ROM to 130 degrees. The 4 bar link system also provides a more anatomical ROM that mimics a more natural movement.

The K100-A is engineered for in-bed use featuring the most advanced technology for safe and reliable patient operation. It provides an adjustable range of motion from -3° hyperextension to 130° of flexion.

The K100-A has been engineered for ultimate patient comfort and safety. During the first two cycles of operation, the K100-A records the force exerted by each individual patient's leg for every 16°. Any deviation caused by a foreign obstacle in the path of the carriage or any significant patient resistance during operation will be instantly detected and the K100-A will automatically reverse direction.

The speed of the carriage is continuously adjusted to maintain a "Constant Angular Velocity." This insures maximum patient comfort and prevents the possibility of "Free-fall" or sudden hyperextension.

The K100-A features a Hand-held Controller which allows the operator/patient to remotely control all K100-A operations. The Controller is used to set, execute and monitor angle parameters for flexion and extension within a 1-2° tolerance. It also controls the speed of the K100-A which can be adjusted up or down.

The K100-A is designed to easily interface with external devices; such as neuromuscular electrical stimulators. These plug directly into the base of the Controller.

An optional PATIENT OVERRIDE SWITCH is included. This performs the same functions as the GO/STOP Button when plugged into the K100-A.

SAFETY PRECAUTIONS

THE JACE K100-A IS INTENDED FOR PHYSICIAN-PRESCRIBED USE ONLY. BEFORE ACTUAL USE, READ OPERATING MANUAL.

KEEP OVERRIDE SWITCH OR HAND CONTROLLER WITHIN PATIENT'S REACH.

ONLY USE IN THE RECOMMENDED RUNNING TEMPERATURE ENVIRONMENT.

CONTACT JACE SYSTEMS REPRESENTATIVE FOR REQUIRED SERVICE OR MAINTENANCE.

DO NOT OPERATE THE JACE UNIVERSAL K100-A IN THE PRESENCE OF FLAMMABLE ANESTHETICS.

DESIGNED TO MEET ALL 60601 SAFETY REQUIREMENTS.

FOR USE ONLY WITH JACE HAND HELD CONTROLLER.

USE ONLY WITH JACE SUPPLIED POWER CORD.

TO AVOID INJURY USE ONLY AS PRESCRIBED BY YOUR PHYSICIAN.

⚠ BEFORE CONNECTING THE POWER CORD, MAKE SURE THE VOLTAGE SELECTION IS SET TO THE CORRECT VOLTAGE FOR YOUR COUNTRY.

STEP 1

UNPACKING THE UNIT

1 After unpacking the K100-A, check for the following components:

- JACE K100-A Base Unit
- Hand-Held Controller*
- Patient Override Switch*
- One set of Softgoods
- Power Cord*
- User Manual *
- Accessory Bag

***NOTE:** These items can be stored in the accessory bag.

SAVE ALL PACKING MATERIAL FOR FUTURE SHIPPING REQUIREMENTS

2 Power switch (located on the side of the Base Unit with the handle) should be in the OFF position.

3 Connect the controller to the Base Unit by plugging into the compartment as shown in the photo above. Tighten thumb screws on either side of plug.

4 Connect the power Cord to the Base Unit before closing lid, carefully align cords to match up to exit slots molded into compartment lid.

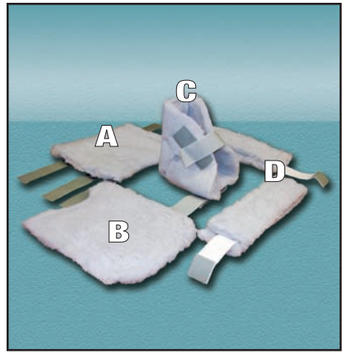
5 OPTIONAL: To use PATIENT OVERRIDE SWITCH plug into receptacle. *(See photo on page 2)*

6 Plug Power Cord into a standard grounded AC wall outlet.

7 Slide the SET/RUN switch on the Hand-Held Controller to the "SET" Position.

REFER TO ALL SAFETY PRECAUTIONS PRIOR TO USE.

8 Unit is ready for operation. Set Power Switch to ON position.



STEP 2

APPLYING SOFTGOODS

1 Each set of softgoods includes:

- **A** Calf Support Pad
- **B** Thigh Support Pad
- **C** Ankle Boot
- **D** Knee Extension Straps (2)

2 Attach the Thigh Support Pad (B) and Ankle boot (C) as shown in photo on page 7. Velcro strips have been provided on the Thigh Support Plate and Foot Plate to keep soft goods securely in place.

3 Fit the Calf Support Pad (A) by wrapping the Velcro straps around the K100-A carriage as shown by simply fastening to the underside of the pad.

4 The (optional) Knee Extension Straps (D) include an elastic strap with a Velcro closure. This helps to maintain proper knee alignment.

CARE/CLEANING: Softgoods are made of a washable synthetic fleece material for easy care and patient comfort. **NOTE: Each softgoods kit is intended for use by one patient only.**

NOTE: Softgoods (International) are applied in the same way. Softgoods must be washed and disinfected in between patient use.

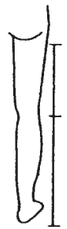
STEP 3

PATIENT FITTING

- **L** Ankle Angle Adjustment Knob(s)
- **C** Foot Plate
- **J** Calf Leg length Pivot Knob(s)
- **K** Thigh Length Adjustment Knob(s)

1 Prior to fitting patient – position the carriage approximately at 30 of flexion. IMPORTANT: If the K100-A isn't in this position, advance to Step #5 Section B "Setting Parameters With Carriage in Motion: (see page 11), to reposition carriage.

Refer to (2)



Refer to (4)

2 With the tape measure, determine the distance between the gluteal crease and popliteal space. (See diagram to the left)

3 Using this distance, adjust Thigh Length Adjustment Knob(s) (K) on both sides of the K100-A Tighten Knobs.

4 Measure the length of the patient's leg from the knee to ¼" beyond the bottom of the foot. (See diagram to the left)

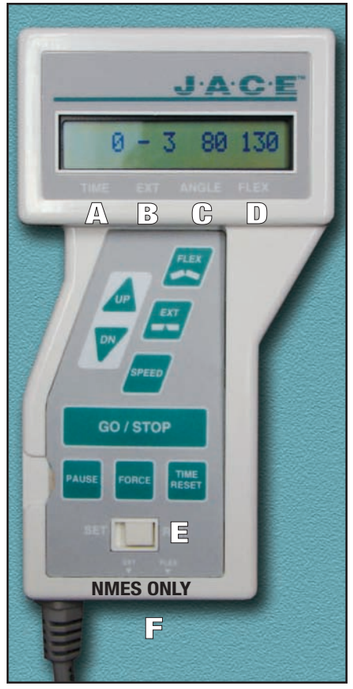
5 Using this distance, adjust the position of the Foot Plate accordingly.

6 Position the patient's leg in the K100-A and make final adjustments as needed for the thigh and lower leg lengths. Using the Ankle Angle Adjustment Knob(s) (L) and the Foot Plate Pivot Knob (C), adjust the angle and rotation to best satisfy patient comfort.

7 Tighten all adjustment knobs securely.

8 The K100-A features a non-skid base which is designed to operate securely for in-bed applications.

IMPORTANT: Do not attempt any fine tuning adjustments of the carriage during the Pause Mode.



STEP 4

CONTROLLER OPERATION

A TIME – Displays Accumulated Run Time in Minutes
"Pause Countdown" – At the end of travel for each parameter (EXT/FLEX), the TIME indicator switches to a pause countdown configuration. The Time can be reset for each new patient.

B EXT – Displays the "pre-set" Extension Limit in angular degrees.

C ANGLE – Displays the exact angle of the carriage at any given time during operation.

D FLEX – Displays the "pre-set" Flexion Limit in angular degrees. **Flashing display for EXT/FLEX Indicates the current direction of travel.)**

E SET/RUN SWITCH – This 2-position switch allows you to select the following operations:

- **SET MODE** – Allows selection and adjustment of all operation parameters.
- **RUN MODE** – Locks in "preset" parameters for required operation of the K100-A

F PLUG-IN – Plug In for external device such as a Neuromuscular Electrical Stimulator (NMES). At the end of travel for each parameter, FLEX/EXT, the K100-A has a pause function which is designed to interface with compatible external devices. The pause can be set for up to ten minutes. The Time indicator on the LCD display window switches to a countdown configuration during the pause.

⚠ **PLUG-INS ARE FOR NMES ONLY**

IMPORTANT:
Once the RUN MODE is selected, all "pre-set" parameters are stored in memory, even when the K100-A has been turned off, unplugged, or in the event of a power failure.

SET MODE FUNCTION BUTTONS

- **FLEX** – Displays the "pre-set" angle for maximum UP/DOWN button(s) allows a new parameter/limit to be set.
- **EXT** – Displays the "pre-set" angle for maximum Extension Limit. Used with the UP/DOWN button(s) allows a new parameter/limit to be set.

NOTE: These functions are normally set without carriage in motion. An alternate mode permits setting with motion as described in Step #5 Section B – "Setting Parameters With Carriage in Motion." (see page 11).

- **SPEED** - Used with the UP/DOWN button(s) to set the desired speed that the K100-A performs each cycle. (Speed is directly related to range of motion).

- **UP/DOWN** - Used to reset a displayed parameter. Depress the UP button to increase or DOWN button to decrease a selected parameter. Constant or intermittent pressure on the button will vary the speed of change.

- **FORCE** – Allows the force of the K100-A to be customized for each patient. Different forces can be set for flexion and extension. Minimum Force is setting "1". Maximum Forces is setting "10".

- **PAUSE** - Allows K100-A to stop at the end of the flexion and extension cycle. Pause can be different for flexion and extension. Minimum Pause is 0:00. Maximum Pause is 9:59.

- **TIME RESET** – The accumulated run time is displayed in minutes. This can be used to monitor patient compliance. To Reset Time see Setting Parameters as described in Step #5 Section A, 15.

RUN MODE FUNCTION BUTTONS:

- **SPEED** – Used with UP/DOWN button(s). Controls the speed of the K100-A.

- **GO/STOP BUTTON** – Pressing this button will start or stop operation of the K100-A. Pressing button a second time in succession reverses the direction of travel.

- **PATIENT OVERRIDE SWITCH** – The PATIENT OVERRIDE SWITCH performs the same function as the GO/STOP button.

IMPORTANT BUILT-IN SAFETY FEATURE:
During the first two cycles of operation, the K100-A records actual patient force profiles for every 16 through flexion and extension. Any deviation caused by a freign obstacle in the path of the carriage or significant patient resistance during operation will be instantly detected and the K100-A will automatically reverse direction. The amount of force required to cause detection is controlled by the FORCE setting. **NOTE:** The unit **MUST** run 2 complete cycles before the force profile will be set.

NOTE:

Storage and Transport Temperature:
-22° F to 160° F (-30° to 70° C)

Running Temperature:
0° to 160° F (-18° to 70° C)

Running Environment Temperature:
50° to 104° F (10° to 40° C)

Min./Max. Voltage:
100V or 120V Service:
90 VAC to 135 VAC
50/60Hz
220V Service:
185 VAC to 260 VAC
50/60Hz.

Maximum Power:
30 Watts

OPERATIONS

STEP 5

SETTING PARAMETERS

SET MODE

All adjustments to the Range of Motion Limits must be made in the SET MODE.

1 Position the SET/RUN button to the "SET" position.

2 Turn Power Switch located on base unit to "ON."

The following message will appear on the display:

Anatomical

Followed by:

Select Parameters

NOTE: The FLEX Limit Setting must be set one degree greater than the EXT Limit.

A - Setting Parameters Without Carriage in Motion

Extension Limit

1 Press the EXT button to display the current setting.

The display will show the extension range of motion Limit from -3° to 129°.

2 Press the UP/DOWN button(s) to set the desired Extension Limit.

Extension Pause

3 To set the Extension Pause, while in the Extension Mode, depress the Pause Button to display the current setting.

4 Press the UP/DOWN button(s) to set the desired Extension Pause.

Extension Force

5 To set the Extension Force, while in the Extension Mode, depress the Force Button to display the current setting.

6 Press the UP/DOWN button(s) to set the desired Extension Force.

Flex Limit

7 Press the FLEX button to display the current setting.

The display will show the flexion range of motion limit from -2° to 130°.

8 Press the UP/DOWN button(s) to set the desired Flexion Limit.

Flexion Pause

9 To set the Flexion Pause, while in the Flexion Mode, depress the Pause Button to display the current setting.

10 Press the UP/DOWN button(s) to set the desired Flexion pause.

Flexion Force

11 To set the Flexion Force, while in the Flexion Mode, depress the Force Button to display the current setting.

12 Press the UP/DOWN button(s) to set the desired Flexion Force.

Speed

13 Press SPEED button to display the current setting.

14 Press the UP/DOWN button(s) to set the desired speed.

Time Reset

15 To reset the Run Time – press the Time Reset Button followed by either the UP/DOWN button(s). Time will automatically reset to zero on the controller display.

Warm Up

16 WARM UP consists of 1 to 255 minutes of CPM at 50% of programmed Range of Motion. This will increase to 100% of the programmed Range of Motion (ROM) during selected WARM UP session.

17 To program WARM UP time, position the SET/RUN button to the "SET" position. Press the PAUSE and TIME RESET buttons simultaneously. Release the **TIME RESET button first**, then the PAUSE button. Program the desired WARM UP time.

18 To bypass the WARM UP feature, position the SET/RUN button to the "SET" position. Press the PAUSE and TIME RESET buttons simultaneously. Release the **TIME RESET button first**, then the PAUSE button. Press the "DN" or "UP" button until WARM UP TIME displays zero.

NOTE: If any parameters are changed during WARM UP treatment, WARM UP will reset to the beginning.

NOTE: Pause and Muscle Stimulation will not operate during WARM UP period.

B - Setting Parameters With Carriage in Motion

(This mode is preferred for fitting patients who are experiencing extreme pain or anxiety.)

1 Press either EXT or FLEX button.

2 Once the window displays the respective message:

Flex Limit

Or

Ext Limit

Press and HOLD the FLEX OR EXT button.

3 Then use the UP/DOWN button(s) to move the K100-A carriage to the desired position.

NOTE: While setting parameters with Carriage in Motion, the previous limit value on the display will "jump" to the current angular position as the UP/DOWN button(s) is pressed.

IMPORTANT: When setting parameters with carriage in motion, DO NOT attempt any fine tuning with patient in device.

RUN MODE

To start or restart the K100-A use the RUN MODE. Once the RUN MODE is selected, all "pre-set" parameters are stored in memory, even after the K100-A has been turned off, unplugged, or in the event of a power failure.

1 Position the SET/RUN button to the "RUN" position.

2 When the K100-A is ready for operation,the display will read:

Push GO to Start

3 Press the GO/STOP button or PATIENT OVERRIDED SWITCH. The K100-A will start carriage operation.

The GO/STOP button or PATIENT OVERRIDE SWITCH can be pressed during operation to stop the K100-A at anytime. Once the GO/STOP button or PATIENT OVERRIDE SWITCH is pressed again, the K100-A will restart in the **opposite** direction.

ERASING FORCE PROFILES:
Unplugging the unit and/or switching POWER switch to OFF position, will immediately erase the current force profiles. The speed button(s) are operative during the first two cycles while the force profiles are recorded.

TROUBLE SHOOTING

Set Orth. (UP)?

This message will appear when the K100-A carriage is outside the Range of Motion Limits while in the RUN MODE.

- Simply press and hold the UP button. This will readjust the K100-A carriage within the "pre-set" Range of Motion and automatically stop. The following will then appear in the Display:

Push GO to Start

No Orthosis!! or **Orthosis Dif>#**

If this appears after turning power on…

- Check to see if the Controller cable is properly connected to the Base Unit

Low Power > 10.4V

ATTENTION: CORRECTIVE ACTION REQUIRED
This indicates the power supply is inadequate.

- Check all power cables and connections. Have an electrician check the AC outlet.
- Check that the factory preset voltage selection indicates the proper AC voltage

Check Parameters or Select Parameters

If this appears...

- Switch to the SET MODE and select parameters as usual.

CARE/CLEANING

CAUTION: Disconnect unit from power when cleaning. Do not immerse the unit. Avoid spilling liquids (or other contaminants) into the moving parts or electrical components of the K100-A. The surfaces of the K100-A may be wiped with a soft cloth or sponge dampened with a mild soap solution. A 10% (1 part bleach to 10 parts water) solution of household bleach (Sodium Hypochlorite) and water may be used as a disinfecting wipe. Dry all surfaces with a clean soft cloth after applying any cleaning solutions.

REPLACEMENT PARTS:

Description	Part No.
Softgood Kit (USA)	MS9916
Softgood Kit (International)	93KA0801
Hand-held Controller	11CA01__
User manual	94MA0306 Rev A
Power Cord	55AA1301
Patient Override Switch	55AA1101
Anti-Slip Pads	93RA0101

LIMITED WARRANTY

The JACE Model K100-A CPM is warranted against defects in material and workmanship for one (1) year from date of initial purchase. During the warranty period, parts will be repaired or replaced by JACE Systems at no charge to the customer, when such defective parts have been properly packaged and returned prepaid to JACE Systems.

This warranty is rendered void if damage to the unit is a result of mishandling, misuse, or abuse. Furthermore, no warranty will apply to damage resulting from the customer's use of parts, fittings, or accessories not specified by JACE Systems or from service or modification performed by unauthorized personnel.

JACE Systems shall not be liable for incidental or consequential damages including loss or use, property damage, or to the extent allowed by law, personal injury, which results from breach of warranty. This warranty is in lieu of all other warranties, expressed or implied, including warranties or merchantability and fitness for particular purpose.

PREVENTATIVE MAINTENANCE

Preventative Maintenance, including calibration, lubrication and electrical safety checks should be performed yearly by JACE Authorized Personnel ONLY. Please contact JACE Systems to schedule maintenance.

DISPOSAL

There are no risks associated with disposal of the JACE K100-A or any accessories at the end of the service life of the equipment (10 years).

Designation: Medical Devices

Model: K100-A

Intended Use:
The JACE K100-A is a CPM (Continuous Passive Motion) device intended for use in a hospital, doctors office, related health care facility or home under the prescription of a physician, for physical rehabilitation of the lower extremity.

Classification:
JACE Systems K100-A complies with the following Safety Standards:

UL 60601-1

IEC/EN 60601-1

IEC/EN 60601-1-2

Meets MDD 93/42/EEC, CE 1984
Electrical Safety Class
Type “B” Applied Parts
Class I
Suitable for continuous operation

User Profile

Health Care Professional, JACE Representative, end user (patient). The age of the patient ranges from children to adults of all ages.The patient may use the JACE K100-A Knee CPM at a hospital, doctors office, related health care facility or home under the prescription of a physician.

⚠ WARNING:

Use of the K100-A may cause the following:

- Bleeding of Wound
- Opening of Stitches
- Chafing of Leg
- Discomfort as range of motion is increased.

Contact you physician if any of these conditions occur.

MODIFICATIONS

⚠ WARNING:

DO NOT modify this equipment without authorization from JACE Systems.

The replacement parts listed are the only user replaceable parts. All other parts MUST be replaced by JACE personnel ONLY. Modification other than the replacement parts listed could cause damage to the equipment and will void the warranty.

⚠ WARNING

- Read, understand and practice the precautionary and operating instructions found in this manual before operating or using the unit. Know the limitations and hazards associated with using the K100-A Continuous Passive Motion (CPM) Therapy Unit.
- Observe any and all precautionary and operational decals placed on the unit.
- Only use the K100-A on firm, flat, level surfaces.
- Extreme caution should be taken when in use with or around children.
- Use the K100-A only for its intended purpose as described in this manual.
- Turn power switch off before unplugging unit from its power source.
- Do not use the cord to unplug the power cord from the unit. Grasp at the power cord base.
- Use care when carrying, transporting or storing the K100-A unit to prevent damage to the unit from dropping or improper transport and storage methods.

⚠ WARNING

- U.S. Federal law restricts this device to sale by, or on the order of, a physician or licensed practitioner.
- Make certain that the unit is electrically grounded by connecting only to a grounded electrical service receptacle conforming to the applicable national and local electrical codes.
- Keep hair, loose clothing, loose bedding, fingers and toes away from the hinge components of the unit.
- Do not use the K100-A outdoors or on wet surfaces. Use only on firm, flat, stable level surfaces to ensure stability of the unit while in operation.
- K100-A has been designed for protection against the exposure of urinary incontinence. Precautionary measures should still be taken when any type of liquid comes in contact with an electrical apparatus.

⚠ WARNING

- Exercise caution when using accessories and auxiliary devices such as muscle stimulators, cold packs and other modalities. Route lead wires, hoses, tubes, etc. away from the working mechanism of the K100-A to help prevent damage to the K100-A and any other modality used with it.
- Unconscious patients or patients under heavy influence of medication must be constantly attended and monitored while the K100-A is in use.
- The K100-A unit must be completely visible at all times during use. Never cover the unit with bedding or any other means of concealment while in operation.

NOTES