# 520 ₺

# **Setup and Operating Manual**



QALMedical
OrthoAgility

MANUAL CAN ALSO BE REFERENCED FOR 500 CPM DEVICE.
PLEASE SEE INSIDE FOR DETAILS.

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### 500 CPM DEVICE:

This manual can be referenced for the 500 CPM. However, please note that unlike the 520, the 500 CPM does not support the "Warm Up Feature" as found on page 4.

### **Device Setup**

#### Indications

Total knee replacement; Ligament reconstruction; Manipulation under anesthesia; Meniscal repair; Articular cartilage regeneration techniques; Stabilized intra- or extra-articular fractures of the femur and tibia.

### 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.

### 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 device to reach room temperature for a minimum of one hour prior to use.

#### Carton should contain:

- One Setup and Operating Manual
- One 520 Device with Motion Controller and power supply
- · One Patient Kit (Disposable Softgoods)
- Patient Thumb Switch
- · Thigh, Hip Pivot Adjuster Assembly
- Foot Plate Assembly

### **Product Description**

The 520 Continuous Passive Motion (CPM) system is designed for the rehabilitation of the lower limbs. The 520 features anatomical alignment of the limb and extended range of motion, the incorporation of muscle stimulation at any angle, and the ability to incorporate controlled cyclic bilateral motion.

\*Expected service life: The device's expected service life is 5 years, which is limited to the life of the motor. With proper maintenance (see page 11), the device can last longer.

### Safety Features

The 520 integrated plug-in power supply delivers less than 24 VDC to the device. The device is available in 120 VAC 60 Hz or 230 VAC 50 Hz models. For more information see detailed specifications included in this manual.

The device is designed to automatically reverse in the event that an obstruction occurs or the patient resists movement. The load reversal setting on the 520 is variable to accommodate a variety of limb weights and specialized therapeutic activities as prescribed by the physician and/or therapist.

The 520 provides immediate patient access to all operating controls via the unique motion controller. Restricted access is also possible by means of a lockout switch located on the CPM device. A Patient Thumb Switch is provided with the device, eliminating patient interface with the motion controller.

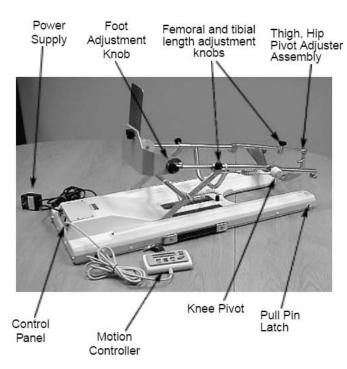
The Start/Stop Button on the Patient Thumb Switch gives the patient the ability to stop or interrupt the action of the device should he/she experience discomfort. The patient can restart the device (in the opposite direction) by pressing the button or switch a second time.

### **Unpacking The Device**

Remove all the 520 CPM system components from the carton.

During unpacking, check for external damage. Report any substantial damage to the shipper. Save packaging for storage when the device is not in use. Additionally, if it is ever necessary to return the device for service, this packaging provides all the protection that is required under warranty.

### **Device Setup**



#### Setup

Remove the power supply from the storage receptacle located in the side of the foot cradle.

Ensure that both power supply and motion controller cord are uncoiled from the device.

Position the Thigh, Hip Pivot Adjuster Assembly to the outside of the treated leg. The square tubing of the hip pivot slides into the matching tubing at the base of the CPM device. Insert square tube and locate the pull pin latch at the base of the device, pull the latch and continue to slide the hip pivot tube. Release the pull pin latch. The latch will return to the locked position upon matching with the hole in the square tubing of the hip pivot tube. If the latch is pulled out and turned by one quarter turn, it will lock in the open position. Check to ensure tube is locked.

The round tubing segment of the thigh adjuster aligns with the thigh cradle segment of the CPM device. A pull pin latch is incorporated with this segment. Upon sliding the tubing of the femoral adjustment component, pull the latch and release upon lining up with the slotted section of the tube. The pull pin latch will return to the locked position indicating the link is locked and stable. Check to ensure the tube is locked.

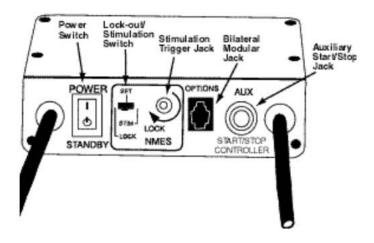
Plug the device into a standard (grounded) wall outlet.

### Operating The CPM

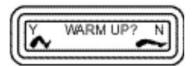
Turn device on via the **Power Switch** located at the base of the device.

The Lock Out/ Stimulation Switch is located at the base of the device. To change Extend, Flex, Speed, Force or Pause settings, place the controller switch in the Set position. The Lock Out/ Stimulation Switch may then be moved to the locked position to ensure the established parameters "original settings" are maintained without continuous monitoring.

Upon completing the range of motion, speed, force and pause setting, the Lock Out/ Stimulation Switch may be moved to the muscle stimulation mode. Upon sliding the switch to the "Stim" mode, the incorporation of muscle stimulation will occur as programmed by the operator. Device sold separately. See Step by Step Neuro-Muscular Electrical Stimulation for more information.



### Device Setup (cont'd.)



#### WARM UP FEATURE

The 520 is equipped with a **WARM UP** feature that, when selected, cycles the device through a much smaller range of motion than programmed, and slowly increases the range over a series of cycles until the full range of motion is reached.

#### Selecting and De-selecting Warm Up Feature:

Turn on the device from the **POWER** Switch located at the base of the device. In the motion controller display window the operator is prompted with the choice of whether to initiate the **WARM UP** feature or not. The operator must choose **YES** or **NO** to proceed.

### Selecting the Warm Up feature:

To select the Warm Up feature, choose YES by pressing the **EXTENSION** Button on the Motion Controller. Upon pressing the **STOP/START** button the device will begin to cycle through a much smaller range of motion than program-med, and slowly increase over a series of cycles until the full range of motion is reached. Once the device has reached the full range of motion, it will continue to cycle at that range.

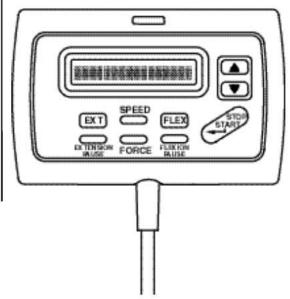
### De-selecting the Warm Up Feature:

Choose **NO** by pressing the **FLEXION** button to avoid the Warm Up feature. Upon pressing the **STOP/START** button the device will run at the full range of motion that was last programmed into the Motion Controller.

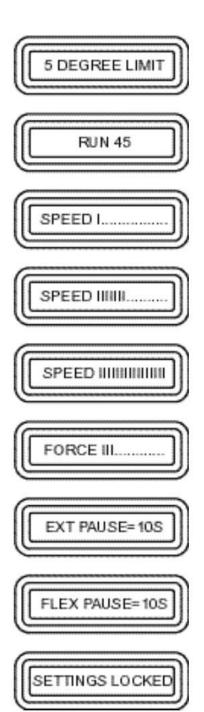
Note: If the device is stopped by depressing the START/ STOP button on the Motion Controller and then restarted, the Warm Up cycle will be repeated. To turn off the Warm Up feature, turn the device off, then on again at the POWER Switch. Then select NO to the Warm Up feature prompt.



The 520 provides a maximum Range of Motion (ROM) of -10° to 125° degrees. The ROM parameters are constantly displayed in the Extend (left) and Flex (right) display area of the motion controller. To change the parameters, depress and hold the **EXTENSION** or **FLEXION** buttons while simultaneously depressing the desired Up or Down button. The Extend and Flex parameters will change slowly for the initial 5 degrees (allowing for precise adjustment); following this, the parameters will change rapidly to facilitate extensive modification.



### Device Setup (cont'd.)



The device has been designed for a 5 degree minimum ROM. Attempting to set the ROM at less than 5° results in a "5 degree LIMIT" message in the center of the display window.

During normal operation, the center display area of the motion controller continuously displays the knee pivot angle of the CPM device.

The 520 operates at speed cycles of 1.5 to 16 minutes/cycle. To check the speed setting, depress and hold the **SPEED** button. The center of the display window will indicate the present speed of the CPM by use of a bar graph. Minimum speed is represented by a single bar at the left of the cursor line. Maximum speed is represented by all bars filling the cursor line in a left to right progression. To alter speed, depress and hold the **SPEED** button while simultaneously depressing either the Up or Down button.

The 520 incorporates a Variable Force Reversal setting. To check the force setting depress and hold the **FORCE** button. The center of the display window will indicate the present force of the CPM by use of a broken line bar graph. Minimum force is represented by a single line at the left of the cursor line. Maximum force is represented by all bars filling the cursor line in a left to right progression. To alter force, depress and hold the **FORCE** button while simultaneously depressing either the Up or Down button. (Adjustable force only affects the device while running into flexion.)

Pause of 0 to 30 seconds may be selected at the end of the Extension and/or Flexion cycles. The pause setting can be checked by depressing the EXTENSION PAUSE or FLEXION PAUSE and the number of seconds selected will appear in the center of the display window. To change the setting, depress and hold either the extend or flex pause button while simultaneously depressing either the Up or Down button.

To prevent inadvertent change to the chosen settings, place the **Lock Out/ Stimulation Switch** in the **Lock** position.

Attempting to alter any settings while in the Locked mode results in "Setting Locked" appearing in the center of the display window.

# Step By Step - Neuro-Muscular Electrical Stimulation

Neuro-Muscular Electrical Stimulation (NMES) may be utilized during Continuous Passive Motion therapy. Stimulation during motion, in static stretch/pause or both is available through the 520 CPM system.

### Device Setup (cont'd.)

Upon completion of the original parameter settings for extension, flexion, speed, force and pause, move the **Lock Out/ Stimulation Switch** on the control panel of the device to the "Stim" position.

#### Muscle-Stim Instruction

Immediately a message will begin to scroll across the control pendant display window:

"NMES I setup: Press T keys to set all parameters.

Press + key to enter data and continue."

Upon pressing the ←, which also functions as the start/stop button, the initial step of the "NMES" set up begins. The display window will read:

"
$$\downarrow$$
 direction  $\stackrel{\triangle}{\nabla}$  EXT".

EXT indicates the muscle stimulation direction and that stimulation will occur while the unit is moving into extension. To change the stimulation direction to flexion, press either the Up or Down button, on the pendant. Three choices are available for the direction in which muscle stimulation will fire, EXT, FLEX or NONE. Identifying "NONE" as the stimulation direction allows stimulation to only occur in the Extension or Flexion Pause Mode and only for the number of seconds indicated during the "original" parameter setup phase.

Use the  $\triangle$  Up or  $\nabla$  Down buttons to choose stimulation firing direction. Upon identifying, depress the  $\leftarrow$  button to confirm your choice and continue the setup.

If muscle stimulation is to fire while moving into extension or flexion, the next instruction screen will establish the **Low Muscle Stimulation Angle**. To change the angle, press the  $\triangle$  Up or  $\nabla$  Down button on the control pendant. Upon determination of the low angle, press the  $\leftarrow$  to confirm the angle selection.

**High Muscle Stimulation Angle** selection will follow. To change the angle, press the  $\triangle$  Up and  $\nabla$  Down button on the control pendant. Upon determination of the high stimulation angle, press the  $\leftarrow$ 

to confirm the angle selection.

The final selection phase of muscle stimulation setup is that of muscle stimulation **Pause**.

To incorporate muscle stimulation during **Extension Pause**, depress the  $\triangle$  Up or  $\nabla$  Down button to indicate "YES". To confirm this selection, depress the  $\leftarrow$  button. To eliminate muscle stimulation during extension pause, depress the  $\triangle$  or  $\nabla$  button to indicate "NO". To confirm this selection, depress the  $\leftarrow$  button.

Muscle stimulation during **Flexion Pause** utilizes the identical set up process as muscle stimulation for extension pause. Choose "YES" or "NO" and confirm by depressing the ← button.

**Special Note:** Muscle stimulation in extension or flexion pause will not operate if the muscle stimulation high and low angle parameter settings do not match that of the "original" range of motion parameters established.

### Finally, the display window will read:

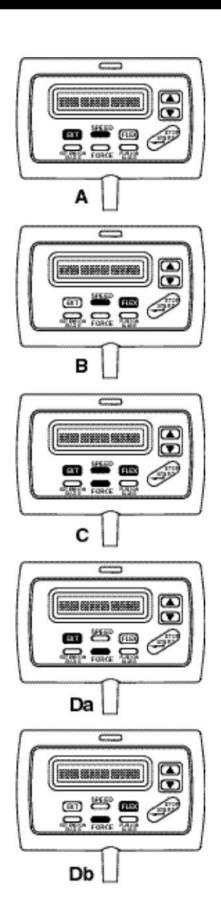
"Setup complete and settings locked ..."

Press the ← button. This returns the display to the "original" range of motion screen, identifying the end parameters of motion and the current angle readout.

At this point, parameter setup is complete, all settings for normal function and muscle stimulation are locked. There is no need to move the Lock-out switch from the "Stim" mode, but in the event you would need to, all muscle stimulation programming will be retained in memory.

During muscle stimulation and/or muscle stimulation pause, a lightening | will appear in the center section of the display window to indicate muscle stimulation is firing.

5	↓ RUN 25	115
EXT		FLEX
5	₽AUSE 15	115
EXT		FLEX



### Device Setup (cont'd.)

The 520 CPM system is now programmed to incorporate muscle stimulation. The system can utilize most popular muscle stimulation devices when used with the proper cable.

A NMES trigger jack located at the base of the device accommodates a linkage cable, allowing the interface between the chosen muscle stimulator and the 520 CPM. It is important to obtain the proper link cable from the muscle stimulator supplier.

Caution: Ensure link cable is securely connected to avoid any chance of disconnection during CPM use. If disconnection occurs, muscle stimulator must be turned off immediately.

#### Use of the Patient Thumb Switch

The patient may stop and restart the CPM at any time by depressing the START/STOP button on the motion controller or the START/STOP button on the patient thumb switch. The device will proceed in the opposite direction upon restarting.



### **Memory Features**

Each time the 520 is powered up, the Extend, Flex, Speed, Force and Pause settings will be the same as when the device was last run.

To check the Number of User Cycles of the CPM since the last reset, simultaneously depress and hold the **EXTENSION** and **SPEED** buttons. "User Cycles" and the number will appear in the display window. (A)

To check the Number of Hours of Operation since last reset, simultaneously depress and hold the **SPEED** and **FLEXION** buttons. "User Hours" and the number will appear in the display window. (B)

To reset the User Cycle and Hours, depress **EXTEN-SION**, **SPEED**, **FLEXION**, and **FORCE** buttons simultaneously. "RESET USER HRS&CYC" will appear in the display window. (C)

To check the Total Cycles since the device was manufactured, depress **EXTENSION** and **FORCE** buttons simultaneously (Da). For Total Hours since the device was manufactured, depress **FLEXION** and **FORCE** buttons (Db). Total cycles and total hours are non-resetable.

### Device Setup (cont'd.)

### Bilateral Application

Two 520 CPM systems may be linked to provide a controlled cyclical motion for bilateral application. A receptacle identified on the control panel at the base of the device as "OPTIONS" accommodates the link cable which connects the two CPM devices and controls the cyclical motion.

The motion controller for each CPM system remains operative, the parameters for each device remain accessible and the settings can be altered. Each motion controller will interrupt motion by depressing the start/stop button. The patient thumb switch will also function in the bilateral application for patient safety. Upon halting one of the CPM devices, the other stops. The same is true for reactivating the CPM devices.

The variation in parameter settings between the two CPM devices is monitored internally to assure the cyclical motion is maintained throughout the application.

# Attachment of the Patient Kit (Softgoods) to Device

Coverings for the 520 are made of a synthetic material. Ease of adjustment offers the necessary limb support and provides a comfortable surface for prolonged contact with body surfaces.

A boot, tibial support, femoral support and auxiliary strap complete each patient kit.

Begin with the femoral support piece. It is identified by the velcro strap located on the middle under surface of the support. Position this strap around the thigh cradle. The rounded edge of the femoral support faces the knee pivot hinges. Loop the Velcro straps around the CPM frame and anchor them to the surface of the femoral support. The Velcro tabs are adjustable to provide the proper troughing and patient alignment.

Next, attach the tibial support piece. The rounded edge of the support must face the knee pivot hinges. Loop the velcro straps around the CPM frame and anchor them to the smooth under surface of the tibial support. Adjust the Velcro tabs for proper troughing for the patient application and patient alignment.

Attach the boot by placing the elastic flap over the foot plate (sole of boot adheres to the Velcro on the foot plate.) After placing patient's foot in the boot, fold



### Device Setup (cont'd.)

the sides inward and attach the straps tightly to hold the foot securely.

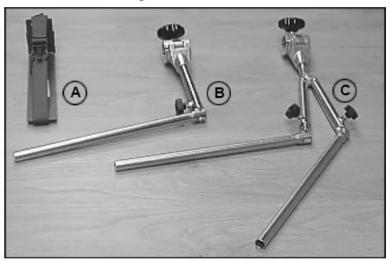
An auxiliary strap is provided and may be used (with physician's prescription only) to securely hold the thigh or calf to the device should enforced patient compliance be necessary.

### Measuring Patient and Adjusting Length of Device

Ensure the thigh, hip pivot adjuster segment is properly secured to the device. Also, position the CPM leg carriage in extension when preparing for the patient fitting.

Determine the height of the patient's greater trochanter. Align the hip pivot hinge to the greater trochanter of the patient. Pull the latch pin on the back of the hip pivot adjuster assembly and select one of the three positioning holes that best matches the patient's trochanter height. Release the latch pin to secure in place. Next, determine the length of the patient's femur. This measurement is taken from the greater trochanter to the center of the knee joint. The femoral length is then transferred to the CPM. The hip pivot hinge and the knee hinge are the starting and ending point for femoral length. To adjust this segment, loosen then depress the femoral adjustment knob. This allows the tube to slide. Upon determining proper femoral length, release the knob and tighten securely.

To determine the length of the tibia and foot



measure from the center of the patient's knee joint to 1/4 inch beyond the heel of the patient's foot, loosen the tibial length adjustment knobs on both sides of the cradle and adjust both sides equally. Tighten both knobs securely. If readjustment is necessary, do not attempt to adjust only one side of the calf cradle. This may cause mechanical damage to the device.

To allow free movement of the ankle, loosen foot adjustment knobs.

For rotation of the foot, loosen the adjuster knob located on the back of the Foot Cradle and reset to the right or left side as required.

### Attaching the CPM System to the Bed

A Home Bed Mount (A) is available for the 520 and secures the CPM to the bed for home use. The home bed mount has a strap which attaches to the CPM via knobs located on both sides of the device base near the foot of the device. The CPM is secured to the bed with the "L" bracket that can be attached to the mattress or the bed frame.

A Standard Hospital Bed Mount (B) is available for the 520 CPM device. This lightweight clamp provides stability and permits maximum flexibility for positioning the device on the bed, allowing for abduction if prescribed.

The standard bed mount will fit on either side of the CPM base. To adjust the position of the bed mount, loosen the knobs, position the device at

any angle, and secure the knobs. (If the bed is raised or lowered, readjust bed mount to proper position.)

A Traction Hospital Bed Mount (C), is available by special order. It provides maximum stability to the CPM if necessary.

The traction bed mount differs from the standard bed mount in that the traction bed mount attaches to the CPM at two points thus forming a stable triangulated attachment.

### Accessories

### Accessories/Cosmetic Parts Ordering Information

5.1	
Description	Part No.
Disposable Softgoods Kit	500PK
Cradle Knob Kit	11261
Universal Handle Kit	11260
Bilateral Cable - Pack of 10	13398-10
Patient Thumb Switch with Clip	13201
Kit - Non-Skid Pads	13462
Product Identification Label 500	13340
Product Identification Label 520	15466
Setup and Operating Manual	MM520OM1
Adult Foot Cradle Assembly Kit	13361
Thigh, Hip Pivot Adjuster Assembly Kit	13461
Plastic Rivet for Kneepot Cover (10)	15066
Universal Velcro Kit	11262
Kneepot Cover and Rivets Kit	13458
Kit – Plastic Fasteners for Cover	11274
Bed Mounts:	
Standard	12138
Traction (double)	10363
Home	12200
Extension Tube Assembly	11339

### Maintenance

\*Information needed for service personnel can be found in the Technical/Service Manual.

#### Maintenance by Patients

 Patients are responsible for using the device according to the setup and Operating Manual. Do not wash softgoods.

#### **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 sign 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 operations 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.
- Fully inspect all internal and external electrical components (including wire connectors and solder joints), and repair or replace as necessary.
- Perform a complete recalibration and subsequent check of electronic and mechanical safety systems including Reverse- On- Load function and Range of Motion controls.
- Complete a final check of the device in accordance with OrthoAgility Final Inspection criteria. (These are available in the appropriate Technical Service Manual or through OrthoAgility Customer Service.)

#### 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.

\*WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

### **Cautions and Warnings**

- Use the device only in accordance with the Physician prescription and Setup and Operating Manual. Failure to do so may result in damage to the device and/ or personal injury.
- The device must not be used in the presence of flammable anesthetics.
- Use only manufacturer's supplied replacement components.
- Do not use the device if there are mental or physical conditions that preclude patient compliance.
- To prevent potential physical injury, such as strangulation and choking hazards, keep the device away from children or individuals with mental or physical conditions that preclude the safe use of the device.
- Position the device in a comfortable and secure position. Ensure that the device is stable through its full range of motion.
- Keep hair, loose clothing, fingers and all parts of body away from moving components of the device.
- Do not expose the device to water or extreme temperatures. See recommended
   Specifications: Environmental Conditions.
- Do not use 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.
- 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.
- Device will produce minimal electromagnetic fields.
- The power supply is part of the device. The supplied power supply MUST be used at all times.
- Ensure placement of device allows plug to be disconnected from the power source.
- Inability to follow manual or service tips may result in unnecessary damage to the operator, patient or device.

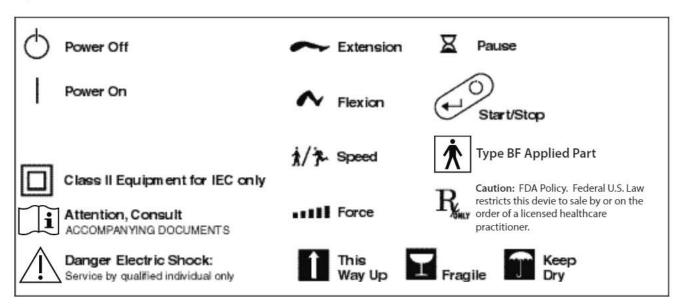
#### Contraindications

Do not use the device if any of the following are present:

- Untreated or uncontrolled infections.
- Known or suspected DVT (Deep Vein Thrombosis)
- Unstable fractures
- Hemorrhage

**Note:** upon using the device if signs of infections 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.

### Symbols and Specifications



### **Specifications**

Weight of Device Approximately 31 lbs. (14.1 kg)

Max. Patient Weight 350 lbs. (158.8 kg)
Max. Patient Height 78" (198.12 cm)

Limb Length 26.5 - 42 in. (67 - 107 cm)

Calf Length 11 - 18.5 in. (28 - 47 cm)

Thigh Length 11.5 - 19.5 in. (29 - 50 cm)

Hip Length 3.25 in (8 cm), 3.75 in. (9.5 cm), 4.25 in. (11 cm)

Range of Motion -10° extension to 125° flexion
Speed 1.5 to 16 minutes per cycle

Pause 0-30 seconds at maximum extension/flexion

Mode of Operation Continuous

Power Supply Input 100-240 VAC, 50-60 Hz

Output 15 VDC 2.0 A

NMES Compatible with various NMES devices

Electric Shock Classification Type BF

Certification CSA Approved, CE Marked

Environmental, Storage and -10° to 35° (14° to 95°F) temperature, 90% max. humidity

Transport Conditions ATM pressure 750 hPa to 1040 hPa.

The device must remain in the operational environment

a minimum of one hour prior to use.

IP Rating\*: IP21 Device, IP22 Controller

\* IP Rating is a rating code that identifies the amount of protection a given product has against dust and fluid.

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

# **Trouble Shooting Guide**

PROBLEM	POSSIBLE CAUSE	FIX
Device will not power up Device does not beep	Not receiving 19-21 Vdc on secondary side	Replace transformer kit or replace switch
	Main PCB failure	Replace PCB
	Motion controller cable disconnected	Check motion controller cable connections at both ends
		Return for service
Motion controller, erratic display	Motion controller cable break	Replace cable
	Motion controller PCB failure	
	Main PCB failure	Replace PCB
		Return for service
Error codes: E1,2,3,4,6,7,8,12,13,14,15,16,18	Out of calibration	Re-calibrate device following calibration procedures
	Main PCB failure	Replace PCB
	Motion controller cable break	Replace motion controller cable
	Motion controller PCB failure	Replace motion controller
		Return for service
Error code E9	Motion controller cable break	Replace motion controller cable
	Motion controller PCB failure	Replace motion controller kit # 13314
		Return for service
Error codes E10,11,21	Knee pot cable break	Replace knee pot cable
	Knee pot	Replace knee pot
	Main PCB failure	Replace main PCB
		Return for service
Error code E15	Slide switch in STIM position during bilateral mode	Move slide switch to SET or LOCK
		Return for service
Mechanical binding/jerking	Insufficient lubrication on track, ballscrew and track seals	Use a Light Lithium based lubricant, Lubriplate #105 on the ballscrews, and a Silicone spray on track seals and track
	Bearing bracket assembly failure	Replace bearing bracket assembly
	Ballscrew failure	Replace ball screw assembly
	U-bracket/slider assembly failure	Replace bracket/slider assembly
	Motor failure	Replace motor
		Return for service
Insufficient lifting power	Motor failure	Replace motor
	Bearing bracket assembly failure	Replace bearing bracket assembly
		Return for service

### 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 the 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 IR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABLITY AND FITNESS FOR A PARTICULAR PURPOSE. NO STATEMENT OF ANY REPRESENTATIVE SHALL EXTEND THE COMPANY'S LIABILITY AS HEREIN ESTABLISHED OR LIMITED. THIS WARRANTY IS PROVIDED TO THE ORIGINAL PURCHASER OF THE PRODUCT AND IS NON-TRANSFERRABLE.

#### **Returning the Device for Service**

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

If any warranted product is found by the Company to have 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:

#### In the USA:

QAL Medical, LLC

A Division of Quality Assembly and Logistics

Attn: Technical Service

1-715-735-4727; 888-430-1625 Fax: 1-715-732-6402

Website: www.galmedical.com

#### International Customer Service:

QAL Medical, LLC

A Division of Quality Assembly and Logistics

Attn: Customer Service 3000 Woleske Road

Marinette, Wisconsin 54143 USA

Tel: 1-715-735-4727 Fax: 1-715-732-6402

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

- Return Authorizations number
- Ship-to Address
- Purchase order for non-warranty repairs
- Name and phone number of a person to contact
- Brief description of the problem

#### Disposal of Device

Contact your distributor for proper disposal.

520 CPM Setup and Operating Manual		
Notes		
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CUSTOMER CONTACTS: In the USA: QAL Medical, LLC®

Website: www.qalmedical.com

Tel: 1.715.735.4727; 1.888.430.1625 Fax: 1.715.732.6402

International: QAL Medical, LLC®

3000 Woleske Road, Marinette, Wisconsin 54143 USA

Tel: 1.715.735.4727 Fax: 1.715.732.6402



#### QAL Medical, 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 <a href="mailto:info@rsqr.co.uk">info@rsqr.co.uk</a> <a href="www.rsqa.co.uk">www.rsqa.co.uk</a>



QAL Medical is registered to ISO 13485 for Quality Assurance