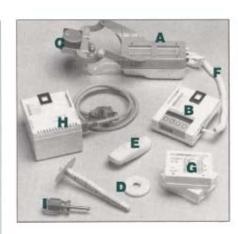
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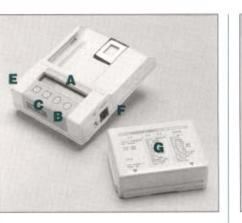
For DYNAMIC TENSION MODE See Program "C" Addendum - Page 16

OPERATING MANUAI



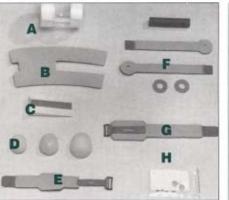
BASE UNIT

- A JACE W550 WRIST DRIVE ORTHOSIS
- **B** CONTROLLER
- C HAND DOME PLATFORM
- POST SUPPORT WITH LOCKING CAP
- **E** HAND REST
- F COILED CABLE
- G BATTERY PACK (2)
- H BATTERY CHARGER WITH POWER CORD
- SCREWDRIVER



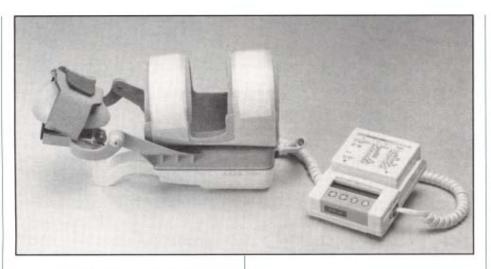
CONTROLLER

- A LCD WINDOW DISPLAY
- **B** UP/DOWN BUTTONS
- C PR/NX (PREVIOUS/NEXT) BUTTONS
- D GO/STOP BUTTON
- **E** ON/OFF SWITCH
- F ACCESSORY JACK
- BATTERY PACK



SOFTGOODS

- A FOREARM SPLINT
- **B** FOREARM SPLINT LINER
- C WRIST HEIGHT ADJUSTMENT WEDGE
- D HAND DOME SUPPORTS (3)
- E HAND DOME STRAP
- F POST SUPPORT COVER WITH STRAPS (2) & PADS (2)
- G HAND REST COVER WITH STRAP
- H CUSTOM SPLINT HOLE TEMPLATE WITH SCREWS & WASHERS



JACE W550 WRIST-CPM

The JACE W550 WRIST CPM is a portable Continuous Passive Motion (CPM) system for rehabilitation therapy of the wrist. The W550 permits either flexion/extension or radial/ulnar deviation motion of the wrist. Total motion of the W550 is 135°. Patient Range of Motion

(ROM) will vary depending on the size and type of hand support chosen.

The W550 is designed for safe, reliable patient operation, and maximum patient comfort. The controller allows the operator/ patient to control all W550 functions. It is used to set, execute and monitor desired angle parameters Range of Motion (ROM) within 2

degree tolerance, as well as angular speed settings from 18 degrees/minute to 240 degrees/ minute.

The W550 controller allows 3 distinct treatment protocols to be entered into the microprocessor. Program 1 enables the user to modify extension, flexion and speed only. Programs 2 & 3 allow complete customization of all parameter settings. The W550 has constant force control with automatic reverse when resistance is detected beyond initial force setting.

The W550 is designed to easily interface with neuromuscular electrical stimulators. These plug directly into standard jacks in the base of the controller.

To ensure patient safety, the W550 is designed to meet UL 544 safety requirements for medical equipment. The Power Supply is a nominal 7.2 Volt DC battery pack that can be charged only with the JACE battery pack charger.

SAFETY PRECAUTIONS

The JACE W550 CPM is intended for physician-prescribed use only. Before actual use, read and understand all operating instructions.

Keep the controller within reach of the patient during operation.

Do not expose to X-Rays. Exposure to X-Rays will damage controller microprocessor programming.

Do not operate unit in a volatile atmosphere, or in the presence of flammable anesthetics,

Do not dispose of battery pack. If battery pack fails and needs to be replaced, contact your Thera-Kinetics representative. Do not discard in fire.

Use only with JACE Battery Pack, Part No.37AA0101 Charge the JACE Battery Pack using only the JACE Battery Pack Charger, Part No.15CA0301.

Do not expose unit or batteries to temperatures below -22°F, (-30°C) or above 122°F, (50°C.)

Contact your JACE SYSTEMS representative for required service or maintenance.

STEP 1 UNPACKING THE UNIT

- 1 After unpacking the W550, check for the following components:
- JACE W550 Wrist Drive Orthosis
- Controller
- Hand Dome Platform
- · Post Support & Locking Cap
- Hand Rest
- Battery Packs (2)
- · JACE Battery Pack Charger
- (1) set of Softgoods
- Operating Manual
- Power cord for charger
- Coiled cable
- Screwdriver
- W550 carrying case

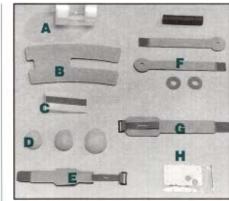
SAVE ALL PACKING MATERIAL FOR FUTURE SHIPPING REQUIREMENTS.

STEP 2 ASSEMBLE UNIT

- Controller should be in OFF position.
- 2 There are three types of Hand Supports to choose from. Hand Dome Platform with Hand Dome Support is for flexion/ extension. Post Support is for radial/ulnar deviation. Hand Rest is used for Flexion/Extension.
- 3 Plug Coiled Cable into W550, then into controller.
- 4 Insert a fully charged battery pack into controller.



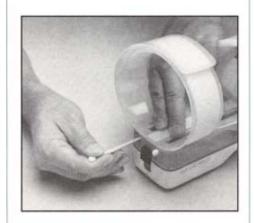
NOTE: Slide battery pack in the direction of arrows on the battery label.



STEP 3 ASSEMBLE SOFTGOODS

- 1 Each set of Softgoods includes:
- A Forearm Splint
- B Forearm Splint Liner
- Wrist Height Adjustment Wedge
- P Hand Dome Supports (3 sizes: small, medium & large)
- E Hand Dome Strap
- F Post Support Cover with Straps (2) & Pads (2)

 G Hand Rest Cover with Strap
 H Custom Splint Hole Template with Screws & Washers



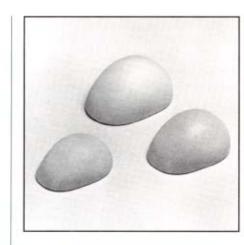
- 2 Attach Forearm Splint to CPM by sliding the 2 locking bars through Forearm Splint attachment grooves. Push down on splint to line up holes to slide locking bars.
- 3 There are three different hand supports. Select proper support and attach to Hand Platform.

4

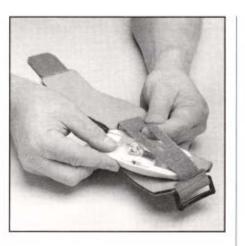
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OPERATIONS



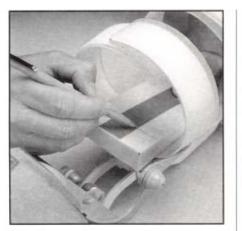
4 The Hand Dome Support comes in three sizes (small, medium & large). Select proper size Hand Dome Support. Position Hand Dome Strap between Hand Dome Platform and Hand Platform and secure with Lock Knob. Velcro selected Hand Dome Support to platform.



5 To use Hand Rest, slip Hand Rest cover with strap over Hand Rest. Attach Hand Rest to Hand Platform with Lock Knob.



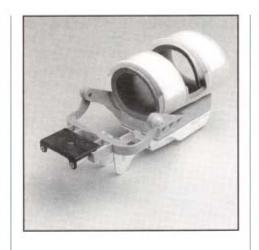
6 The Post Support is used for radial/ulnar deviation. Slide straps then Post Support Cover over Post Support. Place pad on Locking Cap and turn down to contact hand. Wrap straps as required. Note: Post Support cover should be trimmed to fit patients hand.



- 7 To adjust for wrist height, place Wrist Height Adjustment Wedge into Forearm Splint. Trim excess.
- 8 Attach forearm splint liner into Forearm Splint.
- 9 The W550 comes with a custom splint hole template with screws and washers.

CARE/CLEANING: Softgoods are made of a washable material for easy care and patient comfort.

NOTE: Each softgoods kit is intended for use by one patient only.



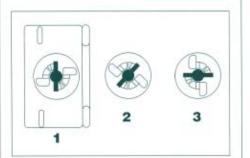
STEP 4 PATIENT FITTING

1 Hand Platform is used to attach all Hand Supports. Attach Hand Support of choice for selected Range of Motion (ROM). Dome Support and Hand Rest for flexion/extension; Post Support for radial/ulnar deviation.

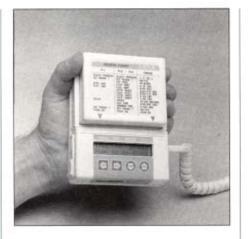
- 2 Be sure to attach Hand Dome Platform with RED DOT towards fingers. This allows Hand Dome Support to float from side to side.
- 3 Position patient's forearm in Forearm Splint so radiocarpal joint is aligned with the W550 hinge axis.

- 4 To adjust wrist joint height, place Wrist Height Adjustment Wedge into Forearm Splint. Move adjustment wedge until proper wrist height is attained. Trim off excess Wrist Height Adjustment Wedge. This ensures axis to axis alignment.
- 5 Secure splint to keep wrist in proper position.
- 6 The Hand Dome and Hand Rest are allowed to float side to side by turning lock knob to the second notch. Turning lock knob to third notch locks hand support in set position.

NOTE: THE LOCK KNOB HAS THREE POSITIONS -



- Releases system such that hand or post support can be changed.
- 2 Allows hand support to "float" from side to side.
- 3 Locks hand support, preventing side to side movement.



STEP 5 UNDERSTANDING THE CONTROLLER

The Controller has a two line window display. The first line shows existing parameters and second line prompts user for any parameter changes.

A LCD Window Display

Top Line:

PRGM - Displays current program in use, 1, 2 or 3.

EXT - Displays preset Extension or Radial deviation limits in degrees.

ANGLE - Displays current angle of wrist axis.

FLEX - Displays preset flexion or ulnar deviation limits in degrees.

Bottom Line:

FORCE: 2 lbs. to 20 lbs.(avg.)

RUN/STOP or WARM-UP mode.

Treatment time or Pause Time.

SET MODE FUNCTION BUTTONS

UP/DOWN - Used to reset a displayed operation parameter. The rate of change increases when continually depressing an UP/DOWN (arrow) button: momentarily releasing it slows the rate for greater control. UP also means Yes, and DOWN means No.

PR/NX - (Previous/Next) These buttons control prompting commands. PR (Previous) will go back to previous step in the program. NX (Next) prompts foreword to next step in the program.

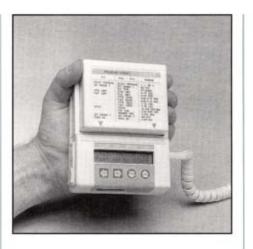
GO/STOP - Initiates or interrupts operation of the W550. Pressing on button a second time in succession reverses direction of travel.

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NOTE: Pushing Safety Stop button on W550 stops all motion. To resume motion. press GO/STOP button on controller.

ACCESSORY JACK

Accessory Jack allows use of Neuromuscular Electrical Stimulators during pause function at the end of travel in each direction. FLEX/EXT or RADIAL/ULNAR deviation, the W550 activates any compatible external device that is connected thorough the Accessory Jack Interface.



STEP 6 SETTING PARAMETERS

to meet patient requirements.

SETTING PARAMETERS WITHOUT MOTION

NOTE: EXT/RADIAL deviation Limit Setting is always set at least five degrees greater than FLEX/Ulnar deviation Limit Setting.

1 Turn Power ON with ON/OFF Switch. The following message will appear in LCD window: "Wrist Orthosis... Push GO to Start. " Push NX to select Program.

NOTE: If power is turned off while unit is running, turning on power to unit will resume running in same direction.

Set Parameters

Set Parameters To set parameters, push UP button. YES will appear on LCD window. Press NX. SET ZERO will appear.

Set Zero

Set Zero Push UP/DOWN arrows and STOP/GO button together to drive orthosis to patients neutral wrist position. Press NX to continue.

NOTE: If zero was previously set, push NX to continue.

Flexion Limit

Flexion Limit (ulnar deviation) Push UP/DOWN buttons to set required limits and push NX to continue. Note: Flexion limits will appear with a minus sign in front if the flexion limit is below neutral wrist position.

Extension Pause

Extension Pause (radial deviation) Push UP/Down buttons to set required pause time and push NX to continue. Maximum pause time 4 minutes 15 seconds.

and push NX to continue. Maximum pause time 4 minutes 15 seconds.

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Extension Force

Extension Force Push UP/DOWN buttons to set required EXT force and push NX to continue. Force settings 2 through 20: [2 pounds to 20 pounds (avg.) of continuous force.1

Flexion Force

Flexion Force Same as above.

The controller accommodates up to Select Program 11 Speed three programmable operations. Program 1 is pre-programmed for Select Program (1,2,3) **Extension Limit Flexion Pause** Speed force and pause. Flexion/Extension Push UP/DOWN buttons to Push UP/DOWN buttons to or Radial/Ulnar deviation Range of Extension Limit (radial deviation) Flexion Pause (ulnar deviation) set required speed and select desired program. Motion (ROM) and speed is pro-Push UP/DOWN buttons to set Push UP/DOWN buttons to push NX to continue. Speed is Then push NX button to grammable. Programs 2 & 3 are not required limits and push NX to set required pause time displayed in degrees per continue. pre-programmed and must be set continue. minute (18 equals 18° per

0

minute) Speed settings 18
through 240: 240 equals fastest
setting. CY shows number of
cycles per hour including
pause times.

12 CIr. Time

Clr. Time
Clr. Time shows total running
time of W550. 0:00 - 999 HRS.
To clear time, press UP button.
Push NX to continue.

3 Warm Up

Warm Up
Warm Up consists of 1 to 255
minutes of CPM at 50% of
programmed Range of Motion
(ROM) that increases to 100%
programmed Range of Motion
(ROM) during selected warm
up session. To bypass warm up
set to 0. Push NX to continue.

NOTE: If any parameters are changed during warm up treatment, warm up will reset to beginning.

NOTE: Pause and Muscle Stimulation will not operate during warm up period.

Run

13533

Run Press GO/STOP button to start CPM.

B SETTING PARAMETERS WITH MOTION

Follow directions described above for all program sequences except when setting Flexion/Extension (Radial/Ulnar deviation) limits. To set Flexion/Extension (Radial/Ulnar deviation) with unit in motion press GO/STOP button simultaneously with either UP or DN button.

STEP 7 NORMAL OPERATION

- During RUN MODE, speed can be changed from 18° per minute to 240° per minute by pressing UP/DOWN buttons.
- FORCE is adjustable from 2 lbs to 20 lbs. (avg.) After Warm Up and during first two (2) cycles of operation, W550 records actual patient force profiles for every 16° of Range of Motion (ROM). Any deviation caused by a foreign obstacle in path of frame or significant patient resistance during operation will be instantly detected and W550 will automatically reverse cycle direction.



- SAFETY STOP BUTTON:
 Pushing the Safety Stop button on W550 orthosis stops all motion. To resume motion, press GO/STOP button on the controller.
- LOW BATTERY: When LOW BATTERY flashes on the LCD, 30 - 60 mins. of operating time remain. To change battery pack during treatment,

turn off power without depressing GO/STOP button. Insert fully charged battery.

 BATTERY CHARGER: Plug charger into any 110 volt outlet. Turn on power and green light should light up. Plug in battery pack with arrows pointing towards green light. Red charging light will light up.
 When red charging light turns off, battery pack is fully charged. Unit requires 4 to 6 hours to fully charge. The battery pack can be left in charger indefinitely.

TROUBLE SHOOTING

NO DISPLAY

 Check power switch. Change battery pack with fully charged battery. Still no display, return unit to JACE.

NO ORTHOSIS

 Check for loose coiled cable connection.

FAULT 04

 Orthosis is forced beyond normal limits. Set orthosis up or down with motion.

FAULT 06

 No angle change when running. Return unit to JACE. ESHOOTII

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FAULT 08

 Micro processor malfunction.
 Push STOP, then press GO.
 If fault re-occurs, return unit to JACE.

FAULT 10

 Mechanical jam. Check for physical jam. Power down and turn back on. If unitstill won't run, return unit to JACE.

FAULT 20

· Return unit to JACE.

FAULT 40

Return unit to JACE.

CARE AND CLEANING

CAUTION: Disconnect unit from power source when cleaning. Do not immerse unit. Avoid spilling liquids (or other contaminates) into moving parts or electrical components of W550.

Surfaces of the W550 may be wiped with a soft cloth or sponge dampened with a mild soap solution. A 10% solution of household bleach (Sodium Hypochlorite) and water may be used as a disinfecting wipe. Avoid caustic cleaners.

Do not expose unit or batteries to temperatures below -22° F (-30°C) or above 122° F (50°C).

LIMITED WARRANTY

The JACE CPM Model W550 is warranted against defects in material and workmanship for one (1) year from the date of initial purchase. During the warranty period defective parts will be repaired or replaced by JACE SYSTEMS, Inc., at no charge to the customer, when such defective parts have been properly packaged and returned prepaid to JACE Systems, Inc.

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

JACE Systems, Inc. shall not be liable for incidental or consequential damages including loss of 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 of merchantability and fitness for a particular purpose.

REPLACEMENT PARTS:

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Description	Part No:	
Power Cord	55AA1302	
Coiled Cable	55AA2101	
Hand Rest (Assembly)	15MA3301	
Post Support	92IA3401	
Lock Knob		
Battery Pack	37AA0101	
Manual		
Locking Bars (Assembly)	15MA3401	
Screwdriver	85SS0002	
Controller	15CA0201	
Charger	15CA0301	
W550	15BA0501	
Hand Dome Platform	15MA3701	
Case/Foam	15MA3501	
Softgoods Kit	15KA1001	
Locking Cap	92IA3901	

TECHNICAL SPECIFICATIONS

W550

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- Weight: Under 20 oz.
- Force: 2 to 20 lbs. (avg.)
- Range of Motion: 135°
- Angular Speed: 18 to 240° per min.
- Electrical Power: 7.2 volts Nicad battery pack
- Battery Life: 8 hours minimum
- Audio Noise: Less than 47 DbA
 20 inches
- Connection to Controller:
 6 conductor coiled cable

Charger Specifications

- Input Power: 110 VAC, 60 HZ
- . Output Power: 7 Watts
- Automatic Charge Rate: Voltage limited
- LED Indicators
- . Charge Time: 4 to 6 hours

Controller

- Power: 7.2 VDC (Nicad Pack)
- · Weight: 15.8 oz. (with battery pack)

IMPORTANT



CAUTION

To reduce the risk of electric shock, do not remove cover (or back). Refer servicing to qualified service personnel.

PROGRAM C

DYNAMIC TENSION MODE

Program C provides the clinician the ability to program a combination of normal CPM with Dynamic Tension (DT). In the DT mode the device provides a constant programmable force to the wrist joint gradually increasing the range of motion. During Program C the unit begins with a programmed CPM time then progresses to Dynamic Tension in Extension, and finally Dynamic Tension in Flexion. This cycle is repeated throughout the use of Program C.

STEP 8

SETTING DT PARAMETERS WITHOUT MOTION

NOTE: EXT/RADIAL deviation Limit Settings is always set at least five degrees greater then FLEX/Ulnar deviation Limit Setting. 1 Turn Power ON with ON/OFF Switch. The following message will appear in LCD window: "Wrist Orthosis... Push GO to Start." Push NX to select Program.

NOTE: If power is turned off while unit is running, turning on power to unit will resume running in same direction.

2 Select Program

Push the UP/DOWN buttons to Select Program "C", then push NX button to continue.

3 Set Parameters

To set parameters, push UP button. YES will appear in the LCD window. Press NX SET ZERO will appear.

4 Set Zero

Push UP/Down arrows and STOP/Go button together to drive orthosis to patients neutral wrist position. Press NX to continue.

NOTE: If zero was previously set, push NX to continue.

5 Extension Limit

Extension Limit (radial deviation). Push UP/DOWN buttons to set required limits and push NX to continue.

6 Flexion Limit

Flexion Limit (ulnar deviation). Push UP/DOWN buttons to set required limits and push NX to continue.

NOTE: Flexion limits will appear with a minus sign below neutral wrist position.

7 Extension DT Time

Extension DT Time (radial deviation). Push UP/Down buttons to set required Extension DT Time and push NX to continue. Maximum Extension DT Time 4 hours 15 minutes.

8 Flexion DT Time

Flextion DT Time (ulnar deviation). Push UP/DOWN buttons to set requied Flexion DT Time and push NX to continue. Maximum Flexion DT Time 4 hours 15 minutes.



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