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OPERATING MANUAL

SUPERIOR BY DESIGN

Base Unit

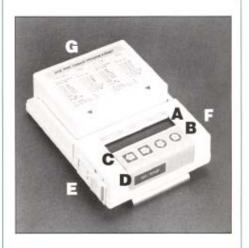
▲ JACE H440 Hand Drive Orthosis (HDO)

B Controller

C Coiled Cable

D Battery Pack (2)

E Battery Charger with Power Cord



Controller

A LCD Window Display

B Up/Down Buttons

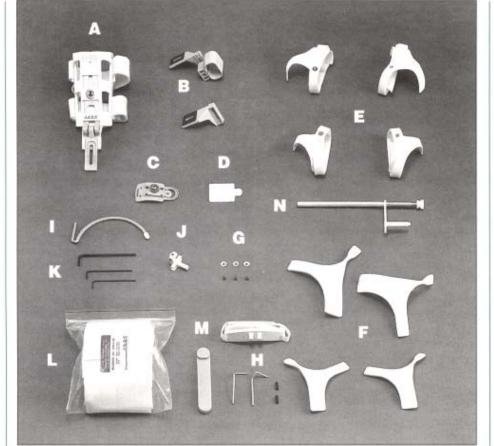
C PR/NX (Previous/Next) Buttons

D Go/Stop Button

E On/Off Switch

F Accessory Jack

G Battery Pack



Softgoods/Splint Assembly

A Forearm Splint Assembly

B HDO Bridge and Clamp Assembly

C Palmar Retainer

D Palmar Retainer foam liner

E Right/Left Palmar splint (small, large)

F Palmar splint foam liner (right, left, small, large)

G Palmar splint hardware kit

■ MCP Block kit with support rods

Curved Drivebar with cap

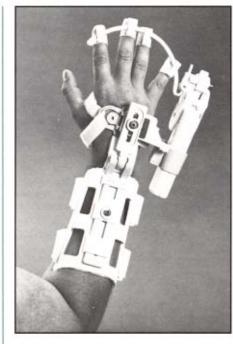
J Drivebar support

K Allen keys

■ Finger tip attachment kit

M Curved Drivebar Bending Tool

N MCP Drivearm Kit with Smart Link



JACE H440 HAND-CPM

The JACE H440 Hand CPM is a portable Continuous Passive Motion (CPM) system for rehabilitation therapy of the digits. The H440 permits either full composite motion of the digits (0-260° degrees), or isolated MCP joint motion (0-90° degrees).

The H440 is designed for safe, reliable patient operation, and maximum patient comfort. The controller allows the operator/patient to controller is used to set, execute and monitor desired angle parameters for Range of Motion (ROM) within a 2 degree tolerance, as well as angular speed settings from 38° degrees/minute to 508° degrees/minute.

The H440 controller has four programmable therapy options; 1. normal CPM operation that includes a 0-255 minute warm-up period for composite motion; 2. normal CPM operation that includes a 0-255 minute warm-up period for MCP joint only motion;
3. Dynamic Tension mode for composite motion, or; 4. Dynamic Tension for MCP joint only motion. The H440 has constant force control with automatic reverse when resistance is detected beyond the force setting during normal CPM operation. In Dynamic Tension Mode the set force is applied for a programmable period of time.

The H440 is designed to easily interface with external devices such as neuromuscular electrical stimulators. These plug directly into standard jacks in the base of the controller.

To ensure patient safety, the H440 is designed to meet UL 544 safety requirements. The Power Supply operates on a nominal 7.2 Volt DC battery pack that can be recharged with the JACE battery pack recharger.

The JACE Battery Charger is UL approved.

SAFETY PRECAUTIONS

The JACE H440 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 operate unit in a volatile atmosphere, or in the presence of flammable anesthetics.

Do not expose to x-rays. Exposure to x-rays will damage controller microprocessor programming.

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

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

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

Contact your local representative for required service or maintenance.

Designed to meet all UL 544 safety requirements. Power Supply operates on a nominal 7.2 Volt DC battery pack.

STEP 1 UNPACKING THE UNIT

- 1 After unpacking the H440, check for the following components:
 - JACE H440 Hand Drive Orthosis (HDO)
- Controller
- Coiled Cable
- Battery Packs (2)
- Battery Charger with Power Cord
- (1) set of Softgoods
- Operating Manual
- H440 Carrying Case

SAVE ALL PACKING MATERIAL FOR FUTURE SHIPPING REQUIREMENTS.

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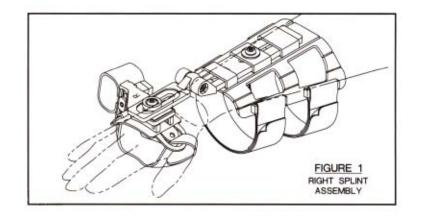
STEP 2 SOFTGOODS/SPLINT **ASSEMBLY** see Figure 1

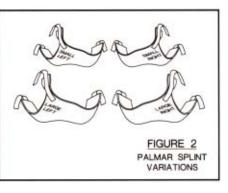
There are several options for splint use:

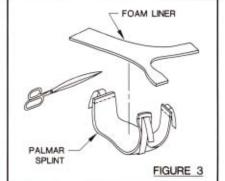
- Wrist immobilization (as shipped)
- Wrist without immobilization
- Use of custom splint (not supplied)

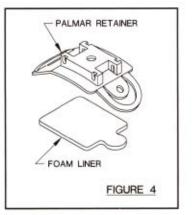
Your selection of right or left splint assembly comes with two palmar sizes, large and small. One of these must be fit to the patient. Follow instructions below:

- Select appropriate palmar splint see Figure 2.
- 2 Trim selected palmar splint to fit patient. Avoid cutting straps see Figure 3.
- 3 Apply foam liner to palmar splint if indicated see Figure 3.
- 4 Apply foam liner to underside of palmar retainer see Figure 4 page 7.



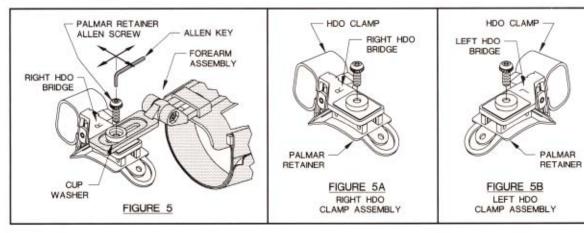






- 5 Attach palmar splint to retainer with hook and loop straps. Adjust length and tension of straps to center retainer on dorsum of hand. See Figure 6 page 8.
- 6 Wrist immobilization
 - 1) The splint comes assembled for immobilizing the wrist.
 - 2) Skip the remainder of STEP 2.
- 7 Wrist without immobilization
 - 1) Remove palmar retainer allen screw.

- 2) Remove entire forearm assembly.
- 3) Reverse orientation of cup washer so that opening faces downward.
- 4) Reassemble as shown in Figure 5A for right hand. 5B for left. Be sure that HDO bridge is oriented toward ulnar side.
- Tighten allen screw.



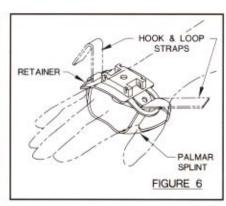
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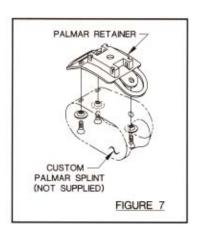
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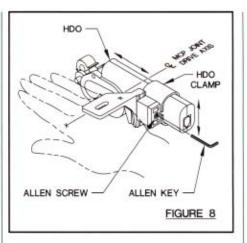


- Custom splint (not supplied)
 - 1) Attach custom palmar splint to palmar retainer using hardware provided as shown in Figure 7.



STEP 3 FITTING HDO TO SPLINT

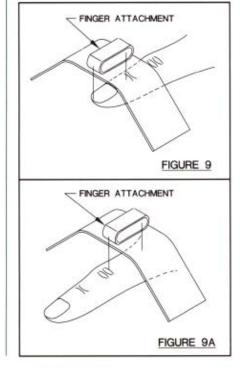
1 Loosen allen screw on HDO clamp with allen key provided and slide H440 Hand Drive Orthosis into HDO clamp see Figure 8.



STEP 4 FITTING OF FINGER **ATTACHMENTS**

1 For composite or isolate DIP & PIP mode affix finger attachments to dorsal aspect of distal phalanx, aligning end of plastic slide with end of fingertip. see Figure 9 page 9.

2 For isolated MCP mode, affix finger attachments to the dorsal aspect of the proximal phalanx see Figure 9A.

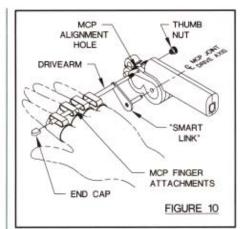


STEP 5 MCP FITTING, THREE **OPTIONS AS FOLLOWS:** (see Quick Reference Chart page 20)

OPTION A: Isolated MCP Joint Motion

- Insert drivearm with "Smart Link" into MCP alignment hole at MCP joint axis and secure with plastic thumb nut see Figure 10.
- 2 Slip MCP finger attachments onto drivearm and capture with end cap see Figure 10.

NOTE: Controller will automatically convert Range of Motion (ROM) to MCP mode (0-90 degrees).



OPTION B: Composite Motion with MCP drivearm added.

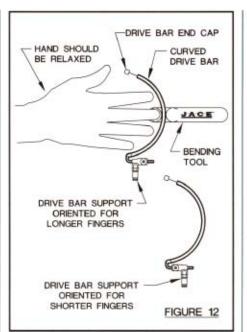
- 1 Remove "Smart Link" from MCP drivearm see Figure 10.
- 2 Insert MCP drivearm into MCP alignment hole and secure with plastic thumb nut see Figure 11.

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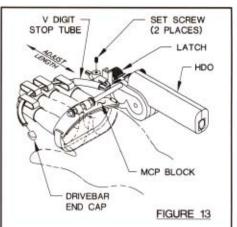
 Position MCP block on MCP drivearm with o-rings see Figure
 Secure proximal phalanx to MCP block with straps.

NOTE: MCP block may be used with or without g-clip. Remove g-clip if not required see Figure 11.

4 Align curved drivebar with end of fingers and bend with bending tool to approximate

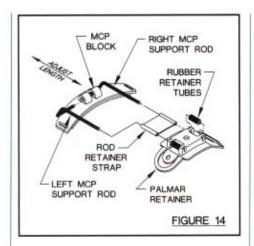


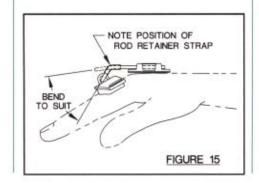
patients varying finger lengths see **Figure 12**. Assemble drivebar support loosely to curved drivebar. Note orientation of Drivebar Support for short or long fingers.



5 Remove drivebar end cap and insert curved drivebar through finger tip attachments beginning at V digit see Figure 13. Open latch and insert curved drivebar support into socket of HDO. Close latch to lock snap shut. Reattach drivebar end cap.

NOTE: If V digit stop tube is too long: remove tube, trim to suit and reassemble see Figure 13.





6 Adjust curved drivebar for proper length and secure by tightening set screws with allen key provided.

OPTION C Isolated PIP and DIP Joint Motion

- Remove g-clip & strap from MCP block.
- Insert right and left MCP Support Rods into MCP Block see Figure 14.
- 3 Slip rod retainer strap onto long end of MCP support rod. Push forward so that it is half onto first bend in rod see Figures 14 & 15.
- 4 Position rubber retainer tubes between insertion holes on palmar retainer see Figure 14.

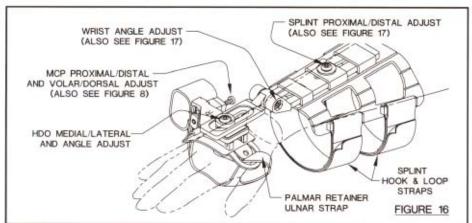
- 5 Insert long end of MCP Support Rods into holes on palmar retainer and through rubber retainer tubes. Adjust to desired distance.
- 6 Bend MCP Support Rods to desired angle to obtain proper angle for blocking MCP joint of digits see Figure 15.
- 7 Proceed by completing instructions for OPTION B numbers 4 through 6.

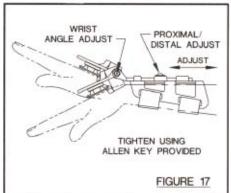
CARE/CLEANING: Softgoods are made of a washable material for easy care and patient comfort.

NOTE: Each Softgoods/Splint Assembly kit is intended for use by one patient only. ERATIONS

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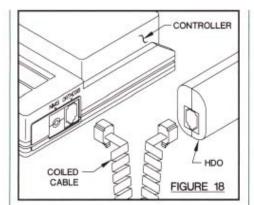


STEP 6 PATIENT FITTING

- Position patients hand into splint and secure with hook and loop straps see Figure 16.
- 2 To adjust forearm splint proximal/distal, loosen allen screw on splint and position comfortably to avoid ulnar and

radial styloid and retighten see Figures 16 &17.

- 3 Confirm that palmar retainer is centered on dorsum of hand by adjusting ulnar strap.
- 4 To adjust wrist angle, loosen allen screw at wrist axis, position at desired angle and retighten. see Figures 16 &17.
- 5 Align MCP joint/drive axis of HDO with V digit MCP by loosening allen screw on HDO clamp and sliding HDO proximal/distal and volarly/ dorsally see Figure 8 page 8 & Figure 16.
- 6 HDO can be further aligned by loosening allen screw on HDO bridge and positioning medial/ lateral or angling to hand see Figure 5 page 7 & Figure 16.



7 Connect coiled cable between HDO and controller see Figure 18.

STEP 7 UNDERSTANDING THE CONTROLLER

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

A LCD Window Display

Top Line:

PRGM - Displays current program in use, 4,5,D,E.

EXT - Displays preset extension limits in degrees.

ANGLE - Displays current angle of axis in degrees.

FLEX - Displays preset flexion limits in degrees.

Bottom Line:

FORCE: 5 oz. to 80 oz. (composite) OR 24 oz. to 320 oz. (MCP only)

RUN/STOP or WARM-UP mode.

Treatment time or Pause Time.

B 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 forward to next step in the program.

GO/STOP - Initiates or interrupts operation of the H440. Pushing on button a second time in succession reverses direction of travel.

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ACCESSORY JACK

Accessory Jack allows use of Neuromuscular Electrical Stimulators during the pause function at the end of travel in FLEX or EXT. The H440 activates any compatible external device that is connected through the Accessory Jack interface.

STEP 8 SETTING PARAMETERS

The controller accommodates up to four programmable operations. Program 4 is pre-programmed for composite normal operation. Program 5 is pre-programmed for MCP normal operation. Program D is pre-programmed for composite Dynamic Tension, and Program E is pre-programmed for MCP Dynamic Tension. All programs must be set to meet patient requirements; Range of Motion (ROM) is set by

the extension and flexion limits. pause, force in each direction, speed, and warm up time.

A SETTING PARAMETERS WITHOUT MOTION

NOTE: The FLEX Limit Setting is always set at least ten degrees in composite mode or seven degrees in MCP mode greater than the EXT Limit Setting.

1 Turn Power ON with the Power Switch. The following message will appear in the LCD window: 'Hand Composite or Hand MCP 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.

Inserting the "Smart Link" for MCP operation will cause the controller to display "Orthosis Differ." Power must be turned off and on with the "Smart Link" inserted, or removed for composite motion.

Select Program

Select Program (4.5.D.E) Push UP/DOWN buttons to select desired program. Then push NX button to continue.

Set Parameters

To set parameters, push UP button. YES will appear on LCD window, Push NX, FLEX LIMIT will appear.

Flexion Limit

Push UP/DOWN buttons to set required limits and push NX to continue.

Extension Limit

Push UP/Down buttons to set required limits and push NX to continue.

Flexion Pause or Flexion DT Time

Push UP/DOWN buttons to set required pause time or DT time and push NX to continue. Maximum pause time 4 minutes 15 seconds. Maximum DT time 4 hours 15 minutes.

Extension Pause or **Extension DT Time**

Push UP/Down buttons to set required pause time or DT time and push NX to continue. Maximum pause time 4 minutes 15 seconds Maximum DT time 4 hours 15 minutes.

8 Flexion Force

Flexion Force Push UP/DOWN buttons to set required EXT force and push NX to continue. Force settings 5 through 80: [5 oz. to 80 oz. (avg.) or 24 to 320 oz. in MCP mode.]

NOTE: If device reverses below the desired patient force settings, increase the EXT/FLEX Force.

Extension Force

Extension Force Same as above.

10 Speed

Speed Push UP/DOWN buttons to set required speed and push NX to continue. Speed is displayed in degrees per minute (38 equals 38° per minute) Speed settings 38 through 508: 508 equals fastest setting. CY shows number of cycles per hour including pause times. Or 14° through 176° in MCP mode.

NOTE: In DT mode speed cannot be set lower than 120°.

11 Clr. Time

Clr. Time Clr. Time shows total running time of H440. 0:00 - 999 HRS. To clear time, push UP button. Push NX to continue.

12 Warm Up

Warm Up Warm Up consists of 1 to 255 minutes of CPM at 50% of programmed Range of Motion

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(ROM) that increases to 100% programmed (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.

13 Run

> Push GO/STOP button to start CPM.

B SETTING PARAMETERS WITH MOTION

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

STEP 9 NORMAL OPERATION

- During RUN MODE, speed can be changed from 38° per minute to 508° in normal mode or 14° to 176° per minute in MCP mode by pushing UP/ DOWN buttons.
- FORCE is adjustable from 5 oz. to 80 oz. (avg.) during Dynamic Tension Extension or Flexion or 24 to 320 oz. in MCP mode cycle.

Any deviation above the set force caused by a foreign obstacle in path of frame or significant patient resistance during operation will be instantly detected and the H440 will automatically reverse cycle direction.

- 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.

FAULT 08

 Controller malfunction. Push STOP, then push GO. If fault re-occurs, return unit to JACE.

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FAULT 10

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

FAULT 20

Return unit to JACE.

FAULT 40

Return unit to JACE.

CAUTION: Disconnect unit from

power source when cleaning. Do

not immerse the unit. Avoid spilling

liquids (or other contaminants) into

the moving parts or electrical

components of the H440.

CARE AND CLEANING

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 H440 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 property 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, 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, 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:

Description	Part No.
Power Cord	55AA1303
Coiled Cable	55AA2101
BatteryPack(1)	37AA0101
Manual	
Softgoods Kit Complete	15KA1401
Splint Assembly Kit	
MCP Block Kit	
Finger Drive Kit	15KA1404
Palmar Kit	
Palmar Hardware Kit	15KA1406
MCP Drivearm Kit	15KA1407
Finger Attachment Kit	93KA1101
Controller	
Battery Pack Recharger	15CA0301
Hand Drive Orthosis (HDO).	15BA0401

TECHNICAL

SPECIFICATIONS H440

- . Weight: Under 10.5 oz.
- . Force: 5 to 80 oz. (avg.) composite 24 to 320 oz. (avg.) MCP
- Range of Motion: 260°
- Angular Speed: 38 to 508° per min.
- . Electrical Power: 7.2 volt Nicad battery pack
- . Battery Life: 8 hours minimum
- Audio Noise: Less than 47 DbA @ 20 inches
- Connection to Controller: 6 conductor coiled cable

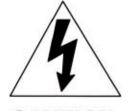
Charger Specifications

- Input Power: Min/Max voltage 100v or 120v service 90vac to 135vac 50/60Hz 230v or 240v service 185vac to 260vac 50/60Hz
- . Output Power: 7 Watts
- · Automatic Charge Rate: Voltage limited
- LED Indicators
- . Charge Time: 4 to 6 hours

Controller

- Power: 7.2 DC
- 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.

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MCP FITTING QUICK REFERENCE CHART OPTION A -ISOLATED MCP JOINT MOTION OPTION B -COMPOSITE MOTION OPTION C -ISOLATED DIP AND PIP JOINT MOTION



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