



DANNIFLEX™
CPM 460
SYSTEM Assembly &
Operations
Manual

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Medical
Technology

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SAFETY PRECAUTIONS

Do not use in a volatile atmosphere.

Do not attempt to power the unit via any means while the power cord is engaged in the storage receptacle.

Do not store unit under a bed which has less than 19 inches of clearance at all times.

Read Before Adjusting or Operating Unit

We recommend that all clinicians and others responsible for the operation of this unit become thoroughly familiar with its capabilities and proper operating procedures prior to actual patient use. Skill at measuring the patient and adjusting the unit accordingly will come with experience and practice.

PRODUCT DESCRIPTION

The DANNIFLEX 460™ Continuous Passive Motion (CPM) system is designed for the rehabilitation of the lower limbs. The DANNIFLEX 460™ CPM offers changeable thigh and calf components allowing pediatric usage.

SAFETY FEATURES

The DANNIFLEX 460™ delivers less than 24 volts DC to the bed through the integrated plug-in power supply. While the unit is designed to operate on the standard electrical supply of 120 volts AC, 60 Hz, the 460 will tolerate electrical supply variations of 105-130 volts AC which may be found in the home or hospital environments.

The unit is designed to automatically reverse in the event that an obstruction occurs.

The DANNIFLEX 460™ provides immediate patient access to all operating controls via the unique Control Pendant. Restricted access is also possible by means of a lock-out switch.

The START/STOP button gives the patient the ability to stop or interrupt the action of the unit should he/she experience discomfort. The patient can restart the unit (in the opposite direction) upon pressing the START/STOP button a second time.

A fuse is located internally and will interrupt power to the motor if there is a power fault in the unit.

Carton should contain:

- 1) One Instruction Manual
- 2) One DANNIFLEX 460™ Orthosis with Control Pendant
- 3) One Thigh Shield
- 4) One Patient Kit (Soft Goods)
- 5) Home Bed Mount Brackets
- 6) Adult Modular Components;
Foot Cradle and Thigh Assembly
(Optional Equipment as Ordered
for Pediatric Conversion)

UNPACKING UNIT

Remove all the DANNIFLEX 460™ CPM system components from the carton. During unpacking, check for external damage. Report any substantial damage to shipper.

SAVE PACKAGING for storage when the unit is not in use. Additionally, if it is ever necessary to return for service, this packaging provides all the protection that is required under warranty.

SET UP

Remove the Power Cord plug from the Storage Receptacle located in the side of the Foot Plate Bracket.

Ensure that both Power Cord and Control Pendant Cord are uncoiled from the unit.

Plug unit into standard (grounded) 120 volt wall outlet.

OPERATING THE CPM

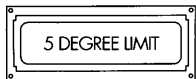
Turn unit on via the **POWER** switch located at the base of the orthosis.

The Pendant lock out switch is located at the base of the orthosis. To change **EXTEND**, **FLEX**, **SPEED** or **PAUSE** settings, place the **PENDANT** switch in the **SET** position.

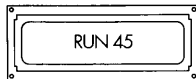


460 Control Pendant

The DANNIFLEX 460™ provides a maximum Range of Motion (ROM) of -5 to 110 degrees. The ROM parameters are constantly displayed in the Extend (left) and Flex (right) display windows of the Control Pendant. To change the parameters, depress and hold the **EXTEND** or **FLEX** 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.

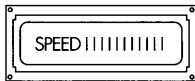
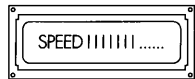
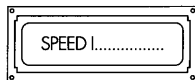


The orthosis has been designed for a 5 degree minimum ROM. Attempting to set the Extension and Flexion within this ROM results in a "5 DEGREE LIMIT" message in the center of the display window.

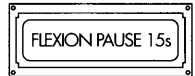
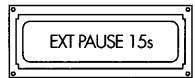


During normal operation, the large center display area of the Control Pendant continuously displays the knee pivot angle of the CPM unit.

The DANNIFLEX 460™ operates at speed cycles of 1 to 10 minute/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 displaying "SPD" and a simple 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.



A 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 EXTEND and/or FLEXION PAUSE. EXTEND PAUSE or FLEX PAUSE and the number of seconds selected will appear in the center of the display window. To change the settings, depress and hold either the ▲ Up or ▼ Down button. When increasing both PAUSE functions, repeat the above steps for set up of each PAUSE function separately (in a cycle).



Neuro-Muscular Electrical Stimulation (NMES) may be utilized during the EXTENSION PAUSE mode. Simply set the desired PAUSE interval and connect a muscle stimulation to the NMES trigger jack located at the base of the orthosis. To prevent inadvertent loss of synchronism between the CPM and the chosen muscle stimulator, use only Danninger Medical link cables with locking plugs. The NMES trigger jack will deactivate the muscle stimulator one second before the end of the EXTENSION PAUSE mode. Refer to the muscle stimulator instruction manual for proper set-up.

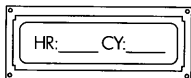
To prevent inadvertent changes to the chosen settings, place the Pendant switch in the LOCK position.

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



USE OF PATIENT CONTROL BUTTON

The patient may stop and restart the CPM at any time by depressing the START/STOP button on the Control Pendant. The unit will proceed in the opposite direction upon restarting.



MEMORY FEATURES

Each time the DANNIFLEX 460™ is powered-up, the Extend, Flex, Speed and Pause settings will be the same as when the unit was last run.

To check the Number of User Cycles since the last reset, simply depress the HOUR/CYCLE button. "User Cycles and hours" will appear in the display window:

To reset the User Cycle and Hours, depress EXTEND, SPEED, HOURS/CYCLES, and FLEX simultaneously. "HRS & CYC RESET" will appear in the display window.

To check the Total Cycles since the unit was manufactured, depress EXTEND and HOURS/CYCLES simultaneously. For Total Hours since the unit was manufactured, depress FLEX and HOURS/CYCLES simultaneously.

Total cycles and hours are non-resettable.

ATTACHMENT OF THE PATIENT KIT (SOFT GOODS) TO UNIT

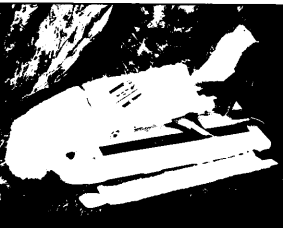
Coverings for the DANNIFLEX 460™ are made of a synthetic material. They are easily adjusted, offer the necessary limb support, provide a comfortable surface for prolonged contact with body surfaces, and are washable in cold water.

Begin with the piece that has two rounded corners. Place on the thigh section of the unit (ensure thigh shield is in place), matching hook and loop fasteners. One strap will attach on the underside of the Thigh Pivot Block. Be sure coverings are adjusted for both support and comfort.

Next, attach the rectangular covering to the Calf Cradle.

To attach the Boot, place the elastic flap over the Foot Cradle (sole of boot adheres to Foot plate). After placing patients foot in the Boot, fold the sides inward and attach the straps tightly to hold the foot securely.

An Auxiliary Strap is provided and may be used to securely hold the thigh or calf to the unit should enforced patient compliance be necessary.



MEASURING PATIENT AND ADJUSTING LENGTH OF UNIT

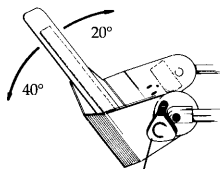
Make sure the leg carriage is in extension when fitting the patient to the unit.

Determine the length of the patient's thigh. Loosen adjustment knobs on both sides of thigh tubes. Fit thigh shield to gluteal crease of patient (the bottom of the buttocks). The knee pivot on the CPM should align with the approximated center of the patient's knee joint. Lengthen or shorten both sides equally. Tighten both adjustment knobs securely.

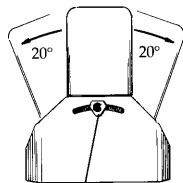
Determine the length of the patient's calf and foot. Measure from the center of the patient's knee joint to 1/4 inch beyond the heel of the patient's foot. Loosen adjustment knobs on both sides of the Calf Cradle and adjust both sides equally. Tighten both knobs securely. If readjustment is necessary, do not attempt to adjust only one side as this can cause damage to the unit.

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

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



Foot Adjustment Knob



Adjustor Knob

ATTACHING THE CPM SYSTEM TO THE BED

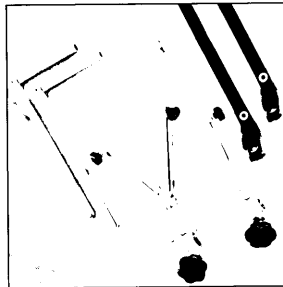
A Home Bed Mount (A) is provided for the DANNIFLEX 460™ and secures the CPM to the bed for home use. The home bed mount has straps which attach to the CPM via knobs which are located on both sides of the orthosis base near the foot of the unit. The CPM is secured to the bed with the "L" brackets that can attach to the mattress or the bed frame.

A Standard Hospital Bed Mount (B) is available for the DANNIFLEX 460™ CPM unit. This lightweight clamp provides stability and permits maximum flexibility for positioning the unit 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 knobs, position the unit 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.



Bed Mounts

CHANGING MODULAR ORTHOSIS

The DANNIFLEX 460™ offers a unique design, accommodating adult/pediatric patients by interchanging modular components on the orthosis. This is accomplished by following these step-by-step instructions:

- 1) See Figure A.

Loosen the Foot Cradle Knobs (1). Remove Foot Cradle from the Main Orthosis (2). Install desired Adult/Pediatric Foot Cradle, making sure the Foot Plate (3) is in the upright position. Select appropriate length for Foot Cradle and tighten Foot Cradle Knobs.

- 2) See Figure B.

Loosen Thigh Cradle Knobs (1). Lengthen the Thigh Segment Tubes until the Cradle is disconnected from the Main Orthosis (2). Detach the Thigh Pivot Block (3) from the base by pulling upward and rotating 1/4 turn on the spring loaded Thigh Pivot (pull pin) Latch (4). Slide Thigh Pivot Block off plate (5). Install the desired Adult/Pediatric Thigh Segment by pulling up the Thigh Pivot Latch. The Pivot Latch will lock into place, with an audible "click," when properly engaged. Insert Thigh Segments into Main Orthosis and tighten Cradle Knobs.

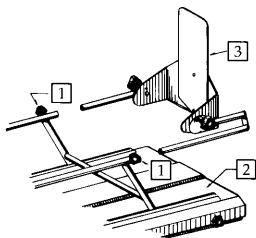


Figure A

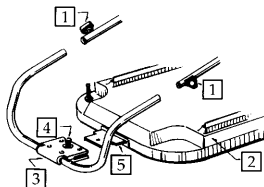


Figure B

RECOMMENDED CARE OF THE CPM UNIT

Use a soft cleaning cloth dampened with mild soap solution or alcohol (avoid abrasive cleaners) to gently wipe all exposed surfaces. To disinfect, it is a common practice to wipe all exposed surfaces with a cloth dampened in a 10% solution of bleach and water.

460™ REPLACEMENT PARTS ORDERING INFORMATION

Description	Part No.
Soft Goods Kit	10516
Thigh Shield (Adult)	11328
Knob Kit	11261
Bed Mount	
Standard	12138
Traction	10363
Home	12200
Knee Pot Cover/Fastener Kit	11329
NMES Cables for:	
Medtronic Respond II	12183
Stoadyne EMS Plus	12184
3M Myocare	12185

460™ MODULAR COMPONENTS REPLACEMENT PARTS ORDERING INFORMATION

Description	Part No.
Pediatric Modular Kit	12601
Adult Modular Kit	11331
Pediatric Thigh Cradle (Includes 11277)	12603
Pediatric Foot Cradle	12604
Adult Thigh Cradle (Includes 11328)	11330
Adult Foot Cradle	12606
Pediatric Thigh Shield	11277

LIMITED WARRANTY

Danninger Medical Technology, Inc. ("Danninger") warrants to the original purchaser ("Buyer") of this Danninger 460 (the "Unit") that the Unit will be free from defects in material or workmanship for a period of one year from the date of initial purchase. This warranty does not obligate Danninger to repair or replace a Unit not defective at the time of purchase which is damaged by accident, abuse, misuse, misapplication, or unauthorized repairs or alterations. DANNINGER MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED (INCLUDING, WITHOUT LIMITATION, MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, OR AGAINST INFRINGEMENT OF ANY PATENT), EXCEPT AS EXPRESSLY PROVIDED HEREIN.

If the Unit does not conform to this warranty, Danninger will at its option repair or replace the defective Unit. The remedy of repair or replacement is Buyer's sole and exclusive remedy and will satisfy all of Danninger's liabilities, whether based on contract, negligence, tort, product liability, strict liability, or otherwise. IN NO EVENT SHALL DANNINGER BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES, NOR SHALL ITS LIABILITY IN CONNECTION WITH ANY DEFECTIVE UNIT EXCEED THE SALES PRICE OF SUCH UNIT.

For this limited warranty to apply, Buyer must provide Danninger with written notice of a claimed defect within thirty days after its discovery, but not later than the expiration date of the warranty term. Within a reasonable time following receipt of such notice, Danninger will advise Buyer of the disposition of the Unit. Unless expressly authorized in writing, the defective Unit must be returned to Danninger for warranty coverage. Danninger reserves the right to inspect the Unit to determine whether the claimed defect is within the coverage of this limited warranty.



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