

**Danniflex 480 CPM**  
Technical & Service Manual

December 1998



*Registered to ISO 9001 for Quality Assurance*

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## 1.0 General Overview

### 1.1 Introduction

The Danniflex 480 Continuous Passive Motion (CPM) system is designed for the rehabilitation of the lower limb. The 480 offers changeable thigh and calf components allowing pediatric use. The purpose of this manual is to provide basic maintenance, repair and service instructions for the Danniflex 480 CPM system.

### 1.2 Safety Precautions

When using your CPM, to reduce the risk of fire, electric shock and injury to persons, basic safety precautions should always be observed, including the following:

1. Read and understand all instructions.
2. Follow all warnings and instructions marked on the product.
3. Use only OrthoLogic parts for repair and/or replacement.
4. Never use parts from other manufacturers' units even though they may seem to fit.
5. Never install the wall transformer in wet locations.
6. Never touch uninsulated transformer wires, or terminals, unless the transformer has been unplugged from the wall.
7. Unplug the 480 product from the wall outlet before cleaning. Do not use liquid cleaners or aerosol cleaners. Use a damp cloth for cleaning.
8. Do not use this product near water.
9. Do not place this product on an unstable cart, stand, or table. The product may fall causing serious injury to the patient or damage to the CPM.
10. This product should be operated only from the type of power source indicated on the marking label. If you are not sure of the type of power supply, consult your OrthoLogic representative or local power company.
11. Do not allow anything to rest on the power cord. Do not locate this product where the cord will become damaged.
12. Do not overload wall outlets or use extension cords as this may result in the risk of fire or electric shock.
13. Never insert objects into the drive unit casing as they may touch dangerous voltage points or short out parts that could result in a risk of fire or electric shock.
14. To reduce the risk of electric shock, do not disassemble this product, but take it to a qualified serviceperson when service or repair work is required. Opening or removing covers may expose you to dangerous voltages or other risks. Incorrect re-assembly can cause electric shock when the unit is subsequently plugged in.

15. If at any time during therapy the patient experiences extreme pain or discomfort, stop therapy and consult their physician.
16. Unplug the product from the wall outlet and refer servicing to qualified personnel under the following conditions:
  - a. If the power supply cord is damaged or frayed.
  - b. If liquid had been spilled into the product.
  - c. If the product has been exposed to rain or water.
  - d. If the product has been dropped or the unit casing has been damaged.
  - e. If the product exhibits a distinct change in performance.
  - f. If the product does not operate normally by following the operating instructions.
17. Adjust only those controls that are covered by the operating instructions.
18. Patient Safety: Patients must be advised to keep clear of moving parts. The unit is designed to force-reverse if an obstruction is under the cradle; however, a patient could experience pain or be injured by the downward pressure of the cradle if a body part is positioned under the cradle.

### 1.3 Specifications and Symbols

Weight	Approximately 24 lbs. (11 kg)	
Range of Motion	-5 degrees extension to 110 degrees flexion	
Safety	UL listed, ECE certified where applicable	
Power Supply	Type 2	
Input	120 VAC 60 Hz or 230 VAC 0.06A-50 Hz	
Output	14 VDC 730 MA or 14 VDC 730 MA	
Pause	0-30 seconds at maximum extension/flexion	
NMES	Compatible with various NMES devices	
Speed	1 to 10 minutes per cycle	
Classification	Class 1 medical device	
Electric shock classification	Type B	
Mode of operation	continuous	
Environmental conditions	-10 <sup>o</sup> to 35 <sup>o</sup> temperature, 90% max. humidity ATM pressure 750 kPa to 1040 kPa	
Limb length	30.5 - 42 in. (77 - 107 cm)	19.5 - 34.5 in. (50 - 88 cm)
Calf length	16.5 - 24 in. (43 - 61 cm)	9.5 - 18.5 in. (24 - 47 cm)
Thigh length	14 - 18 in. (36 - 46 cm)	10 - 16 in. (25 - 41 cm)

## 1.4 Symbols



Power Off



Power On



Model 480 classifications (regulatory classes defined). This unit is classified by IEC standards as Class II, Type "B", Category AP.



Class II Equipment - Equipment in which protection against electric shock does not rely on "basic insulation" only; but, in which additional safety precautions such as "double insulation" or "reinforced insulation" are provided, there being no provision for protective earthing or reliance upon installation conditions.



Type B applied part - Equipment providing a particular degree of protection against electric shock, particularly regarding allowable "leakage current" and/or reliability of the protective earth connection (if present).



Category AP (Danger Explosive) - Equipment or equipment part complying with specified requirements on construction, marking and documentation in order to avoid sources of ignition in a "flammable anesthetic mixture with air".



Danger Electric Shock: Service by a qualified individual only.



Attention, consult accompanying documents

## 1.5 Suggested Maintenance Schedule

### Between Patients

1. Check entire unit for any visible evidence of damage, such as bent sliders, cracked or broken covers, frayed or damaged wires, etc. If any signs of damage are found, the unit must be repaired before use.
2. Ensure that all knobs and/or levers are usable and in place.
3. Ensure that all moving components move freely as required.
4. Check all displays and electronic controls for proper operation.
5. Check all mechanical pivot and linkage points for smooth operation and secure mechanical connection. Make sure all screws, nuts, bolts, rivets, pivot pins, and other fasteners are secure.
6. Gently wipe clean all exposed surfaces with a soft cloth dampened with a mild soap solution or alcohol. Avoid abrasive cleansers. To disinfect, wipe all exposed surfaces with a 1% to 10% solution of bleach and water, or other suitable disinfectants.

7. Ensure that all labels are present.
8. Replace patient softgoods.
9. Verify that the device operates to its set limits over several complete cycles.
10. For devices offering absolute 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 machine's pivot points. Compare the ROM settings of the device with the goniometer readings. ROM readings should be within +/- 5 degrees of the set parameters. If the readings do not fall within the set parameters, the unit needs to be checked and recalibrated by a properly trained Service Technician.

#### **Every six Months**

1. Repeat steps 1 through 10 of "BETWEEN PATIENTS" procedures.
2. Verify 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.

#### **Every Eighteen Months**

A full inspection of the device by a properly trained Service Technician is recommended every 18 months. The following points should be covered:

1. Steps 1 and 2 of "EVERY SIX MONTHS" above.
2. Fully inspect all internal and external mechanical and drive components, and repair or replace as necessary.
3. Fully inspect all internal and external electrical components (including wires, connectors and solder joints), and repair or replace as necessary.
4. Perform a complete recalibration and subsequent check of electronic and mechanical safety systems including Reverse-On-Load and Range of Motion.
5. Complete a final check of the device in accordance with OrthoLogic Final Inspection criteria (these are available in the appropriate Technical Service Manual or on request from OrthoLogic).

## **2.0 Covers**

### **2.1 Bottom Cover**

#### *Removal:*

**Note:** Avoid cutting the heads off the plastic fasteners as these can be reused to reattach the covers.

1. Remove the Handle by removing the two Phillips screws located at each end of the Handle attachment.
2. Remove all 11 plastic fasteners from around the cover using the following method:
  - a. With a flat head screwdriver, lift up and remove the male half of the fastener.
  - b. With diagonal cutters, lift the female half of the fastener from each hole.
  - c. Separate the bottom cover from the unit.

#### *Installation:*

1. With the unit upside down, carefully place the bottom cover on the exposed frame.
2. With the unit upside down, align the bottom cover's holes with the holes in the top cover.
3. Insert the female halves of the plastic fastener into the holes from which they came and insert the males halves into the females halves.
4. Insert one male half into each of the female halves.
5. With a small hammer gently seat the two sections together.
6. Reinstall the handle. Use one drop of Loctite #425 on each attachment screw.

## 2.2 Top cover

### *Removal:*

1. Remove bottom cover (refer to section 2.1).
2. Remove cradle (refer to section 3.0).
3. With the bottom cover and cradle removed, the top cover comes free.

### *Installation:*

1. Place the top cover on top of the exposed base frame.
2. Install cradle (refer to section 3.0).
3. Install bottom cover (refer to section 2.1).

## 3.0 Cradle

### *Removal:*

1. Remove the bottom cover (refer to section 2.1).
2. Remove kneepot cable plug from the connector jack on the main PC board.
3. Using a pair of diagonal cutters, remove the ty-rap that holds the kneepot cable secure to the base.
4. Remove the kneepot cable strain relief from the top cover by removing the underside nut.
5. Pull the kneepot cable gently through the hole in the top cover.
6. Remove both 3/16" cradle pivot Allen bolts from the U-bracket assembly to detach the cradle from the ballscrew. (If you run into difficulty removing the bolt, apply a slight tilt to the Allen wrench and pull the entire bolt, threaded insert, and pivot sleeve straight out. Replace the slider blocks with new ones.)
7. Lift the cradle through the top cover.

### *Installation:*

1. Gently spread apart rubber track seals and slide cradle struts between the track seals through the top cover.
2. Position the cradle strut between the slider blocks and the U-bracket, and re-insert the spacer into the hole in the cradle strut.
3. Place both pivot sleeves into their proper locations.
4. Apply one drop of Loctite #242 on the threads of each cradle pivot Allen bolt and using a 3/16" hex key, install the two Allen bolts into the U-bracket assembly.
5. Slide the kneepot cable through both the top cover and the base.
6. Reinstall the kneepot cable (refer to section 4.2)

## 4.0 Kneepot

### 4.1 Kneepot Cover

**Note:** Plastic rivets may be re-used if not damaged during removal.

### *Removal:*

1. Push the center pins of the plastic rivets through the center of the rivet castings.
2. With a pair of diagonal cutters, carefully lift out the center of the rivet to free the kneepot cover.
3. Remove the kneepot cover.  
**Important:** Remove center of kneepot rivet from casting by moving outer thigh tube so they fall out.