

DanniFlex 400iTM

DanniFlex 400i modularTM

CPM Systems

**Assembly
and
Operations
Manual**

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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.

Safety Precautions

Do no use in a volatile atmosphere.

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

Safety Features

The DANNIFLEX 400i delivers only 24 volts DC to the bed through the integrated wall transformer. While the unit is designed to operate on the standard electrical supply of 115V AC, 60 Hz, the 400i will tolerate electrical supply variations of 105 - 130V AC which may be found in home use environment.

The DANNIFLEX 400i provides immediate patient access to all operating controls via the unique Hand Control Pendant.

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

The Patient Control Button (PCB) 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 PCB for a second time.

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

When flexion and extension settings are positioned incorrectly, the DanniFlex 400i will shut down and activate an audio alert.

Unpacking Unit

Remove all DanniFlex 400i CPM System components from carton. During unpacking, check for external damage. Report any substantial damage to shipper.

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

Carton should contain:

- 1) One 400i integrated orthosis with Hand Control Pendant
- 2) One or more Bed Mounts (As Ordered)
- 3) One Patient Kit (soft goods)
- 4) Two or more Adult/Pediatric Modular Components (Optional Equipment as Ordered)
- 5) One Instruction Manual



Set Up

Remove the Hand Control Pendant from the hook and loop fastener located on the Foot Plate.

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

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

Attaching Patient Kit (Soft Goods) to Unit

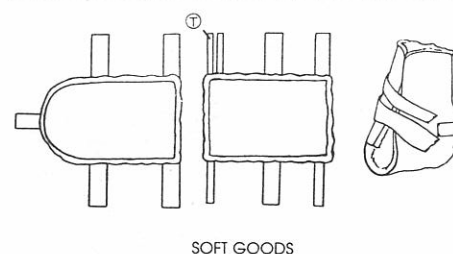
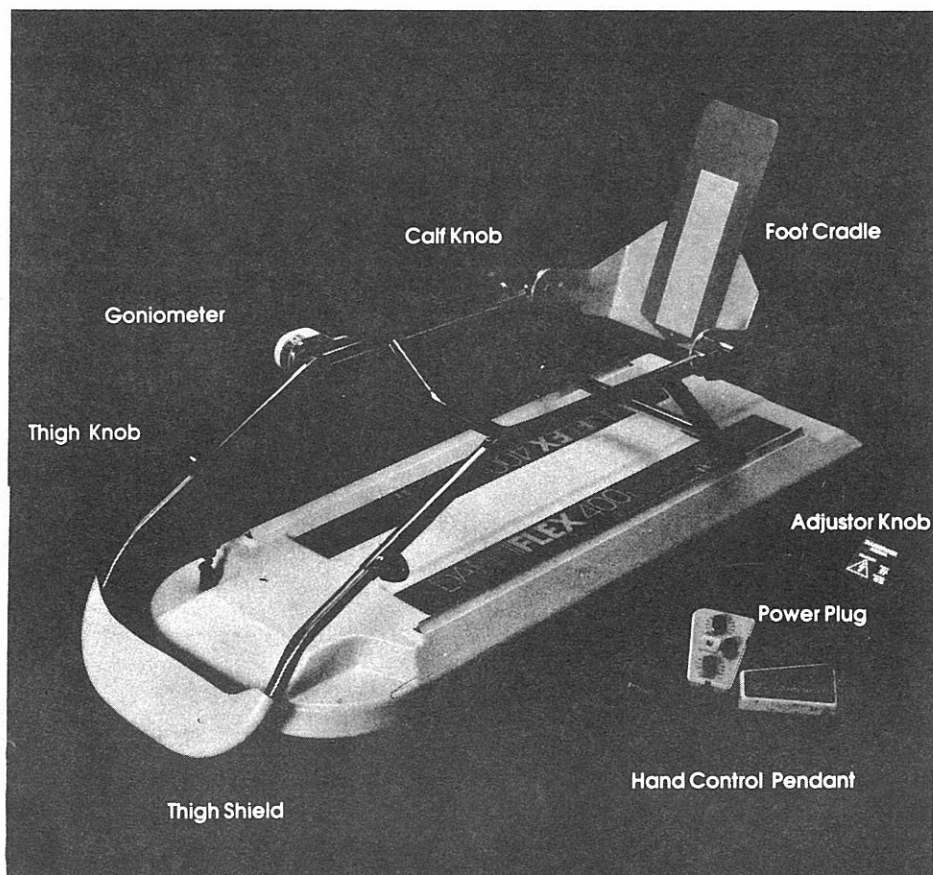
Coverings for the DanniFlex 400i System are made of a synthetic material. They are easily adjusted, offer the necessary limb support, provide a comfortable surface for prolonged contact with body surfaces, and are washable in cold water.

Begin with the piece which has two rounded corners. Place on the thigh section of the unit, 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. Be sure to orient the covering so that the narrow strap (t) passes directly behind the Goniometer.

To attach the Boot, place the elastic flap over the Foot Cradle (Sole of Boot adheres to foot plate). After placing patient's foot in Boot, fold over sides and attach the straps tightly to hold the foot securely.

An auxiliary strap (not shown) 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 patient's thigh. Loosen adjustment knobs on both sides of thigh tubes. Fit thigh plate to gluteal crease of patient (the bottom of the buttocks). The knee joint 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 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 adjustment knobs securely and equally.

If readjustment is necessary, do not attempt to adjust only one side as this can damage 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.

Attaching the CPM System to the Bed

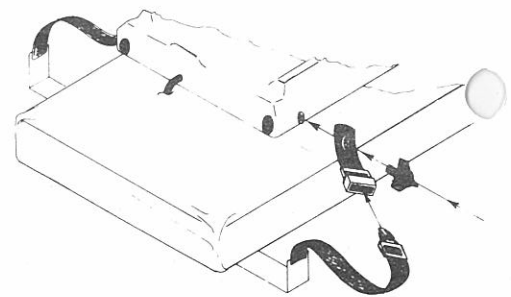
A HOME bed mount is provided for the DanniFlex 400i and secures the CPM to the bed for home use. The HOME bed mount has straps which attach to the CPM via knobs which are located on both sides of the orthosis base near the foot of the unit. The CPM is secured to the bed with the "L" brackets that can attach to the mattress, the bed frame, etc.

A STANDARD hospital bed mount is available for the DanniFlex 400i CPM unit. This lightweight clamp provides stability and permits maximum flexibility for positioning unit on 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).

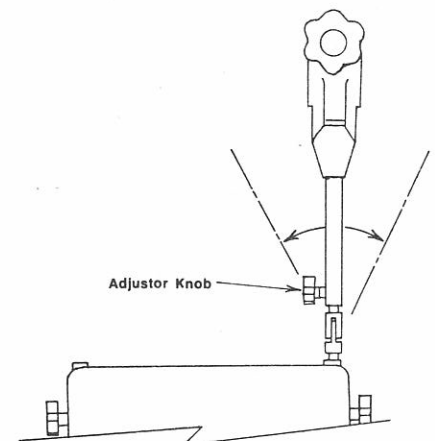
A TRACTION hospital bed mount is available by special order. It provides maximum stability to the CPM if necessary.

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



Home Bed Mount

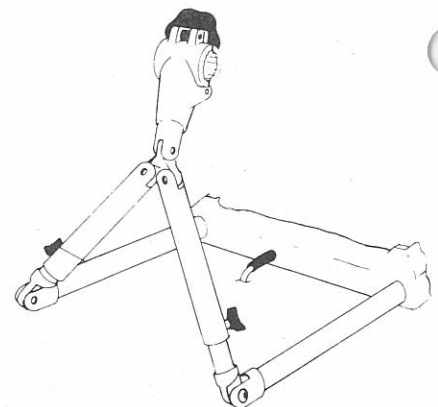
12200



Adjustor Knob

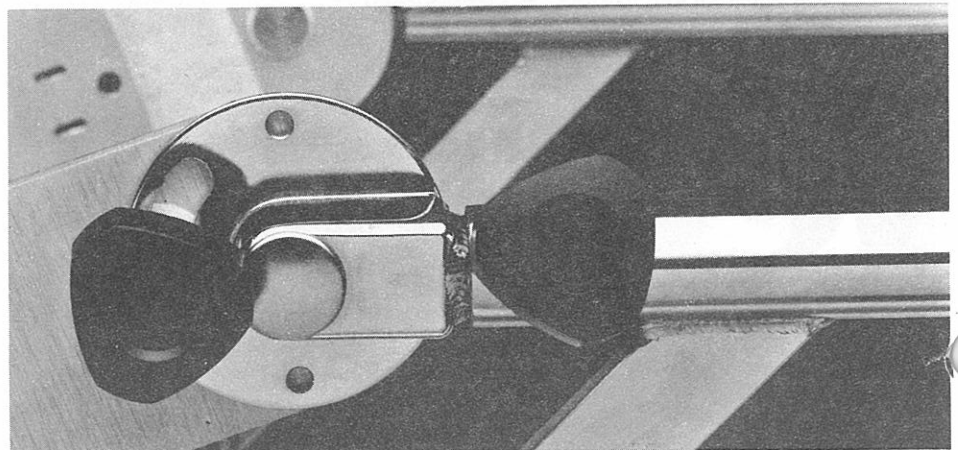
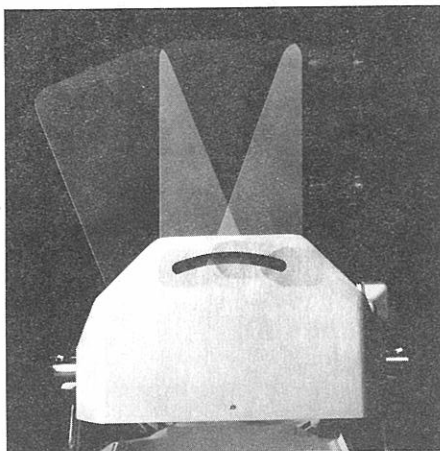
Standard Bed Mount

12138



Traction Bed Mount

10363



Symptom	Probable cause	Solution
Unit will not operate	No power to unit	Plug unit into energized outlet Verify that the power switch is in the 'on' position
Unit will not operate and audio alert activates	Inverted ROM setting Range of Motion is less than ten (10) degrees	Set the Extension at least ten (10) degrees less than Flexion Set the Extension at least ten (10) degrees less than Flexion
For additional assistance contact your Danninger representative		

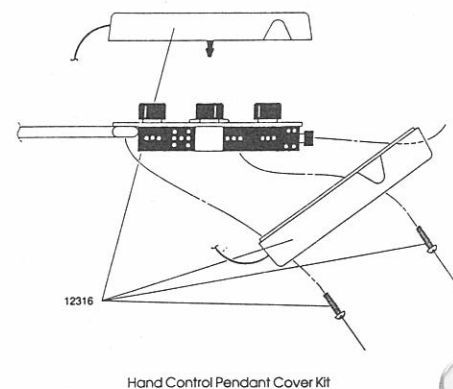
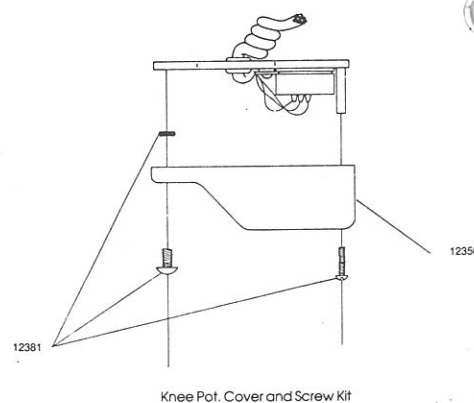
CAUTION: Do not store CPM unit under a bed which has less than 19 inches of clearance at all times

400i/400i modular Replacement Parts Ordering Information

Description	Part #
Soft Goods Kit	10516
Thigh Shield	12220
Knob Kit	12371
Bed Mount	
Standard	12138
Traction	10363
Home	12200
Knee Pot. Cover	12350
Knee Pot. Cover screw Kit	12381
ROM Scale Label	12270
Hand Control Pendant Cover Kit	12316

400i modular Components Replacement Parts Ordering Information

Description	Part #
Pediatric Modular Kit	12601
Adult Modular Kit	12602
Pediatric Thigh Cradle	12603
Pediatric Calf Cradle	12604
Adult Thigh Cradle	12605
Adult Calf Cradle	12606
Pediatric Thigh Shield	12490



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- Salter, R.B., and Harris, O.J., "The Healing of Intra-Articular Fractures with Continuous Passive Motion," American Academy of Orthopedic Surgeons Lecture Series, Chapter 6, 102-117, Vol. 28, 1979.

Limited Warranty

Danninger Medical Technology, Inc.
880 Kinnear Road, Columbus, Ohio 43212
(614) 488-7961
Outside Ohio: 800-225-1814

Danninger Medical Technology, Inc. ("Danninger") warrants the DanniFlex 400i™ CPM and DanniFlex 400i modular™ CPM to be free from defects in materials and workmanship for a warranty period of one (1) year from date of initial purchase. No warranty shall apply if the goods have been damaged by accident, abuse, misuse, or misapplication, or as a result of service or modification by other than a person authorized by Danninger. Danninger's liability under this warranty, and Buyer's exclusive remedy, is limited to the cost of materials and labor to repair the defective goods, or to their replacement, and in no event shall exceed the purchase price. Repair or replacement of defective goods under warranty will be made only upon their return to Danninger after notice to Danninger and Buyer's receipt of shipping instructions. Upon receipt of goods returned under warranty, Danninger will inspect the goods, and will notify Buyer of the extent of repair or replacement which Danninger will perform under warranty, which shall be conclusive of Danninger's liability.

Danninger is not responsible for incidental or consequential damages resulting from the breach of any expressed or implied warranty, including damage to property and, to the extent permitted by law, damages for personal injury. The warranty contained herein is in lieu of all warranties, expressed or implied, including implied warranties of merchantability and fitness for a particular purpose. No statement of any representative shall extend Danninger's liability as herein established or limited.

Danninger Medical Technology, Inc.
880 Kinnear Road
Columbus, Ohio 43212
614-488-7961
Outside Ohio call 800-225-1814



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DANNIFLEX MODEL 400i TROUBLE SHOOTING
GUIDE FOR ELECTRONIC SERVICE TECHNICIANS

EQUIPMENT NEEDED

- 1) Digital Multimeter
- 2) Large diagonal cutters

ABBREVIATIONS

(PCB) - Printed circuit board
(CKT) - Circuit

NOTE

Range of motion calibration should be checked following any repairs.

COVER DISASSEMBLY

To remove bottom-base cover of cpm, use large pair of diagonal cutters to carefully pry plastic fasteners apart and remove them from base cover. Turn cpm machine on its side and remove bottom cover.
(Plastic fasteners may be reused if they are not damaged).

If you have any questions, please contact our service department at:

1-800-225-1814 or 614-488-7961

DANNIFLEX MODEL 400i TROUBLE SHOOTING
GUIDE FOR ELECTRONIC SERVICE TECHNICIANS

PROBLEM	WHAT TO CHECK	ANSWER	NEXT STEP
1. Machine does not run and beeper does not beep when power	<u>1-1</u> Is transformer plugged in and power switch turned on?	Yes No	Go to 1-2 Plus in trans- former and turn power switch on.
	<u>1-2</u> Turn power switch off and then on again. Does beeper beep?	Yes No	Go to 2-1 a) Check .5A fuse on PCB. b) Check for 14V-21V dc across pins 6 and 5 of connector P2 on PCB. (out- put of trans- former). c) Check on- off switch. d) Check for 8V D.C. on connec- tor P3 pin 3 (output of 7808 regulator).
2. Machine does not run but beeper beeps when power is turned on.	<u>2-1</u> Does continuous beeper sound only when flexion control is set at a lesser angle than extension control?	Yes No	Go to 2-2 a) Check for +5V on connector P1 pin 1 on PCB. b) Check for varying voltages while turning flexion and extension controls on connector P1 at pins marked E and F. (pins 3 and 5) c) Check pendant buffers and flex/ext overlap detector ckt.

Troubleshooting Guide Cont.

PROBLEMS	WHAT TO CHECK	ANSWER	NEXT
2. continued	<u>2-2</u> Does pin 6 of U5 go alternately high and low when start/stop switch is depressed?	Yes No	Go to 2-3 Depress start/stop switch again. b) Check for a logic high on s/s pin of connector P1 (pin 4) while pressing start/stop switch. c) Troubleshoot start/stop toggle ckt.
	<u>2-3</u> Is center wiper of knee-pivot potentiometer, voltage between flexion and extension buffer output voltages? (center wiper voltage can be checked on pot and on connector P3 at the pin marked W).	Yes No	Go to 2-4 Check for +8V dc and ground on remaining pins of knee-pot and pins marked 8V and G on connector P3. (pins 4 and 5)
	<u>2-4</u> Is pin 4 of U6 high?	Yes No	Go to 3 Troubleshoot flex. & ext. pause ckt.
3. Machine oscillates back and forth.	<u>3-1</u> Does motor function properly? (motor can be connected to a 12 volt dc source, it should draw less than 200 ma.	Yes No	Go to 3-2 Replace motor

60-70mA NO LOAD

120-150mA Attached to Unit

300-350 mA Force Reverse
When Extending
400-450 mA Force Reverse
When Flexing

...ouleshooting Guide Cont.

PROBLEM	WHAT TO CHECK	ANSWER	NEXT STEP
3. Cont.	<u>3-2</u> Does pin 14 of U4 alternate between high and low?	Yes No	Go to 3-3 a) Check for mechanical binding of drive orthosis. b) Troubleshoot load reversal filter & comparator, and constant speed circuit.

3-2 Troubleshoot motor control circuit:

The speed/stop bus should not be less than 2.5V dc unless:

- 1) the machine is in the stop mode (section 2-2)
- 2) the Knee pot out of limits shut-down has been activated (section 2-3)
- 3) the flex & ext. pause is activated (section 2-4)

The direction mosfets are not pulse width modulated, either Q1 or Q2 will be on.

In the stop mode, pin 13 of U4 will be low and a pair of mosfets directly opposite each other will be on (Q1 and Q2) or (Q3 and Q4).

In the start mode, Q2 and Q4 are pulse width modulated. The speed of the motor depends upon the duty cycle of the rectangular waveform on pin 13 of U4, which will be proportional to the point at which the voltage at pin 7 of U1 intersects the sawtooth wave on pin 10 of U4.

MODEL 400i CALIBRATION INSTRUCTIONS

EQUIPMENT NEEDED

- 1) Digital multimeter
- 2) 6-10 inch square
- 3) Tachometer or 12-inch rule
- 4) Small screwdriver
- 5) 1/8 inch hex driver
- 6) Large diagonal cutters

COVER ASSEMBLY - In order to access PCB, the bottom cover of cpm must be removed. The plastic fasteners can be removed with large diagonal cutters. (See page 1 for details).

I) SPEED CALIBRATION

NOTE: Range of motion calibration will be affected by this procedure and must be checked following the completion of this section.

- 1) Set flexion - adjust knob to 90 degrees.
- 2) Set extension - adjust knob to 0 degrees.
- 3) Set speed - adjust knob to minimum (fully counter-clockwise).
- 4) Depress start button to start machine.
- 5) As machine is running, adjust LOW CAL potentiometer (located inside drive on printed circuit board (PCB)) so that ballscrew is turning at a rate of 15 rpm $\pm 1/-0$ rpm. (15 rpm is equivalent to 3 inches per minute of cradle travel with a tolerance of $\pm 1/4$ in./-0 in.).

NOTE: The above procedure is for the adjustment of low speed only. High speed is not adjustable but should range between 100 to 110 rpm (20 to 22 inches of cradle travel per minute) if low speed is properly calibrated.

II) RANGE OF MOTION CALIBRATION

NOTE: Sections A, B, and C must be performed in the order presented to insure proper calibration.

A) KNEE-PIVOT POTENTIOMETER CALIBRATION

- 1) Set flexion - adjust knob to 90 degrees.
- 2) Set extension - adjust knob to 0 degrees.
- 3) Depress start/stop button and let machine run to 0 degrees.
- 4) Depress start/stop button to stop machine.
- 5) Check knee-pivot angle with straight edge by laying straight edge on top of cradle at knee-pivot junction. (measure on the potentiometer side of the cradle).
- 6) Repeat steps 2-5 until knee-pivot angle is 0 degrees.

NOTE: You may have to set the flexion-adjust potentiometer to a lesser angle than 0 degrees in order for the cradle to reach 0 degrees.

- 7) Check extension-adjust knob to assure that it is set at 0 degrees.
- 8) Connect one lead of dc-voltmeter to "<E" (located on connector P2 of PCB).
- 9) Connect second lead of voltmeter to Connector P2 pin 3 on PCB.
- 10) Select the minimum scale of dc-volts on your voltmeter (200-millivolt scale for the most meters).
- 11) Remove white, plastic knee-pivot potentiometer cover.
- 12) Slightly loosen knee-pivot-potentiometer by loosening the two screws which hold the potentiometer on the mounting bracket.

ibration Cont.

- 13) Turn the knee-pivot-potentiometer until voltmeter reads 000.0 mV (\pm 5.0 mV).
- 14) Tighten knee-pivot-potentiometer, making sure voltmeter reading stays within \pm 5.0 mV.

B) EXTENSION ANGLE CALIBRATION

NOTE: Flexion angle calibration may be affected by this procedure, and must be checked following the completion of this section.

- 1) Depress start button to start machine. Let machine flex to approximately 15 degrees.
- 2) Depress start button twice to reverse direction of motion. (Machine is now traveling in extension).
- 3) When motion stops, and machine pauses at approximately 0 degrees, depress start button to stop machine.
- 4) Check knee pivot angle with straight edge.

NOTE: If knee pivot angle is more than \pm 1 degree, repeat section IIA. (1 degree is equal to 1/8 inch error, measured at a point 6 inches from the knee pivot)

- 5) If knee pivot angle is within \pm 1 degree, adjust LOW CAL potentiometer located on PCB.

NOTE: (Turning LOW CAL clockwise will increase knee-pivot angle toward 0 degrees).

- 6) Repeat steps 1-5 until knee pivot angle is at 0 degrees (\pm .5 degrees) when motion stops.

NOTE: An adjustment of less than \pm 1 degree to the extension angle calibration will effect the low speed setting by \pm 1 prm, which is acceptable.

C) FLEXION ANGLE CALIBRATION

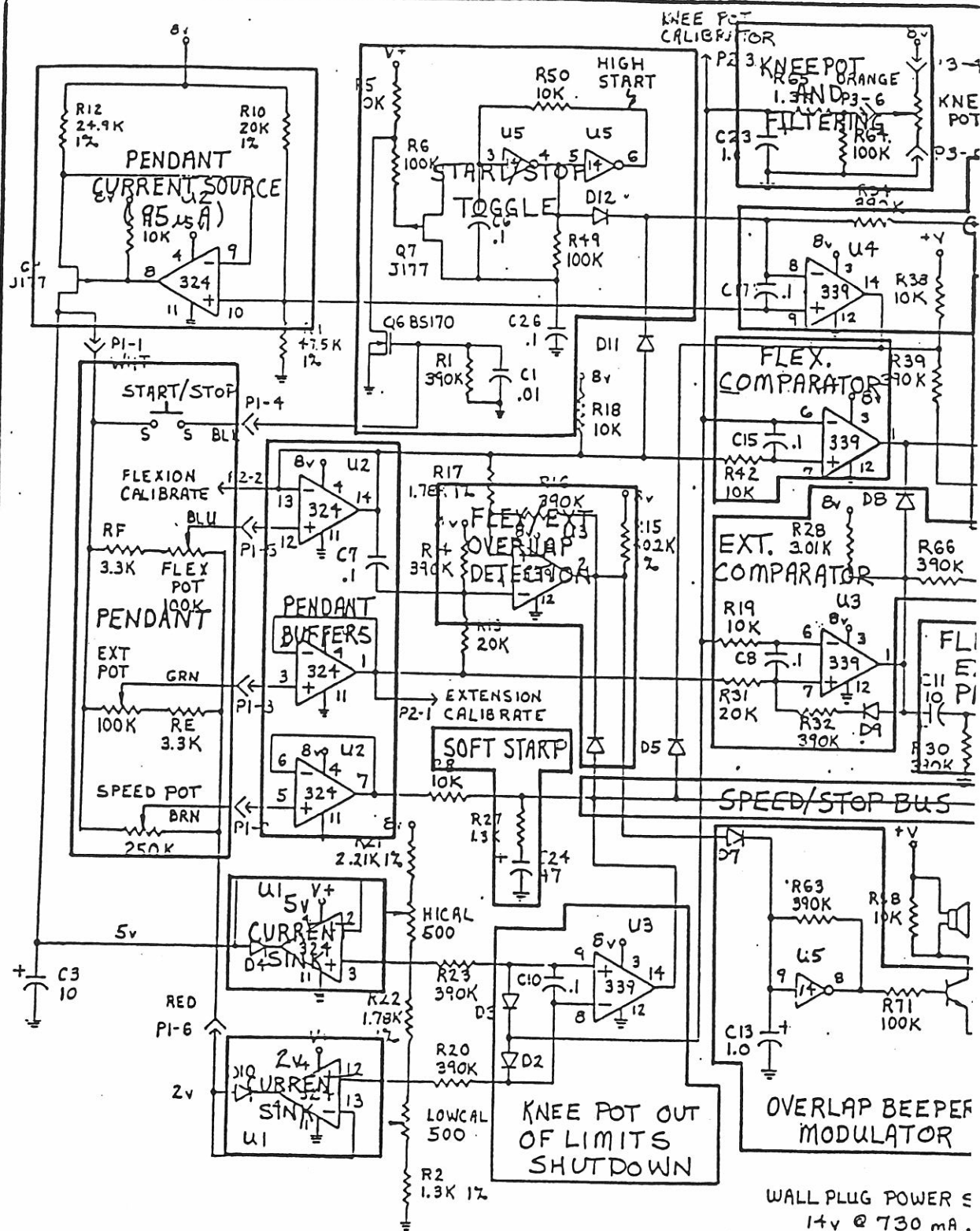
NOTE: Extension angle calibration may be affected by this procedure, and must be checked following the completion of this section.

- 1) Set flexion-adjust knob to 90 degrees.
- 2) Set extension-adjust knob to 0 degrees.
- 3) Depress start button and let machine run until it stops at maximum flexion.
- 4) Depress start button to stop machine as soon as it pauses at maximum flexion.
- 5) Check 90 degree angle with square.
- 6) If 90 degree angle has an error of more than $\pm .5$ degrees, adjust HI CAL potentiometer located on PCB. (see note under section II B, step 4 for further information on error)

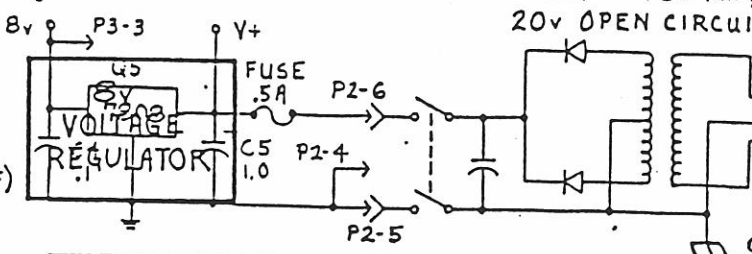
NOTE: Turning HI CAL potentiometer clockwise causes angle to increase toward 110 degrees.

- 7) Repeat steps 3-6 until maximum flexion equals 90 degrees.

Cut out to permit insertion into a
aid, three ring binder



NOTES:
ALL RESISTORS ARE 1/4 WATT, 5% UNLESS
OTHERWISE NOTED
ALL CAPACITORS ARE IN MICROFARADS
ALL DIODES ARE IN 1A8
SUPPLY FILTER CAPS ARE NOT
SHOWN ON SCHEMATIC C22,25,28 (0.1μF)

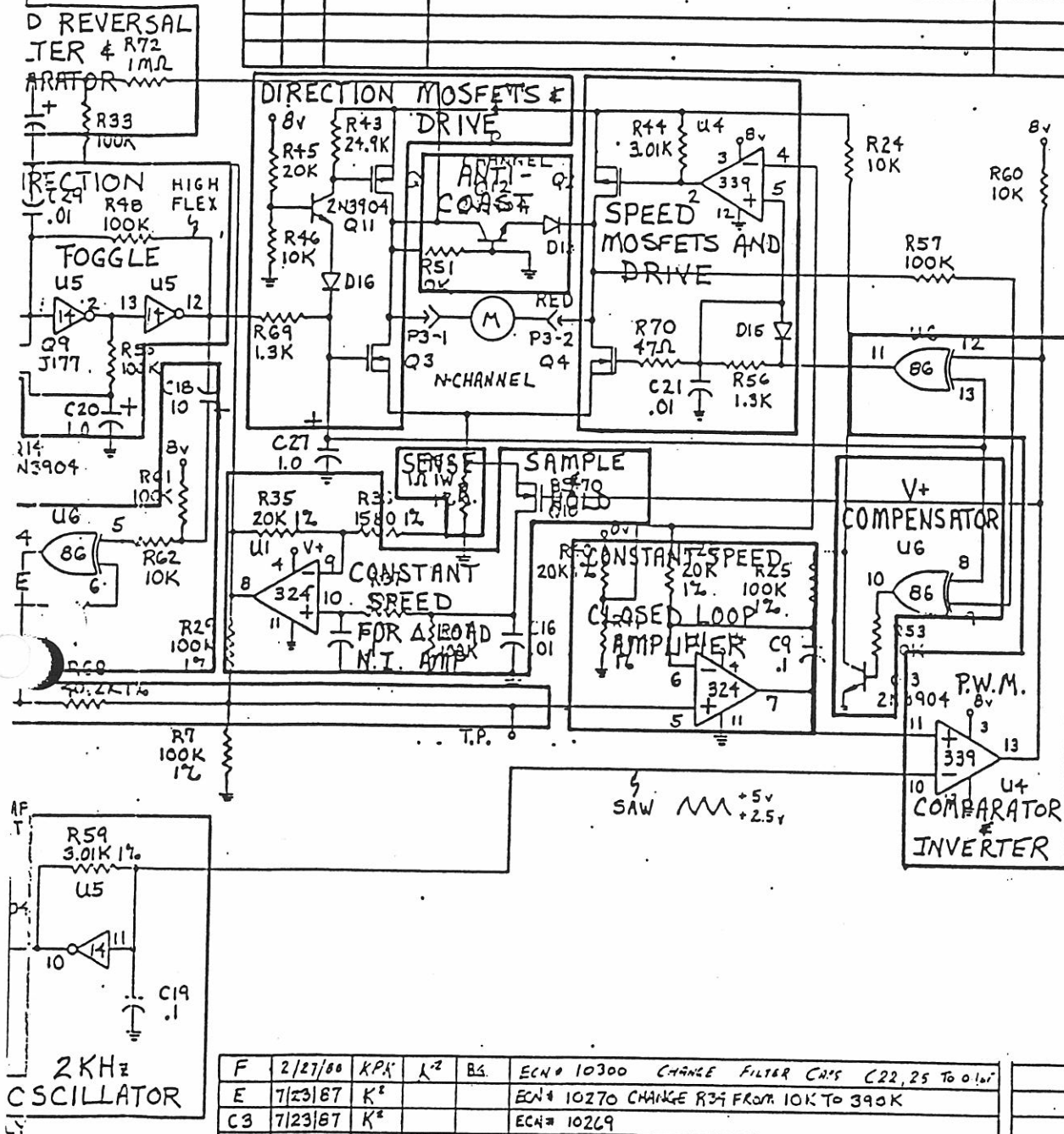


HIGHEST SYMBOL USED	AVAILABLE GATES
C29	U6-1,2,3
D17	U3-10,11,13
Q15	
R72	
U6	

2. BREAK ALL
1. USE STATED
PRINTS!
NOTES:

BILL OF MATERIAL

ITEM	QUAN	PART NO.	DESCRIPTION	MISC. INFO.



REV.	DATE	OWN.	CD.	APPD.	DESCRIPTION
F	2/27/88	KPK	K ²	BS	ECN# 10300 CHANGE FILTER CAPS C22, 25 TO 0.1u
E	7/23/87	K ²			ECN# 10270 CHANGE R34 FROM 10K TO 390K
C3	7/23/87	K ²			ECN# 10269
D	6/9/87	K ²	KPK		ECN# 10252 LOUDER ALERT, ELM, R54, R2, R3, ADJ POT, C2, CORRECT SUPPLY
C2	6/6/87	K ²	KPK		ECN# 10258, INCREASE N.T. AMP GAIN, ELM NOISE ON U5-1, ADD R72
C	4/9/87	K ²	KPK		ECN# 10251 CHANGED EXT HYSTERESIS, 31-03 OVERLAP, U1 SUPPLY
B	3/25/87	K ²			CHANGED FDI REFLECT# 12294: REV'D SCHEMATIC (NO EX)
A	11/11/87	K ²			NEW RELEASE

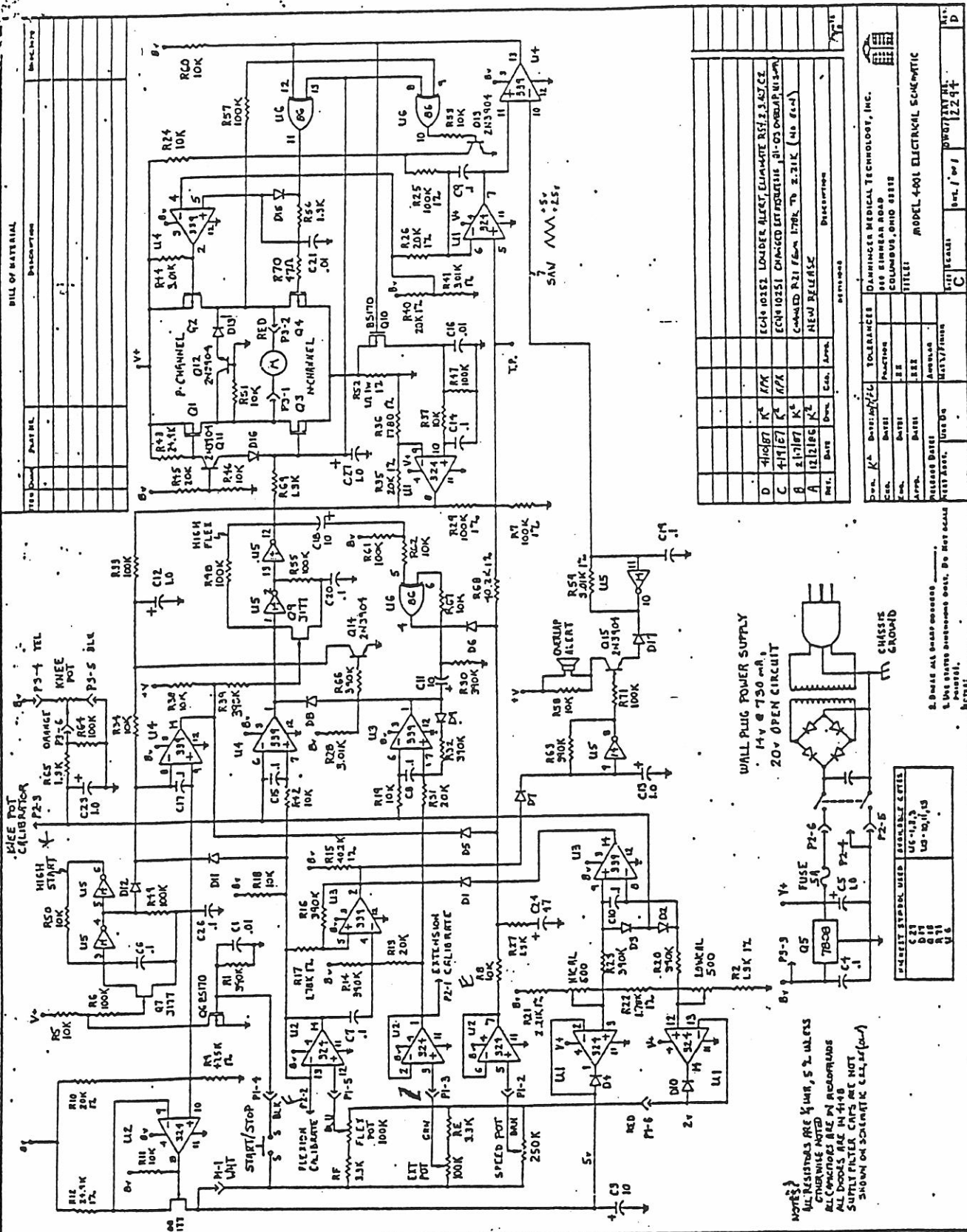
OWN.	DATE	TOLERANCES	DESCRIPTION
CD.	DATE	FRACTION	
ENG.	DATE	.XX	
APPD.	DATE	.XXX	
RELEASE DATE:		ANGULAR	
NEXT ASST.	USE ON	MAT'L/FINISH	
	12272		

DANNINGER MEDICAL TECHNOLOGY, INC.
888 KINNEAR ROAD
COLUMBUS, OHIO 43212

TITLE:
MODEL M-100L ELECTROPHYSIOLOGICAL SCHEMATIC
OVERLAY

SIZE: SCALE: SHT. 1 OF 1 DWG/PART NO. 12294 REV.

CURVES
SIDES ONLY. DO NOT SCALE



DAWSONS MEDICAL TECHNOLOGY, INC.
COLUMBIAN ROAD
COLUMBUS, OHIO 43218

TITLE: MODEL 4001 ELECTRICAL SCHEMATIC
REV: 1.0
DATE: 12/24/74

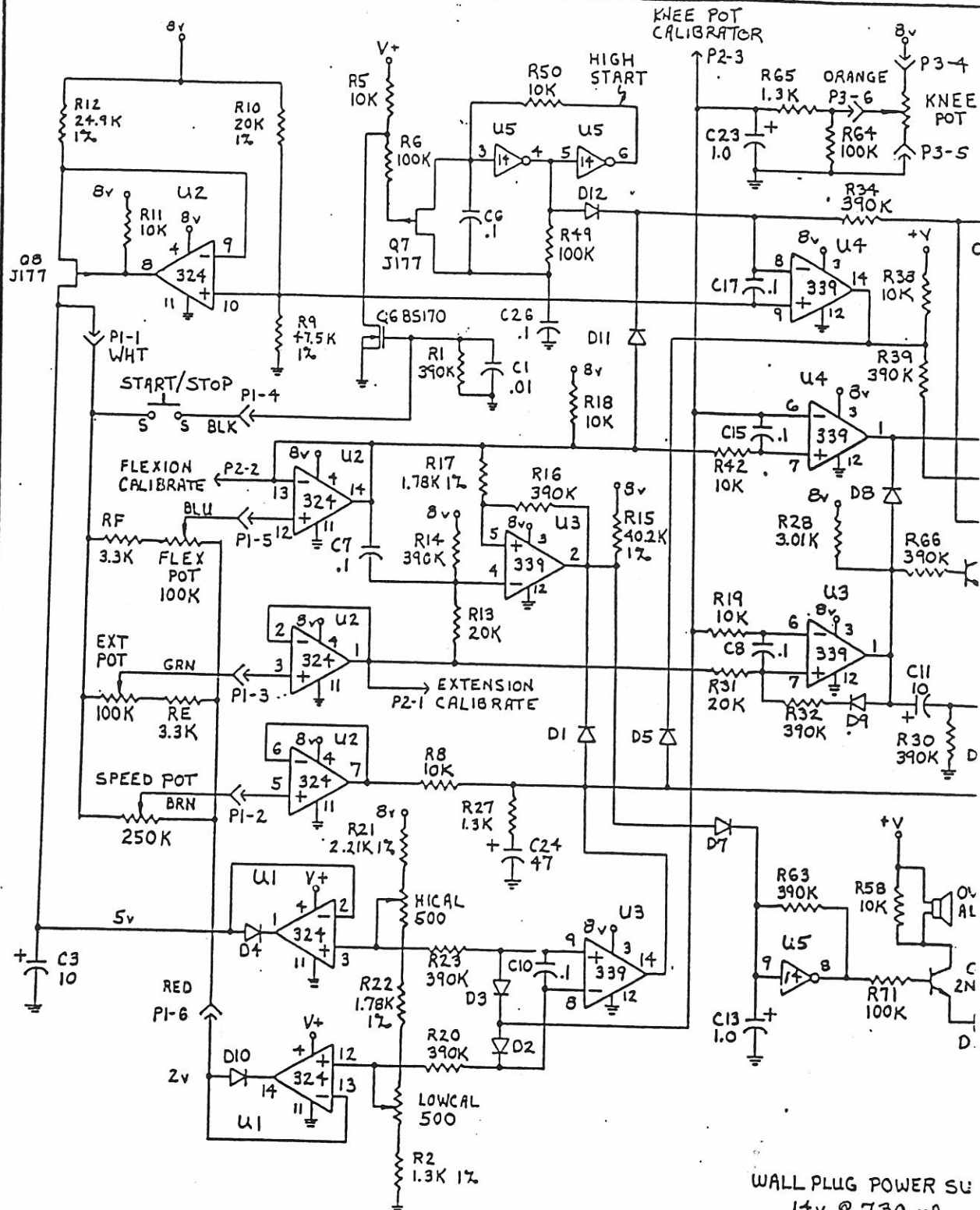
DESIGNED BY: J. L. DAWSON
CHECKED BY: J. L. DAWSON
APPROVED BY: J. L. DAWSON

ALL DIMENSIONS ARE IN INCHES
UNLESS OTHERWISE SPECIFIED

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UNLESS OTHERWISE SPECIFIED

ALL DIMENSIONS ARE IN INCHES
UNLESS OTHERWISE SPECIFIED

Cut out to permit insertion into a
side, three ring binder

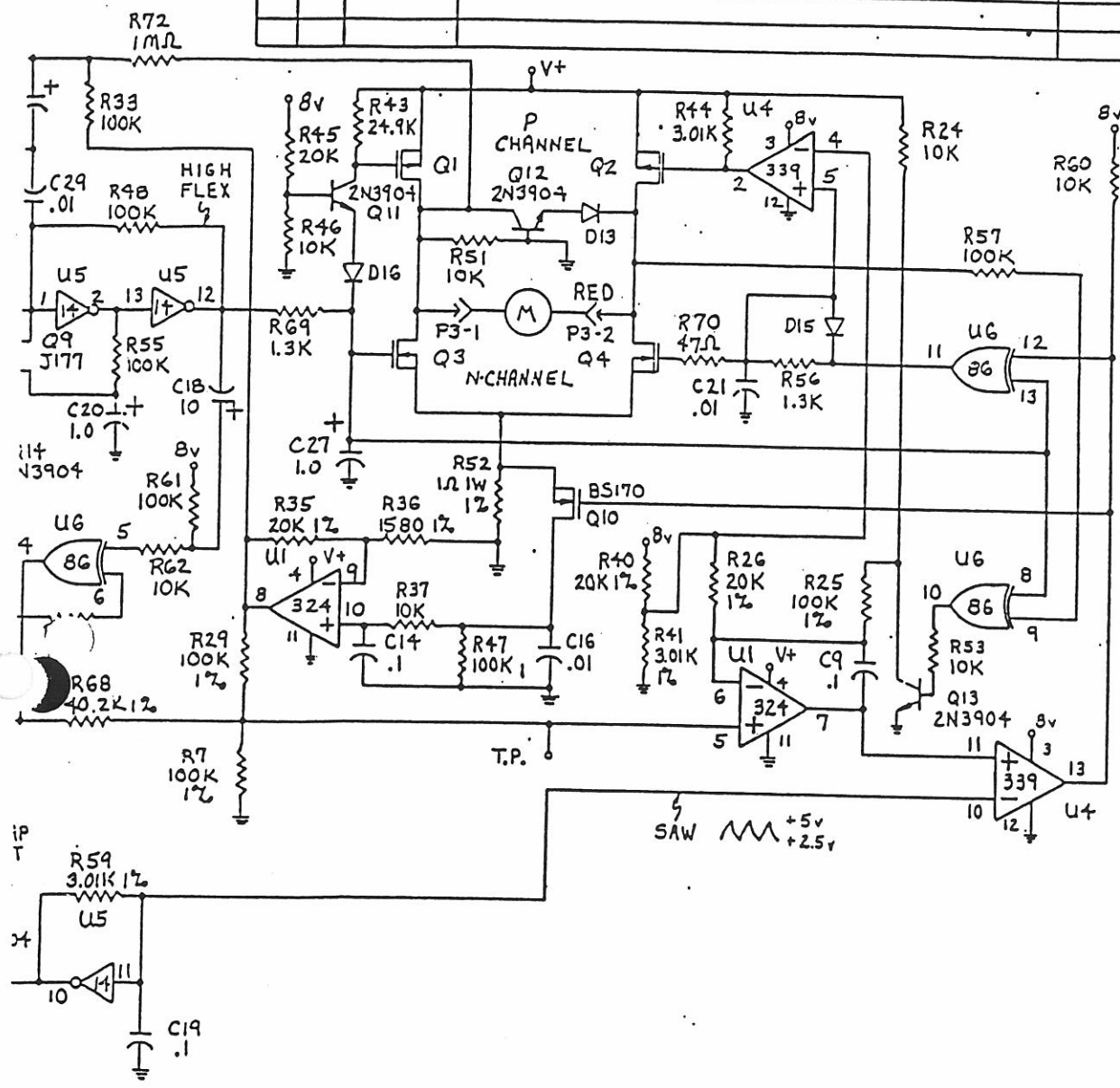


NOTES:
ALL RESISTORS ARE 1/4 WATT, 5% UNLESS
OTHERWISE NOTED
ALL CAPACITORS ARE IN MICROFARADS
ALL DIODES ARE IN 1418
SUPPLY FILTER CAPS ARE NOT
SHOWN ON SCHEMATIC C22,25,28 (0.1μF)

HIGHEST SYMBOL USED	AVAILABLE GATES
C29	U6-1,2,3
D17	U3-10,11,13
Q15	
R72	
U6	

2. BREAK ALL SH...
1. USE STATED DIS...
PRINTS!
NOTES:

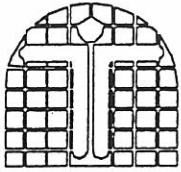
BILL OF MATERIAL				
ITEM	QUAN	PART NO.	DESCRIPTION	MISC. INFO.



F	2/27/88	KPK	K ²	BG	ECN # 10300 CHANGE FILTER CAPS C22, 25 TO 0.1µF
E	7/23/87	K ²			ECN # 10270 CHANGE R34 FROM 10K TO 390K
C3	7/23/87	K ²			ECN # 10269
D	6/9/87	K ²	KPK		ECN # 10252 LOUDER ALERT, ELIM R54, R2, R3, ALT POT, C2, CORRECT SUPPLY
C2	6/6/87	K ²	KPK		ECN # 10258, INCREASE N-LAMP GAIN, ELIM NOISE ON U5-1, ADD R72
C	4/9/87	K ²	KPK		ECN # 10251 CHANGED EXT HYSTERESIS, Q1-Q3 OVERLAP, U1 SUPPLY
B	2/17/87	K ²			CHANGED R21 FROM 1.72K TO 2.21K (NO ECN)
A	12/2/86	K ²			NEW RELEASE
REV.	DATE	DWN.	CKD.	APPD.	DESCRIPTION
REVISIONS					

DWN. K ² DATE: 10/7/86		TOLERANCES		DANNINGER MEDICAL TECHNOLOGY, INC. 880 KINNEAR ROAD COLUMBUS, OHIO 43212	
CKD.	DATE:	FRACTION			
ENG.	DATE:	.XX		TITLE: MODEL 4-00L ELECTRICAL SCHEMATIC	
APPD.	DATE:	.XXX			
RELEASE DATE:		ANGULAR		SIZE SCALE: SHT. 1 of 1 DWG/PART NO. 12294	
NEXT ASST.	USE ON	MAT'L/FINISH			
12272					

COANERS _____
IONS ONLY. DO NOT SCALE



**DANNINGER MEDICAL
TECHNOLOGY, INC.**

CONTROLLED COPY

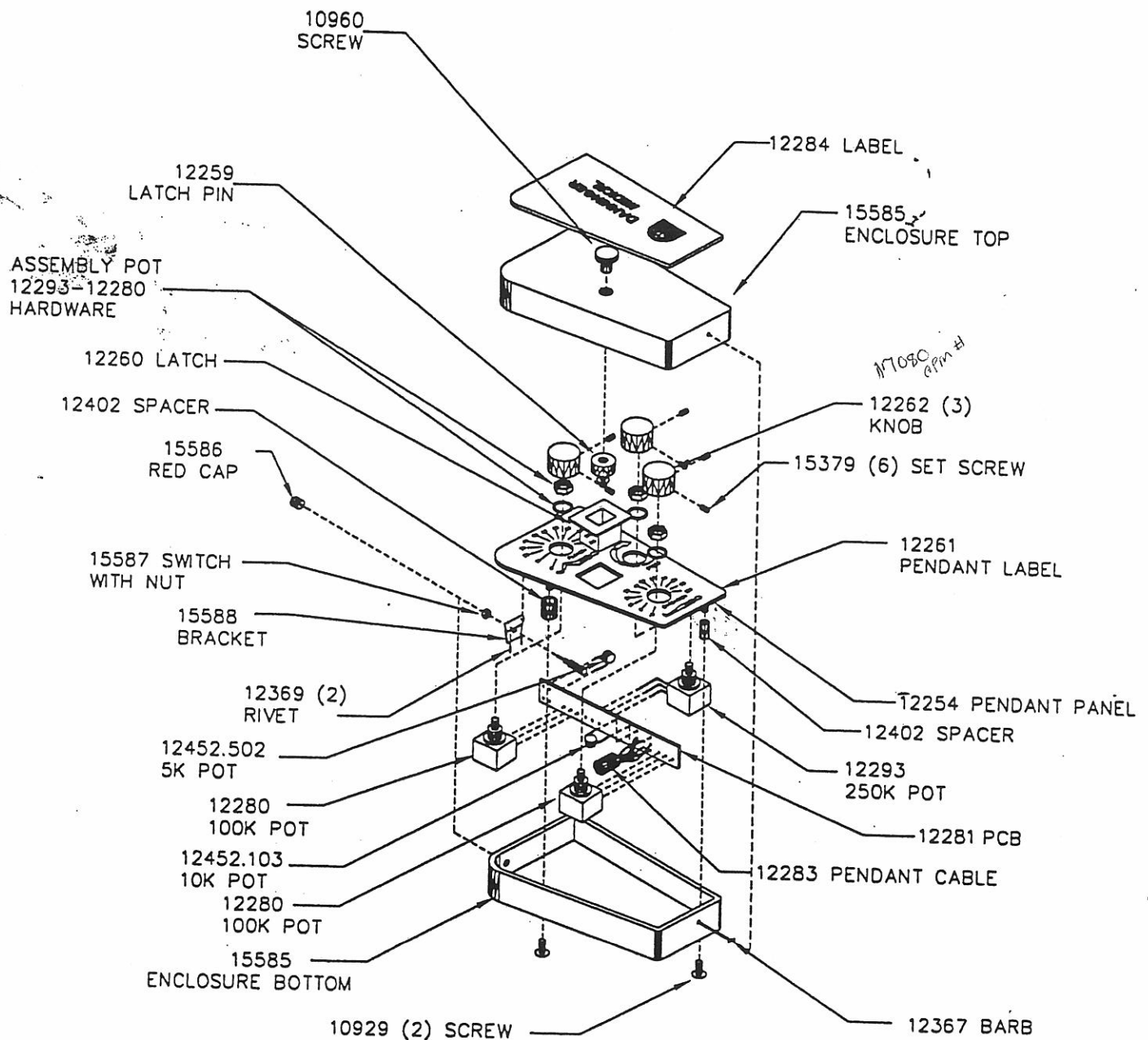
CPM

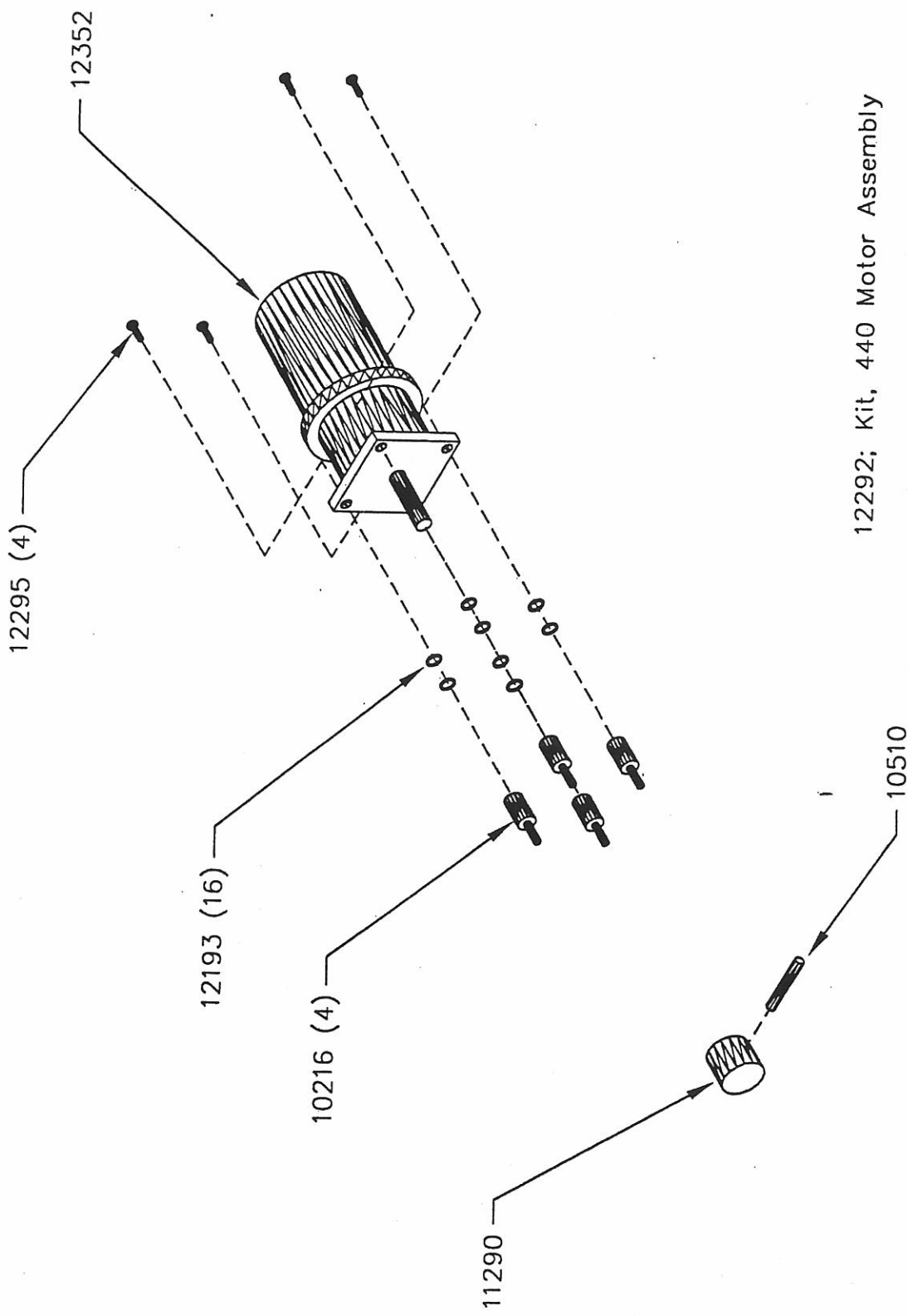
DANNIFLEX 400i

EXPLODED VIEW DRAWINGS

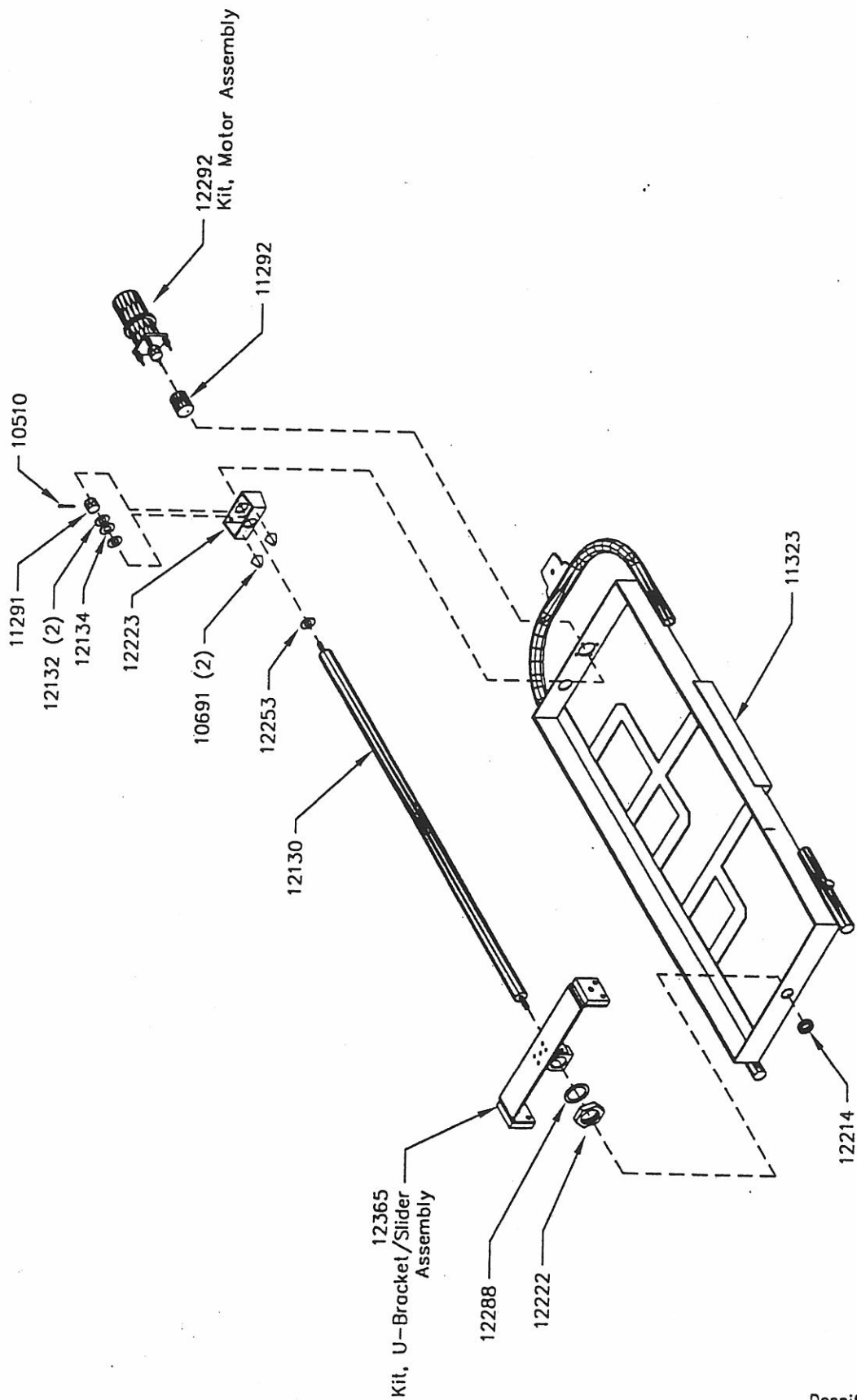
PART NUMBER: 15389
September 16, 1996

PAGE	DESCRIPTION	REVISION
1	400i / 440 Assembly	A
2	Adult thigh foot assembly	A
3	Adult thigh assembly	A
4	Adult foot assembly	A
5	Handle bottom cover assembly	A
6	U-Bracket frame assembly	A
7	U-Bracket slider assembly	A
8	Motor assembly	A
9	Wiring harness assembly	B
10	Pendant assembly	A

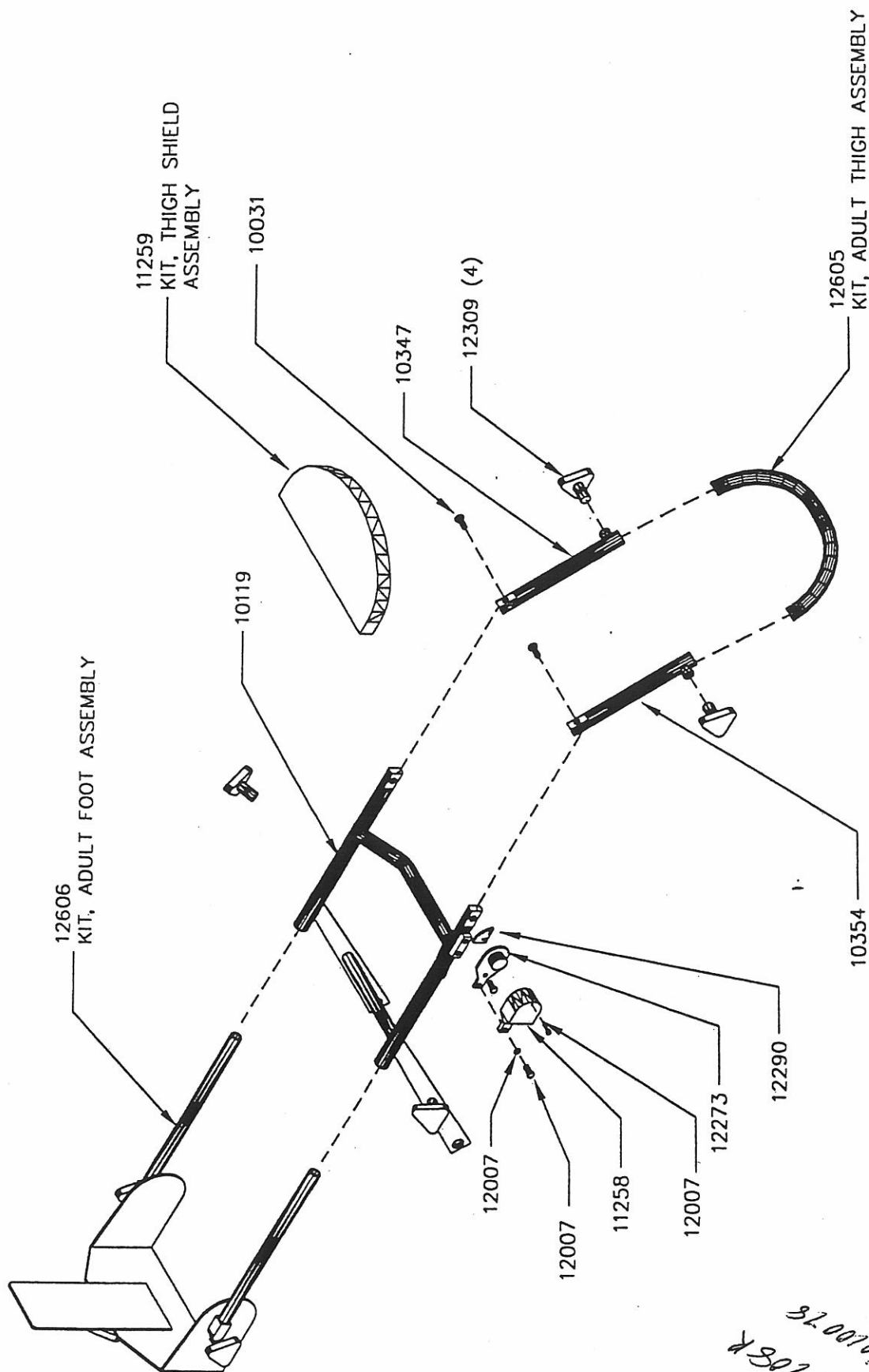




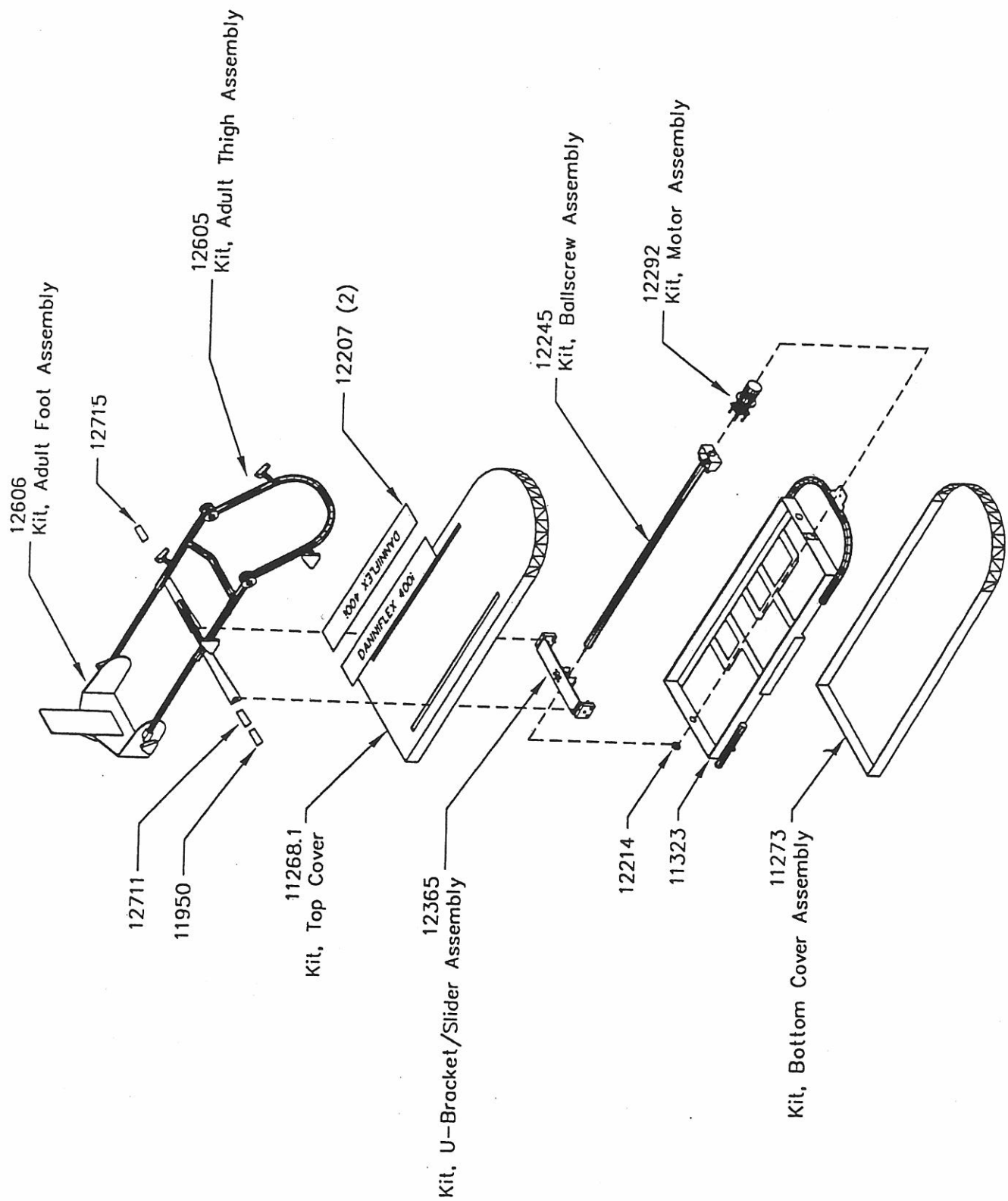
12292; Kit, 440 Motor Assembly

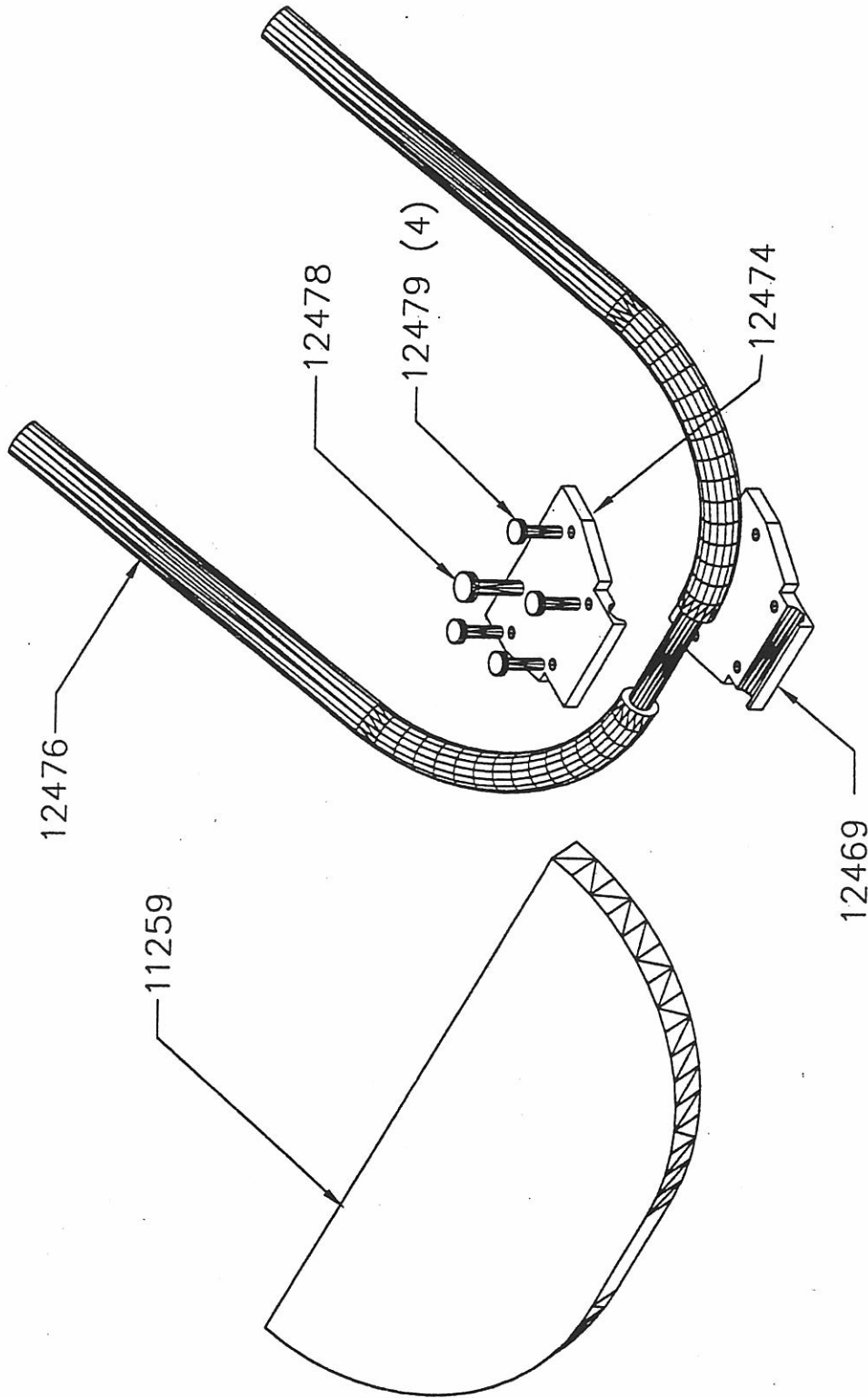


12245; Kit, Ballscrow Assembly

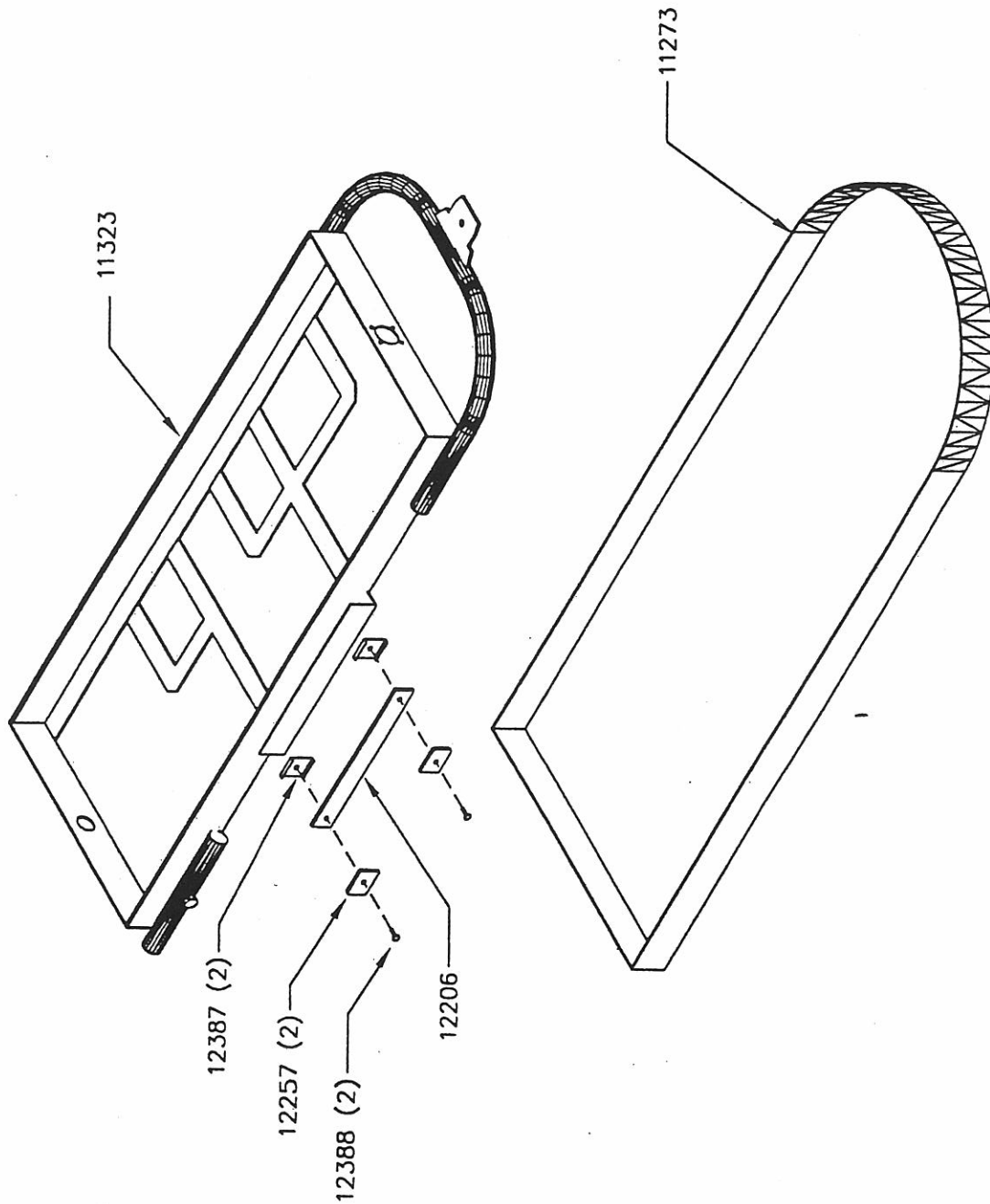


10708K
1010078

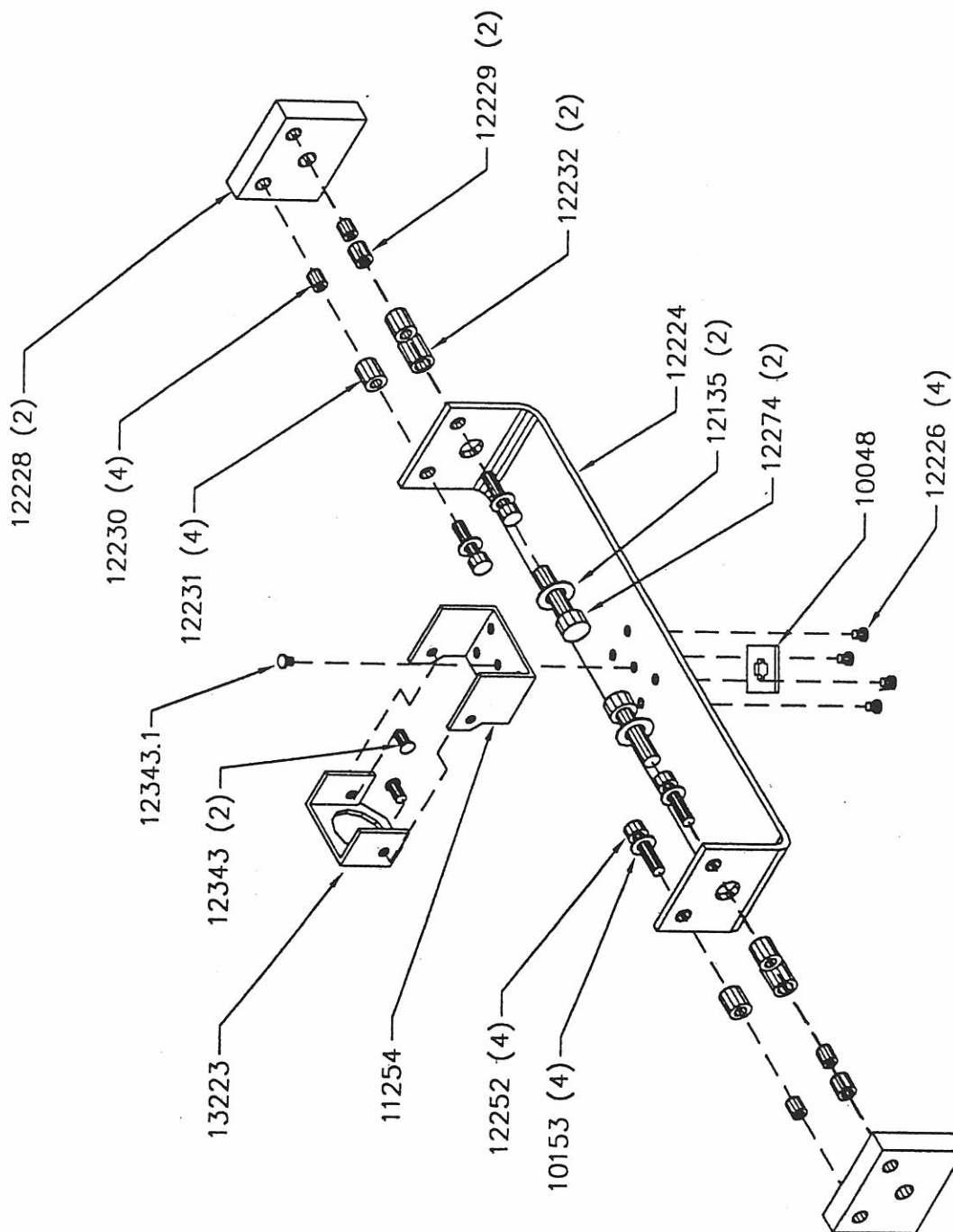




12605; Kit, Adult Thigh Assembly – 400 Series



11260; Kit, Handle - Leg CPM's
 11273; Kit, Bottom Cover (New) - 400 Series



12319; Kit, Slider Block Assembly
 12365; Kit, U-Brocket / Slider Assembly Complete

BOTTOM VIEW

