

SIKOV & WONCHECK, P.C.

LAW OFFICES

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PLAZA 5 - SUITE 5
ASTRONA HEIGHTS, PA 15065
TELEPHONE (724) 224-5545
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9698 '00 APR -4 AIO 100

March 30, 2000

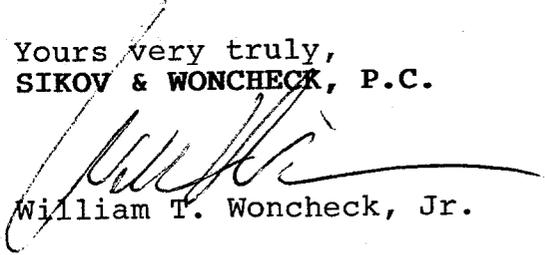
Food and Drug Administration
Department of Health and Human Services
Room 1-23, 12420 Parklawn Drive
Rockville, MD 20857

Gentlemen:

Please be advised that I represent CPR Medical Products, Inc., a Pennsylvania corporation, which distributes various types of muscle and nerve stimulating devices.

Enclosed herewith for filing is a Citizen Petition seeking a variance from the Performance Standard for Electrode Lead Wires and Patient Cables.

Yours very truly,
SIKOV & WONCHECK, P.C.


William T. Woncheck, Jr.

WTW:beo

Enclosures

OOP-12400

CPI

9699 TO APR -4 10 19

(Date) March 13, 2000

Dockets Management Branch. Food and Drug Administration.
Department of Health and Human Services, rm. 1-23, 12420 Parklawn
Drive, Rockville, Maryland 20857.

CITIZEN PETITION

The undersigned submits this Petition under 21 CFR, Section
10.20.

1. Your Petitioner herein is CPR Medical Products, Inc., a
corporation existing under the laws of the Commonwealth of
Pennsylvania, with its principal place of business at 2840
Leechburg Road, Lower Burrell, Pennsylvania 15068.

2. Your Petitioner herein is a distributor of various types
of muscle and nerve stimulating devices throughout the United
States.

3. Your Petitioner herein currently has 2,914 outstanding
patient accounts with units in rental or purchase status.

4. Your Petitioner herein is currently a distributor of 63
different types of stimulating units; utilizing 28 different
manufacturers; with 6 different modalities, including but not

limited to, Tens units, muscle stimulators, interferential units and galvanics. Attached hereto and made a part hereof and marked Exhibits A through D are directional drawings of Lead Wire Jacks utilized by the specific units which have been distributed by your Petitioner herein.

5. Your Petitioner herein is a small business with less than 15 employees and a single business location.

6. As of the date of this Petition, there is no adaptor or adapting device available to your Petitioner for its numerous outstanding units to enable it to comply with the Performance Standard for Electrode Lead Wires and Patient Cables as set forth in Title 21 CFR part 898.

7. Without the availability of any adapting device mandatory compliance with the aforerecited Performance Standard would create an unbearable economic hardship and overwhelming financial burden as to potentially force your Petitioner out of business.

WHEREFORE, your Petitioner requests that the Commissioner grant Petitioner a variance from the Performance Standard for Electrode Lead Wires and Patient Cables as set forth in Title 21 CFR part 898 with regard to its current outstanding units.

CERTIFICATION

The undersigned certifies that to the best knowledge and belief of the undersigned, this Petition includes all information and views of which the Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the Petition.

CPR Medical Products, Inc.
FRANCIS J. COSENTINO

By:



2840 Leechburg Road
Lower Burrell, PA 15068
(724) 337-7531

03/06

03/15 '00 14:25 NO.593

6515653971

UN1-PA1CH

REVISIONS		
REV	DATE	INITIALS

DESCRIPTION

467 plug

For part numbers

80324-2

80336-2

80348-2

86536-2

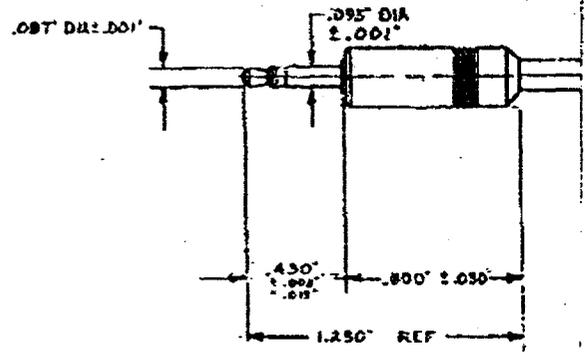


EXHIBIT "A"



CPR MEDICAL PRODUCTS, INC.

2840 LEECHBURG ROAD

LOWER BURRELL, PA 15068

(724) 337-7531 1-800-235-5675

FAX (724) 337-0556

803/865

Agar
Uni-Tens

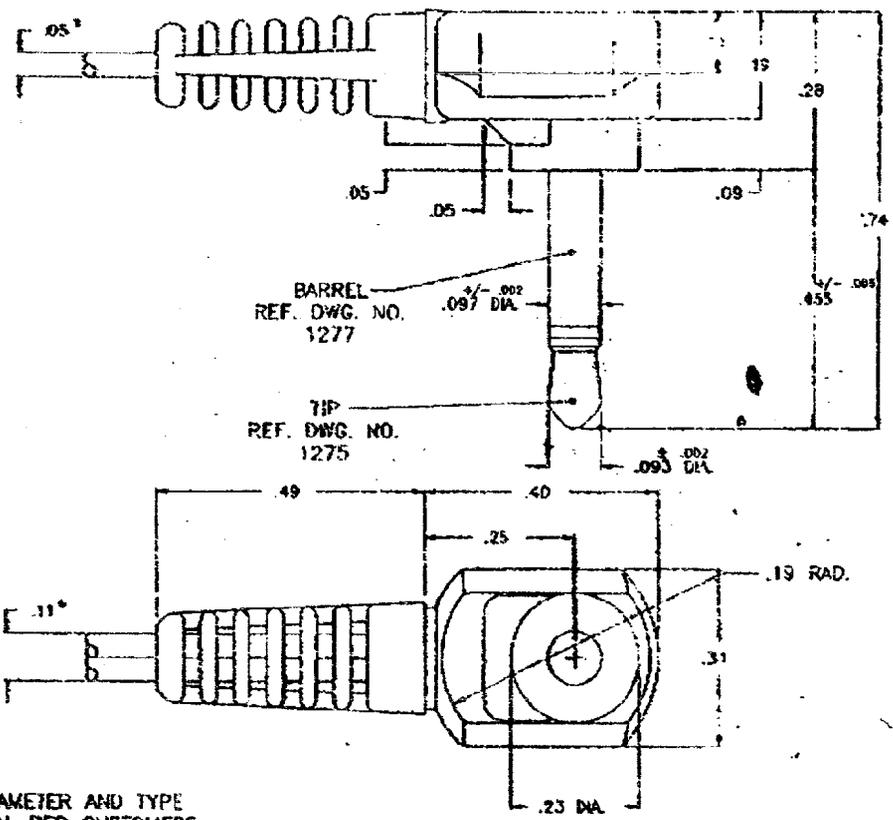
Rehabicare
Matrix

03/15 '00 14:25 NO.393 04/06

6515653971

UNI-PATCH

REV.	CHANGE	DATE	BY
1	REDRAWN ON ACAD DIMENSIONS REDEFINED	20	KAD 1990



* WIRE DIAMETER AND TYPE
OPTIONAL PER CUSTOMERS
SPECIFICATIONS.

For Part numbers
 81724-2
 81736-2
 81748-2
 81760-2
 86136-2
 87240-2
 86240-2

DET. DES.	DESIGN	PARAMETER	RECORDED
TOLERANCES UNLESS OTHERWISE SPECIFIED			
FRACTIONAL 9/16"	NAME: 237 PLUG		
REVISION NO. 1	DATE	APPROVED	DATE
5X	5/1/90		
2329	REV. 1 OF 1		

EXHIBIT "B"

CPR MEDICAL

CPR MEDICAL PRODUCTS, INC.

2840 LEECHBURG ROAD
LOWER BURRELL, PA 15068
(724) 337-7531 1-800-235-5675
FAX (724) 337-0556

817/861/872/862

Century
2100

American Imex
A-Tens

Avionix
EZ Stim
Micro Tens

Bio Medical Life Systems
Therapulse Bio Med 2000
Systems 2000 Micro Plus
INF 4150 EMS 2000
INF Plus

Empi/Medtronic
Epix XL Respond + Respond Select
Focus Eclipse +

Global
Gold

Henley
Team
Isowave

Jace
Tri-Stim
Jace Stim II

CPR MEDICAL

CPR MEDICAL PRODUCTS, INC.

2840 LEECHBURG ROAD
LOWER BURRELL, PA 15068
(724) 337-7531 1-800-235-5675
FAX (724) 337-0556

Lumiscop
2000
2000T
EMS 400

Meda
Crown

Rehabicare
SMP IFII
Amatron NMIII
Ultrapac SX

Graham Field
GF3

MediStim
MS23T

TX3

Q TENS

Neuro Medics
Omega T100
Omega T200

Micro Q

Painmaster 2002

Sterling
Simplex
Sterling PC



CPR MEDICAL PRODUCTS, INC.

2840 LEECHBURG ROAD

LOWER BURRELL, PA 15068

(724) 337-7531 1-800-235-5675

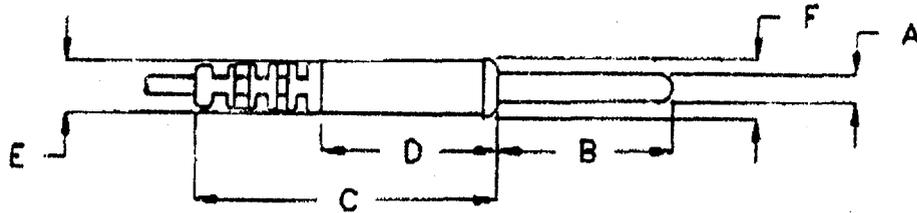
FAX (724) 337-0556

Prism

Z-StimII

Electromedical Products International, Inc.

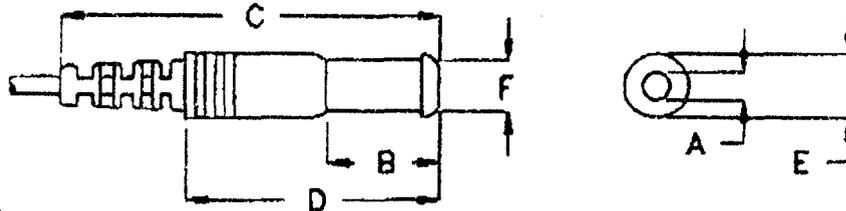
Alpha Stim 100



FEATURES:

- 1) Nickel plated solid brass pins ; optional gold plate.
- 2) Chemical resistant molding material - fifteen standard color options.
- 3) Flexmaster bend relief provides rugged durability.
Minimum 100,000 180° flexes at 8 ounce (225 gram) load.
- 4) Wire size and type options to suit specific applications. Minimum 12 pound pull off force. Standard size .050 (1.27mm).
- 5) Locking ring for latching to mating parts.

CONNECTOR P/N	A PIN DIA. (IN/MM)	B PIN LENGTH (IN/MM)	C BODY O.A.L. (IN/MM)	D BODY LENGTH (IN/MM)	E BODY O.D. (IN/MM)	F (IN/MM)	
202	.080/2.00	.48/12.07	.86/21.84	.50/12.70	.15/3.81	N/A	
* 203	.080/2.00	.44/11.18	.90/22.86	.42/10.54	.22/5.59	N/A	84/81536
232	.080/2.00	.38/9.53	.85/21.84	.50/12.70	.15/3.81	N/A	
* 244	.080/2.00	.48/12.19	1.35/34.29	.50/12.70	.15/3.81	.17/4.32	
* 245	.080/2.00	.38/9.53	1.24/31.50	.50/12.70	.15/3.81	.17/4.32	
402	.080/2.00	.48/12.07	.86/21.84	.50/12.70	.15/3.81	N/A	



FEATURES:

- 6) Tinned brass sockets.
- 7) Chemical resistant molding material - fifteen standard color options.
- 8) Flexmaster bend relief provides rugged durability.
Minimum 100,000 180° flexes at 8 ounce (225 gram) load.
- 9) Wire size and type options to suit specific applications. Minimum 12 pound pull off force. Standard size .050 (1.27mm).
- 10) Lock ring for latching to mating parts.

CONNECTOR P/N	A PIN DIA. (IN/MM)	B PIN LENGTH (IN/MM)	C BODY O.A.L. (IN/MM)	D BODY LENGTH (IN/MM)	E BODY O.D. (IN/MM)	F (IN/MM)		
294	.08/2.03	.33/8.26	1.09/27.56	.73/18.42	.18/4.57	.15/3.81		
442	.08/2.03	.58/14.73	1.41/35.81	1.1/26.67	.230/5.72	.18/4.50		
					REV B	DATE 11-09-92	BY RMJ	DWG# 9041

EXHIBIT "C"



CPR MEDICAL PRODUCTS, INC.

2840 LEECHBURG ROAD

LOWER BURRELL, PA 15068

(724) 337-7531 1-800-235-5675

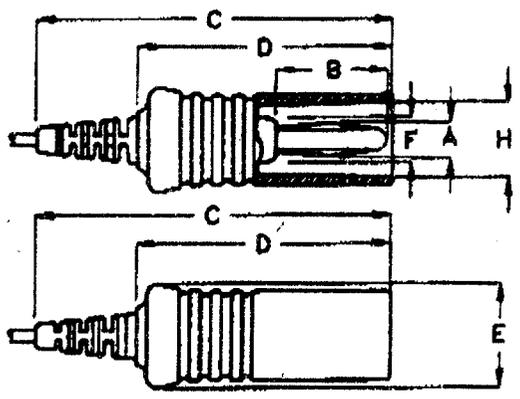
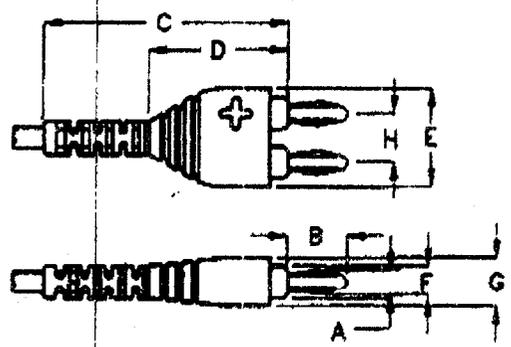
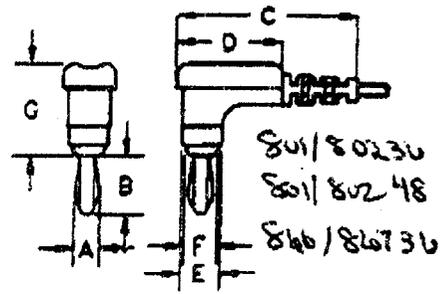
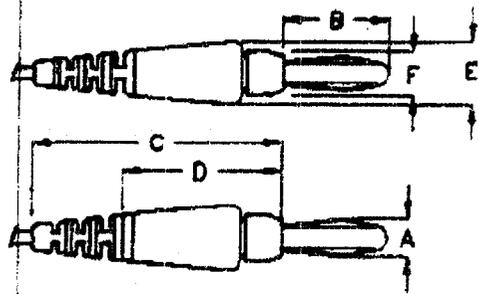
FAX (724) 337-0556

814/815/805/870

Empi/Medtronic
Quadriflex

Rehabicare
GVII

UTS
PGS3000



CONNECTOR P/N	A PIN DIA. (IN/MM)	B PIN LENGTH (IN/MM)	C BODY O.A.L. (IN/MM)	D BODY LENGTH (IN/MM)	E BODY DIA. (IN/MM)	F (IN/MM)	G (IN/MM)	H (IN/MM)
* 165	.12/3.05	.29/7.37	.97/24.64	.50/12.70	.19/4.75	.16/3.99	.46/11.56	.48/12.14
191	.18/4.57	.53/13.34	1.21/30.61	.72/18.29	.31/7.98	.22/5.59	N/A	N/A
265	.12/3.05	.29/7.37	.94/23.93	.58/14.73	.23/5.72	.16/3.99	N/A	N/A
428	.18/4.57	.53/13.34	1.70/43.18	1.22/30.86	.51/12.95	.22/5.59	N/A	N/A
475	.12/3.05	.53/13.34	1.18/29.92	.68/17.15	.48/12.19	.16/3.99	.24/6.00	.24/6.00
491	.18/4.57	.53/13.34	1.21/30.61	.72/18.29	.31/7.98	.22/5.59	N/A	N/A
493	.18/4.57	.53/13.34	2.05/52.09	1.57/39.77	.33/8.50	.22/5.59	N/A	N/A
810	.12/3.05	.29/7.37	1.18/29.97	.70/17.65	.30/7.62	.16/3.99	N/A	N/A

FEATURES:

- 1) Beryllium copper bananas spring with nickel plated brass body. Spring will withstand 50 Oz-in torque.
- 2) Chemical resistant molding material - fifteen standard color options.
- 3) Flexmaster bend relief provides rugged durability.
- 4) Wire size and type options to suit specific applications.
- 5) Location for customer logo

REV	DATE	BY	SHT 1	DWG#
B	10-16-92	RMJ	OF 1	9054

EXHIBIT "D"

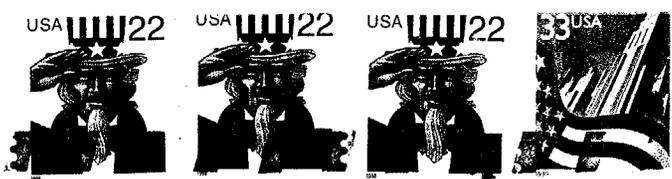


CPR MEDICAL PRODUCTS, INC.

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LOWER BURRELL, PA 15068
(724) 337-7531 1-800-235-5675
FAX (724) 337-0556

801/866

Stadyn
Maxima
Maxima II
Maxima III
EMS+2



PA 152

MSC PITTSBURGH, PA 152

MSC

MAR 30 2000 PM

MAR 30 2000

SIKOV & WONCHECK, P.C.

Attorneys At Law
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Natrona Heights, PA 15065

TO:

FOOD AND DRUG ADMINISTRATION
Dept. of Health and
Human Services
Room 1-23, 12420 Parklawn Dr.
Rockville, MD 20857