



PRIZM MEDICAL INC.

May 1, 2000

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

6012 '00 MAY -9 P2:08

CITIZEN PETITION

The undersigned submits this petition under 21 CFR § 898.14 to request the Commissioner of Food and Drugs to allow a variance for Prizm Medical, Inc., a manufacturer of NeuroMuscular Electrical Stimulators (NMES), to extend the effective date of 21 CFR § 898 – "Performance Standard for Electrode Lead Wires and Patient Cables" from May 9, 2000 to August 9, 2000 for the Z-watch System described in 510(k)# K951727.

A. Action Requested

- 1) With respect to 21 CFR Part 898, Performance Standard for Electrode Lead Wires and Patient Cables", Prizm Medical, Inc. has complied with the standard for all Micro-Z™ Stimulators (Part of Z-Watch System) manufactured after September 1999. See attachment A, Micro-Z™ Operations Manual for intended use and added statement of compliance. The design change for compliance to the standard was not a simple addition of an adapter as suggested in the following excerpt from the guidance document:

"Continued availability of compatible electrode lead wires and patient cables for existing devices is a concern for the user community. It is anticipated that relatively inexpensive adapters will be available and can be used to economically convert existing devices already in the marketplace to accept compliant electrode lead wires and patient cables. However, the performance standard also accounts for the possibility that there may be circumstances where adapters are not feasible. In such circumstances, the manufacturer may request a variance or exemption from compliance with the standard. Criteria and procedures for submission of a variance/exemption may be found in 21 CFR, section 898.14, and 21 CFR, section 10.30."

The product design changes included a change to the internal connectors, therefore, rework includes a new PCB, additional machining to the housing pieces and new leadwires. This is a costly rework. Prizm is continuing to work with our leadwire supplier to obtain a more inexpensive fix, however, Prizm is not financially able to pay for the tooling requirements at this point. See Attachment B, leadwire and connector drawings for our current product.

B) Reason for Request

- 1) Prizm has recently obtained approximately 150-200 units with the old style leadwires from dealers that no longer wish to sell our product. Prizm wishes to refurbish these units (keeping the old style leadwire design) and sell them at a discount to patients and clinics that may not normally be able to afford our products. We are requesting variance from the standard until August 9, 2000 to be able to distribute this unexpected inventory.

00P-1290

CP1



PRIZM MEDICAL INC.

These units will be distributed with a letter of explanation to the user that they are not compliant with 21 CFR Part 898, Performance Standard for Electrode Lead Wires and Patient Cables." They will be advised that they may at anytime after the sale return the device and have it updated to the new style connectors and leadwires at a cost of \$100.00 - \$125.00. (Final cost has not yet been determined.) They will also be notified if Prizm Medical, Inc. develops a more inexpensive fix such as an adapter.

Prizm Medical, Inc. believes that this extension does not significantly affect the safety of the device. The Micro-Z™ Stimulator is normally used with our Electro-Mesh Garment Electrodes. The stimulator can be used in a clinic or in the home. Home use patients receive an in-service that explains the use of the equipment. The leadwires themselves are short, approximately 18" when stretched limiting the likelihood of a patient putting the 2.0mm pin into an electrical outlet.

C) Certification

The undersigned certifies, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that in includes representative data and information known to the petitioner which are unfavorable to the petition.

D) Environmental impact

There is no environmental impact statement required.

E) Economic Impact

There is no economic impact statement required.

Loretta A Mooney,
Director of Quality and Regulatory Affairs
Prizm Medical, Inc.
3400 corporate Way, Suite I
Duluth, GA 30096



PRIZM MEDICAL INC.

Attachment A

Micro-Z™ Operations Manual, System Description, Patient Information and System Components

Micro-Z™ Operations Manual

Please read all instructions
carefully before use

Manufactured by:



PRIZM MEDICAL INC.

3400 Corporate Way, Suite I
Duluth, GA 30096 USA
Tel: (770) 622-0933

Rev. 1999 – P/N 0-61-MCZMA2-0-0

1.0 MICRO-Z™ SYSTEM DESCRIPTION

The Micro-Z™ is:

- ***A one channel electrical neuromuscular stimulator*** that delivers a pulsed DC current with a monophasic waveform to the surface area of our garment electrodes to provide electrical stimulation where there is an indication for use.
- ***Microprocessor controlled***, allowing easy alteration of the treatment parameters and precise control of each setting.
- ***Designed for ease of patient use*** with clearly marked patient intensity buttons.
- ***Designed for stand-alone use or, when used with an external programmer, as a programmable device*** for a full variety of frequencies, time settings, and delivery schedules.
- ***Designed for use with our patented garment electrodes***; wearable electrodes that cover a large surface area providing total stimulation to the treatment area.
- ***Wearable*** with the Velcro® strip that attaches the device to the arm/leg strap.

2.0 PATIENT INFORMATION

2.1 INDICATIONS FOR USE

- Relaxation of muscle spasm
- Prevention or retardation of disuse atrophy
- Increasing of local blood circulation
- Muscle reeducation
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

Electrical stimulation devices should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

2.2 CONTRAINDICATIONS

- Electrical stimulation devices are contraindicated for patients with cardiac demand pacemakers.
- Electric stimulation devices should not be used on cancer patients.

2.3 WARNINGS

1. Safety has not been established for the use of electrical stimulation devices during pregnancy.
2. Long-term effects of chronic electrical stimulation are unknown.
3. Precautions should be taken in the case of persons with suspected or diagnosed epilepsy.
4. Precautions should be taken in the case of persons with suspected heart problems.
5. Due to possible arrhythmia, do not place an electrical stimulator across a patient's heart or transthoracically.
6. Do not stimulate over the carotid sinus nerves; especially for patients with known sensitivity to the carotid sinus reflex.
7. Severe spasm of the laryngeal or pharyngeal muscles may occur when electrodes are placed over the neck or mouth area. Contractions may be strong enough to close the airway or cause difficulty in breathing.
8. Do not apply electrical stimulation transcerebrally.
9. Do not use electrical stimulation over swollen, infected or inflamed areas, or skin eruptions such as phlebitis, thrombophlebitis, or varicose veins.
10. Keep electrical stimulators out of the reach of children.

2.4 PRECAUTIONS

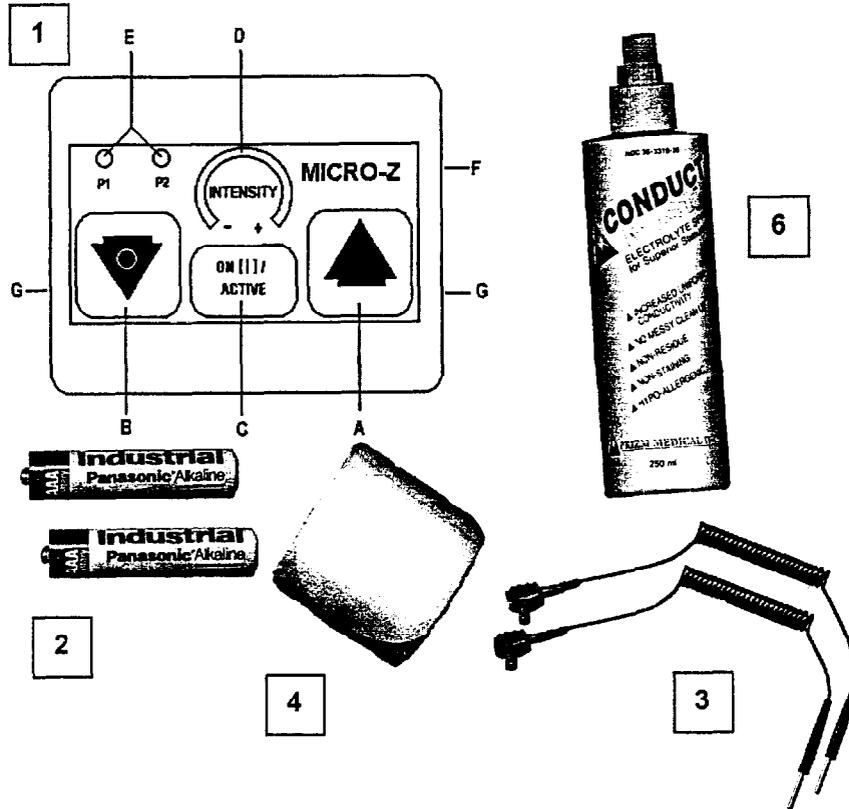
1. Precautions should be taken in the presence of:
 - A tendency to hemorrhage following acute trauma or fracture
 - Recent surgical procedures when muscle contraction may disrupt the healing process.
 - A menstruating uterus.
 - Sensory nerve damage (loss of normal skin sensation).
2. Some patients experience skin irritation or hypersensitivity due to the conductive medium or electrical stimulation. This condition can usually be reduced by alternative electrode placement or use of additional or a different conductive medium.

2.5 ADVERSE EFFECTS

Skin irritation and burns beneath the electrodes have been reported from use of electrical stimulators.

3.0 SYSTEM COMPONENTS DEVICE COMPONENTS AND MARKINGS

- | | |
|--------------------------|-------------------------------|
| 1. Micro-Z™ Device | A. Intensity Control Increase |
| 2. Two (2) AAA Batteries | B. Intensity Control Decrease |
| 3. Two (2) Leadwires | C. On/Active Switch |
| One black (-) | D. Intensity Indicator Light |
| One red (+) | E. Protocol Indicator Lights |
| 4. Velcro Strap | F. Serial Port for Programmer |
| 5. Garment Electrodes | G. Leadwire Insert Jacks |
| 6. Conduct-Mist™ Spray | |



Micro-Z™
 SN B XXXXXX
 Manufactured by: Prizm Medical, Inc.
 Duluth, GA 30096 USA
 Caution: Federal law (USA) restricts this device to
 sale by or on the order of a physician



This Symbol
 denotes an
 applied part



PRIZM MEDICAL INC.

Attachment B

Index of Attached Drawings

Drawing of old-style leadwire –

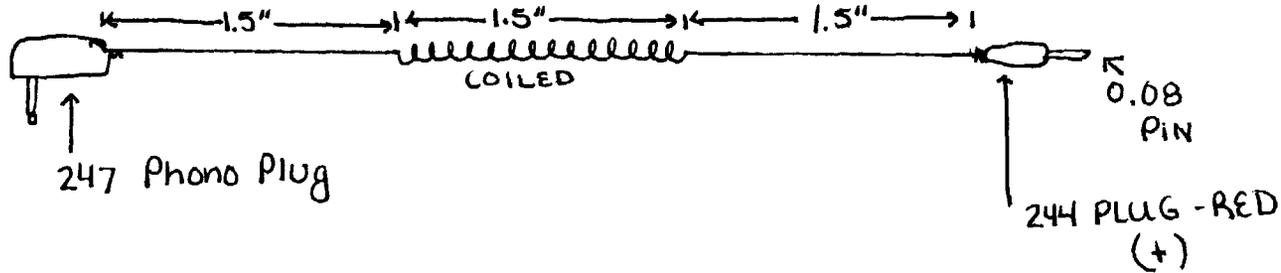
247 Phono plug fits into internal PCB Jack of unit

Current leadwire with Touch Proof connector

Manufacturer drawing of connector

Manufacturer drawing of connector, con't

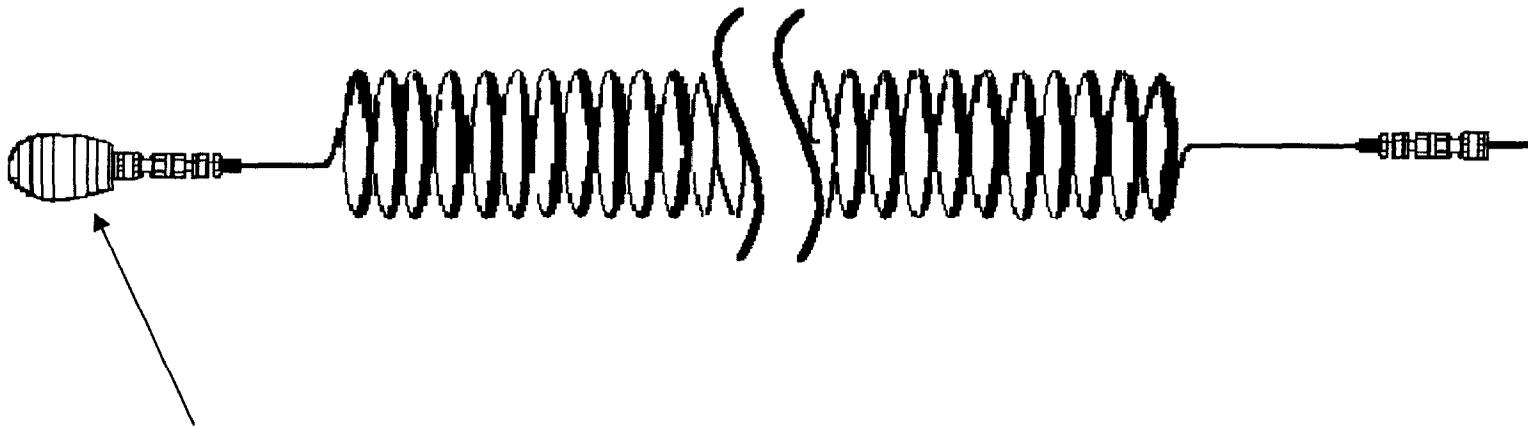
REV. NO.	DESCRIPTION OF REVISION	APPROVED BY:	DATE:	DRAWING: ASSEMBLY
1	RELEASED	<i>L. Rucker</i>	5/20/96	P/N: MLW 102
2	Reference Plug Dwg P/N and Canged Dwg Number from MLW 102	<i>L. Rucker</i>	7/24/98	



Reference the Prizm Drawings,
PMD 022-00 and PMD 023-00 for
Plug specifications.

PRIZM MEDICAL, INC.		
SCALE: N/A	APPROVED BY: <i>L. Rucker</i>	DRAWN BY: J. Johnson
DATE: 5/20/96	Single coiled RED leadwire with (#244) positive pole connected to phone plug	REVISED:
TOLERANCES: N/A		DRAWING NO. PMD 031-02
CAT. NO.	MLW 102	

Revision:	Description of Revision:	Released By:	Date:	Drawing: Assembly / Component
1	Require Tapered Pin in connector end. Add Inspection Ref.	<i>L. Rucker</i>	11/4/99	P/N: 0-24-MLWBLK-0-1



Leadwire connector is Touch Proof which is compliant with EN 60601-0 and the CFR The Performance Standard for Electrode Lead Wires and patient Cables, found in Title 21 CFR part 898

Plastics One will use only tapered pins in the connector end. Reference Standards 001 and 002

Connector is a Plastics One Connector, Part Number 454, mates with Part Number 8S0038101F

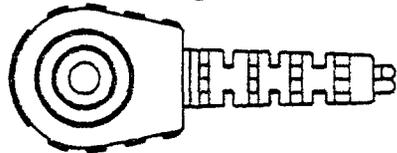
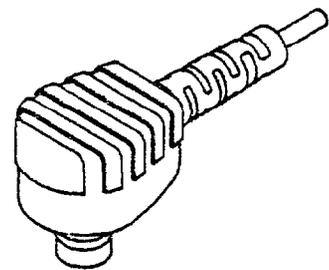
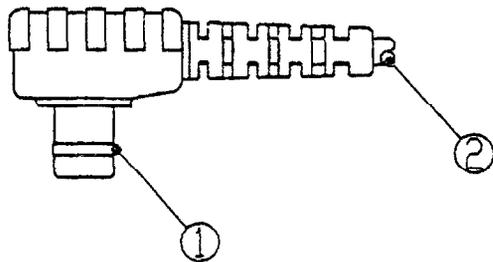
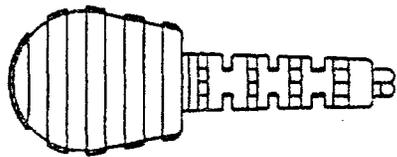
Reference Plastics One Inc. Drawings, 9093 and 9094.

Inspect Per DF 0993-00, File completed paperwork into a dedicated file with Micro-Z Device History Records

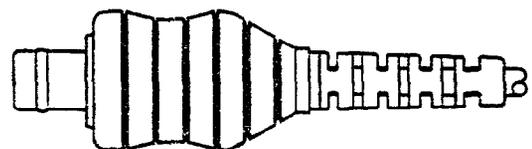
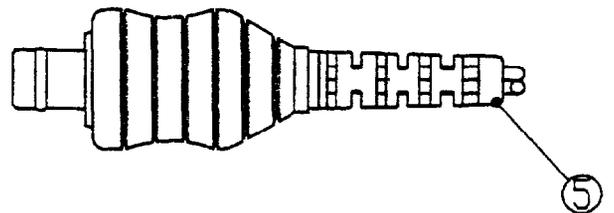
	PRIZM MEDICAL INC.	CRN 9911002
Original Date: 7/26/99	Approved By: D. Brauckman	Drawn By: L. Mooney
Description:	Black Leadwire with Touch Proof Connector	Revised By: L. Mooney
Tolerances:	N/A	Drawing No.
Part Number:	0-24-MLWBLK-0-1	1-24-MLWBLK-0-1

TOUCH PROOF Concentric Connectors (Rotatable)

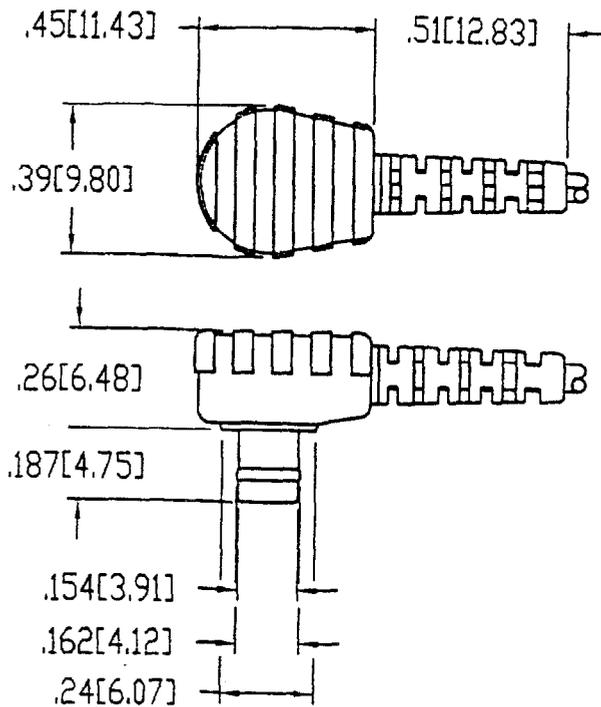
(Ref: EN 60601-1)
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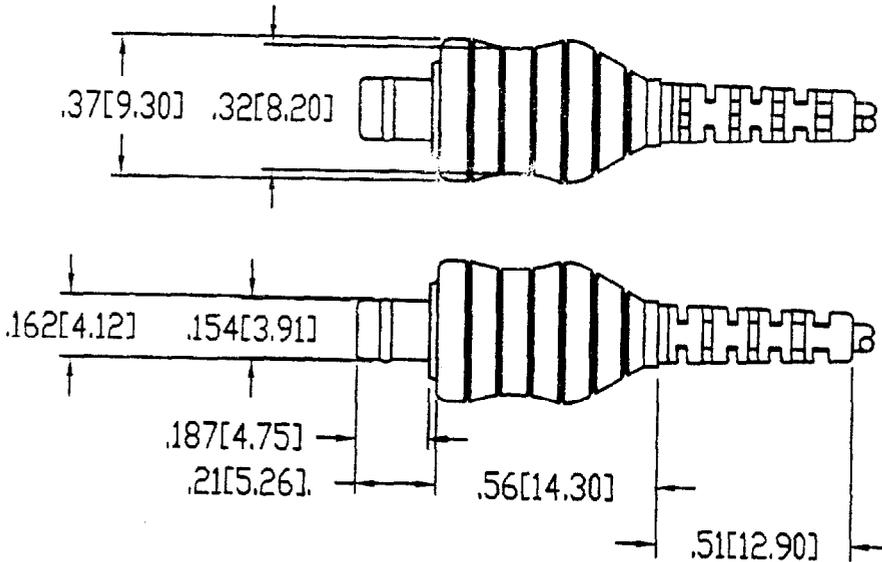
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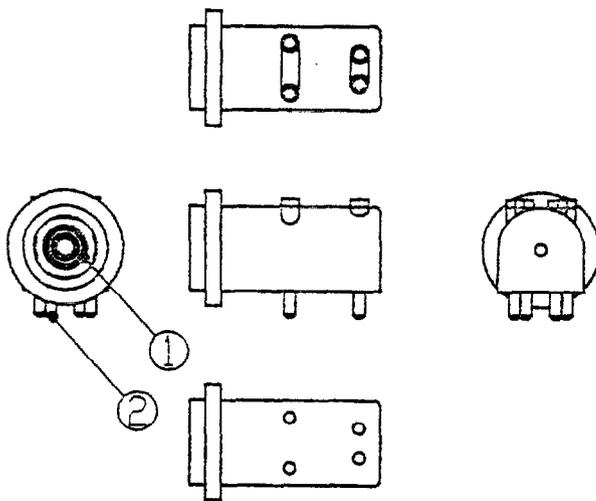
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FEATURES:

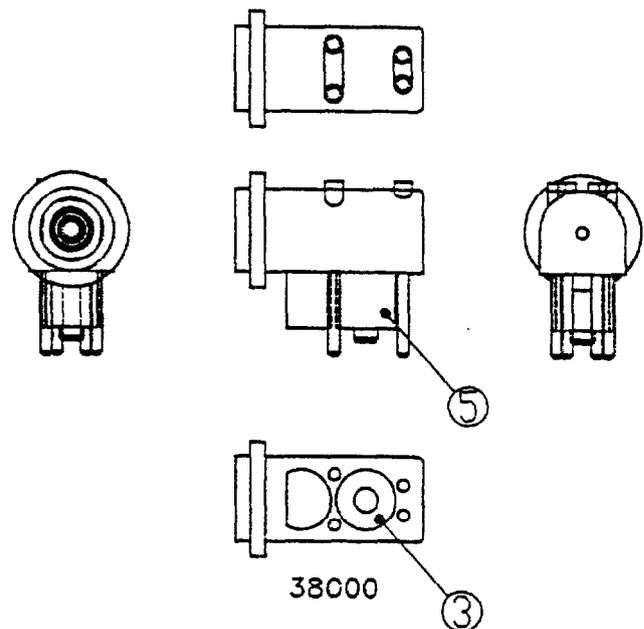
- 1) Lock Ring Notch.
- 2) Wire Size And Type Options To Suit Specific Applications.
- 3) Chemical Resistant Molding Material; Ten Standard Color Options Available.
- 4) Customized Jacks And Multi-Port Yokes Can Be Designed For Specific Applications.
- 5) Flexmaster Bend Relief Provides Rugged Durability.

TOUCH PROOF PCB Jacks (Rotatable)

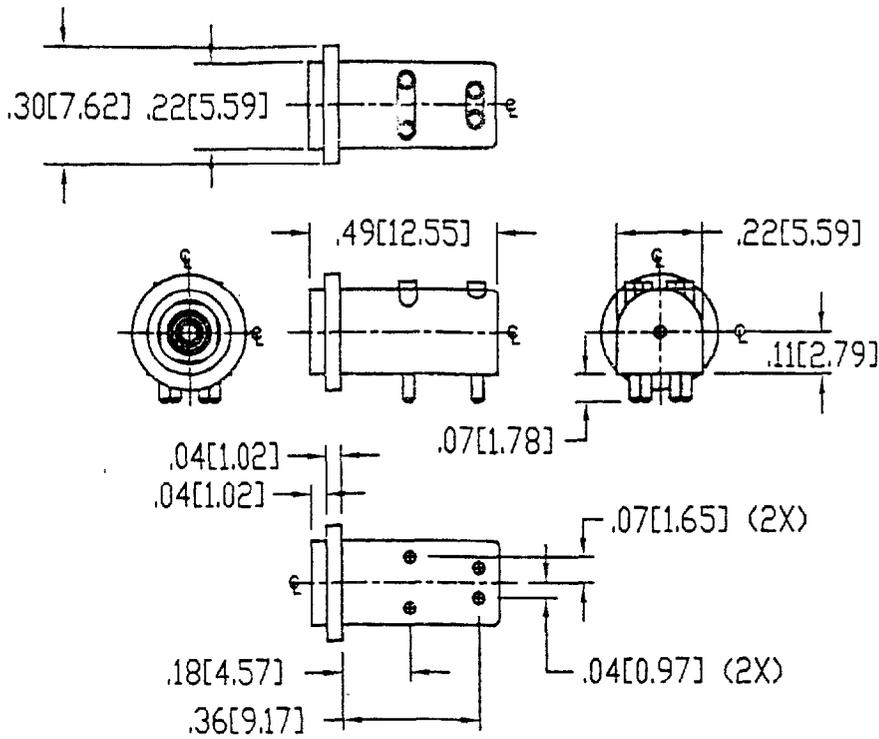
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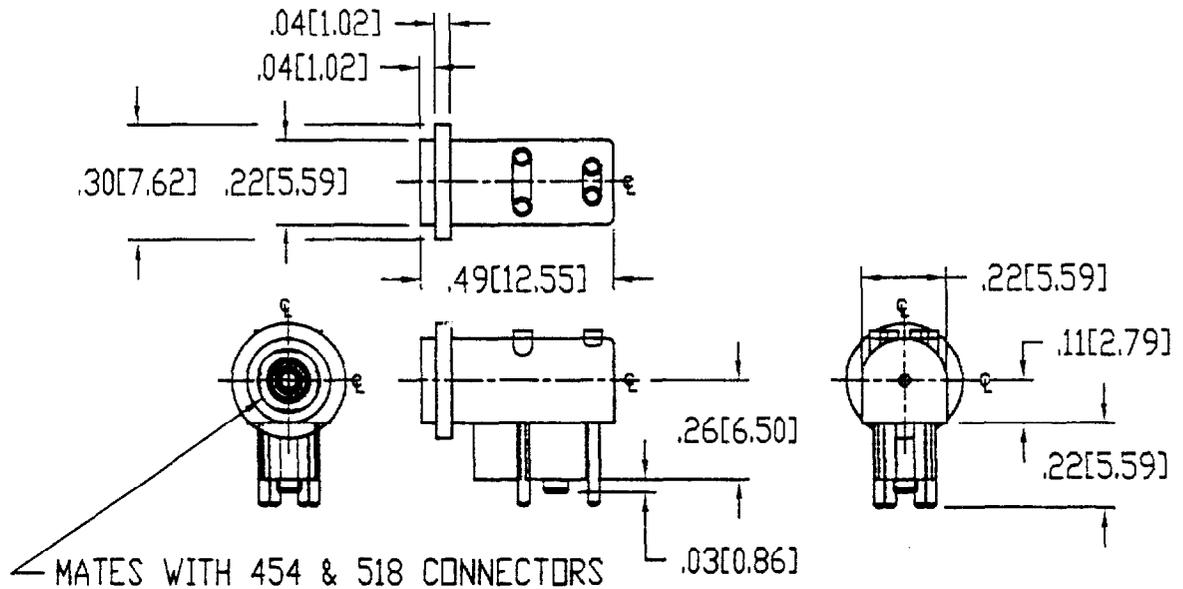
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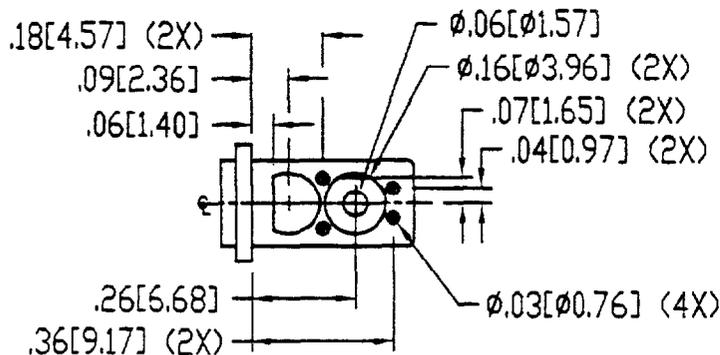
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FEATURES:

- 1) Lock Ring Notch.
- 2) Gold Plated Contacts.
- 3) Plastic Mounting Posts; Height And Number Of Posts Are Optional.
- 4) Chemical Resistant Molding Material; Ten Standard Color Options Available.
- 5) Multiple Circuit Board Elevations Are Available.
- 6) Customized Jacks And Multi-Port Yokes Can Be Designed For Specific Applications.

Specifications subject to change without notice.
For latest design specifications 540-772-7977

ECO 3575

REV A

DATE 5/27/98

BY: JAMISON

SHT 1 OF 1

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