



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (cwf)
FOLDER: K842262 - 88 pages
COMPANY: PIRDY, INC. (PIRDY)
PRODUCT: STIMULATOR, MUSCLE, DIAGNOSTIC (ISB)
SUMMARY: Product: PIRD-Y

DATE REQUESTED: Aug 30, 2016

DATE PRINTED: Aug 30, 2016

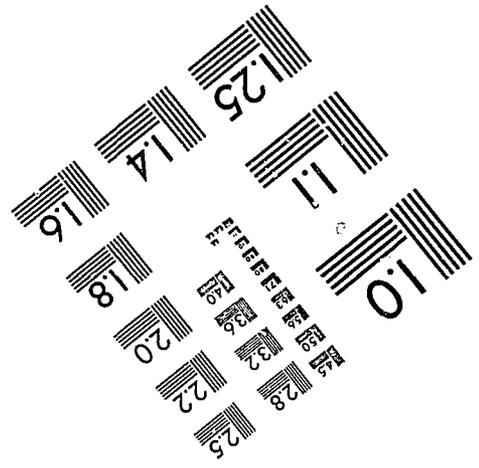
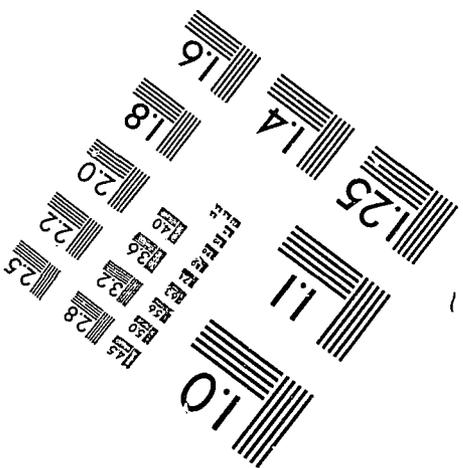
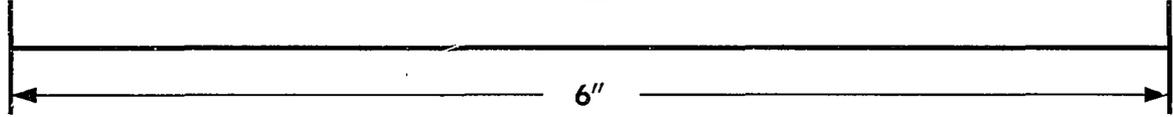
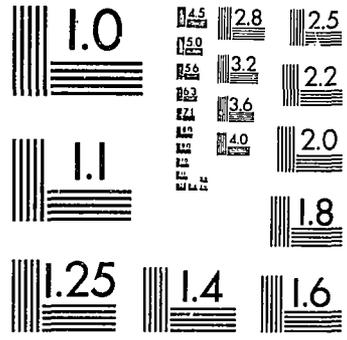
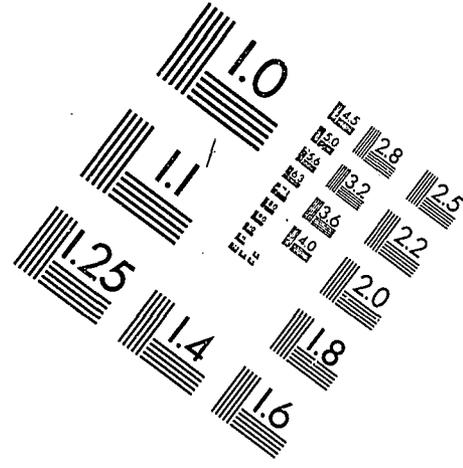
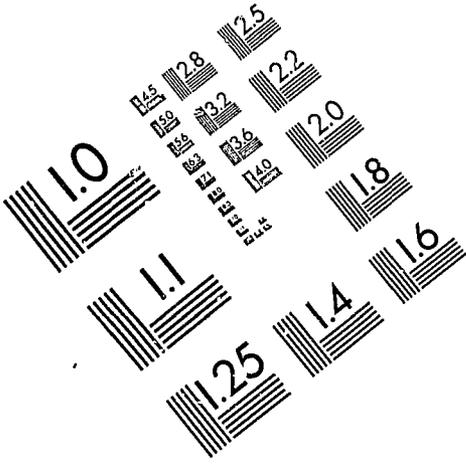
Note: Printed



QUESTIONS? CONTACT FDA/CDRH/OCED/DA/CURR/FOUNSTAT/USO/OF/IAS/OV/OUR/FA/SE/

K 8 4 2 2 6 2

89



K842262



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Mr. John R. Howard
Pirby, Incorporated
522 SW 5th
Suite 725
Portland, Oregon 97204

JUN 28 1984

Re: K842262
PIRD-Y

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

Dear Mr. Howard:

Dated:
Received: June 7, 1984
Regulatory Class: II

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). This device has been placed into the regulatory class shown above, by a final regulation published in the Federal Register. All classes of devices are regulated by the general controls provisions of the Act applicable to all medical devices including annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act; class II devices must also meet present or future performance standards; class III devices will be required to undergo premarket approval at some time in the future.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. We suggest you subscribe to this publication so you can convey your views to FDA if you desire and be notified of any additional requirements subsequently imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

Robert G. Britain
Director
Office of Device Evaluation
Center for Devices and Radiological Health

BEST AVAILABLE COPY



Memorandum

Date June 25, 1984

From REVIEWER(S) - NAME(S) Mara R. Williams

Subject 510(k) NOTIFICATION K842262

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

- (A) Is substantially equivalent to marketed devices.
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Is an incomplete submission. (See Submission Sheet).

Additional Comments:

Subs equiv to
Stimulator, Muscle, Diagnostic
Class II

The submitter requests:

Class Code w/Panel:

No Confidentiality

89 ISB

Confidentiality for 90 days

Continued Confidentiality exceeding 90 days

REVIEW:

Nimmajadda V Rao Jr. Mehra
(BRANCH CHIEF)

6/25/84
(DATE)

FINAL REVIEW:

Carl A. Larson
(DIVISION DIRECTOR)

6/27/84
(DATE)

BEST AVAILABLE COPY



Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

JUN 12 1984

Piridy, Incorporated
Attn: John R. Howard
522 SW 5th
Suite 725
Portland, OR 97204

D.C. Number : K842262
Received : 6/7/84
Product : PIRD-Y

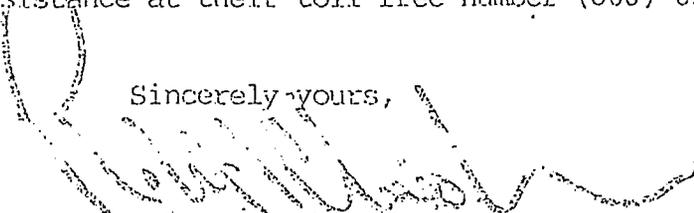
The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug and Cosmetic Act for the above referenced device has been received and assigned a unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. I suggest that you contact us if you have not been notified in writing at the end of this ninety (90) day period before you begin marketing your device. Written questions concerning the status of your submission should be sent to:

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at their toll-free number (800) 638-2041 or me at (301) 427-7230.

Sincerely yours,


Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

BEST AVAILABLE COPY

15842262

RECEIVED
FDA/BMDCP

2004 JUN -7 AM 8:32

DOCUMENT CONTROL
CENTER

Food and Drug Administration

Bureau of Medical Devices

HFK - 20

8757 Georgia Avenue

Silver Spring, Maryland 20910

PREMARKET NOTIFICATION LETTER

"510(k) SUBMISSION"

Gentlemen:

This letter serves as "510(k) Notification" of the intention of Piridy, Inc. to market a device which aids neuromuscular rehabilitation and neuromuscular re-education. The following section headings directly correspond to the analogous sections of 21 CFR 807.87, to aid your review.

807.87(a) Device Name. The proprietary name is PIRD-Y. The instrument is a state-of-the-art, battery powered combination of a skin surface Electromyograph and a Powered Muscle Stimulator.

BEST AVAILABLE COPY

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
INITIAL REGISTRATION
OF MEDICAL DEVICE ESTABLISHMENT
(Shaded Areas Are For FDA Use Only)

OMB No. 0910-0019, Approval Expires October 31, 1983.

VALIDATION

1 REGISTRATION NO.

R

NOTE: This form is authorized by Section 510 of the Food, Drug and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of new Section 301(p) of the act (21 U.S.C. 331 (p)). Persons who violate this provision may, if convicted, be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of new Section 301(q) (2) (21 U.S.C. 331(q) (2) and may be a violation of 18 U.S.C. 1001.

SECTION A

2. ESTABLISHMENT NAME PIRDY, INC.				3. RECORD DATE (Mo.) (DAY) (Yr) 05 31 84			
4. NUMBER AND STREET 522 SW 5TH				5. CITY PORTLAND		6. STATE OR	7. ZIP CODE 97204
8. FOREIGN COUNTRY		9. OTHER FDA REGISTRIES (Check applicable) DRUGS <input type="checkbox"/> 1 COSMETICS <input type="checkbox"/> 3 BLOOD PRODUCTS <input type="checkbox"/> 6			10. ESTABLISHMENT TYPES (Check all applicable) INIT DISTR OF IMPORTED DEVICES <input type="checkbox"/> D MANUFACTURER <input checked="" type="checkbox"/> M REPACKAGER OR RELABELER <input type="checkbox"/> R		

SECTION B

11. OWNER/OPERATOR PIRDY MEDICAL, INC.				12. OWNER/OPERATOR I.D.			
13. NUMBER AND STREET 595 HOWE STREET, SUITE 401				14. CITY VANCOUVER		15. STATE B.C.	16. ZIP CODE V6C 2T5
17. FOREIGN COUNTRY CANADA		18. ESTIMATED NO. OF DEVICES ONE					

SECTION C

19. OFFICIAL CORRESPONDENT JOHN R. HOWARD				20. TELEPHONE (Area Code) (Number) (503) 241-3372			
21. BUSINESS NAME PIRDY, INC.							
22. NUMBER AND STREET 522 SW 5TH				23. CITY PORTLAND		24. STATE OR	25. ZIP CODE 97204
26. FOREIGN COUNTRY							

SECTION D

27. OTHER BUSINESS TRADING NAMES							
B 10 11				50 B 10 11			
SEQ ESTABLISHMENT NAME				SEQ ESTABLISHMENT NAME			
501 NONE				502			
503				504			
505				506			

SECTION E

28. SIGNATURE OF OFFICIAL CORRESPONDENT <i>John R. Howard</i>				29. TITLE PRESIDENT AND CHAIRMAN, PIRDY, INC.			
--	--	--	--	---	--	--	--

FORM FDA 2891 (2/80)

U. S. GOVERNMENT PRINTING OFFICE: 1982-359-301/1821

BEST AVAILABLE COPY

BEST AVAILABLE COPY

807.87(b) Establishment Registration Number. A completed Form FD-2891 (Initial Registration of Device Establishments) has been included with the present 510(k) submission.

807.87(c) Section 513 Classification. Both components of PIRD-Y are directly equivalent to Class II instruments as listed in 21 CFR 890 - Physical Medicine Devices. Actually, PIRD-Y only involves a limited complement of capabilities included in the two classifications, as can be seen from the following description:

- A. Diagnostic Electromyograph (890.1375). PIRD-Y functions as an electromyograph, monitoring and displaying electromyographic (EMG) signals in an audio and/or visual format. However, PIRD-Y capabilities are limited to skin surface recordings only; the sophisticated electronics required for invasive needle electrode recordings and other specialty features have not been included.

- B. Powered Muscle Stimulator (890.5850). PIRD-Y functions as an electrically powered muscle stimulator. Muscle activation is limited to large skin surface electrodes; because point and needle electrodes are excluded, maximum voltage requirements are much less than some other commercial products. PIRD-Y's indications for use reside completely within the bounds of those specified for popular, commercially available muscle stimulators.

BEST AVAILABLE COPY

We are not sure what the Isokinetic Testing and Evaluation System classification (890.1925) constitutes, over and above that encompassed by the combination of Diagnostic Electromyographs and Powered Muscle Stimulators. The crucial fact is that PIRD-Y instruments are not designed for rehabilitative exercise or any other purpose distinct from the indications for use applicable to commercially available Powered Muscle Stimulators (e.g. items 2, 4, and 5, Section 807.87(f) below).

Some instrument combinations composed of both of the above Class II device categories are presently available commercially, but to the knowledge of Piridy, Inc., specific classifications have not been issued for such device combinations. As long as the component devices in a combination do not actively interact in such a manner as to introduce additional concerns of safety and efficacy, we feel that separate classification categories for various combinations is unnecessary and would introduce needless redundancy. It is our belief that the PIRD-Y device combination falls under Class II (Performance Standards.)

21 CFR 890 states that the appropriate classification panel for physical medicine devices is the Physical Medicine Device Section of the Surgical and Rehabilitation Devices Panel (formerly the Physical Medicine Device Classification Panel). The latter panel, in our opinion, is the appropriate classification body for PIRD-Y devices.

807.87(d) Compliance with Performance Standards. It is our understanding that no specific action is required relative to Performance Standard compliance under Section 514 of the Act, since the Bureau of Medical Devices (BMD) has not as yet developed or approved any Performance Standards for physical medicine equipment. Nevertheless, Pird-y, Inc. intends to fully comply with all applicable BMD and popularly recognized (e.g. AAMI, ANSI) performance standards as they become effective. Compliance will be achieved through comprehensive, independent review of all designs by Engineering, Manufacturing and Quality Assurance personnel.

807.87(e) Device Description and Labeling. As previously specified, PIRD-Y is a state-of-the-art, battery powered device composed of two functional sections. First, the PIRD-Y Electromyograph section records a conventional EMG through commercially available skin surface electrodes. As with virtually all commercially available electromyographs, the EMG is processed to provide auditory and visual indices of muscle activity for presentation to the patient; such "EMG Biofeedback" capabilities are widely used in contemporary neuromuscular rehabilitation and re-education. Secondly, the PIRD-Y Muscle Stimulator allows operator control of peak voltage, pulse frequency, and pulse width of the otherwise invariant pulsating direct current waveform.

Stimulation can be initiated manually or, in another operational mode, triggered by the EMG signal if it exceeds an operator-set EMG threshold. In the latter mode of operation, the EMG exerts absolutely no control over the parameters of muscle stimulation; EMG triggering simply offers an additional stimulus initiation means for operator convenience and flexibility, in the spirit of timer, foot-pedal and tendon-hammer stimulus activation features. The latter capabilities are offered by commercially available muscle stimulators widely used to augment movement and exercise underused muscles in neuromuscular rehabilitation and re-education.

As mentioned, the intended use of PIRD-Y is in neuromuscular rehabilitation (e.g., after stroke, brain injury, spinal cord injury, etc.) and in neuromuscular re-education (e.g., relaxation training, chiropractic treatments, biofeedback programs, etc.). The indications for use of PIRD-Y are strictly limited to those for pre-enactment electromyographs and powered muscle stimulators, used singly or in combination; there are no situations outside of the latter circumstances in which PIRD-Y will be recommended for use.

Proposed operators manual information, device labels, and preliminary advertising claims have been included as follows:

A. Operators Manual. Attachment I presents the preliminary Operator's Manual, which includes the following sections:

1. Introduction
2. Indications/Contraindications
3. Precautions and Warnings
4. Device Description
5. Routine Operating Techniques
6. How To Use PIRD-Y Devices
7. Theory of Operation
8. Maintenance
9. Specifications
10. Limited Warranty
11. Damage in Shipment
12. Returning Devices to Piridy, Inc.

B. Machine Labels. Preliminary device labels are presented in Attachment II.

C. Advertising Material. Attachment III is composed of the preliminary advertising claims for PIRD-Y devices.

807.87(f) Substantial Equivalency. Listed below are prominent commercially marketed pre-enactment and post-enactment devices relevant to consideration of substantial equivalency for the PIRD-Y instrument. Stand-alone Muscle Stimulators and Stand-alone Electromyographs are available at present and have been on the market for over a decade, so respective categories for these devices have been included in the following list. The last device category below represents Electromyograph-Muscle Stimulator combination devices. Each listing is followed by an indication of whether the earliest evidence of commercial availability which we were able to find was pre-enactment or post-enactment. In most if not all cases, an indicated pre-enactment device was also available for some post-enactment interval. Note that each cited device has been identified with a unique line item number for convenience of later reference.

A. Powered Muscle Stimulators

1. TECA Model CH3 Variable Pulse Generator and Chronaxie Meter (pre-enactment)
2. Medtronic Respond Neuromuscular Stimulator (post-enactment)
3. TECA Model SP2/T Therapeutic Stimulator (post-enactment)

4. Mentor Activator Neuromuscular Stimulator
(post-enactment)
5. Patient Care Systems Myoguard Muscle Stimulator
(post-enactment)

B. Diagnostic Electromyographs

6. Autogenic Systems Autogen Biofeedback instruments
(pre-enactment)
7. Cyborg EMG J33 EMG Biofeedback device
(pre-enactment)
8. ISIS Medical Instruments Myo-Tone EMG Biofeedback
device (pre-enactment)
9. Coulbourn Autolab 21 EMG Biofeedback device
(post-enactment)
10. Autogenics Autogen HT-1 EMG Biofeedback device
(post-enactment)
11. Thought Technology EMG 100T - GSR 2 EMG Biofeedback
combination (post-enactment)
12. Stoelting-Cyborg P303 Clinical EMG Biofeedback
device (post-enactment)

C. Diagnostic Electromyograph - Powered Muscle Stimulator
Combinations

13. TECA Model JM Modular Portable
Electromyograph-Muscle Stimulator (pre-enactment)

14. Life-Tech Instruments Model LT 9000 Portable Electromyograph-Muscle Stimulator (pre-enactment)
15. Disa Model 14A11 Portable Electromyograph - Biofeedback - Stimulator combination (pre-enactment).
16. Medic Portaline 500 B Electromyograph - Biofeedback - Stimulator combination (pre-enactment).
17. Cadwell Laboratories Model 5200 Electromyograph - Biofeedback - Stimulator combination (post-enactment).
18. Neuro Diagnostics LBM Electromyograph - Biofeedback - Stimulator combination (post-enactment).
19. Disa Neuromatic 2000-M Electromyograph - Biofeedback - Stimulator combination (post-enactment).

Attachment IV presents copies of professional journal advertisements or promotional literature mailings for each of the above listed devices. Each listing is captioned with the unique item number from the list above, a specification of the information source, and the relevant time period of verified commercial availability. Proprietary information confirming actual device sales was unavailable to Piridy, Inc.

To further detail data relevant to our claims of substantial equivalency, Attachment V itemizes PIRD-Y's major features and the corresponding devices from the list above (and Attachment IV) which have the substantially equivalent feature.

807.87(g) Non-Significant Modification. The combined use of electromyography and muscle stimulation in the PIRD-Y device does not in any way constitute a significant modification relative to previous devices combining the same functions (Category "C", Attachment IV.) The only unique feature of PIRD-Y is the EMG triggering of muscle stimulation, as an additional alternative to other traditional means of initiating muscle stimulation. PIRD-Y EMG triggering is quite similar or analogous to EMG goal thresholds in Electromyographic devices and to timer, foot-pedal and tendon-hammer triggering of Muscle Stimulators (e.g., items 7, 12, and 19 of Attachment IV, as cited in Attachment V); it simply provides added operator convenience and flexibility in certain treatment situations.

Request for Confidential Treatment of the Present 510(k) Submission. As President of Piridy, Inc., I hereby request that the Food and Drug Administration hold as confidential commercial information Piridy, Inc.'s intent to market the PIRD-Y device. Pursuant to the latter request, the following certifications are hereby provided:

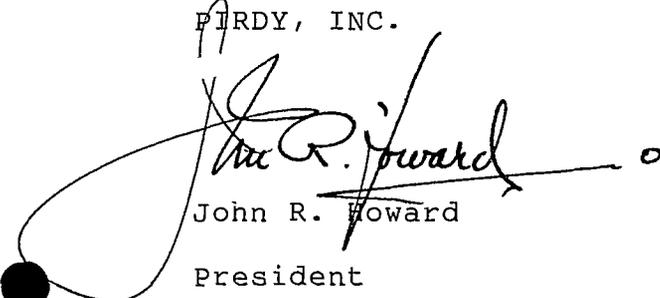
-11-

1. I consider our intent to market the PIRD-Y device to be confidential commercial information;
2. Neither I nor, to the best of my knowledge, anyone else associated with Piridy, Inc., has disclosed through advertising or any other manner, our intent to market the device to any person not associated with Piridy, Inc. as board members, employees, consultants, or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy;
3. I will immediately notify the Food and Drug Administration if I disclose the intent to market the device to anyone not associated with Piridy, Inc. as board members, employees, consultants, or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy;
4. I have taken precautions to protect the confidentiality of the intent to market the device; and
5. I understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Your prompt consideration of the present submission would be most appreciated.

Sincerely,

PIRDY, INC.



John R. Howard

President

Pirdy, Inc.

522 SW 5th

Suite #725

Portland, Or 97204

Phone: (503)241-3372

JH:lg

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 PUBLIC HEALTH SERVICE
 FOOD AND DRUG ADMINISTRATION
 INITIAL REGISTRATION
 OF MEDICAL DEVICE ESTABLISHMENT
 (Shaded Areas Are For FDA Use Only)

OMB No. 0910-0039, Approval Expires October 31, 1983.

VALIDATION	
1 REGISTRATION NO.	R

NOTE: This form is authorized by Section 510 of the Food, Drug and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of new Section 301(p) of the act (21 U.S.C. 331 (p)). Persons who violate this provision may, if convicted, be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of new Section 301(q) (2) (21 U.S.C. 331(q) (2) and may be a violation of 18 U.S.C. 1001.

SECTION A

2. ESTABLISHMENT NAME PIRDY, INC.				3. RECORD DATE (Mo.) (DAY) (Yr) 05 31 84				
4. NUMBER AND STREET 522 SW 5TH		5. CITY PORTLAND		6. STATE OR		7. ZIP CODE 97204		
8. FOREIGN COUNTRY			9. OTHER FDA REGISTRIES (Check applicable)			10. ESTABLISHMENT TYPES (Check all applicable)		
			<input type="checkbox"/> DRUGS <input type="checkbox"/> COSMETICS <input type="checkbox"/> BLOOD PRODUCTS			<input type="checkbox"/> INIT DISTR OF IMPORTED DEVICES <input checked="" type="checkbox"/> MANUFACTURER <input type="checkbox"/> REPACKAGER OR RELABELLER		

SECTION B

11. OWNER/OPERATOR PIRDY MEDICAL, INC.				12. OWNER/OPERATOR I.D.			
13. NUMBER AND STREET 595 HOWE STREET, SUITE 401		14. CITY VANCOUVER		15. STATE B.C.		16. ZIP CODE V6C 2T5	
17. FOREIGN COUNTRY CANADA		18. ESTIMATED NO. OF DEVICES ONE					

SECTION C

19. OFFICIAL CORRESPONDENT JOHN R. HOWARD				20. TELEPHONE (Area Code) (Number) (503) 241-3372			
21. BUSINESS NAME PIRDY, INC.							
22. NUMBER AND STREET 522 SW 5TH		23. CITY PORTLAND		24. STATE OR		25. ZIP CODE 97204	
26. FOREIGN COUNTRY							

SECTION D

27. OTHER BUSINESS TRADING NAMES			
SEQ	ESTABLISHMENT NAME	SEQ	ESTABLISHMENT NAME
501	NONE	502	
503		504	
505		506	

SECTION E

28. SIGNATURE OF OFFICIAL CORRESPONDENT <i>John R. Howard</i>		29. TITLE PRESIDENT AND CHAIRMAN, PIRDY, INC	
--	--	---	--

FORM FDA 2891 (2/80)

U. S. GOVERNMENT PRINTING OFFICE: 1982-359-301/1821

K842262

510 (k) PREMARKET NOTIFICATION
LETTER AND ATTACHMENTS

MAY 31, 1984

PIRDY, INC.
522 SW 5TH, SUITE 725
PORTLAND, OR 97204
(503) 241-3372

BEST AVAILABLE COPY

Food and Drug Administration
Bureau of Medical Devices
HFK - 20
8757 Georgia Avenue
Silver Spring, Maryland 20910

PREMARKET NOTIFICATION LETTER

"510(k) SUBMISSION"

Gentlemen:

This letter serves as "510(k) Notification" of the intention of Piridy, Inc. to market a device which aids neuromuscular rehabilitation and neuromuscular re-education. The following section headings directly correspond to the analogous sections of 21 CFR 807.87, to aid your review.

807.87(a) Device Name. The proprietary name is PIRD-Y. The instrument is a state-of-the-art, battery powered combination of a skin surface Electromyograph and a Powered Muscle Stimulator.

BEST AVAILABLE COPY

807.87(b) Establishment Registration Number. A completed Form FD-2891 (Initial Registration of Device Establishments) has been included with the present 510(k) submission.

807.87(c) Section 513 Classification. Both components of PIRD-Y are directly equivalent to Class II instruments as listed in 21 CFR 890 - Physical Medicine Devices. Actually, PIRD-Y only involves a limited complement of capabilities included in the two classifications, as can be seen from the following description:

A. Diagnostic Electromyograph (890.1375). PIRD-Y functions as an electromyograph, monitoring and displaying electromyographic (EMG) signals in an audio and/or visual format. However, PIRD-Y capabilities are limited to skin surface recordings only; the sophisticated electronics required for invasive needle electrode recordings and other specialty features have not been included.

BEST AVAILABLE COPY

B. Powered Muscle Stimulator (890.5850). PIRD-Y functions as an electrically powered muscle stimulator. Muscle activation is limited to large skin surface electrodes; because point and needle electrodes are excluded, maximum voltage requirements are much less than some other commercial products. PIRD-Y's indications for use reside completely within the bounds of those specified for popular, commercially available muscle stimulators.

We are not sure what the Isokinetic Testing and Evaluation System classification (890.1925) constitutes, over and above that encompassed by the combination of Diagnostic Electromyographs and Powered Muscle Stimulators. The crucial fact is that PIRD-Y instruments are not designed for rehabilitative exercise or any other purpose distinct from the indications for use applicable to commercially available Powered Muscle Stimulators (e.g. items 2, 4, and 5, Section 807.87(f) below).

Some instrument combinations composed of both of the above Class II device categories are presently available commercially, but to the knowledge of Piridy, Inc., specific classifications have not been issued for such device combinations. As long as the component devices in a combination do not actively interact in such a manner as to introduce additional concerns of safety and efficacy, we feel that separate classification categories for various combinations is unnecessary and would introduce needless redundancy. It is our belief that the PIRD-Y device combination falls under Class II (~~Performance Standards.~~)

BEST AVAILABLE COPY

21 CFR 890 states that the appropriate classification panel for physical medicine devices is the Physical Medicine Device Section of the Surgical and Rehabilitation Devices Panel (formerly the Physical Medicine Device Classification Panel). The latter panel, in our opinion, is the appropriate classification body for PIRD-Y devices.

807.87(d) Compliance with Performance Standards. It is our understanding that no specific action is required relative to Performance Standard compliance under Section 514 of the Act, since the Bureau of Medical Devices (BMD) has not as yet developed or approved any Performance Standards for physical medicine equipment. Nevertheless, Pird-y, Inc. intends to fully comply with all applicable BMD and popularly recognized (e.g. AAMI, ANSI) performance standards as they become effective. Compliance will be achieved through comprehensive, independent review of all designs by Engineering, Manufacturing and Quality Assurance personnel.

807.87(e) Device Description and Labeling. As previously specified, PIRD-Y is a state-of-the-art, battery powered device composed of two functional sections. First, the PIRD-Y Electromyograph section records a conventional EMG through commercially available skin surface electrodes. As with virtually all commercially available electromyographs, the EMG is processed to provide auditory and visual indices of muscle activity for presentation to the patient; such "EMG Biofeedback" capabilities are widely used in contemporary neuromuscular rehabilitation and re-education. Secondly, the PIRD-Y Muscle Stimulator allows operator control of peak voltage, pulse frequency, and pulse width of the otherwise invariant pulsating direct current waveform.

BEST AVAILABLE COPY

Stimulation can be initiated manually or, in another operational mode, triggered by the EMG signal if it exceeds an operator-set EMG threshold. In the latter mode of operation, the EMG exerts absolutely no control over the parameters of muscle stimulation; EMG triggering simply offers an additional stimulus initiation means for operator convenience and flexibility, in the spirit of timer, foot-pedal and tendon-hammer stimulus activation features. The latter capabilities are offered by commercially available muscle stimulators widely used to augment movement and exercise underused muscles in neuromuscular rehabilitation and re-education.

As mentioned, the intended use of PIRD-Y is in neuromuscular rehabilitation (e.g., after stroke, brain injury, spinal cord injury, etc.) and in neuromuscular re-education (e.g., relaxation training, chiropractic treatments, biofeedback programs, etc.). The indications for use of PIRD-Y are strictly limited to those for pre-enactment electromyographs and powered muscle stimulators, used singly or in combination; there are no situations outside of the latter circumstances in which PIRD-Y will be recommended for use.

BEST AVAILABLE COPY

Proposed operators manual information, device labels, and preliminary advertising claims have been included as follows:

A. Operators Manual. Attachment I presents the preliminary Operator's Manual, which includes the following sections:

1. Introduction
2. Indications/Contraindications
3. Precautions and Warnings
4. Device Description
5. Routine Operating Techniques
6. How To Use PIRD-Y Devices
7. Theory of Operation
8. Maintenance
9. Specifications
10. Limited Warranty
11. Damage in Shipment
12. Returning Devices to Piridy, Inc.

B. Machine Labels. Preliminary device labels are presented in Attachment II.

C. Advertising Material. Attachment III is composed of the preliminary advertising claims for PIRD-Y devices.

BEST AVAILABLE COPY

807.87(f) Substantial Equivalency. Listed below are prominent commercially marketed pre-enactment and post-enactment devices relevant to consideration of substantial equivalency for the PIRD-Y instrument. Stand-alone Muscle Stimulators and Stand-alone Electromyographs are available at present and have been on the market for over a decade, so respective categories for these devices have been included in the following list. The last device category below represents Electromyograph-Muscle Stimulator combination devices. Each listing is followed by an indication of whether the earliest evidence of commercial availability which we were able to find was pre-enactment or post-enactment. In most if not all cases, an indicated pre-enactment device was also available for some post-enactment interval. Note that each cited device has been identified with a unique line item number for convenience of later reference.

A. Powered Muscle Stimulators

1. TECA Model CH3 Variable Pulse Generator and Chronaxie Meter (pre-enactment)
2. Medtronic Respond Neuromuscular Stimulator (post-enactment)
3. TECA Model SP2/T Therapeutic Stimulator (post-enactment)

BEST AVAILABLE COPY

4. Mentor Activator Neuromuscular Stimulator
(post-enactment)

5. Patient Care Systems Myoguard Muscle Stimulator
(post-enactment)

B. Diagnostic Electromyographs

6. Autogenic Systems Autogen Biofeedback instruments
(pre-enactment)

7. Cyborg EMG J33 EMG Biofeedback device
(pre-enactment)

8. ISIS Medical Instruments Myo-Tone EMG Biofeedback
device (pre-enactment)

9. Coulbourn Autolab 21 EMG Biofeedback device
(post-enactment)

10. Autogenics Autogen HT-1 EMG Biofeedback device
(post-enactment)

11. Thought Technology EMG 100T - GSR 2 EMG Biofeedback
combination (post-enactment)

12. Stoelting-Cyborg P303 Clinical EMG Biofeedback
device (post-enactment)

C. Diagnostic Electromyograph - Powered Muscle Stimulator
Combinations

13. TECA Model JM Modular Portable
Electromyograph-Muscle Stimulator (pre-enactment)

14. Life-Tech Instruments Model LT 9000 Portable Electromyograph-Muscle Stimulator (pre-enactment)
15. Disa Model 14All Portable Electromyograph - Biofeedback - Stimulator combination (pre-enactment).
16. Medic Portaline 500 B Electromyograph - Biofeedback - Stimulator combination (pre-enactment).
17. Cadwell Laboratories Model 5200 Electromyograph - Biofeedback - Stimulator combination (post-enactment).
18. Neuro Diagnostics LBM Electromyograph - Biofeedback - Stimulator combination (post-enactment).
19. Disa Neuromatic 2000-M Electromyograph - Biofeedback - Stimulator combination (post-enactment).

Attachment IV presents copies of professional journal advertisements or promotional literature mailings for each of the above listed devices. Each listing is captioned with the unique item number from the list above, a specification of the information source, and the relevant time period of verified commercial availability. Proprietary information confirming actual device sales was unavailable to Piridy, Inc.

BEST AVAILABLE COPY

To further detail data relevant to our claims of substantial equivalency, Attachment V itemizes PIRD-Y's major features and the corresponding devices from the list above (and Attachment IV) which have the substantially equivalent feature.

807.87(g) Non-Significant Modification. The combined use of electromyography and muscle stimulation in the PIRD-Y device does not in any way constitute a significant modification relative to previous devices combining the same functions (Category "C", Attachment IV.) The only unique feature of PIRD-Y is the EMG triggering of muscle stimulation, as an additional alternative to other traditional means of initiating muscle stimulation. PIRD-Y EMG triggering is quite similar or analogous to EMG goal thresholds in Electromyographic devices and to timer, foot-pedal and tendon-hammer triggering of Muscle Stimulators (e.g., items 7, 12, and 19 of Attachment IV, as cited in Attachment V); it simply provides added operator convenience and flexibility in certain treatment situations.

Request for Confidential Treatment of the Present 510(k) Submission. As President of Piridy, Inc., I hereby request that the Food and Drug Administration hold as confidential commercial information Piridy, Inc.'s intent to market the PIRD-Y device. Pursuant to the latter request, the following certifications are hereby provided:

BEST AVAILABLE COPY

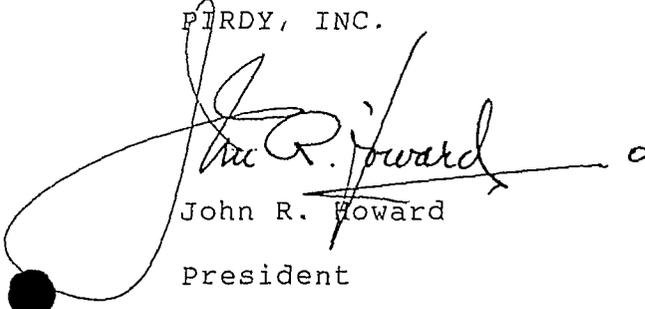
1. I consider our intent to market the PIRD-Y device to be confidential commercial information;
2. Neither I nor, to the best of my knowledge, anyone else associated with Piridy, Inc., has disclosed through advertising or any other manner, our intent to market the device to any person not associated with Piridy, Inc. as board members, employees, consultants, or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy;
3. I will immediately notify the Food and Drug Administration if I disclose the intent to market the device to anyone not associated with Piridy, Inc. as board members, employees, consultants, or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy;
4. I have taken precautions to protect the confidentiality of the intent to market the device; and
5. I understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

BEST AVAILABLE COPY

Your prompt consideration of the present submission would be most appreciated.

Sincerely,

PIRDY, INC.



John R. Howard

President

Pirdy, Inc.

522 SW 5th

Suite #725

Portland, Or 97204

Phone: (503)241-3372

JH:lg

BEST AVAILABLE COPY

ATTACHMENT I

PIRD-Y

(PRELIMINARY) OPERATORS MANUAL

MAY, 1984

Pirby, Inc.
522 S.W. 5th - Suite 725
Portland, Oregon 97204
(503) 241-3372

=====
TABLE OF CONTENTS
=====

	<u>Page</u>
1. INTRODUCTION	1
2. INDICATIONS/CONTRAINDICATIONS	2
3. PRECAUTIONS AND WARNINGS	3
4. DEVICE DESCRIPTION	4
5. ROUTINE OPERATING TECHNIQUES	7
6. HOW TO USE PIRD-Y DEVICES	8
7. THEORY OF OPERATION	13
8. MAINTENANCE	15
9. SPECIFICATIONS	16
10. LIMITED WARRANTY	18
11. DAMAGE IN SHIPMENT	18
12. RETURNING DEVICES TO PIRDY, INC.	18

PIRD-Y (PRELIMINARY) OPERATORS MANUAL

=====
INTRODUCTION
=====

PIRD-Y is a combination instrument composed of an electromyograph and a muscle stimulator. Its basic uses are in the diagnosis of muscular disfunction, and in neuromuscular rehabilitation (e.g., after stroke, brain injury, spinal cord trauma, etc.) and neuromuscular re-education (e.g., relaxation training, chiropractic treatments, biofeedback programs, etc.). The PIRD-Y system is composed of the device itself, and an accessory pack containing necessary electrodes (with leads), electrode paste, and electrode retention tape.

PIRD-Y's hallmark is its simplicity of operation and state-of-the-art design. The quite complicated circuitry and operation exhibited by many commercial products dedicated to sophisticated tasks such as NCV and MUP have been deliberately avoided. The primary goal was to provide a very simple to operate and economical device, suitable for routine use by the average practitioner. Specifically, PIRD-Y devices possess the following features:

- * simple to use
- * easy setup
- * truly portable
- * non-invasive
- * economical
- * battery powered
- * rechargeable
- * solid-state electronics

=====
INDICATIONS AND CONTRAINDICATIONS
=====

PIRD-Y devices are indicated for the following:

1. Neuromuscular rehabilitation following CVA (stroke), brain injury, spinal cord trauma, cerebral palsy, etc.;
2. Neuromuscular re-education accompanying relaxation training, chiropractic treatments, biofeedback programs, etc.;
3. Retardation of disuse atrophy secondary to CVA (stroke), paralysis, trauma, CNS injury, cerebral palsy, lower motor neuron disease, etc.;
4. Facilitation of voluntary motor function;
5. Circulatory stimulation of selected muscle groups following surgery, injury, or relative disuse; and
6. Maintenance or enhancement of range of motion.

There are presently no known contraindications for using PIRD-Y devices.

=====
PRECAUTIONS AND WARNINGS
=====

WARNING: Do not, under any circumstances, perform any testing or maintenance on PIRD-Y instruments, cables, or electrodes while they are being used with a patient.

IMPORTANT: Disconnect the detachable power cord from the PIRD-Y device prior to use.

Cardiac Pacemakers: some cardiac pacemakers can be inhibited or otherwise disturbed by transcutaneous neuromuscular stimulation; therefore, PIRD-Y devices are not recommended for use with patients on cardiac pacemakers.

Heart Patients: it is essential to address all relevant precautionary measures applicable to the subject case prior to applying muscle stimulation to a patient diagnosed or suspected of having heart disease. Available clinical data does not preclude adverse results when administering muscle stimulation to such patients.

Neck Stimulation: muscle stimulation in the region of the neck may induce spasm of laryngeal and pharyngeal muscles; if severe, this could induce airway obstruction.

Carotid Sinus: muscle stimulation should never be applied over the carotid sinus nerves, especially if sinus reflex sensitivity is known to be present.

Pregnancy: inadequate clinical data is available at present to determine the safety of muscle stimulation applied during pregnancy.

Children: keep all PIRD-Y devices out of the reach of children.

Skin Irritation: skin irritation may occasionally occur at the site of muscle stimulation electrodes; upon the observation of irritation, terminate all stimulation until the source of irritation is determined. Skin irritation problems may be solved by moving the electrodes to an adjacent location, by careful uniform reapplication of electrode gel to the electrodes, and/or by reduction in the time-averaged power of stimulation.

Note: Complete maintenance instructions for this instrument are contained in the PIRD-Y Devices Maintenance Manual. Refer all repairs and maintenance to qualified personnel.

=====
DEVICE DESCRIPTION
=====

Modes of Operation

PIRD-Y has five operational modes. The EMG Mode (see the PIRD-Y front panel depicted in Figure 1) is an Electromyographic function, where EMG (electromyographic) potentials are detected through skin surface electrodes, and processed to provide a bargraph and a digital display of EMG amplitude (in microvolts). The digital display temporarily 'holds' at the EMG maximum value during a muscle action trial, for convenience in diagnosis or for EMG Biofeedback^K (when the patient is allowed to observe the displays).

In the STIM Mode, PIRD-Y functions as a stand-alone Muscle Stimulator, permitting the application of stimuli to skin surface electrodes, with operator control of intensity, pulse width, and frequency. PIRD-Y's output waveform is a two-second train of monophasic, constant-power pulses, each pulse having a rounded rising phase and an approximately exponential decay. The operator manually controls stimulation, by moving the Run/Setup switch to the Run position for stimulus initiation and to the Setup position for stimulus termination.

Muscle stimulation in the EMG-STIM Mode is identical to that of the STIM Mode, but the two-second period of muscle stimulation is triggered when the simultaneously recorded EMG exceeds an operator-set threshold value; this feature provides operator convenience and flexibility in stimulus triggering, but the recorded EMG exerts no control whatsoever over the parameters of muscle stimulation. In the EMG-STIM Mode, EMG recording and muscle stimulation are accomplished through the same pair of skin surface electrodes.

The EMG-REMOTE Mode is analogous to the EMG-STIM Mode, except that EMG recording is accomplished through one set of electrodes (overlying one muscle or group) while muscle stimulation is applied to a second muscle group.

Finally, the EMG-AUDIO Mode is similar to the EMG-STIM Mode, but involves presentation of a two-second audio tone, rather than two-seconds of muscle stimulation, when the EMG trigger threshold is exceeded. The EMG-AUDIO Mode provides the second sensory modality of auditory feedback, in addition to the visual feedback featured in the EMG Mode.

FIGURE 1A: PIRD-Y CONTROL PANEL

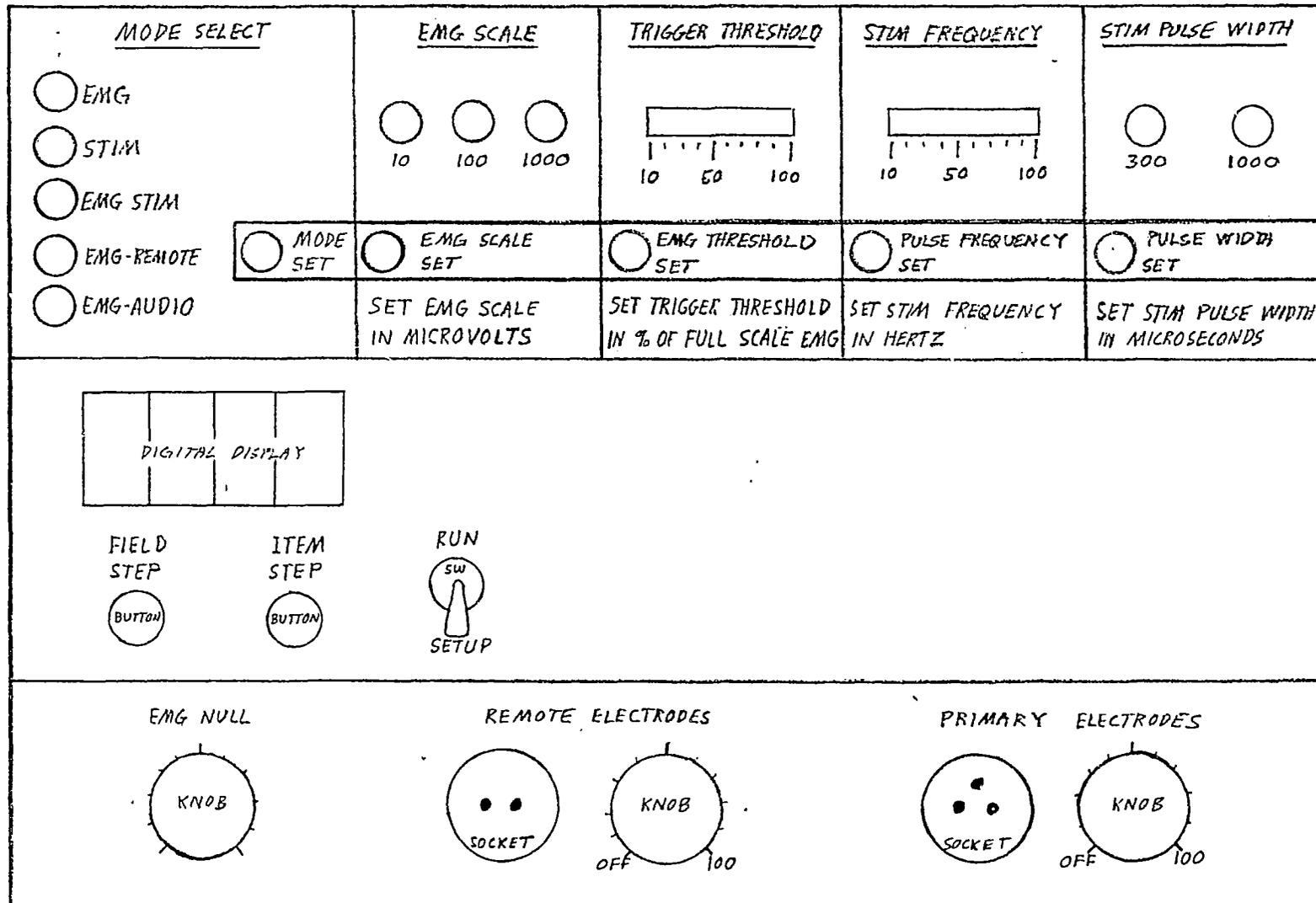
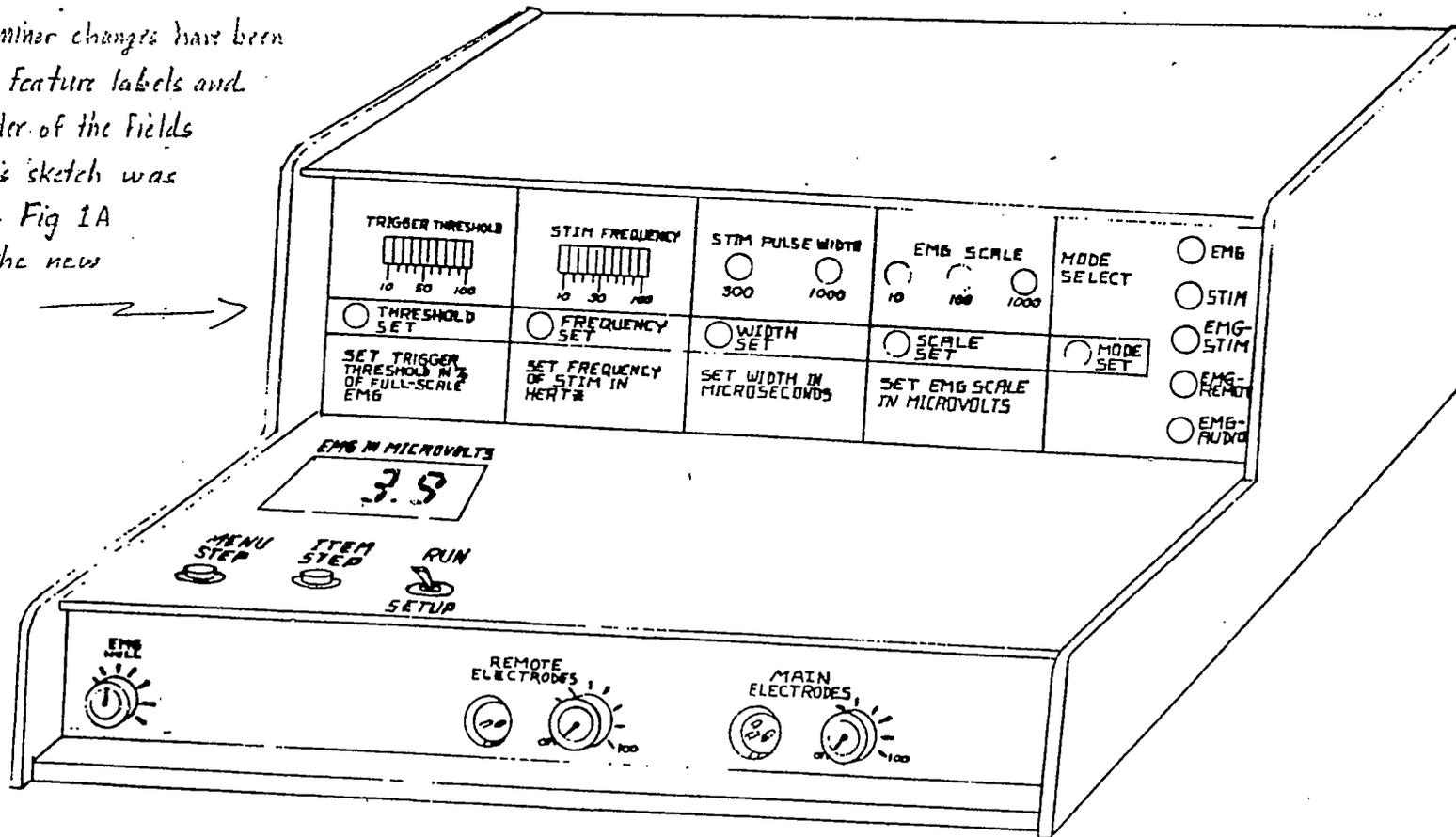


FIGURE 1B: SKETCH OF PIRD-Y DEVICE

Note: minor changes have been made to feature labels and to the order of the fields since this sketch was drawn - Fig 1A shows the new details



Control Functions and Displays

The PIRD-Y interface panel (see Figure 1) is composed of five fields which direct setup and operation, accompanied by electrode connection sockets and appropriate control knobs and switches. Each interface panel feature is described below:

On/Off Switch (on the back of the instrument): when the PIRD-Y device is turned on, it comes up in the EMG Mode, so that the Muscle Stimulator is deactivated (see the "How to Use PIRD-Y" section). PIRD-Y will produce a chirping sound when turned on if the Run/Setup switch was inadvertently left in the Run position; move the switch to the Setup position to mute the chirping sound.

Run/Setup Switch: the Setup Mode permits selection of desired recording and stimulation parameters, while the Run Mode activates PIRD-Y for clinical treatment.

Field Step: each depression of the button successively 'walks' through the five 'Set' fields; the presently addressed field is indicated by the respective front panel field indicator light located in the broad central band traversing the five fields.

Item Step: within a given Set field, the desired choice of operation is selected by depressing the Item Step button until the desired function (acknowledged by the appropriate indicator light) is activated.

EMG Null: this control permits the digital display to be adjusted to a reading of zero, for readout calibration under conditions of minimal muscle activity.

Primary Electrodes: the three-pronged connector permits attachment of the two active EMG leads and the ground lead to the PIRD-Y input stage. When the operator desires to monitor EMG's and apply muscle stimulation to the same muscle, PIRD-Y allows both procedures to be accomplished through the same electrodes (for this configuration, the electrodes must be attached to the Primary Electrodes connector). The knob adjacent to the electrode connector permits On/Off and Intensity control of such muscle stimulation.

Remote Electrodes: this two pronged connector permits attachment of (remote) electrodes, for stimulating a muscle other than that serving as the source of EMG signals. The Remote Electrodes are never used alone, but only in concert with the Primary Electrodes when separate EMG Monitoring and Muscle Stimulation sites are employed. The knob adjacent to the electrode connector permits On/Off and intensity control of muscle stimulation through the Remote Electrodes.

Mode Set Field: successive depression of the Item Set button allows the operator to select one of five PIRD-Y modes of operation. The five operational modes have been previously described (see Modes of Operation Section).

EMG Scale Set Field: successive depression of the Item Set button allows selection of the EMG recording scale range (in microvolts). In all cases, the lower limit of the EMG recording scale is zero.

Threshold Set Field: depression of the Item Set button while in the Threshold Set Field allows the operator to select a desired EMG threshold level for triggering muscle stimulation. The bargraph scale is calibrated as a percentage of full scale EMG; full scale EMG is set separately, as described above. The Threshold Set operation applies only to the EMG-STIM, EMG-REMOTE and EMG-AUDIO Modes of operation (see below).

Frequency Set Field: depression of the Item Set button allows selection of the desired muscle stimulation pulse frequency (in Hertz).

Pulse Width Set: successive depression of the Item Set button permits alternative selection of either a 300 us or a 1000 us pulse width for muscle stimulation. Pulse width should be selected based on the optimal combination of patient comfort and muscle stimulation effectiveness.

Digital Display: the instantaneous value of the EMG, updated many times each second, is displayed. For diagnostic convenience, the display holds the maximum value achieved (defined as that value just preceding any period of 2 seconds in which the value does not rise) for a period of 2 seconds.

EMG Trigger Threshold Display (Bargraph): when PIRD-Y is in the Run Mode, the EMG trigger threshold bargraph displays a value of 100% (every bargraph element is lit) when the previously set EMG threshold value is exceeded. This provides a dramatic indication of goal achievement. Prior to exceeding the threshold, the EMG Trigger Threshold Display indicates the actual instantaneous EMG value, providing an alternative to observation of the digital display for tracking progress of the emerging EMG.

Stimulation Frequency Display (Bargraph): the display indicates the existent setting for the muscle stimulation pulse frequency, in Hertz.

=====
ROUTINE OPERATING TECHNIQUE
=====

Recording Environment. The EMG Recording portion of PIRD-Y is highly sensitive, as it must be for appropriate responsiveness to the quite weak and elusive voltages available at the skin surface from underlying muscle activity.

CAUTION: the pronounced electromyograph sensitivity of PIRD-Y means that, in addition, any electrical artifacts (e.g., A.C., movement artifacts, etc.) that are present may also be recorded. Careful attention to the technical instructions in this manual can permit elimination or minimization of any artifacts which are present.

Instrument Location. The device and patient should be located as far as possible from equipment cords, fluorescent lights, office or house wiring, and other potential sources of electrical interference. Reasonable precautions can nearly always obviate the need for shielding.

Electrodes. The accessory package includes electrodes which are specifically compatible with this instrument. The use of other electrodes is not recommended, since the metals may be dissimilar and considerable baseline drifting or blocking may result.

Electrodes should be initially clean and dry. Apply a high quality electrolyte gel as a thin, uniform layer covering the entire electrode surface. After thoroughly cleansing the skin with alcohol, apply the electrodes to preselected skin locations according to established procedures for the desired clinical treatment. The electrodes should be firmly held in place using non-allergic tape or some other suitable retention mechanism.

=====
HOW TO USE PIRD-Y DEVICES
=====

EMG Monitoring/EMG Biofeedback

To operate the instrument as a stand-alone EMG Monitor:

1. Insure that both the PRIMARY ELECTRODE and the REMOTE ELECTRODE knobs are in the full counterclockwise (OFF) positions.
2. Move the RUN/SETUP toggle switch to the SETUP position, and turn the instrument ON (switch on the back panel).
3. Successively depress the FIELD STEP button until the MODE SET indicator is lit. (An instrument which was just turned ON will 'come up' in the Mode Set Field automatically).
4. Successively depress the ITEM STEP button until the EMG indicator is lit.
5. Depress the FIELD SET button once, to select the EMG SCALE field (the EMG SCALE SET indicator will be illuminated).
6. While the patient deeply relaxes the subject muscle, adjust the EMG NULL knob until the digital display reads zero (or, on average, as near to zero as possible).
7. During several trials of maximal patient effort to activate the subject muscle, observe the maximum EMG signal reading on the DIGITAL DISPLAY. From the latter readings, determine a desired EMG signal range (10, 100, or 1000 uvolts) such that maximal efforts result in conveniently observable changes that do not exceed the range maximum.
8. Depress the ITEM SET button, if necessary, to select the desired EMG SCALE maximum value (10, 100, or 1000 microvolts, as signaled by the respective indicator light in the EMG SCALE field).
9. Place the instrument in the RUN Mode by moving the RUN/SETUP toggle switch to the RUN position.
10. Visual EMG Biofeedback can be directly accomplished in the EMG Mode by allowing the patient to observe the instrument control panel (the DIGITAL DISPLAY and/or the TRIGGER THRESHOLD BARGRAPH, as desired).

Muscle Stimulation

To operate the instrument as a stand-alone Muscle Stimulator:

1. Insure that the PRIMARY ELECTRODES and the REMOTE ELECTRODES knobs are in full counterclockwise (OFF) positions.
2. Move the RUN/SETUP toggle switch to the SETUP position, and turn the instrument ON (switch on the back panel).
3. Successively depress the FIELD STEP button until the MODE SET indicator is lit (an instrument which was just turned ON will 'come up' in the Mode Set Field automatically).
4. Successively depress the ITEM STEP button until the STIM (Stimulation) button is lit.
5. Successively depress the FIELD STEP button until the FREQUENCY SET indicator is lit.
6. Continuously depress the ITEM SET button until the desired muscle stimulus frequency in Hertz (as shown on the STIM FREQUENCY BARGRAPH) is achieved.
7. Depress the FIELD STEP button once to select the PULSE WIDTH SET Field (the PULSE WIDTH SET indicator will be illuminated).
8. If the desired pulse width is incorrect, as revealed by the respective indicator for the 300 us or 1000 us pulse width alternatives, depress the ITEM STEP button once to select the other pulse width alternative.
9. To initiate a stimulus trial, place the instrument in the RUN Mode by moving the RUN/SETUP toggle switch to the RUN position; the stimulus train will continue until the RUN/SETUP toggle switch is returned to the SETUP position.
10. Rotate the PRIMARY ELECTRODES knob clockwise from the (OFF) position to the point where it has been turned on but resides at minimal intensity.
11. With the patient repeatedly attempting a series of the desired treatment movements, adjust the intensity of muscle stimulation to an appropriate level by rotating the PRIMARY ELECTRODES knob.
12. If necessary, readjust the stimulus pulse width (see steps 7 and 8 above) to achieve the optimal combination of stimulus comfort and effectiveness.

EMG-Triggered Muscle Stimulation

To operate the instrument as a Muscle Stimulator triggered by the EMG:

1. Insure that the PRIMARY ELECTRODE and the REMOTE ELECTRODE knobs are in the full counterclockwise (OFF) positions.
2. Move the RUN/SETUP toggle switch to the SETUP position, and turn the instrument ON (switch on the back panel).
3. Successively depress the FIELD STEP button until the MODE SET indicator is lit (an instrument which was just turned ON will 'come up' in the Mode Set Field automatically.
4. Successively depress the ITEM STEP button until the desired operational Mode has been selected, as revealed by illumination of the appropriate indicator light in the MODE SET Field menu. The relevant choices are as follows:
 - A. EMG-STIM Mode: EMG Monitoring and Muscle Stimulation applied to the same muscle through the same electrodes (one set of electrodes, connected to the PRIMARY ELECTRODE connector);
 - B. EMG-REMOTE Mode: EMG Monitoring through the PRIMARY ELECTRODES connector leads and Muscle Stimulation through the REMOTE ELECTRODES connector; this Mode permits activation of the Muscle Stimulator by EMG activity in a separate muscle on the same or opposite side of the body; and
 - C. EMG-AUDIO Mode: this Mode is similar to the EMG-STIM Mode, but involves presentation of a two-second tone instead of a two-second period of muscle stimulation.
5. Depress the FIELD SET button once, to select the EMG SCALE field (the EMG SCALE SET indicator will be illuminated).

6. The particular patient movement which is the subject of the present treatment should now be attempted several times; depress the ITEM STEP button successively to select an EMG recording range such that the response is readily measurable but does not exceed the upper scale boundary.
7. Continue to attempt the subject patient movement several times while observing the TRIGGER THRESHOLD BARGRAPH, to determine an appropriate EMG Threshold Level (usually, a level 90-100% of the maximum EMG value which, on average, the patient can achieve). Depress the FIELD STEP button once, to select the Trigger Threshold Field. Then, successively depress the ITEM STEP button until the Trigger Threshold Bargraph indicates the desired EMG trigger threshold.
8. Adjust the Muscle Stimulation intensity, using either the PRIMARY ELECTRODES OFF/INTENSITY knob or the REMOTE ELECTRODES OFF/INTENSITY knob, as appropriate to the Mode of operation previously selected.
9. Successively depress the FIELD STEP button until the FREQUENCY SET indicator is lit.
10. Continuously depress the ITEM SET button until the desired muscle stimulus frequency in Hertz (as shown on the STIM FREQUENCY BARGRAPH) is achieved.
11. Depress the FIELD STEP button once, to select the PULSE WIDTH SET Field (the PULSE WIDTH SET indicator will be illuminated). Pulse width should be selected based on a balance between desired muscle effect and patient comfort.
12. If the desired pulse width is incorrect, as revealed by the respective indicator for the 300 us or 1000 us pulse width alternatives, depress the ITEM STEP button once to select the other pulse width alternative.
13. Place the Instrument in the RUN Mode by moving the RUN/SETUP toggle switch to the RUN position. Treatment can now be initiated, with a 2 second muscle stimulation episode being initiated every time the patient causes, through a conscious effort at movement, a suprathreshold EMG in the muscle which is the target of EMG monitoring.

Treatment Termination

Instrument operations to terminate treatment are as follows:

1. Insure that both the PRIMARY ELECTRODE and REMOTE ELECTRODE knobs are positioned to the full counterclockwise (OFF) positions.
2. Move the RUN/SETUP toggle switch to the SETUP position, and turn the instrument Off by moving the switch on the back panel to the OFF/CHARGE position .
3. Remove the electrodes from the patient and carefully clean them in preparation for storage.

Battery Recharging

After 5-10 hours (or less) of instrument use, the batteries of the unit should be recharged. This is accomplished by connecting the female connector of the detachable power cord to the receptacle on the back of the PIRD-Y unit and plugging the other end of the power cord into an appropriate electrical power outlet.

WARNING: Never operate the PIRD-Y instrument for treatment or test while the unit is recharging. The ON/OFF switch on the instrument back panel must be set to the OFF/CHARGE position for recharging.

WARNING: Always insure that the parameters of electrical power available at the power outlet are compatible with the power requirement specifications of the PIRD-Y device.

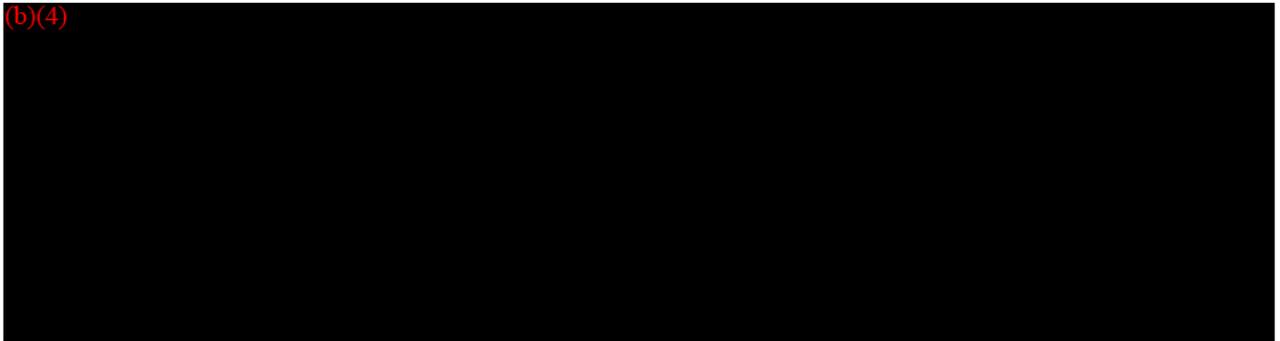
=====
THEORY OF OPERATION
=====

Signal Detection and Processing. Reference should be made to Figure 2 for the following descriptions. An electromyographic (EMG) signal received by the two ungrounded **PRIMARY ELECTRODES** is transmitted through a pair of

(b)(4)

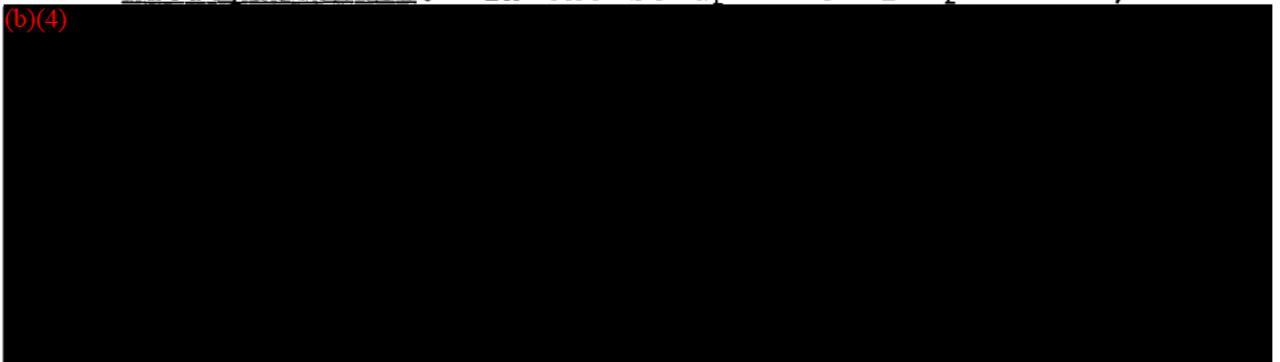


(b)(4)



Microprocessor. In the Setup Mode of Operation, the

(b)(4)

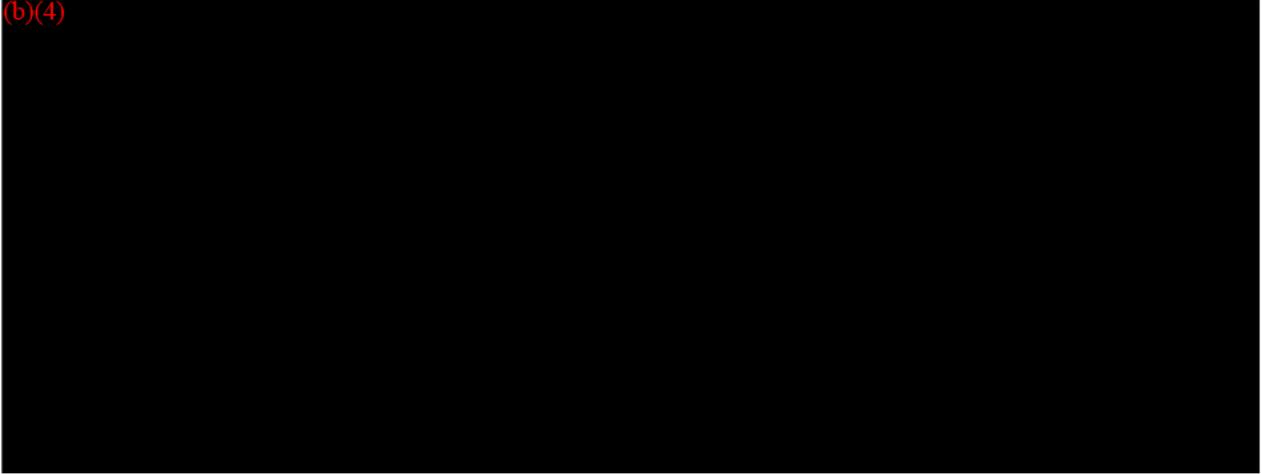


In the Run Mode of Operation, the **MICROPROCESSOR**

(b)(4)



(b)(4)

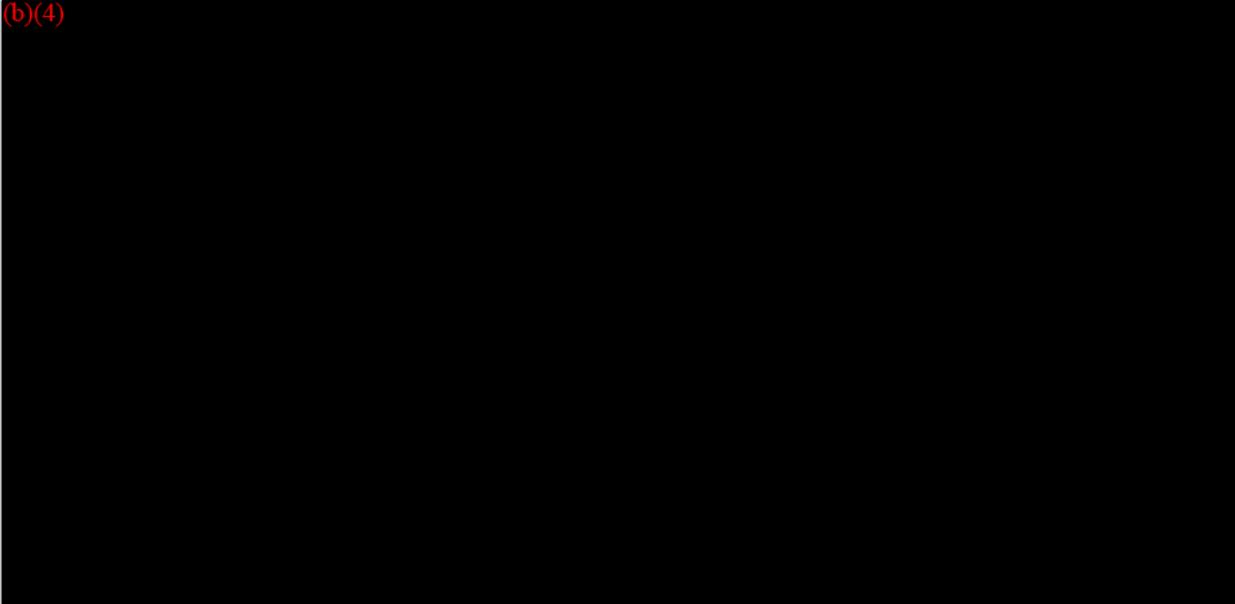


(b)(4)



Muscle Stimulation Channels. Proceeding peripherally

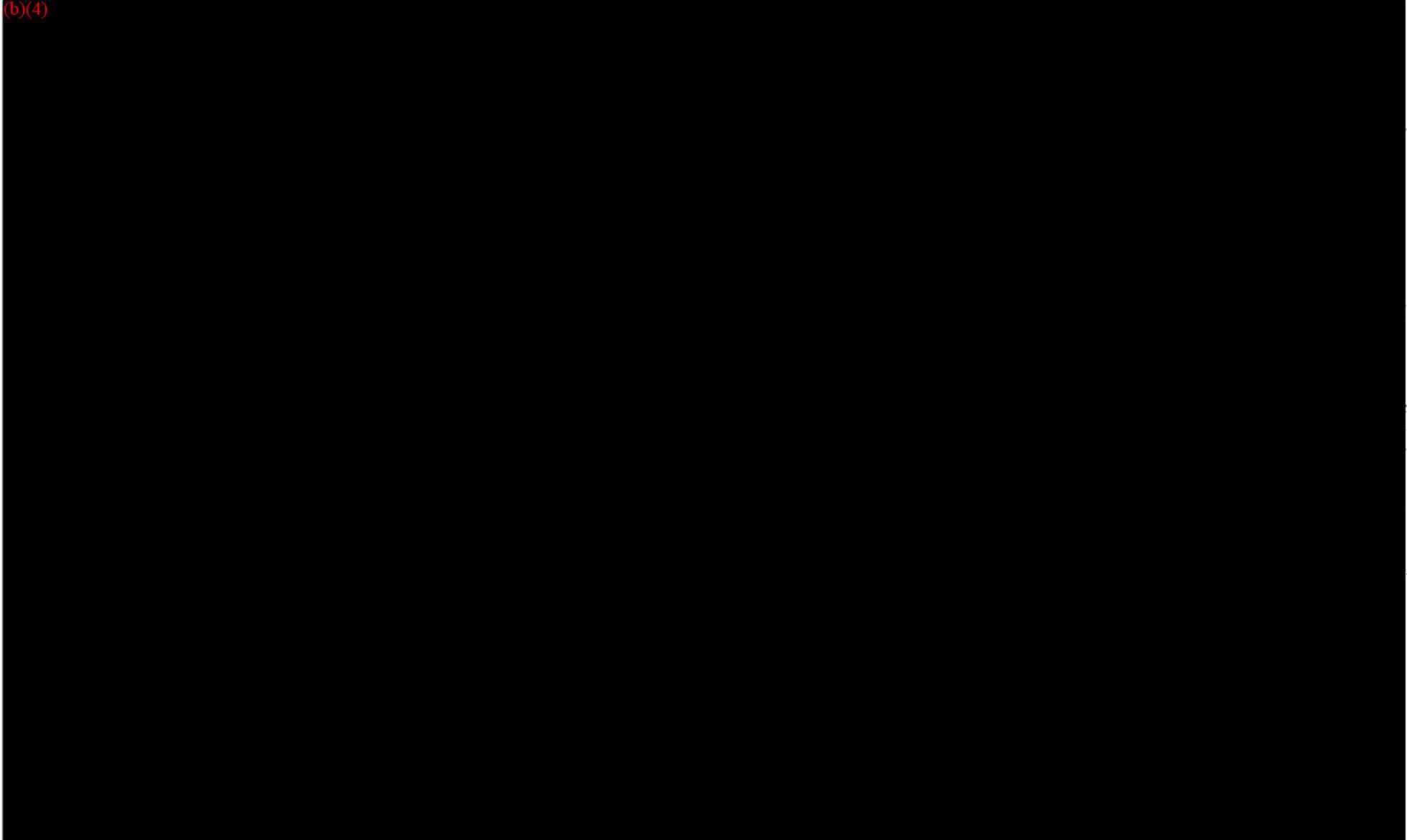
(b)(4)



The use of a step-up transformer design provides a major safety feature, in that for a worst-case shorting of the primary and secondary windings, the subject could only be exposed to about 9 volts.

FIGURE 2

(b)(4)



Power Source. Of fourteen 1.25 volt rechargeable Nicad batteries making up the BATTERY PACK, eight batteries are used to obtain the +10 volt supply (with a center-tap to also provide +5 volts), and six batteries are used to obtain the -7.5 volt supply. The BATTERY PACK is concomitantly disconnected from 110 VAC power for PIRD-Y operation by placing the POWER SWITCH in the down position (OFF/CHARGE). Moving the POWER SWITCH to the up position (POWER ON) disconnects all PIRD-Y internal circuitry from the BATTERY PACK, and connects the BATTERY PACK to 110 VAC power (through a back-panel CHARGER CORD PLUG and a BATTERY CHARGER unit featuring an ISOLATION TRANSFORMER) by moving the POWER SWITCH to the up position (POWER ON).

Three layers of protection are imposed to prevent the possibility of the PIRD-Y device becoming connected to earth ground through the battery recharging circuitry. First, the POWER SWITCH prevents simultaneous operation and recharging. Secondly, the device is labeled for disconnection of the detachable power cord during PIRD-Y operation. Finally, the BATTERY CHARGER unit contains an isolation transformer which effectively disrupts earth ground. All PIRD-Y cabinetry is non-conductive.

=====
MAINTENANCE
=====

A normally functioning PIRD-Y instrument does not require routine maintenance. The PIRD-Y Devices Maintenance Manual describes certain troubleshooting and maintenance operations amenable to technically competent users. All other device problems are to be referred to qualified Piridy, Inc. service representatives. To optimize customer convenience, Piridy, Inc. offers a board exchange program at all service centers to minimize repair time.

=====
SPECIFICATIONS
=====

EMG Recorder

Leads: two a.c.-coupled differential; one ground.
Range: three; 0-10 uv, 0-100 uv, and 0-1000 uv.
Maximum Sensitivity: 5 uv.

EMG Indications (EMG Biofeedback)

Visual: three and one half digit display; maximum value during an individual muscle movement trial is held for two seconds.
Auditory: EMG-AUDIO Mode; 2 second, fixed-frequency tone triggered by suprathreshold EMG signal.
EMG-STIM and EMG-REMOTE Modes (some models); fixed-intensity tone proportional in frequency to the EMG signal intensity.

Muscle Stimulator

Output voltage: 20-120 volts, approximately constant power output.
Output impedance: 1000 ohms maximum.
Pulse duration: 300 us or 1000 us, selectable.
Pulse waveform: monophasic; rounded rising phase, and approximate exponential decay.
Stimulus: electrodes shared with the EMG recording, or independent from EMG recording.
Pulse repetition rate: 20-100 Hz, selectable

External Connectors

Three-pronged connector for EMG recording leads (muscle stimulation can be accomplished through the same electrodes in certain operational modes).

Two-pronged connector for Remote Muscle Stimulation (used when EMG Recording and Muscle Stimulation involve different muscles).

Three-pronged power cord connector for power cord (used during battery recharging only).

Power

Internal rechargeable batteries (14): 1.25 volt Nicad

Battery Charger power requirements: 110-120 volts,
50-60 Hz.

Mechanical

Dimensions: 12" width, 8" depth, 5" max. height
Weight: 4 lbs. Shipping Weight: 5 lbs.

=====
LIMITED WARRANTY
=====

PIRD-Y Electromyographic stimulators are guaranteed against workmanship and material defects for a period of one year. During the latter period, repairs or replacements will be made at the manufacturing facility or service center at no cost to the purchaser, provided that the instrument is returned transportation prepaid. Notify the destination Piridy, Inc. facility prior to shipment.

Service personnel will be made available at the customer's location in the Continental U.S. and Canada within one week of notice, the cost of round-trip airfare to be paid by the customer.

A visit to the customer's facility can be made at no charge, when scheduled at the option of Piridy, Inc.

The PIRD-Y Limited Warranty excludes the following situations from this guarantee: mishandled or abused equipment; and any devices that have been modified without the prior approval of Piridy, Inc.

=====
DAMAGE IN SHIPMENT
=====

Inspect all shipping cartons for damage, and record all damage on the transportation carrier's shipping manifest before signing. Upon detection of internal damage, immediately stop the unpacking procedure and request an inspection by the transportation carrier. Also, notify Piridy, Inc. of any damage or loss.

=====
RETURNING DEVICES TO PIRDY, INC.
=====

Notify the destination Piridy, Inc. facility prior to shipment of any devices. Packages must include detailed information regarding the name and facility of the customer and the reason for shipment. Shipping charges must be prepaid unless alternative arrangements have been authorized by Piridy, Inc. For protection of the customer, all return shipments should be insured for full product value.

ATTACHMENT II

MACHINE LABELS

The preliminary text of all machine labels is presented below. Each label is intended to be directly printed on an instrument face or applied to an instrument face as a permanent sticker.

Front Panel

1. **IMPORTANT:** Charge Battery and then Disconnect the Power Cord from the Back Panel Before Use.
2. PIRD-Y Model _____ Electromyographic Stimulator

Back Panel

1. **IMPORTANT:** Always disconnect the detachable power cord prior to using this device. Never attach the power cord to the device during operation.
2. Model Number _____, Serial Number _____. Recharging requirements: 110-120 volts, 50-60 Hz.
3. **CAUTION:** Electric Shock Hazard; Do Not Remove Cover. Refer servicing to qualified service personnel. Refer to Operators and Maintenance Manual supplied with this instrument.
4. **IMPORTANT:** Improper battery insertion will cause batteries to heat. Use rechargeable 1.25 Nicad batteries only.
5. Piridy, Inc. 522 S.W. 5th Avenue, Suite 725, Portland, Oregon 97204. Phone: (503) 241-3372.
6. **CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of a physician.

BEST AVAILABLE COPY

ATTACHMENT III

ADVERTISING MATERIAL

The following list represents preliminary information and marketing claims to be presented in advertisements, product information brochures, and product data sheets:

1. PIRD-Y Electromyographic Stimulators are quite affordable, state-of-the-art devices featuring pronounced simplicity of operation and true portability.
2. PIRD-Y Electromyographic stimulators possess these key attributes:
 - * state-of-the-art design
 - * solid-state electronics
 - * simplicity of operation
 - * totally self-contained
 - * very affordable
 - * non-invasive
 - * battery powered for optional safety and portability
 - * rechargeable batteries for maximal convenience and economy
 - * EMG Monitoring
 - * EMG Biofeedback
 - * Muscle Stimulation
3. EMG Monitoring and EMG Biofeedback
 - * 3 EMG ranges: 0-10 uv, 0-100 uv, and 0-1000 uv
 - * 2 Visual displays of the EMG
 - A. Digital - rapidly updated continuously during a movement
 - display holds for two seconds the maximum EMG value achieved during the movement, for convenience in diagnosis and for patient feedback
 - B. Bargraph - rapidly updated continuously during a movement
 - entire display lights up as an indication of goal achievement, when an EMG trigger level is exceeded
 - * Audio biofeedback signal available in selected operating modes
 - * All recordings obtained non-invasively through skin-surface electrodes
4. Muscle Stimulation
 - * Voltage range 0-120 volts; the necessarily much higher voltages required for NCV and other sophisticated diagnostic and stimulation regimens (ranging to 300 volts or more in certain complex competitive products) have not been included with PIRD-Y, in the interest of true economy and simplicity of operation

BEST AVAILABLE COPY

- * Simple operator control of stimulus intensity, stimulus pulse frequency, and stimulus pulse width
- * Approximate constant power output
- * 2 stimulus configurations
 - A. Primary Electrodes connector - both EMG Monitoring and Muscle Stimulation are accomplished through the same skin surface electrodes
 - B. Remote Electrodes connector - stimulation electrodes are connected to this socket when it is desired to stimulate a different muscle from the one used for EMG monitoring
- * All stimulation is accomplished non-invasively through skin-surface electrodes

5. Electrodes and Cables

- * low-noise, reusable electrodes and cables are supplied with each PIRD-Y instrument.

6. Indications and Contraindications

PIRD-Y devices are indicated for the following:

1. Neuromuscular rehabilitation following CVA (stroke), brain injury, spinal cord trauma, cerebral palsy, etc.;
2. Neuromuscular re-education accompanying relaxation training, chiropractic treatments, biofeedback programs, etc.;
3. Prevention or retardation of disuse atrophy secondary to CVA (stroke), paralysis, trauma, CNS injury, cerebral palsy, lower motor neuron disease, etc.;
4. Facilitation of voluntary motor function;
5. Circulatory stimulation of selected muscle groups following surgery, injury, or relative disuse; and
6. Maintenance or enhancement of range of motion.

There are presently no known contraindications for using PIRD-Y devices.

BEST AVAILABLE COPY

ATTACHMENT IV

PROFESSIONAL JOURNAL ADVERTISEMENTS AND PRODUCT SPECIFICATION SHEETS FOR THE SUBSTANTIALLY EQUIVALENT DEVICES LISTED IN SECTION 807.87(f).

As mentioned in the body of this 510(k) Submission, each listing is captioned with the unique item number from Section 807.87(f), specification of the source of the item, and the range of dates for which commercial availability of the device or quite similar models was verified.

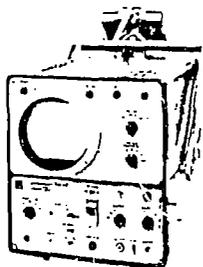
from: Arch. Phys. Med. + Rehab, Feb. 1976
verified availability: 1976-1977

Records processed under FOIA #2016-2195 Released by CDRH on 9/2/16

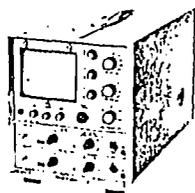
ITEM # 1

TECA:EMG SPECIALISTS

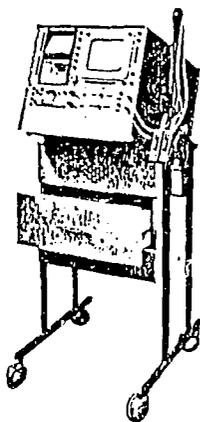
most complete/proven range of electromyographs



Model B-2/CT Compact Single Channel Electromyograph—comprehensive facility for all motor and sensory nerve measurements—automatic Polaroid photo-recording—digital latency indicator—provision for external stimulation and recording accessories.

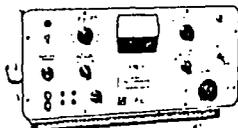


Model JM Modular Portable Electromyograph—available with one or two channels—plug-in modules: Integrator, Strain Gauge Amplifier, Muscle Stimulator, etc., provide versatility—performs all clinical tests—also valuable for teaching and research.



Model TE-4 Direct Recording Multichannel Electromyograph—for clinical and research studies—incorporates a unique fiber optic recorder that makes graphic records in seconds of four beams of information displayed on the monitor screen—basic unit provides many new operation and performance features which make a wide range of tests available and simplify operation—can accept up to eight modular plug-in units which can extend the capability of the instrument to include such facilities as Evoked Potential Averaging, Signal Delay Line, Strain Gauge Recording, Multipulse Pulse Stimulation, EMG Action Potential Analyzer, and others.

Add Stop Action Display to any TECA EMG with TECA Slaved Storage display Model SSD includes new time saving automatic features.



Model CH3 Variable Pulse Generator and Chronaxie Meter — a wide-range, precise, stabilized current pulse generator widely used in electrodiagnostic testing.

TECA manufactures a full complement of autoclavable needle and surface electrodes for recording and stimulation. Selected regional representatives and/or factory field service available in all areas.

Phone at our expense for additional information or demonstration

TECA

CORPORATION

220 FERRIS AVE. □ WHITE PLAINS, NEW YORK 10603 □ 914 WH 6-1593

Questions? contact FDA/CDRH/OCE/DID at CDRH-FOI (202) 418-5528 or (408) 418-5528

BEST AVAILABLE COPY

Now there's a way for your casted patients to get the benefits of muscle exercise, without the discomfort of physical activity.

Presenting the Respond™ Neuromuscular Stimulator from Medtronic. The Respond™ stimulator contracts muscles with safe, comfortable electrical stimulation which can retard disuse atrophy in casted patients. And that can mean faster recovery.

Studies show that casted patients who use a combination of muscle stimulation and isometric contractions show more improvement in muscle function and limb circumference than those who use only isometric contractions. (Write Medtronic for a complete list of muscle stimulation studies.)

The Medtronic Respond™ system is the most advanced neuromuscular



stimulator available. The Respond™ system offers dual-channels for simultaneous stimulation of two muscle areas. And only the Respond™ neuromuscular stimulator offers comfort and efficiency features like amperage limitation, variable-duty cycling and adjustable rise time... combined with dual channel capability in a single unit.

The Respond™ neuromuscular stimulator is part of a complete family of Medtronic neuro products... including implantable and TENS pain control devices. Like all Medtronic products, each one is backed by our reputation as the leader in electronic medical devices.

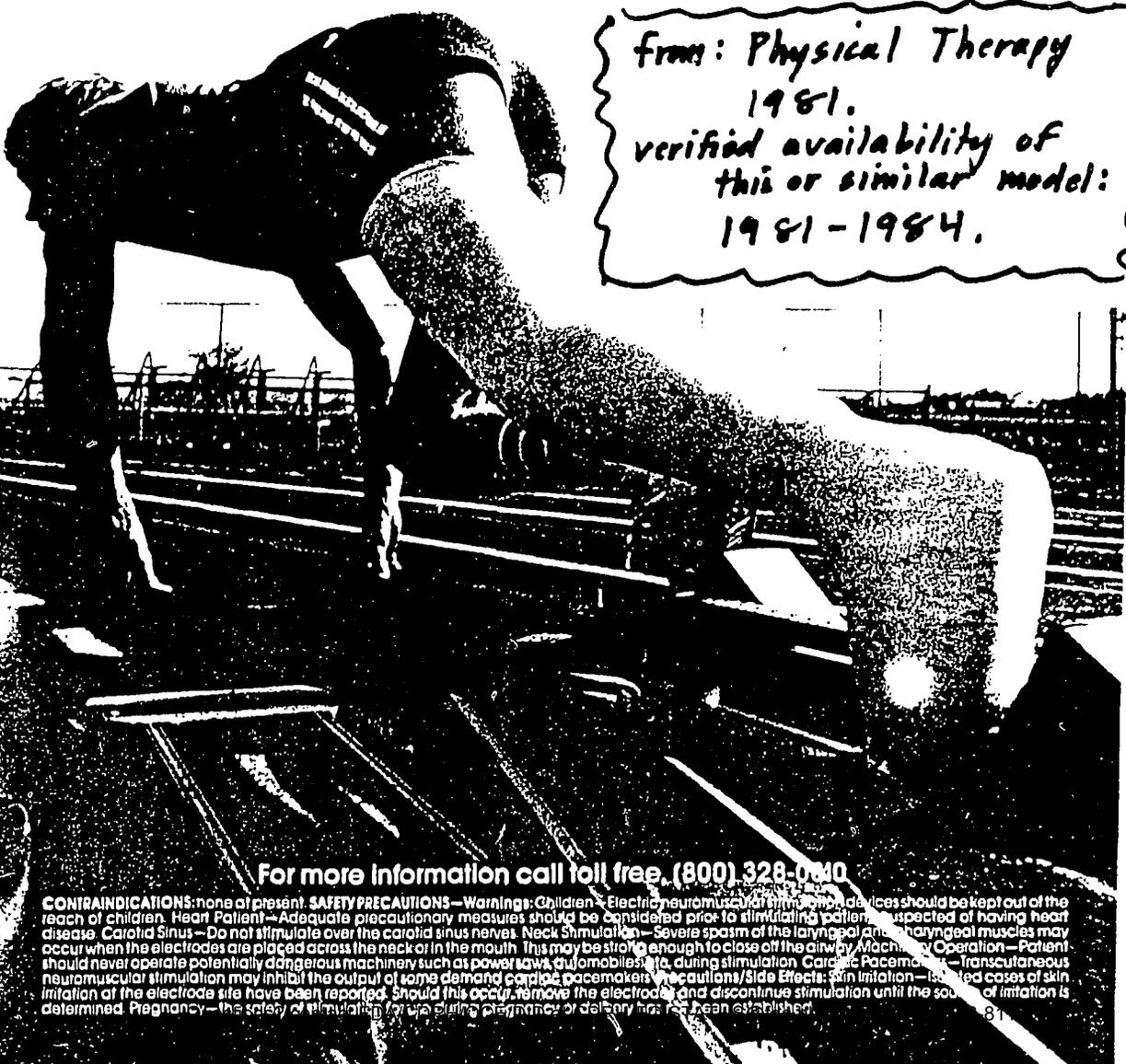


Neuro Division, 3055 Old Highway Eight, Minneapolis, MN 55418

ITEM # 2

BEST AVAILABLE COPY

HOW TO RUN A MILE WITH A BROKEN LEG.



*from: Physical Therapy
1981.
verified availability of
this or similar model:
1981-1984.*

For more information call toll free, (800) 328-0340

CONTRAINDICATIONS: none at present. **SAFETY PRECAUTIONS—Warnings:** Children—Electric neuromuscular stimulators should be kept out of the reach of children. Heart Patient—Adequate precautionary measures should be considered prior to stimulating patient suspected of having heart disease. Carotid Sinus—Do not stimulate over the carotid sinus nerves. Neck Stimulation—Severe spasm of the laryngeal and pharyngeal muscles may occur when the electrodes are placed across the neck or in the mouth. This may be strong enough to close off the airway. Machinery Operation—Patient should never operate potentially dangerous machinery such as power saws, automobiles, etc., during stimulation. Cardiac Pacemakers—Transcutaneous neuromuscular stimulation may inhibit the output of some demand cardiac pacemakers. **Precautions/Side Effects:** Skin Irritation—Isolated cases of skin irritation of the electrode site have been reported. Should this occur, remove the electrodes and discontinue stimulation until the source of irritation is determined. Pregnancy—the safety of stimulation of a pregnant pregnancy or delivery has not been established.

logical coping, social functioning, and vocational rehabilitation. In addition, specific complications or activities associated with spinal cord injuries were addressed which included the neurogenic bladder, sexual function, autonomic dysreflexia, pressure sores, and lower extremity orthotics. The material provided in these subject areas has been well organized, is clearly written, and is appropriate for the stated purposes of the book. Concern must be raised, however, in relation to the references provided by most of the authors since the majority of those cited have a publication date prior to 1970. Thus, recent research relevant to spinal cord injury does not appear to have been utilized during the preparation of the text.

The book is an appropriate reference text for the several types of health professionals who would be associated with the care and management of persons with spinal cord injury (e.g., nurses, occupational and physical therapists, social workers, vocational counselors, physicians, and clinical psychologists). The most complete chapters are those that deal with the management (spinal cord injury). The amount of information is greatly from a somewhat limited perspective. The use of the book for ways to help injured persons is personal-patient

problems, reference to recreational or sport activities, and drivers' training).

The photographs, charts, diagrams, and other illustrations are beneficial and adequately complement the written text.

The text was not designed to be a "how to" book, but is more a descriptive compendium of the various aspects of care and management of the person with a spinal cord injury. Individuals who seek detailed and specific information in several areas presented will find they must refer to other sources.

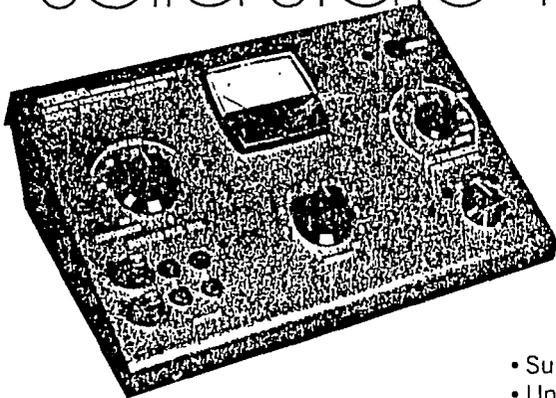
FRANK M. PIERSON

Stroke and its Rehabilitation. Edited by Licht S. Baltimore, Williams & Wilkins, Inc, 1975, cloth, 562 pp, illus. \$20

This volume is the 12th in the Physical Medicine Library volumes in the series, the most up-to-date as much information as possible on stroke from both medical and rehabilitation aspects. This book includes an extensive list of all areas. It is written by a different contributor. It deals with the medical aspects of stroke as a rehabilitative process. It includes a historical overview of stroke beginning with the Greeks.

*from: Physical Therapy, 1978
verified availability:
1978-1982*

new · portable model solid state · light weight



Light weight — 12 lbs. — heavy duty construction. Meter: LED indicator lamps and calibrated controls make this a truly professional instrument.

THERAPEUTIC MUSCLE STIMULATOR

SP2/T

- Surging DC currents (in addition to AC).
- Unique graded surge build-up.
- Exceeds latest power line safety recommendations.

TECA

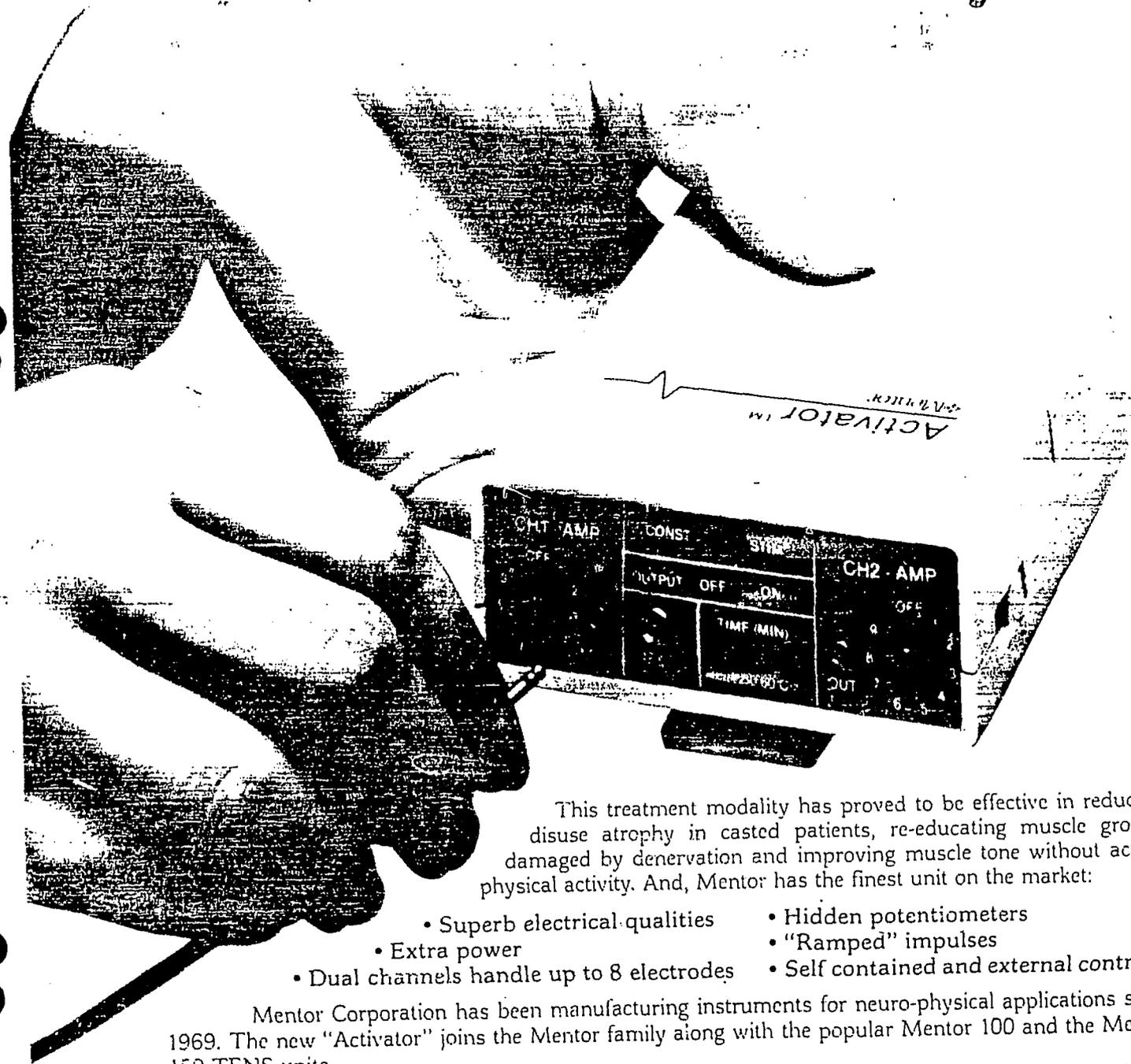
CORPORATION

220 FERRIS AVE. □ WHITE PLAINS, NEW YORK 10603 □ 914 WH 6-4593 / TWX: 710 568 1378

ITEM # 4

from: Physical
Therapy, 1984
verified availability:
1982-1984

MENTOR presents the Activator...TM a new, superb quality Neuromuscular Stimulation System



This treatment modality has proved to be effective in reducing disuse atrophy in casted patients, re-educating muscle groups damaged by denervation and improving muscle tone without actual physical activity. And, Mentor has the finest unit on the market:

- Superb electrical qualities
- Extra power
- Dual channels handle up to 8 electrodes
- Hidden potentiometers
- "Ramped" impulses
- Self contained and external controls.

Mentor Corporation has been manufacturing instruments for neuro-physical applications since 1969. The new "Activator" joins the Mentor family along with the popular Mentor 100 and the Mentor 150 TENS units.

Call or write for details.

MENTOR CORPORATION
2700 Freeway Boulevard #750
Minneapolis, Minnesota 55430
Toll Free 800-328-1023
In Minnesota, call 612-560-3320

Questions? contact FDA/CDRH/OIS/DID at CDRH-FOISTATUS@fda.hhs.gov 96-8118
BEST AVAILABLE COPY



From: Physical Therapy #2, Vol. 11, No. 1, p. 16
verified availability: 1982-1984

ITEM #5

Zimmer introduces its new electrical muscle stimulator:

The MYOGUARD* Stimulator... minimizes disuse atrophy and hastens recovery.

What is the MYOGUARD Stimulator?

The MYOGUARD Stimulator is a small, self-contained battery-operated unit that transcutaneously stimulates the musculature of the postsurgically immobilized patient, causing muscle contraction that simulates exercise.

What are the benefits?

Electrical muscle stimulation initiated *immediately* postoperatively minimizes disuse atrophy. Result - more rapid return to *optimal* activity with reduced need for rehabilitation.

What are the applications?

MYOGUARD therapy is particularly useful in sports medicine and in trauma cases when patients are in traction. Excellent results have been reported with postsurgical knee-immobilized patients.

How difficult is MYOGUARD to use?

This is a very simple, easy-to-use device that is totally preprogrammed. The output is fixed and only the amplitude (intensity) is controllable. It is powered by a single, long-life, replaceable battery.

Are there economic implications to the use of this therapeutic technique?

Yes, because patients can return to their normal activity—with optimal performance levels—more rapidly. This has obvious economic advantages for all patients and especially for athletes. In addition, the reduction in the duration of physical therapy required can help contain the usual rehabilitation costs.

Does this therapy affect blood flow?

As with all exercise, blood circulation is enhanced. There is speculation that this improved blood circulation might have an influence on the incidence of deep vein thrombosis. (Substantial exploratory research is now underway in this area, especially following orthopaedic surgery. To learn of future developments, please complete and return the attached coupon.)

Is the MYOGUARD Stimulator compatible with continuous passive motion exercise?

Yes, early work suggests that these two modalities may well function synergistically. (For information on the ZIMMER* CAPE* Continual Anatomical Passive Exerciser, please use the attached coupon.)

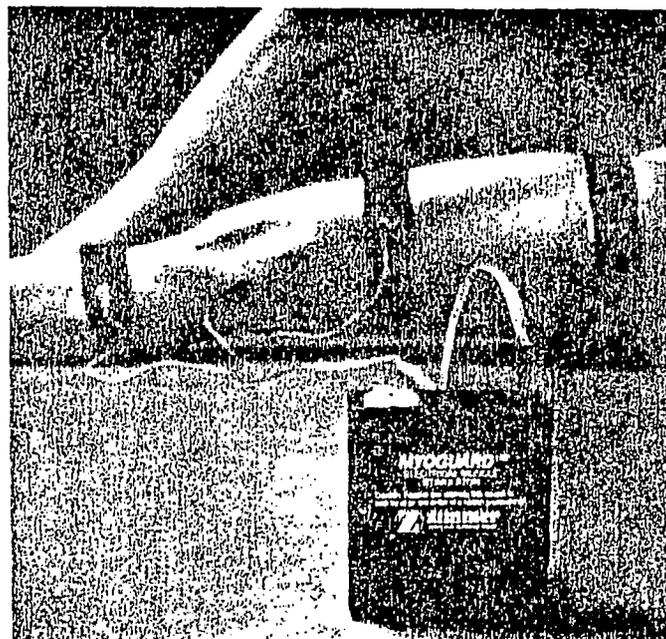
What electrodes are available for MYOGUARD?

There is a choice of strap and spot electrodes with either CONDUCTOL* Foam or karaya gum.

How can I get more information?

Please complete and mail the attached coupon or call 800/222-4443. In North Carolina call 704/568-9120 collect.

The MYOGUARD Stimulator:
minimizes disuse atrophy, speeds
recovery, reduces the need for
rehabilitation.



The MYOGUARD Stimulator...
brought to you by your professional
Zimmer representative.

Data on file and available on request.



Patient Care Systems

Division of Zimmer
5701 Executive Center Drive
Suite 210
Charlotte, North Carolina 28212
Phone 800/222-4443
In NC, call 704/568-9120 collect

- Please forward reprints and MYOGUARD literature
- Please forward information on the CAPE Continual Anatomical Passive Exerciser
- Please put me on your mailing list for future information on deep vein thrombosis
- Please ask my Zimmer representative to call me for an appointment.

Area Code _____ Number _____ Ext. _____

Name _____

Title _____

Department _____

Institution _____

Address _____

BEST AVAILABLE COPY

MYOGUARD Electrical Muscle Stimulator and CAPE* Continual Anatomical Passive Exerciser are trademarks of Zimmer, Inc.
**CONDUCTOL* Conductive Foam is a trademark of Aspen Laboratories, a subsidiary of Zimmer, Inc.

With stroke and other disorders involving neuromuscular paralysis, biofeedback may be of substantial assistance in relearning muscle control and facilitating optimal use of available neural activity.

What is biofeedback? It is a unique departure from traditional treatment approaches that allows an individual to recognize and influence his own internal body states. Thus, a patient may be able to assume a target role in guiding his own health. Evolving out of a half-century of autogenic techniques and electronic technology, biofeedback utilizes a new generation of precision electronic equipment especially designed to meaningfully translate measurements of internal body processes to the individual who produced them.

ASI is the leading manufacturer of advanced biofeedback circuitry and instrumentation. Our equipment is being used in leading hospitals, universities and research centers throughout the U.S. and the world. Specifications for our feedback units have not been duplicated by others costing considerably more.

We currently offer a variety of complete feedback systems. Our feedback myographs are learning tools that may enable

an individual to monitor and influence his own muscle tension and relaxation; similarly, our feedback thermometers can assist in subject control over sympathetic activity, and our feedback encephalographs are the most accurate monitors and analyzers of brain wave function in their respective price ranges.

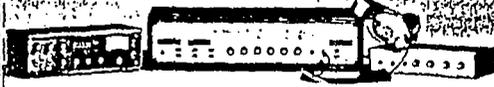
Any Autogen unit can be sent to you on a 10-day trial period. Product demonstrations are available to professionals anywhere in North America. For further information return the coupon below. If you have other questions or are interested in other forms of biofeedback, call or write us to see how we can best serve your needs. Every ASI instrument comes with appropriate electrodes or probes, batteries, and detailed training manual. And every unit is covered by the longest warranty in the industry—five years. We welcome your inquiries and comments.

Gentlemen, please send me complete literature _____

Name _____

Street _____

City _____ State _____ ZIP _____

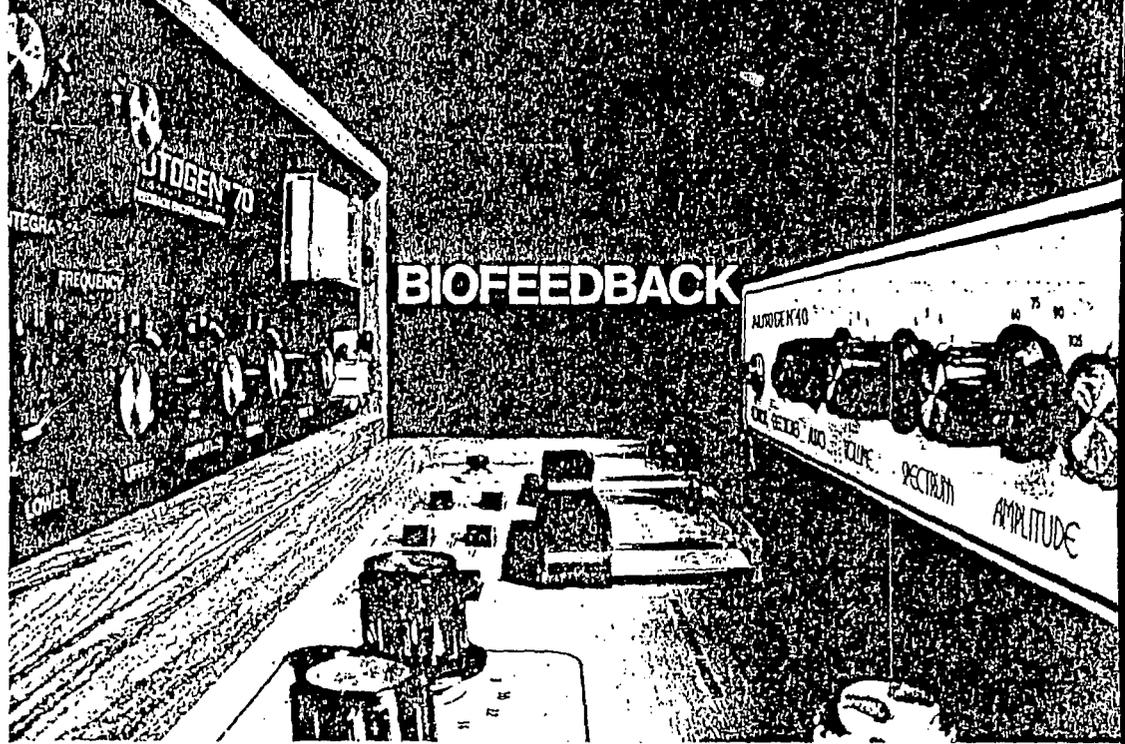


Write: Dept. D-7

ASI

AUTOMATIC SYSTEMS INCORPORATED

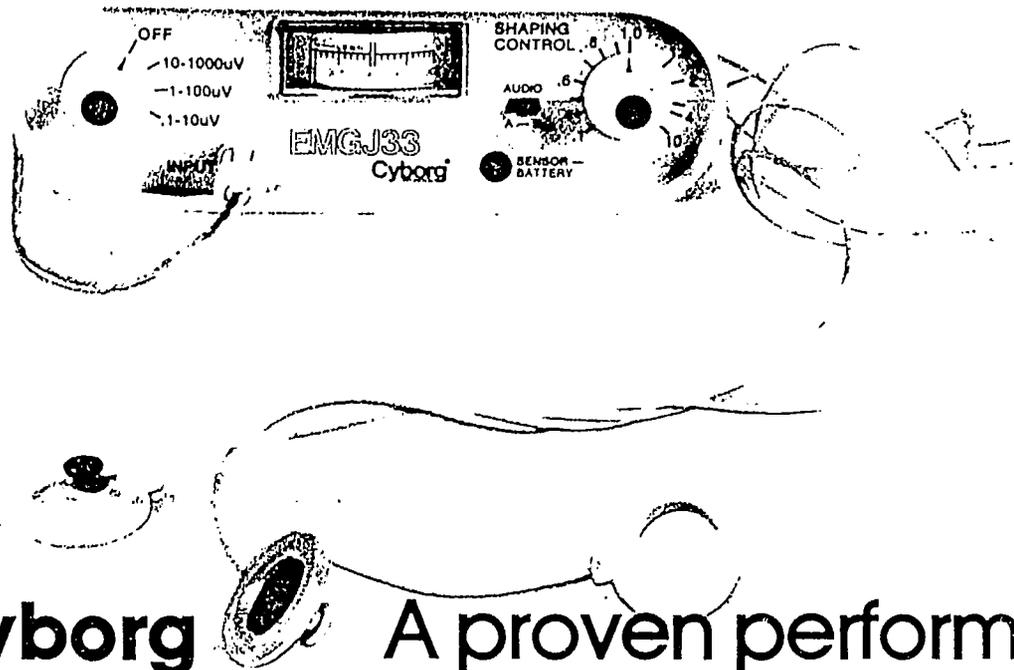
809 Allston Way
Berkeley, California 94710
(415) 548-6058



From: 1994 Product Spec. Sheet
Records processed under FOIA on 02/19/2015. Released by DDP on 09/2/16

Availability verified 1976-1984

ITEM #7,
page 1



The Cyborg J33 Muscle Trainer

A proven performer

The Cyborg J33 Muscle Trainer is the world's largest selling EMG biofeedback instrument. It is a completely self-contained portable instrument specifically designed for EMG biofeedback training in or outside the clinic or office. Battery powered, extremely compact, lightweight, and conveniently used in any environment.

Systems Capability

Unique flexibility and low cost make the J33 an ideal initial investment in biofeedback capability which may later be expanded into a total processing system. J33 Trainers serve as input modules to P600 and BL900 distributive processors to avoid unnecessary expenditures in acquiring systems capability.

Sophisticated Controls

Meter readout gives EMG level relative to pre-set training goals. Direct visual feedback, together with a calibrated shaping control, makes it possible to set reasonable training goals relative to initial EMG activity levels, to determine EMG level in microvolts, to observe approximation to those goals, and to alter goals progressively as training proceeds.

Audio Modes

Two audio feedback modes permit a choice of rising and falling tone or variable repetition rate clicks, both proportional to EMG signal level. An earphone output may be used for private listening.

Range

A wide sensitivity range makes it possible to detect extremely low-level muscle activity. Three sensitivity range settings provide optimal readout at different activity levels.

Options

A variety of sensors adapted to specific clinical needs are available. Automatic sensor contact and battery checks are made by the instrument.

BEST AVAILABLE COPY

ITEM # 7,
page 2

Specifications

Shaping Control

The shaping control permits selection of progressive training goals reasonably distant from initially determined baseline activity. Actual EMG voltage levels can be read directly from the shaping control.

Meter Readout

A ratio meter indicates continuously the difference between actual EMG level and preset goal, giving visual feedback of training progress.

Two Audio Feedback Modes

Audio feedback comes on at and above the goal set on the shaping control. A switch permits choice of audio feedback in the form of rising and falling tone or as a variable repetition rate of clicks. Both are proportional to EMG level, increasing as EMG activity rises, decreasing as activity drops.

Earphone Audio Output

For private listening, an earphone output, which cuts off the built-in speaker, is provided on the back of the instrument case.

Sensitivity

The J33 measures signals from 0.7-1000 uV. For optimal readout at different levels, three sensitivity ranges may be selected: 0.1-10 uV, 1-100 uV, and 10-1000 uV.

Sensor Contact and Low Battery Indicator

A front panel light indicates inadequate sensor contact and provides warning when batteries require replacement. Two 9-volt transistor batteries are included with the instrument.

Variety of Sensors

Large sensors for monitoring muscle group activity, smaller ones for single muscle training, and sub-dermal sensors for special applications are available for the J33. Sensors have disposable adhesive discs, headband for forehead placement, and color-coded leads for the two signal and one ground attachments.

Low Noise Amplifier

Input noise: typical 0.6 uv RMS.

Differential input impedance: greater than 2 megohms.

Common mode input impedance greater than 50 megohms

Input current: less than 100 nanoAmps.

Common mode rejection ratio: 100 db (100,000:1).

Filter bandpass: 100-1000 Hz; notch filter greater than 40 db rejection at 60 Hz.

Processing System Output

The J33 may be used as the satellite unit input to Cyborg P600 and BL900 Processors, which perform complex integrating and display functions, add a large variety of feedback modes, and permit analog and digital data recording as well as interface with programming equipment.

Physical Characteristics

Size: 7" x 2" x 4" deep;

Weight: 16 oz.

Convenience Features

The compact, lightweight, battery-powered J33 comes with a convenient carrying case and may be used in any environment.

Standard Accessories Included

Complete sensor assembly including three individual EMG sensors (15mm)

Adjustable headband

One tube electrode paste

Two skin preparation pads

100 Adhesive discs

Carrying case

Shoulder strap

Instruction manual

Warranty

Five years on all electronic parts; one year on labor and electromechanical parts.

Cyborg Corporation
55 Chapel Street
Newton, Massachusetts 02158
U.S.A.
Telephone: (617) 782-9820

Copyright © 1979, Cyborg Corporation. All rights reserved. Printed in U.S.A. Patents issued and pending. Sales restricted to professionals only.

All specifications subject to change without notice.

Cyborg[®]
CORPORATION

BEST AVAILABLE COPY

From: Arch. Phys. Med. + Rehabil. Mar. 1976

verified availability: 1976-1978
Records processed under DTIC #0162111 Released by CDRH on 9/2/1

ITEM #8

Finally. Therapeutic Myography.

Facilitating the disabled proprioceptive sense is vital for neuromuscular re-education of neurologic patients^{1,3,4,6-9}. Sensory awareness of the prime mover's action is essential for relearning coordination^{6,8}. And contemporary therapy specifically stresses feedback to the patient through undamaged senses³.

But this behavioral feedback is usually inadequate. It doesn't meet the requirements^{5,6} of being immediate, continuous, sensitive, and truly proportional to activity.

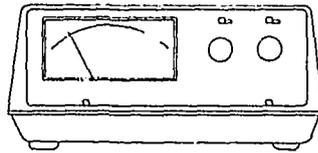
After early reports of the effectiveness of myographic feedback for rehabilitation⁷ and exquisitely fine control of muscular activity², much attention has been focused on using it in clinical practice⁸. Several authors present dramatic success for flaccid and spastic hemiplegia, re-innervation, spasmodic torticollis, drop-foot, cerebral palsy, and a variety of other neuromuscular disorders.

But routine myographic feedback hasn't been practical or affordable⁶.

Now it is.

The Myo-Tone™ feedback myograph is the first practical for long-term patient use. It's truly ambulatory. From the easily used controls to the ultra-comfortable flexible electrodes it's made for the patient.

And detailed training programs help you start using it today. You don't have to re-organize your therapy around the Myo-Tone. It fits right in with the patterns and exercises you use now. But its ability to pick up even the tiniest activity gives you a powerful tool that helps make exercise patterns effective much earlier than usual. And it similarly helps inhibit spastic contractions that interfere with coordination.



A complete range of accessories gives you the freedom to use just the kind of equipment needed for a



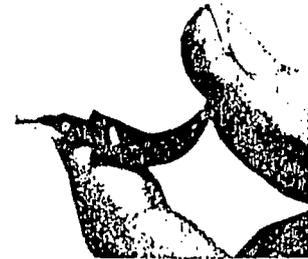
particular situation. Besides the normal auditory feedback, there's a meter and lighted bar graph for visual display.

References

1. Andrews, J.M.: Neuromuscular Re-education of the Hemiplegic with the Aid of the Electromyograph. *Arch. Phys. Med. & Rehab.* 45: 530 (1964).
2. Basmajian, J.V.: Control and Training of Individual Motor Units. *Science* 143: 440 (1963).
3. Griffin, J.W.: Use of Proprioceptive Stimuli in Therapeutic Exercise. *Phy. & Ther.* 54: 1072 (1974).
4. Johnson, H.E. & W.H. Garton: Muscle Re-education in Hemiplegia by Use of Electromyographic Device. *Arch. Phys. Med. & Rehab.* 54: 320 (1973).
5. Kreilfeldt, J.C.: Signal vs. Noise Characteristics of Filtered EMG Used as a Control Source. *IEEE Trans. Bio-Med. Engr.* BME-18: 16 (1971).
6. Licht, S., ed.: Stroke and its Rehabilitation. New Haven, E. Licht, 1975. See especially chapters by Kuttke and Friedland.
7. Marinacci, A.A.: Applied Electromyography. Philadelphia, Lea & Febiger, 1968. Chapters 26 & 27.
8. Smith, K.U. & J.P. Henry: Cybernetic Foundations for Rehabilitation. *Amer. J. Phys. Med.* 46: 379 (1967).
9. References to clinical practice are too numerous to list here. The free Report has an extensive bibliography.

And special electrodes for small muscles. And all the bits and pieces that make the system easy to use.

Best of all, a rental makes the entire system, or just part of it, easily affordable.



For you and your patient.

Ask for details and you'll get our free Report on *Neuromuscular Re-education*.

It reviews in depth the physiology and clinical practice of feedback myography, including practical descriptions of specific applications.

Send us the coupon and start using this important new approach to therapeutic exercise today.



Please send your free Report on Neuromuscular Re-education.

We want to try a system, free, for two weeks. Send details.

Isis
DeWitt Building 764
Ithaca, New York 14850
607-272-3020

Name _____

Institution _____

Address _____

City _____ State _____ Zip _____

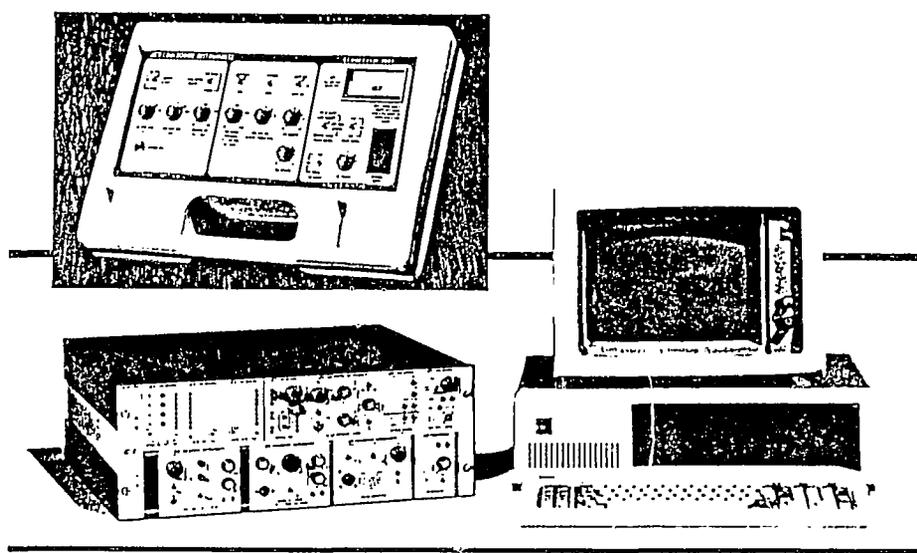
BEST AVAILABLE COPY

from : 1984 Product Brochure
Records processed under FOIA #201 by CDRH on 9/2/16

verified availability : 1980-1984

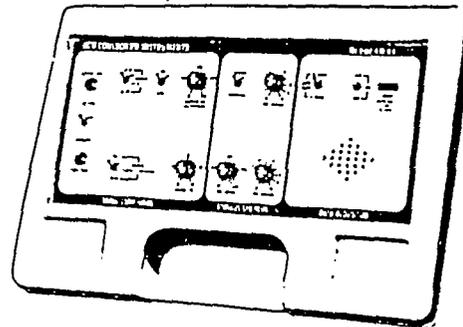
ITEM # 9,
page 1

WHEN YOU'RE SERIOUS ABOUT
BIOFEEDBACK
YOU CHOOSE
COULBOURN



BEST AVAILABLE COPY

ITEM #9,
PAGE 2



AUTOLAB 21
EMG, Alpha EEG, Temperature

The Autolab 21 is designed for the serious educator and the clinical practitioner requiring the economy of 3 modalities in a single instrument. The unit features both proportional and threshold feedback in the auditory mode and proportional feedback in the visual mode by means of a remote meter display furnished with the instrument. Automatically timed digital data sampling, not found in competitive instruments, provides the precision, objective data needed in any biofeedback application.

AUTOLAB 21 SPECIFICATIONS		STIMULUS SYNTHESIS	
SIGNAL CONDITIONING		Tone Control	
Bioamplifier Section / Filter Section		THRESHOLD SELECT:	
INPUT RESISTANCE: 10 ⁴ Ohms		Above Threshold Range 100 Hz to 2000 Hz (Fixed)	
(Differential & Common Mode)		Below Threshold No Tone Generated	
INPUT BIAS CURRENT: 10 nA		PROPORTIONAL SELECT:	
COMMON MODE REJECTION RATIO (CMRR):		Sweep Range 50 Hz to 2000 Hz for a zero to full scale reading	
DC to 100 Hz	115 dB Typical	Meter Reading (Fixed)	
100 to 1000 Hz	100 dB Typical	104 dB Min.	
FREQUENCY RESPONSE:		94 dB Min.	
ALPHA MODE	8 Hz to 13 Hz	(-3 dB points)	
ENG MODE	300 Hz to 1000 Hz	(-3 dB points)	
ROLL OFF TYPICALLY 18 dB PER OCTAVE		DATA ACQUISITION	
GAIN: 10,000 (100 Microvolt Sensitivity)		METER—Provides continuous indication of biopotential or temperature activity	
100,000 (10 Microvolt Sensitivity)		DISPLAY: Resolution Sensitivity	
NOISE:		Temperature ±0.001°C 0-1°C ±4,999 Max. Over Range	
8-10 Hz to 13.0 Hz	0.3 Microvolts RMS Typical	Temperature ±0.01°C 0-10°C ±49.99 Max. Over Range	
100 Hz to 1000 Hz	0.3 Microvolts RMS Max.	EMG/EEG 0.01 uV 0-10 uV ±9.99 Max. Over Range	
200 Hz to 1000 Hz	0.3 Microvolts RMS typical	0.1 uV 0-100 uV ±99.9 Max. Over Range	
0.4 Microvolts RMS Max.		ACCURACY: ±2%	
INTEGRATOR TIME CONSTANT:		SAMPLE PERIODS: 1 Sec. and 10 Sec.	
Adjustable 20-2000 Milliseconds (EEG/EMG only)		POWER REQUIREMENTS	
TEMPERATURE SECTION		105 to 125 VAC 60 Hz 10 Watts (50 Hz Available)	
ACCURACY: ±2%		Operating Range 0° to 50° Centigrade	
RESOLUTION: ±0.001°C 0-1°C Sensitivity		ISOLATION INFORMATION	
±0.01°C 0-10° Sensitivity		Patient connections and all exposed metal parts are isolated from earth ground and labeled as such.	
		LEAKAGE: 10 uA A.C. 5.0 uA AC Typical	

BEST AVAILABLE COPY

BLANK PAGE

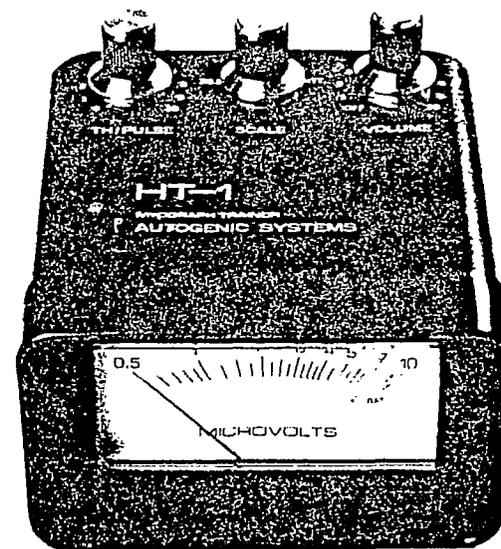
AUTOGEN[®] HT-1

THE INSTRUMENT The HT-1 EMG is an easy to use portable trainer with specifications which substantially exceed those of competing home training units (see reverse side). Electromyographic feedback requires extensive filtering of non-EMG signals; the HT-1 provides a cleaner feedback signal than any competitive portable device. The instrument is housed in a tough outer shell which enhances durability and stability of the instrument over extended usage.

For Home and Clinical Training

FEATURES

- COMPATIBLE WITH ALL AUTOGENICS[®] INSTRUMENTS
 - HIGH SENSITIVITY (0.4 MICROVOLTS RMS)
 - LARGE, EASY TO READ METER
 - FIVE SELECTABLE METER SENSITIVITY SCALES
 - TWO AUDIO FEEDBACK MODES
 - BUILT-IN SPEAKER
 - VOLUME CONTROL
 - INSTRUMENTATION OUTPUT FOR DATA ACQUISITION
 - ATTACHES TO HEADPHONES OR EXTERNAL SPEAKERS
 - BATTERY TEST FUNCTION



electromyograph

*From: 1984 Product Spec. Sheet
verified availability: 1983-1984*

BEST AVAILABLE COPY

*ITEM # 10,
page 1.*

AUTOGEN[®] HT-1 specifications

AMPLIFIER

Input noise: 0.4 μ V RMS (100-200 Hz)
Filters: 60 Hz powerline rejection (50 Hz optional): 46 dB; high pass; 20 dB/octave below 100 Hz; low pass: 6 dB/octave above 200 Hz
Bandpass: 100-200 Hz (high pass: 20 dB/octave; low pass: 6 dB/octave)

FEEDBACK

Analog tone
Variable pulsated analog tone
Direct audio feedback optional

METER FUNCTIONS

Logarithmic meter with 5 selectable scales:
0.15-3.0 μ V, 0.5-10 μ V, 1.5-30 μ V, 5-100 μ V, 50-1000 μ V,
Battery test

CONTROLS

Power off/on/volume
Meter scale selector
Threshold selector (above threshold standard; below threshold optional)
Audio feedback mode selector

OUTPUTS

Built-in speaker
Audio connector for external speaker or stereo headphones: 8 ohms
Absolute EMG level

PHYSICAL

Environmental operating range: 0°-50°C (32°-122°F)
Power: rechargeable batteries
Size: 2 $\frac{3}{4}$ " high x 4" wide x 4 $\frac{1}{2}$ " deep
Weight: 1 $\frac{1}{2}$ lbs.

BEST AVAILABLE COPY

ITEM #10,
page 2

ITEM # 11

An EMG breakthrough! A monitor that is precise, portable & affordable.



EMG 100TTM
for only
\$199.95

This micro-electronic instrument offers... clinical precision in a highly-affordable, portable package. EMG 100T is ideal for use in muscle rehabilitation following injury or stroke because it can isolate and register visually EMG activity of less than 0.3uV RMS and provide true DC RMS EMG and raw EMG for data acquisition. High input impedance (100 million ohms) renders gel virtually unnecessary.

Connected to the equally-compact GSR 2 monitor, it can also provide sensitive tonal analog feedback for threshold information and relaxation training.

EMG 100T is also excellent in the treatment of tension-related ailments such as migraine and skeletal muscular disorders.

System includes meter, electrodes, headband, cassette tape and manual. One year warranty.

Thought Technology Ltd.,
2180 Belgrave Ave., Dept. #363
Montreal, Que., Canada H4A 2L8

*from: Physical Therapy, 1984
verified availability: 1982-1984*



Name _____

Address _____

City _____ State _____

Zip _____

Please send me _____ EMG 100T units @ \$199.95 ea plus shipping \$5.95; _____ GSR 2 units @ 49.95 ea plus shipping \$3.95. I understand if I am not completely satisfied within 30 days, I may return the item for a prompt and courteous refund.

I wish to pay by cheque Master Card Visa Amex

Card # _____ Expires: _____

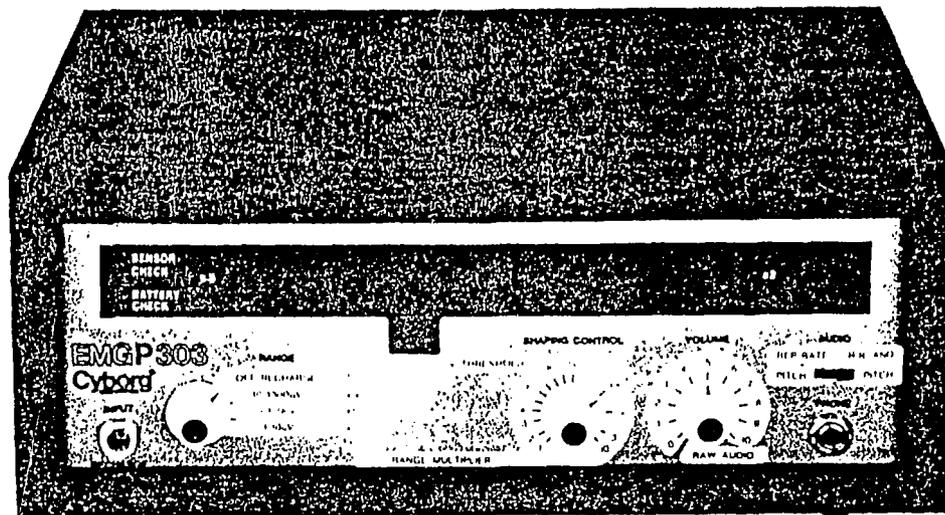
Signature _____

SEND TO: **Thought Technology Ltd.**
2180 Belgrave Avenue, Dept. # 363
Montreal, Quebec Canada H4A 2L8 (514) 489-8251

BEST AVAILABLE COPY

From: 1984 Product Spec. Sheet
verified availability: 1979-1984

ITEM 12,
page 1



Stoelting-Cyborg P303 Clinical EMG

Featuring Litebar™ Display

The P303 Clinical EMG is a unique visual display training instrument for clinic or office. It offers the most advanced and easily readable visual feedback available today. Cyborg LITEBAR™ display shows EMG level as a continuous sequence of color-coded lights, clearly indicating whether muscle activity is above (red), below (green) or at (yellow) pre-set training goals, as well as showing direction of change and relative proximity to goal.

Multiple Modes

Four audio feedback modes permit choice of a continuous tone with rising and falling pitch, a click series with variable repetition rate, a combination of tone and click, or the raw EMG signal itself.

Setting Criteria

The calibrated shaping control makes it possible to set progressive training goals. Exact EMG voltage level is determined

by a simple adjustment of the shaping control which may be set to any goal reasonable in terms of baseline activity. Goal may be altered progressively as training continues.

Wide Sensitivity Range

A wide sensitivity range makes possible to detect extremely low level muscle activity. Three sensitivity range settings provide optimal readout at different activity levels.

Power

Rechargeable batteries and recharger are included, as is automatic battery-check light.

Flexible Sensor System

A variety of sensors, adapted to specific clinical needs, are available, including large sensors for general muscle activity, smaller ones for single muscle training and disposable sensors. An automatic sensor-control check light is standard.

BEST AVAILABLE COPY

ITEM 12,
page 2

Specifications

LITEBAR™ Display

A horizontal row of LEDs light in sequence as EMG signal shifts above (red) or below (green) pre-set training goals, giving the appearance of continuous motion. Three vertically-arranged yellow LEDs, between "above" and "below" series, light when EMG signal is at goal. Rate of change in EMG level is reflected in rate of LITEBAR™ movement, and proximity to goal is easily seen.

Shaping Control

The exact value of the baseline EMG voltage level is read from a shaping control, adjusted until yellow goal indicators light. A training goal reasonably distant from baseline is then selected by adjusting the shaping control to a new level. Calibration matches lowest sensitivity range; multipliers of 10 and 100 give readings in higher ranges.

Audio Feedback Modes

The P303 is the only EMG instrument coordinating audio and visual feedback in a single calibrated control. Four audio modes offer a choice of 1) a continuous tone whose pitch rises and falls in proportion to the EMG signal, 2) a click series whose repetition rate increases and decreases in proportion to the EMG signal, 3) a combination of tone and click, and 4) the raw EMG signal itself. Volume of the first three is adjustable.

Headphone Audio Output

For private listening, a headphone output, which cuts off the built-in speaker, is provided.

Sensitivity

The P303 measures signals from 0.6-1,000 uV. For optimal readout at different levels, three sensitivity ranges may be selected: .1-10 uV, 1-100 uV, and 10-1000 uV.

Rechargeable Power System

The P303 is powered by a permanent battery, which is rechargeable. The automatic battery check light indicates when recharging is necessary. The recharger is supplied with the instrument and plugs into the input jack.

Sensors and Sensor Check

Larger sensors for monitoring muscle group activity, smaller ones for single muscle training, and convenient disposable sensors are available for the P303.

A sensor check light on the P303 indicates when poor sensor contact is made.

Low-noise Amplifier

Input noise: typical 0.5 uV RMS.

Differential Input Impedance: greater than 2 megohms.

Common mode input impedance greater than 50 megohms.

Input current: less than 100 nanoAmps.

Common mode rejection ratio: 100 db (100,000:1).

Notch filter: greater than 45 db rejection at 60 Hz (50 Hz optional).

Filter bandpass: 100-1000 Hz

High pass greater than 60 db/decade (100 Hz); low pass greater than 60 db/decade (1000 Hz).

Physical Characteristics

Size: 13" x 5" x 8.5" deep.

Weight: 5 lbs.

Standard Accessories Included

Senscr cable with junction box

50 Quick Stick disposable sensors

One tube electrode paste

Skin preparation pads

Battery recharger

Instruction Manual

Warranty

5 years on all electronics and electromechanical parts.

1 year on labor.

Stoelting-Cyborg

1350 S. Kostner Avenue

Chicago, IL 60623 U.S.A.

Telephone: (312) 522-7777

BEST AVAILABLE COPY

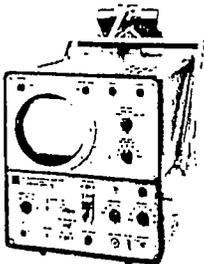
From: Arch. Phys. Med. + Rehabil, Feb. 1976
verified availability: 1976-1980

Record is processed under FOIA #2016-2195 Released by CDRH on 9/2/16

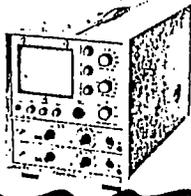
ITEM #13

TECA:EMG SPECIALISTS

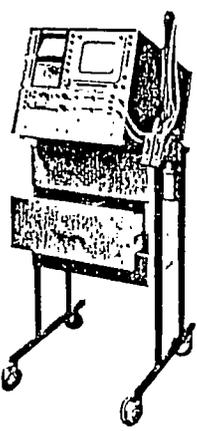
most complete/proven range of electromyographs



Model B-2/CT Compact Single Channel Electromyograph—comprehensive facility for all motor and sensory nerve measurements—automatic Polaroid photo-recording—digital latency indicator—provision for external stimulation and recording accessories.



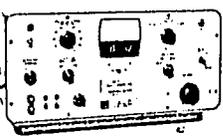
Model JM Modular Portable Electromyograph—available with one or two channels—plug-in modules: Integrator, Strain Gauge Amplifier, Muscle Stimulator, etc., provide versatility—performs all clinical tests—also valuable for teaching and research.



Model TE-4 Direct Recording Multichannel Electromyograph—for clinical and research studies—incorporates a unique fiber optic recorder that makes graphic records in seconds of four beams of information displayed on the monitor screen—basic unit provides many new operation and performance features which make a wide range of tests available and simplify operation—can accept up to eight modular plug-in units which can extend the capability of the instrument to include such facilities as Evoked Potential Averaging, Signal Delay Line, Strain Gauge Recording, Multipulse Pulse Stimulation, EMG Action Potential Analyzer, and others.

Add Stop Action Display to any TECA EMG with TECA Slaved Storage display Model SSD includes new time saving automatic features.

BEST AVAILABLE COPY



Model CH3 Variable Pulse Generator and Chronaxie Meter — a wide-range, precise, stabilized current pulse generator widely used in electrodiagnostic testing.

TECA manufactures a full complement of autoclavable needle and surface electrodes for recording and stimulation. Selected regional representatives and/or factory field service available in all areas.

Phone at our expense for additional information or demonstration

TECA

CORPORATION

220 FERRIS AVE. □ WHITE PLAINS, NEW YORK 10603 □ 914 WH 6-4593
Questions? contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov OR 301-796-8118

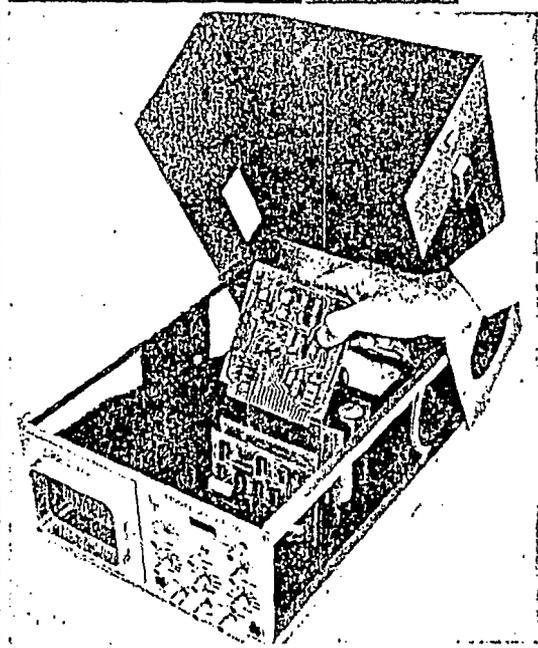
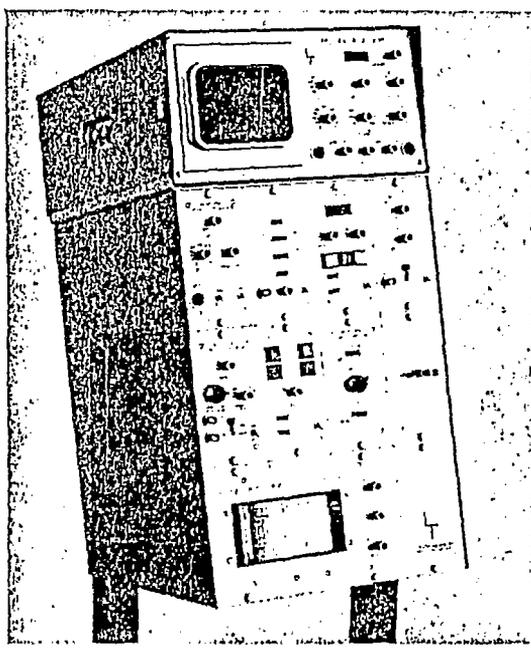
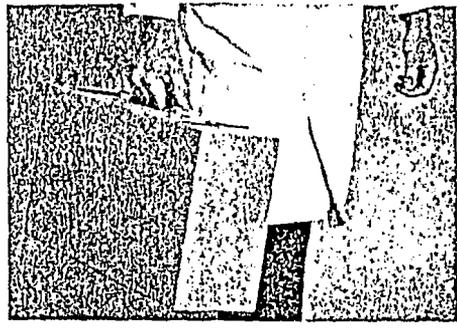
verified availability: 1976 - 1977

ELECTROMYOGRAPH

LT Model 9000

Portable

The Model 9000 is a rugged, compact, exceptionally easy-to-use single channel EMG. It is smaller and lighter than any comparable instrument, yet has a full 5" oscilloscope face.



Expandable

The Model 9000 plugs into a module bay which accepts a variety of expansion modules. Modules include a channel expander, stimulus programmer, signal averager, and signal store and record system. The Model 9000 can be quickly unplugged from the module bay, taken into the field for testing, then returned and just as quickly plugged back into the module bay.

Serviceable

We have expended considerable effort to reduce both the cost and inconvenience of servicing the Model 9000. The instrument's design is modular throughout, and all functional components can be replaced by simply unplugging. Indicator lights quickly identify malfunctioning modules. Thus, repairs normally taking hours often can be effected in minutes. In addition, a nationwide service center network supports all of LTI's electronic medical instrument lines.

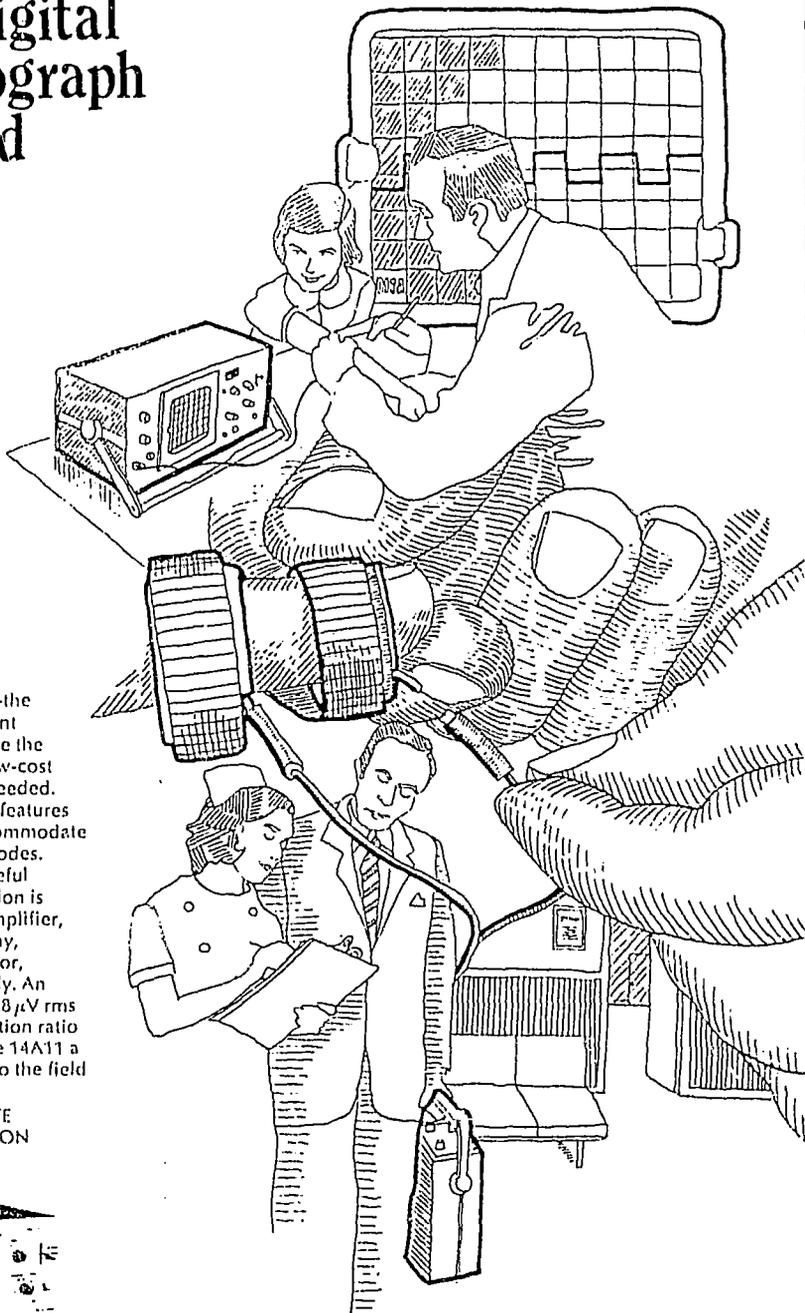
For complete technical literature write or phone.



P.O. BOX 26721 HOUSTON, TEXAS 77226 (713) 787-8493

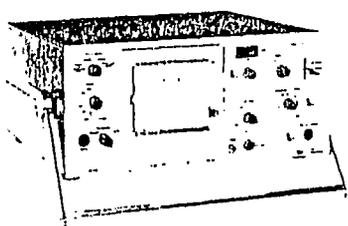
BEST AVAILABLE COPY

Portable, low-cost digital electromyograph can be used anywhere



Use the Disa 14A11 portable electromyograph anywhere—the hospital, your office, for patient visits, in schools and anywhere the convenience of a portable, low-cost single channel myograph is needed. The low noise EMG amplifier features high impedance input to accommodate the use of small needle electrodes. Every system required for careful electromyographic investigation is included in one unit: EMG amplifier, monitor, digital latency display, calibrated time base, stimulator, loudspeaker and power supply. An extremely low noise level— $0.8 \mu\text{V rms}$ —and a common mode rejection ratio of 90 dB combine to make the 14A11 a very important contribution to the field of electromyography.

SEND TODAY FOR COMPLETE TECHNICAL AND APPLICATION LITERATURE



DISA ELECTRONICS

Division of Disamatic Inc.

779 Susquehanna Ave., Franklin Lakes, N. J. 07417
201-891-9460

BEST AVAILABLE COPY

Questions? contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov OR 301-796-8118

from: 1984 Product Brochure
verified availability: 1976-1984

ITEM #16,
page 1

Medic



PRODUCT CATALOGUE

1981

Medical Instrument Company

⁹
MEDICAL INSTRUMENT COMPANY
(714) 560-3105 310 S VIA VERÁ CRUZ • SUITE 100 95-4977
SAN MARCOS CA 92069
(619) 744-9652

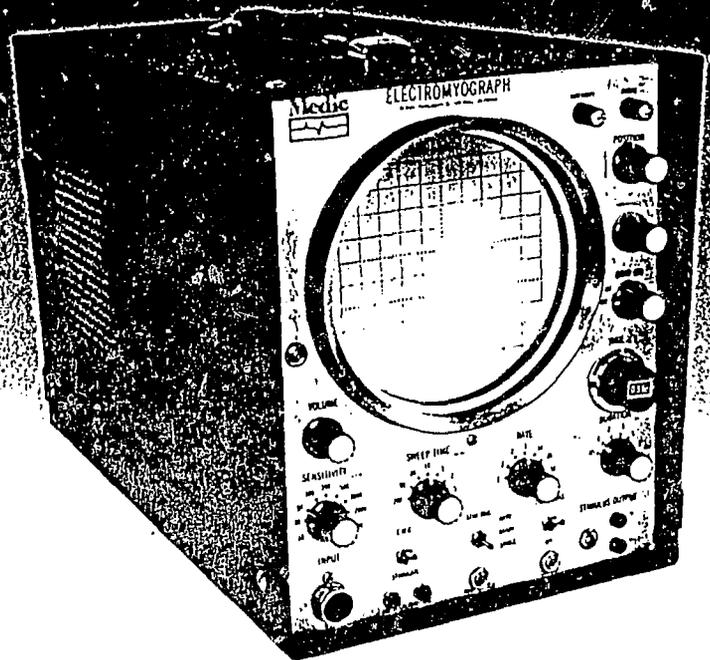


Miller Medical Electronics, Inc.

BEST AVAILABLE COPY

ITEM # 16, page 2

THE SOLID STATE LIGHTWEIGHT



Look to Medic for the finest in Electromyographic Instrumentation.

They're here. The latest solid state innovations.

All in our new portable, lightweight electromyograph, the Portaline 500B. It features integrated circuits and chips, portability and "state of the art" circuitry that dramatically improves performance. It features a constant voltage transformer isolated stimulator, a footswitch stimulator control, and a standard free-running mode. There are no relays

or electro-mechanical parts to wear out.

The one year MEDIC warranty and service policies gives trouble free service from America's leading manufacturer of electromyographic equipment.

It's the lowest cost, lightest, smallest, high quality electromyograph available today. The cover has ample room to carry all that is necessary to conduct NCV or EMG studies and everything is included in the one low cost.

PORTALINE 500B

BEST AVAILABLE COPY

SPECIFICATIONS

VERTICAL AMPLIFIER: Sensitivity: 5 μ /cm (Model 2000), 10 μ /cm (Model 500B and Model 2000) to 5mv/cm — 1, 2 and 5 sequence. Frequency Response, 2 Hz — 20 KHz. Input Impedance, Signal Mode: 100 Megohms. Input Impedance, Common Mode: 250 Megohms. Common Mode Rejection: 10,000:1 at 60 Hz. Short Circuit Noise: < 1 μ v RMS at 1 KHz bandwidth (typical), < 3 μ v RMS at 10 KHz bandwidth (typical). Amplitude calibration: 100 uv P-P Signal.

TIME BASE: Sweep Times: 1 to 200 ms/cm. Free running or triggered by stimulator.

NERVE STIMULATOR: Transformer Isolated, constant voltage type. Rate: .5 to 50 pulses

per second, free running or foot-switch controlled. Duration: .05 to 2 ms. Amplitude: 0-300 volts

CONDUCTION INDICATOR: Multi-turn direct reading digital dial.

TIME MARKS: 1 ms or 2 ms superimposed on trace, when selected by operator. (2 ms only on Model 500B).

AUDIO: 2W RMS to 4" Diameter integral speaker. (Model 2500, 5W RMS 4 x 6").

POWER SUPPLIES: 115V AC 50/60 Hz. 1 Amp. Stabilized for \pm 10% variation from nominal input voltage. (230V AC available on special order.)

LIMITED WARRANTY AND SERVICE POLICIES

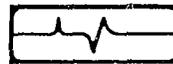
LIMITED WARRANTY

Each MEDIC unit is warranted against defective materials and workmanship for one year from date of delivery when returned to our manufacturing facility. (Limited warranty does not include shipping.)

SERVICE POLICIES

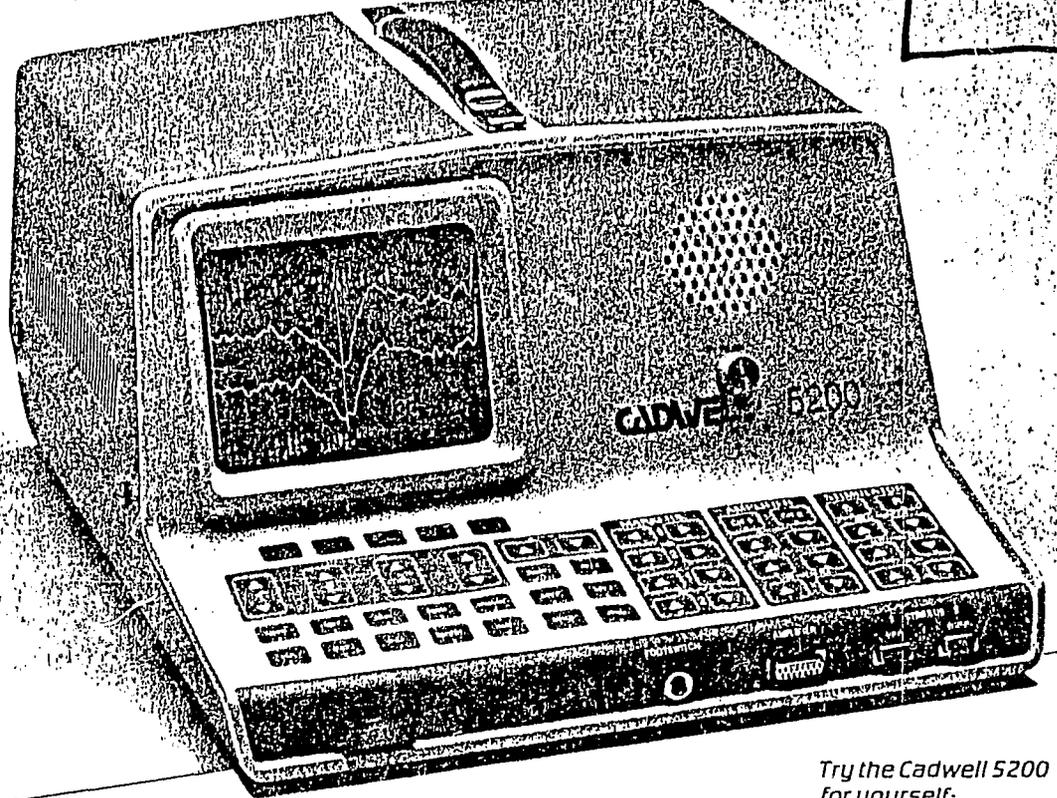
Extended service policies are available that will in effect extend the limited warranty for many years. Policies are tailored to meet many needs. They may include only preventative maintenance or may include full unlimited maintenance. Tell us your needs, and we will develop a program to fit. Loan equipment for use during repair is generally available at no cost, other than shipping charges.

Medic



MEDICAL INSTRUMENT COMPANY
310 S. VIA VERA CRUZ • SUITE 108
SAN MARCOS CA 92069
(619) 744-9652

BEST AVAILABLE COPY



The Cadwell 5200

Now more than ever it's time to own a Cadwell.

*from: Arch. Phys. Med. + Rehabil.
1982.
verified availability of this and
a similar upgraded model
1990 - 1984*

A head-to-head comparison: the decision is yours.

	Cadwell 5200	Teca TD10
Modes	EMG with back-up trigger and delay NCV with calculation optional dual stimulus with delay Somatosensory evoked potential one or optional 2 channel	EMG with trigger and delay line NCV Somatosensory evoked potential
Repetition Rate	0.25-90 pps in approx. 16,000 steps	0.5-50 pps in 8 steps
Input channels	1 or optional 2	1
Traces displayed	Up to 4	Up to 2
Time and amplitude markers	Yes	Time only
Averager	One or optional 2 channels	Single channel
Digital filter	Standard	Not available
Print-out	4 traces patient name, date, time and amplitude markers, instrument settings, stimulus, parameters NCV.	1 trace, gain, speed
Display gain	1 to 100 100 steps	1 to 50 6 steps
Computer interface	Standard	Not available
Weight	25 lb	33 lb
Price*	\$9,850	\$13,500

*Based on manufacturer's suggested retail price, with printer August 1981. Options are extra.

Try the Cadwell 5200 for yourself:

as described or with built-in Visual or Brain-stem Evoked Potential options. Hands-on experience will show you how high performance and ease of operation combine to give better results at reasonable cost.

The decision is still yours. Call us at (509) 735-6481 for more information or to arrange a demonstration.

CADWELL

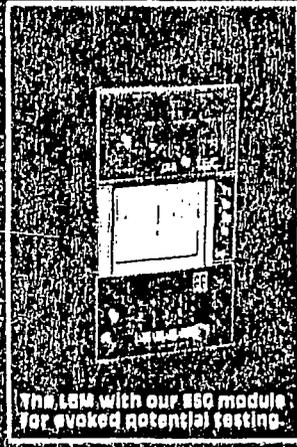
Cadwell Laboratories, Inc.
4312 S. Annenwick Avenue
Kennewick, Washington 99336
509 735 6481

BEST AVAILABLE COPY

The LBM computerized neuromyograph

We haven't forgotten EMG!

In recent months, our engineers have dramatically improved our computerized neuromyograph, the LBM. They've made it more powerful, more versatile, more portable, and able to perform a variety of tests more effectively than any other instrument of its type. But they understood that a majority of your business involves EMG, so they didn't



The LBM with our EMG module for evoked potential testing.

compromise the features which make the LBM so easy to use and cost-effective for those types of tests.

For EMG, the LBM boasts these advantages:

- real time EMG
- the highest digital frequency response for EMG traces.

- a time "zoom" which allows you to compress or expand your reading
- rastered or superimposed display
- a "trigger-and-trap" delay line, which automatically freezes any potential over a user-selected level
- clear, accurate printouts in as many as four colors
- up to five banks of memory

Of course, the LBM can do much more than EMG testing:

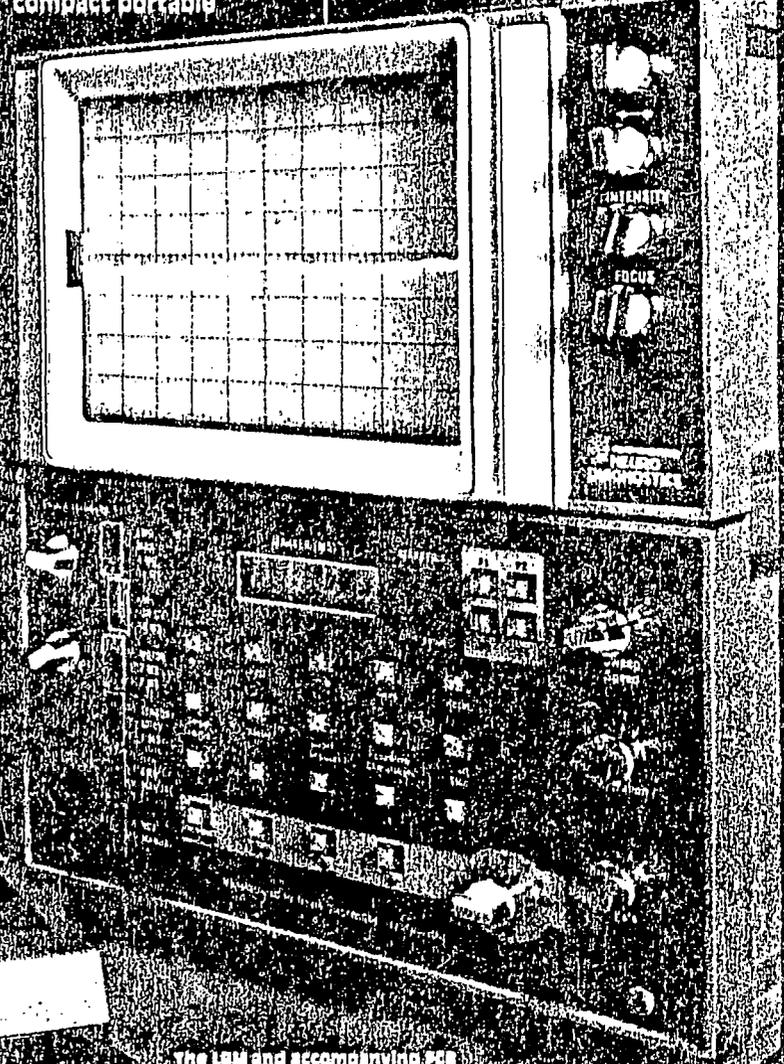
- for NCV and averaging, it has the ability to store and compare five individual NCV or evoked potential traces
- the NCV's can be mixed with the averages
- a single sweep and

stimulus function in addition to a push-to-start/push-to-stop operation.

- repetitive stimulation results can be displayed in x-axis shifted, envelope, or serial display formats.
- a smaller, more compact portable

evoked potential package.

There are so many advantages to the LBM — more than we can list here. For additional information and a demonstration, contact your nearest NDJ representative.



The LBM and accompanying color printer.

BEST AVAILABLE COPY

From: Muscle + Nerve, May '84.

Listing # 19

Availability of this or similar model verified 1980-1984.

Questions



111 WEST DYER ROAD, SANTA ANA, CA 92707 / 714-556-0039

4430 • NEW YORK — Abe Goldman 212-241-7700 • OREGON — Mel Arndt 503-667-2225 • TEXAS — Ray Lorch 714-772-0180
 1400 BOSTON — Tom 977-9252 • ILLINOIS — Mike Harris 312-247-4055 • PENNSYLVANIA — Ed Bang 717-244-0425

ITEM #19, page 1

Neuromatic[®] 2000 M

*Highly Advanced 2-Channel Neuro-Myograph for Clinical
Electromyography and Electroneurography*



*from: 1984 Product Brochure
verified availability: 1982-1984*

BEST AVAILABLE COPY

Technical Data

Active Electrode Box

Galvanically isolated preamplifiers (2 ch.)
Impedance test of electrodes:
2, 5, 10, 20, 50, > 50 k Ω
Isolation mode rejection ratio:
From input to chassis 160 dB
Dimensions (HWD): 60X100X200 mm
Weight: 1.5 kg

EMG-Amplifiers (2 Channels)

Balanced AC input with electrode cable capacitance reduction
Input Impedance: 200 M Ω /25 pF (balanced) > 1500 M Ω (common mode)
Noise Level: Typically, 0.7 μ Vrms at bandwidth 2 Hz to 10 kHz and shorted input
Common mode rejection ratio: From tip of concentric electrode through electrode box, cable and amplifier:
> 55 dB (2 Hz to 10 kHz)
Direct: > 100 dB
Lower frequency limits (-3 dB):
0.5, 2, 5, 10, 20, 50, 100, 200, 500 Hz
Upper frequency limits (-3 dB):
0.1, 0.2, 0.5, 1, 2, 5, 10, 20 kHz
Sensitivity factors: From 0.5 μ V/DIV to 10 mV/DIV in 14 steps

Digital Section

Digital resolution:
40 mV (8 bit A/D conv.)
Time windows: 5 to 1000 msec FS
Memory: 512 addresses per channel
Sampling rate: 100 kHz/channel
Averagers: 1- and 2-channel, run. norm.
Signal rejection: 1 DIV overload
Average memory: 20 bits
Auto stops: 1, 2, 5, 10, 20, 50, 100, 200, 500, 1000, 2000 and 4000 epochs
Calibration pulse: 1 DIV added to input
Output gain: Individual gain and level shift. Gain up to X25 (actual sensitivity is displayed)
Delay line: 0, 1, 2, 3, 4 and 5 DIV

Monitor

Picture tube: 9-inch TV scanning, monochr.
Graticule: Electronically generated, 10X10 DIV

Markers: Time and amplitude markers (amplitude with + or - sign), 3-digit display

Stimulator Functions

Stimulus modes: Single, recurrent and train
Recurrent: 0.5, 1, 1.5, 2, 3, 5, 7, 10, 15, 20, 30, 50 stimuli/sec, accuracy \pm 1%
Single-External: Manually released or external (foot switch or tendon hammer optional)
Train: 5, 10, 20, 30, 50, 100 200 pulses

Somatosensory Stimulator

Pulse duration: 0.1, 0.2, 0.5 and 1 msec, accuracy 1% \pm 10 μ sec (at > 0.4 mA)
Stimulus polarity: Positive and negative
Stimulus output: Constant current stimulation. Max. output 99.9 mA. Max. output mean power 0.5 W. Source voltage min. 300 V. 3-digit display shows current, accuracy better than 3% \pm 1 digit. Output resistance > 5 M Ω

Patient security: Insulation between output and power line > 4 kV AC
Insulation between output and ground > 2 kV DC. Output-to-ground leakage current < 10 μ A

Chart Recorder

Printout: 1 or 2 channels, time bars, time or amplitude markers, alphanumeric shortform of parameters
Recording paper: Aluminized Z-folded, 250 charts of 178X65 mm
Code No. 9020M1032
Paper speed: 2, 5, 10 and 20 cm/sec, accuracy < 5%
Recording modes: Continuous (real time)
Single shot (time transferred)
Special (real time + time transferred)
Max. writing span: 5 cm, traces may overlap
Upper frequency limit: 10 kHz (-3 dB)
Resolution: 7 bits, 33 kHz sample frequency per channel

Loudspeaker Circuit

Output power: 2 W/4 Ω

20M30 Interface (optional)

I/O port: 8-bit parallel, TTL levels IEEE-488 format
Data rate: Max. data transfer time 0.06 ms
Resolution: Blocks of 521 samples (corresponding to a monitor trace), resolution 8 bits/sample
Sampling frequency: Up to 25 kHz
Status transfer: All settings and parameters of Neuromatic[®] 2000

Power Supply

Power line: 100, 120, 140, 200, 220, 240 V, 50/60 Hz. Stabilized against line-voltage variations of \pm 10%. Shielded power transformer
Power consumption: Approx. 200 VA
Rear panel terminals: Preamplifier, accessory, print (manual), speaker, video output (slave monitor), IEEE interface (option)

Mechanical Data

Dimensions (HWD): 350X600X520 mm
Weight: 35 kg

Optional Accessory Equipment

20B01 Arm: Max. length 80 cm. Weight 2 kg
20B02 trolley: (HWD) 650X560X560 mm. Weight 14 kg
20B103 package of recording paper, 250 charts
20B102 Set of extension boards
Neuromatic service case
20M584 Test PROMs, Incl. instructions
20M30 IEEE-488 interface
20M31 Apple II software

We reserve the right to make, without notice, such changes in our published data as we may deem necessary or desirable.

DISA

DANTEC Electronics, INC.

779 Susquehanna Ave., Franklin Lakes, NJ 07417 • 201 891-9460 • Telex: 219 205
Sales and service: Houston, TX • Naperville, IL • Marina Del Rey, CA • Atlanta, GA • Toronto, Ont., Can.

Printed in Denmark, February 1984

Publ. No. 4701E

BEST AVAILABLE COPY

ATTACHMENT VFEATURE BY FEATURE COMPARISON OF PIRD-Y WITH PRE-ENACTMENT
COMMERCIAL DEVICES

<u>PIRD-Y Features, by Component Section</u>	<u>Examples of Substantially Equivalent Devices</u>
EMG Monitor:	
* EMG range 0.1 - 1000 microvolts	* 7, 10, 12, 16-19
* uses commercially available skin surface electrodes	* 2, 4, 5, 7, 8, 12, 13-15, 17
* adjustment for EMG range (sensitivity)	* all systems with EMG Monitors
Biofeedback Function:	
* visual index of EMG activity available to the patient and operator	* 6, 7, 8, 10-12, 15-19
* audio index of EMG activity available to the patient and operator	* 6-11, 10, 12, 15-17
* operator-set EMG goal level or muscle-activated stim. trigger	* 7, 12, 19
Muscle Stimulation Function	
* 0-120 volts peak pulse amplitude	* 1-5, 13-19
* Pulse frequencies less than 100 Hz	* 15-19, etc.
* 300 us or 1000 us pulse width	* 15-19, etc.
* skin surface electrodes	* 2, 4, 5, 15, 17, 19, etc
General Features	
* portable	* 2, 4, 5, 7, 10-12, 15-17
* battery powered	* 2, 4, 5, 7, 8, 11, 12
* rechargeable batteries	* 12