<table>
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<tr>
<th>Device Classification Name</th>
<th>Device, Biofeedback</th>
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<tr>
<td>510(k) Number</td>
<td>K092114</td>
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<tr>
<td>Device Name</td>
<td>ELECTRO-PHYSIO-FEEDBACK-APPROD® SYSTEM</td>
</tr>
<tr>
<td>Applicant</td>
<td>ECLISION, INC.</td>
</tr>
<tr>
<td>Applicant Contact</td>
<td>Frank Dimarco</td>
</tr>
<tr>
<td>Correspondent</td>
<td>ECLISION, INC.</td>
</tr>
<tr>
<td>Correspondent Contact</td>
<td>Frank Dimarco</td>
</tr>
<tr>
<td>Registration Number</td>
<td>512.550</td>
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<td>Classification Product Code</td>
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<td>03/30/1988</td>
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<td>Decision Date</td>
<td>10/13/1988</td>
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<td>Neurology</td>
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<td>Neurology</td>
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<td>Type</td>
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<td>Reviewed by Third Party</td>
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<td>Combination Product</td>
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Establishment Registration Database

Establishment:
ECLOSION KFT.
Kalvaria Ter 2
Budapest, HUNGARY 1089
Registration Number: 3004444071
Operations: Remanufacturer
Status: Active
Date Of Registration Status: 2004

Owner/Operator:
ECLOSION KFT.
Kalvaria Ter 2
Budapest, HUNGARY 1089
Owner/Operator Number: 9061821

Official Correspondent:
Mr. Richard Lloyd
ECLOSION KFT.
Kalvaria Ter 2
Budapest, HUNGARY 1089
Phone: 361-303-6043

US Agent:
Ms. Kara Nelson
414 Ridgefield Ave.
Boardman, OH 44512
Phone: 330-629-9159
Fax: 914-931-3462
Email: INFO@QXSUBSPACE.COM
Re: K892114A
Electro-Physio-Feedback-Xrroid*
System
Dated: Undated
Received: July 18, 1989
Regulatory Class: II

Eclosion Corporation
Attn: Frank DiMauro
3936-A Niagara Street
Denver, Colorado 80207

Dear Mr. DiMauro:

We have reviewed your Section 510(k) notification of intent to market the
device referenced above and we have determined the device is substantially
equivalent to devices marketed in interstate commerce prior to Mar. 28, 1976,
the enactment date of the Medical Device Amendments. You may, therefore,
market the device, subject to the general controls provisions of the Federal
Food, Drug, and Cosmetic Act (act). The general controls provisions of the
act include requirements for annual registration, listing of devices; good
manufacturing practices, and labeling, and prohibitions against misbranding
and adulteration.

If your device is classified (see above) into either class II (Performance
Standards) or class III (Premarket Approval) it may be subject to such
additional controls. 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. Please note:
this response to your premarket notification submission does not affect any
obligation you might have under the Radiation Control for Health and Safety
Act of 1968, or other Federal laws or regulations.

This letter immediately will allow you to begin marketing your device as
described. An FDA finding of substantial equivalence of your device to a
pre-Amendments device results in a classification for your device and
permits your device to proceed to the market, but it does not mean that FDA
approves your device. Therefore, you may not promote or in any way
represent your device or its labeling as being approved by FDA. If you
desire specific advice on the labeling for your device, please contact the
Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at
(301) 427-8040. Other general information on your responsibilities under
the act, may be obtained from the Division of Small Manufacturers Assistance
at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

George C. Murray, Ph.D.
Director
Division of Anesthesiology, Neurology,
and Radiology Devices
Office of Device Evaluation
Center for Devices and
Radiological Health
We have reviewed your Section 510-k notification of intent to market the device referenced above and we have determined the device is 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 the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (act). The general controls provisions of the act include requirements for annual registration, listing of devices; good manufacturing practices, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) it may be subject to such additional controls. 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. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal laws or regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-Amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Operations, Regulatory Guidance Branch (HFA-323) at (301) 427-8040. Other general information on your responsibilities under the act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

George C. Murray, Ph.D.
Director
Division of Anesthesiology, Neurology, and Radiology Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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7. [Redacted] has been consulted concerning the [Redacted] of Eclosion to biofeedback [Redacted].

8. Software is validated. The software is [Redacted].

In my discussion with Mr. DiMauro he explained that the biofeedback system is composed of; a computer, terminal, keyboard, printer, software and the GSR, ENG, skin temperature monitoring components.

[Signature]
Stephen M. Hinckley
MEMORANDUM OF TELEPHONE CONVERSATION

Between: Frank DiMauro & Bill Schlining
Eclosion Corp.
3960-A Niagara St.
Denver, CO 80207
(303) 322-8978

And: Stephen M. Hinckley, Physiologist,
DANRD, HP2-430

Date: 29 September, 1989

Subject: Premarket Notification N892114

I called Mr. DiMauro to discuss the addendum he submitted to this file. He referred me to Mr. Schlining for any information or discussion concerning this file. Prior to completing our conversation he said that

Mr. Schlining and I discussed this file. During our conversation he made the following comments:

1. The labeling for this device has been redrafted and does not include any reference to the use of this device for treating any medical condition. The labeling also only includes instructions for monitoring only those physiological parameters the device is capable of, i.e. GSR, ENG and skin temperature. There is no reference to using this device to monitor ECG, blood pressure or any other physiological phenomenon.

2. The firm only intends to sell this device to clinicians, they do not intend to sell it as an OTC device.

3. The electrodes for monitoring GSR and ENG are electrodes.

4. The physiological parameter monitoring components of this device are a switching box which allows the clinician to switch from one monitoring location on the body to the next without disconnecting the patient. The patient is isolated from the amplifier and any other source of AC current.

5. The electrode gel supplied with the device is manufactured by

6. The list of reference material included in the addendum is not going to be included in the labeling for the device. It was only included in the file as reference material for the FDA.

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CONSUMER NAME: Eclosion Corporation

DEVICE NAME: Electro-Physio-Feedback-7rroid System

1. Life-sustaining or life-supporting: No
2. Implant (short-term or long-term): No
3. Software-driven: Yes Moderate level of concern

4. Device(s) to which equivalence is claimed and manufacturer:
   Professional Series Model 421/Self Regulation Systems

5. Submission provides comparative specifications:
   Instructions for use
   comparative in vitro data: No
   summary of animal testing: No
   summary of clinical testing: No

6. Description of device and similarities and differences between device and
   pre-existing predicates device(s), including indication for use, new
   technology and new kinds of safety issues:

1. Performs EEG, GSR and skin temperature biofeedback.
2. Four channels; 2 temperatures, 1 GSR, 1 EEG.
3. GSR range, 0-100 Kohms; EEG, 0-10 millivolts, bandpass 100-200 Hz or 15-1000
   Hz; temperature range, 60°-100° F.
4. Eclosion Corp. manufactures biofeedback components, the computer, the printer,
   the keyboard, software and the switching box. Eclosion manufactures and
   provides a switching box which allows the user to switch
   from monitoring at one position on the body to another without disconnecting
   the subject.
5. isolation is used to isolate the subject from any line voltage. Firm
   indicates the biofeedback monitoring system meets UL 544.
6. Through software the user is capable of storing data, performing statistical
   evaluation of data, change monitoring ranges, change feedback displays or
   tones.
7. Firm states that the labeling will not contain any reference to the use of
   this equipment for treating any medical condition and will only provide
   instructions for use which relate to the capabilities of the device, i.e.
   GSR, EEG and skin temp. Re. phone memo dated 29 Sept., 1989.
8. Software validation procedures are followed.

7. RECOMMENDATION:

   I believe that this device is equivalent to:

   Classification should be known as: 882.5020 Biofeedback Device
   Section Number and Device Name
   Class: Class II

   Stephen M. Hinckley 10/4/89

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ATTACHMENT IV

Use Description

The sole purpose of the E.P.F.X. System is to provide the patient with insight into the subtle changes in the temperature, skin resistance (sweat), and muscle voltage. No claims are made by the Eclosion Corporation for the ability of biofeedback to treat any medical condition. Even claims for stress reduction are not without critics or criticism.

What we do claim is that the system measures subtle body electric and thermal changes in the patient and feeds them back to the patient via audio or video signals. These signals give the patient awareness of the electrical and thermal changes and thus allows them to better relax.
Eclosion Corporation introduces a new biofeedback system, the Electro-Physio-Feedback-Xrroid (a Xrroid is our coined word for our computer interfacing biofeedback system)

The Newest in Biofeedback Analysis with Capabilities for:

- 6 to 8 position thermography
- 8 point galvanic skin resistance readings
- 9 point EMG system for muscle tension

This system can analyze two or three modality changes for mixed variable feedback. Software allows for display of variables in multiple fashion such as barograph, kaleidoscope, multiple circles, or various games such as Egg Catching, River Rafting, etc. Patient awareness can be increased with the new E.P.F.X. System.

Contact your nearest Eclosion salesman or phone 1-800-950-8551 for more information. In Colorado, phone 322-8978.
510(k) "Substantial Equivalence" Decision-Making Process (Detailed)

New Device Is Compared to Marketed Device

- Does New Device Have Same Indication Statements? Yes → New Device Has Same Intended Use and May Be "Substantially Equivalent"

- New Device Has Same Intended Use and May Be "Substantially Equivalent"

- Could the New Characteristics Affect Safety or Effectiveness? Yes → Do the New Characteristics Raise New Types of Safety or Effectiveness Questions?

- Do Accepted Scientific Methods Exist for Assessing Effects of the New Characteristics? Yes → Are Performance Data Available to Assess Effects of New Characteristics?

- Are Performance Data Available? Yes → Performance Data Demonstrate Equivalence? Yes → "Substantially Equivalent" Determination

- Performance Data Demonstrate Equivalence? Yes → Performance Data Required

- Are Performance Data Available? Yes → Performance Data Required

- Do the Differences After the Intended Therapeutic/Diagnostic/etc Effect (in Deciding, May Consider Impact on Safety and Effectiveness)? Yes → Not Substantially Equivalent Determination

- New Device Has New Intended Use

- New Device Has Same Intended Use and May Be "Substantially Equivalent"

- Descriptive Information about New or Marketed Device Requested as Needed


2. This Decision Is Normally Based on Descriptive Information Alone. A Limited Testing Information Is Sometimes Required. There May Be Other Limits. The General Statement "Yes" in the Text etc.
DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

The submitter requests under 21 CFR 1847.95:

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code - Panel and class:

Additional Product Code(s) w Panel (optional):

REVIEW: (BRANCH CHIEF) (DATE)

FINAL REVIEW: (DIVISION DIRECTOR) (DATE)

BEST COPY AVAILABLE
ELECTRO-PHYSIO-FEEDBACK-XRROID® SYSTEM

510 K NOTIFICATION

March 15, 1989

From: Eclosion Corporation, NDC# 172-1698
3960-A Niagara St.
Denver, CO 80207
(303) 322-8978

Contact Person: Frank DiMauro

Physio feedback-Xrroid (E.P.F.X.)

E.P.F.X. system is a simple biofeedback with computer graphics. Eclosion Corporation wishes to apply for equivalency to devices sold before marketing the E.P.F.X. System. The Eclosion Corporation also wishes to have this application and any FDA correspondence kept confidential.

Xrroid is a potential trademark term of Eclosion Corporation for computer biofeedback connection.
March 15, 1989

Food and Drug Administration
Center for Devices and Radiologic Health
Document Mail Center (HFZ-401)
8757 Georgia Ave.
Silver Spring, Maryland 20910

Attention: Document Control Clerk

Re: 510 K

Dear Sir Madam:

The Eclosion Corporation wishes to request marketing clearance for its computerized biofeedback system (Class II). The pre-market notification information required is as follows:

A. Classification Name: Computerized biofeedback system (feeds back skin impedance, point milli-voltage, and temperature).

B. Preregistration: The establishment registration number is 172-1698.

C. Classification: Skin impedance instrument measuring galvanic skin resistance is FDA number 84GZO; Electromyograph, 84HCC; and temperature feedback is FDA number 80FLL.

D. Eclosion Federal I.D. number is 84-1108034.

E. Performance Standards: September 5, 1980, the FDA set general safety guidelines (45FR58970) for electromedical devices. We are aware of no other performance standards for biofeedback devices. Eclosion corporation has provided ground fault protector attachment to all wall plug units. Micro-circuit breakers (50 milliamps) are attached to all probes and wires attached to the patient. Absolute safety is assured the patient. (See electrical diagram.) The test in transcutaneous (skin contact) only and is not invasive.

Best Copy Available
F. Labeling Promotional Material: Labeling specimen and draft copies of promotional literature are enclosed.

G. Substantial Equivalence: The E.P.F.X. System is a simple biofeedback machine for stress reduction use only. It measures skin resistance, dermal voltage, and skin temperature. This is equivalent to the autogenic system, the Davicon system, an several other pre-amendment systems pre-1976.

Sincerely,

ECLOSION CORP.

Frank DiMauro
President

FD 1d

Attachments
<table>
<thead>
<tr>
<th>ATTACHMENT</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Software Description and Operators Manual</td>
</tr>
<tr>
<td>II</td>
<td>Electrical Schematic</td>
</tr>
<tr>
<td>III</td>
<td>Promotional Literature (draft)</td>
</tr>
<tr>
<td>IV</td>
<td>Intended Use</td>
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<tr>
<td>V</td>
<td>Safety Description</td>
</tr>
<tr>
<td>VI</td>
<td>Label Sample</td>
</tr>
</tbody>
</table>
PRECAUTIONS OF USING E.P.F.X. MACHINE

A. Do not use on small infants or children under 3 years of age.

B. Do not use on pregnant women.

C. Do no use over irritated, inflamed, red, or broken skin.

D. Do not use on patients with electrical sensitivity.

E. Do not use on patients who are under the influence of alcohol or drugs.

F. Do not use on patients with a history of epilepsy.

G. Use caution with psychotic or patients with histories of electro-shock.

H. The E.P.F.X. is for biofeedback use only.
A Message

from the president of Davicon:

As a health care professional, you want to provide the best care you can for your patients. In clinical biofeedback, that starts with using the best tools. I believe Davicon makes the best instruments and systems for biofeedback. Consider some of the product advances pioneered by Davicon:

- Automated research protocols for biofeedback
- Comprehensive stress profiling using both self-report and psychophysiological assessment
- Use of photoplethysmography (PPG) for heart rate and real-time vascular monitoring
- Implementation of an advanced systems approach to EMG that includes 16 sensors, extended bandwidth, and enhanced artifact rejection

These are not "paper-spectaculars." Each one of these advances has real clinical utility. Davicon was the first company to introduce these advances to biofeedback. And our extensive experience and aggressive product development have established us as the continued leader in these and many other areas of clinical technology.

We are rightfully proud of our product development team. But we're not the only ones who appreciate their work. You may have noticed that many of our product "firsts" are being imitated by other manufacturers. Also, Davicon was recently awarded a grant by the National Institute of Health to develop improved means for assessing stress. The bottom line is that when you buy a Davicon product, you know that you are getting the most advanced clinical technology available.

But we know that no matter how good our product is, our job doesn't end when we hand you a box. We are committed to service. We have the most complete customer support services in the industry. You can talk to our customer service staff by calling our toll-free Service Hot-line: 1-800-DAVICON (How many other manufacturers offer that?) And we service everything we sell, including Apple and IBM equipment. Davicon has the most complete line of biofeedback products and the people to support you in using them.

Biofeedback is our only business. I have personally made my career in biofeedback since 1972, when I was president of Autogenic Systems. And every member of the Davicon team is equally committed to advancing biofeedback. You can count on us to be here when you need us and to deliver what we promise.

Sincerely,

Kevin M. Connolly
President

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Clinically Proven Products for Biofeedback

Excellent instruments with excellent and ease of operation. I am also very happy with the muscle sensory thresholds and the fact that the thresholds are extremely adjustable. The true dual display in the MEDAC EMG is essential for determining tension and the use of active electrodes as exception. Movement is highly recommended to patients.

L. Libo, Ph.D. Director
Aquaequity Biofeedback Center

A complete system for biofeedback and stress profiling. Clinically proven and easy to use.

"MEDAC has been very reliable. I am particularly happy with the single program. It is very useful in the treatment of migraine and head-upright problems. The instructions are very comprehensive and the telephone support is available." - F. Scopadros, M.D.
Rhode Island Hospital

The Monitor Series

State-of-the-art biofeedback instruments, for stand-alone use or as part of a computer system.

"In general, I am quite satisfied with the overall quality of the instruments. The visual and audio feedbacks are very helpful. I have been totally satisfied." - Peter Remac, M.S., Therapist
St. Luke's Hosp., Mesa, AZ

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Reasons to Choose the MEDAC System

The MEDAC System is a proven performer whose reliability and clinical utility have been demonstrated in years of use. Its integrated software is designed by clinicians, for clinicians. You don’t have to be a programmer or an engineer to run MEDAC. It works the way you do.

There are no “hidden costs” to MEDAC. Complete systems include all necessary instrumentation for up to eight channels of physiological monitoring, software, and the best in micro-brand computer equipment.

MEDAC is the serious system for biofeedback, with hospital-grade instrumentation and more clinical programs than any other integrated software. Standard types of biofeedback programs include single and dual channel EMG, arterial pulse, heart rate, heart rate sensitive skin conductance, skin temperature, and multi-channel for up to seven channels simultaneously.

MEDAC is also a powerful tool for prescriptive diagnostics. MEDAC is the only system to have comprehensive stress profiling, with programs that make it possible to quantify individual stress responses. Stress profiling can add a new dimension to the practice of clinical biofeedback.

MEDAC software is the best of both worlds. Its standard mode makes MEDAC a user-friendly system to use. Programs use clinically proven protocols for biofeedback and collect data automatically. But you can easily modify standard protocols and even create and save your own protocols in a software “library” (MEDAC 3000 only). This means that not only is MEDAC easy enough for you to use immediately, it is flexible enough for you to use for years to come!

MEDAC automatically keeps biofeedback session records, scores and graphs questionnaires, and performs data acquisition for physiological monitoring. Each patient has an individual desk on which all MEDAC data are kept. And you can print any portion of a patient’s record at any time. Reports are suitable for referral sources or insurance companies.

MEDAC has always emulated the most advanced signal analysis and electrode systems. Now MEDAC has been re-designed, based on new technology and Davison’s extensive experience with computerized instrumentation. New MEDAC instruments feature significantly enhanced skin conductance, photoplethysmography, temperature, and a long-life Gei-cell battery system. In addition, a new interface card provides high-quality audio feedback with more flexibility than any other system, plus allows use of an optional Remote Control Box.

MEDAC is now available for use with the new IBM Personal System/2 Model 50, as well as the IBM PC/XT™, IBM AT®, or compatible. MEDAC takes full advantage of the power of the new IBM computers with high resolution (EGA) color displays and constant 14 bit resolution. This allows fully auto-ranging instrumentation for “hands off” operation, while maintaining the highest sensitivity in the industry, including resolution of 1 mV, and 0.01 mV ECG activity.

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MIDAC is now available for Apple’s new high-performance Lisa computer, as well as for the dependable and familiar Apple IIc.

MIDAC is a versatile system that pays for itself in numerous ways:
- By providing several distinct and billable procedures, including the PSA, Stress Age, and Henchman Questionnaire, as well as bloodwork.
- By producing reports for third-party reimbursement and referral sources.
- With software complexity that minimizes training costs for new personnel.

Finally, don’t forget that your computer is not dedicated to MIDAC. You can still use it for word processing, spreadsheet, and office billing programs.

Let’s talk money. MIDAC is fairly priced, but it is not the least expensive system. So consider leasing. With leasing, you pay almost no money down and payments can come from cash-flow. And if you compare the monthly payments for various systems, you might be surprised to see how little it costs to buy the best.

DaVicca offers the most complete customer support services in the industry. This support begins with the MIDAC System itself. MIDAC is self-documenting and easy to use. MIDAC is also extremely reliable, but if it should ever require repair, it is designed for convenient field service. Instruments and software have built-in diagnostics. These tools will usually allow us to isolate any problems over the phone. And because hardware is modular, parts can easily be exchanged.

Support is always available by calling our toll-free Service hotline, 1-800-DAVICO. We have found that most problems can be actually cleared over the phone. And current MIDAC users have told us that about dealing with us. We are committed to supporting you.

DaVicca’s extended warranty just been to upgrade systems as needed or as soon. Whenever practical, upgrades to improve performance and reliability are offered to MIDAC users.

“I am still impressed with your equipment after a year and a half of use. It is well designed and it works. It is the best system available for my purposes. Excellent features (include the) Arter Electrocardiography are key system, and upgrade to software.”

J. Zavag, Ph.D., Saffrony, MD

“I have my system and I must have gotten good support.”

D. Wad, Ph.D., Marshall Univ., Huntington, WV

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**MUO EMG**

Features a new sensor for muscle scan; a highly flexible feedback and real digital integration leveraging built-in, with a choice of three discrete trial periods.

The MUO incorporates the MyoProcessor, advanced systems approach to neuromuscular measurement. The MyoProcessor advances the state-of-the-art in all phases of EMG with a new kind of "near the Active Electrode" extended bandwidth and a uniquely sophisticated power detection circuit. See Danicon's publication "New Technology of EMG Bioread protests" for a complete description. The result is EMG that is both more accurate and easier to use.

** Ordering Information:**
- The MUO comes complete with Active Electrode, AE, 28 gage needle recording system and operating manual.
- SAMPLER SUPPLEMENTS Packages of 20 ea.
  - Single-use solid disposables, Danicon P/N AE-1
  - "Three-prong" standard disposable electrodes, Danicon P/N AE-3

---

**C20 EDR**

Features simultaneous measurement of tonic and phasic responses, high resistance to artifact, unequalled precision, and excellent feedback. The C20 is the only biofeedback EDR with logarithmic feedback of phasic responses, a choice of manual or automatic operation and 42 analog modes, including "silent windowing."

The C20 utilizes Constant Current Conductance, a proprietary system which is the most accurate means available for measuring skin conductance. As a result the C20 offers outstanding deficiencies of ERG-type devices and should be considered by those whose practices involve systematic desensitization, psychological testing, or stress-related skin disorders.

** Ordering Information:**
- The C20 comes complete with gold-plated sensors, recording system, and operating manual.

---

**T90 TEMP**

Features both the highest digital resolution (0.01°F at all times) and the highest feedback sensitivity of any biofeedback TEMP 0.01°F change (full scale).

The T90 utilizes a "chopper stabilized" front-end for maximum temperature stability, artifact rejection, and linearity. And it is the only biofeedback TEMP to provide a choice of manual or automatic operation manual for precisely controllable shaping or automatic for the convenience of "hands off" use.

** Ordering Information:**
- The T90 comes complete with a thermometer sensor, recording system, and operating manual.

Consultant EDR: Works with CT1 EDR Converter
The Monitor Series

No frills" instruments

The Monitor Series are "no frills" instruments that are highly accurate and have exceptional feedback displays. Instruments are available in each of the three most commonly used modalities: EMG, EDR, and skin temperature. Despite their low cost, their accuracy makes them appropriate for routine clinical work. Their durability and ease of use also make them particularly well suited for use by patients at home training.

**M4 EMG**
Features flexible thresholding and the Active Electrode, the most accurate and flexible EMG sensor available with a built-in preamp that virtually eliminates artifact. The Active Electrode can be used dry, for muscle scanning, or with standard disposable electrodes. Audio feedback includes precisely adjustable thresholding and raw EMG sound.

**C2 EDR**
Features two sensitivity ranges and two display modes for measuring skin conductance: NORM for most relaxation therapies, and DERIV for highly responsive mode useful for psychological auditing. Also uses dry, gold-plated sensors.

**T3 or T3H TEMP**
Features exceptional resolution of temperature changes and the fastest responding sensor in the industry. In its Derivative mode, the T3 tracks only the changes in temperature and resets displays after each change, allowing hands-off operation. Optional sensor allows automatic multisite averaging. Available in °C or °F.

Ordering Information:
Each Monitor Series unit has everything necessary for clinical instanlitate in a single self-contained package, including rechargeable batteries, a built-in speaker, and a combination transducer. Units also come with a recharger, sensors, and operating manual. The kit also includes AE-128 data cards.

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The Stress Audit

Paper and Pencil Version

The Stress Audit presents a quick and comprehensive summary of stress-relevant data that translates easily into intervention and treatment planning. The Stress Audit is a 236 item Likert scale instrument that samples the magnitude and types of stress experienced or expected by the respondent and assesses relative vulnerability to stress. The Stress Audit yields a profile that reflects three facets of stress:

- Situational stress items, divided into six scales,
- Stress symptom items, organized into seven physiological system scales, and
- Vulnerability scales.

administration based tests with a profile sheet for scoring on automatic machines. A comprehensive manual aids in interpretation of the profile. Scores from these tests may also be entered into the MEDAC System for a comprehensive interpretation.
510(k) NOTIFICATION

THE RECOMMENDATION

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:

The submitter requests:

- [ ] No Confidentiality
- [X] Confidentiality for 90 days
- [ ] Continued Confidentiality exceeding 90 days

REVIEW:

[Branch Chief]

(DATE)

FINAL REVIEW:

(DIVISION DIRECTOR)

(DATE)

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BioLab System
Information

The BioLab's modular design allows unparalleled flexibility. Standard "nursery" systems are available for applications in clinical biofeedback, psychophysiological research and rehabilitation medicine. Or, special systems can be easily configured to meet your unique clinical or research needs. One of our Ph.D. psychologists would be happy to discuss your requirements with you.

BioLab Modules

The BioLab offers a variety of psychophysiological monitoring modules for applications in clinical biofeedback and psychophysiological research.

BioLab will accept up to eight of the following modules:
- Physiology
  - Heart Rate
- Biofeedback
  - Skin Temperature
- EMG
  - Skin Temperature and
  - Conductance
- EEG
  - Frequency and Amplitude
- GSR
  - Electrical Parameters
- SPO2
  - Pulse Oxygen (and
  - Heart Rate
- Resting Data

Special monitoring or data acquisition requirements can be accommodated by the BioLab's Isolated Instrument Interface Module. This module accepts the voltage output (+10 volt range) from virtually any type of free-standing clinical or laboratory instrument.

BioLab Software

BiText®, the BioLab's powerful operating software, is the heart of the BioLab system. It is an easy-to-use program to run training, therapy, or research sessions. Summary statistics are automatically calculated and recorded for each session by BiText®.

Demonstration Disks

Convinc yourself. The new IBM and Apple compatible BioLab is the superior choice for clinical biofeedback or research by ordering the BiText® software demonstration disk.

Additional Information:
- Please send complete detailed information and prices on BioLab components and software.
- Please send demonstration disk ($15.00) circle one: Apple IBM
- Please have representative phone to discuss any needs.

Name:
Title or Department:
Organization:
Address:
City State Zip
Telephone:

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Autogenic Systems
820 Wavel Lane
Wood Dale, Illinois 60191 USA
Phone: *(312) 526-9700
Fax: *(312) 526-8775

(Withed 11-9457 for use only if our phone and this are charged to 180)}
Clinical Biofeedback

Ease of Operation
Combined with Superior Performance

Why Computerize Your Biofeedback Practice?

The BioLab streamlines the patient management aspects of your practice and greatly increases the effectiveness of each session.

Imagine telling a patient to warm the hands of the human figure on the monitor and they do so by warming their own. Or telling them to lower the heart rate of the human figure on the monitor, and they do so by lowering their own. Or perhaps, for audio feedback, have them close their eyes and listen to melodic, relaxing tunes specifically designed to deepen relaxation. Then, imagine being free of record keeping and statistical analyses, allowing more time for interaction with your patient. And you'll begin to understand the power and purpose of the BioLab.

Patient Motivating Visual Feedback

Patients relate easily to BioLab displays, becoming enthusiastic participants in the therapeutic process. Among the BioLab's proprietary visual feedback displays are:

- Analogous Biofeedback Display:
  This display provides a reflection of generic male and female, adult and adolescent human figures. Changes in the patient's EMG activity, skin temperature and heart rate are reflected back to the patient by their "analog" on the BioLab's monitor. Analogous biofeedback lets the patient "see" the improvement occurring in his or her body.

- Composite Biofeedback greatly simplifies biofeedback training when more than one site or type of physiological activity is monitored. It displays from two to eight channels of activity on a single color-coding display.

The BioLab's color-coded Line Graph plots up to four physiological measures on a single large graph or, alternatively, one measure each on its own graph in a quadrant of the monitor screen.

The BioLab's Illusor Graph simultaneously displays up to four physiological measurements as color-coded bars.

The Mandala Display is an ever-changing kaleidoscope pattern that feeds back the patient's physiological signal as proportional changes in the pattern.

These and other BioLab displays, assure you and your patients of the most interesting and efficacious visual feedback in biofeedback.

Superior Audio Feedback

The BioLab's new audio module utilizes a Yamaha, eight-channel music synthesizer for the finest audio in biofeedback.

The module has four modes of operation: proprational audio feedback, background audio, reinforcement audio and auditory stimulus presentation.

Standard music selections are provided for each type of audio. Significantly, the module also allows the clinician or researcher complete freedom to create their own totally new audio feedback.

Proportional Audio Feedback provides audio feedback directly or inversely proportionally to the patient's physiological activity.

Background Audio feature provides a selection of pleasing background audio, ranging from meditative Tibetan Bells to the sound of the ocean surf (white noise).

Reinforcement Audio allows the option of playing a song or music for reinforcement upon goal attainment.

Stimulating Audio allows the triggering of an auditory stimulus at a specified time or event.

Clinical Applications

Hundreds of BioLabs are in clinical use in relaxation training, neuromuscular re-education and in the treatment of essential hypertension, tension/migraine headaches, insomnia and many other physiological disorders.

BioLab features especially useful to the clinician are:

- Easily understood audio and visual feedback designed to stimulate and maintain patient interest.
- Automated record keeping, including patient history and session notes.
- Session trials can be recalled, displayed and overwritten, dramatically demonstrating progress and providing positive reinforcement for patients.
- For muscle re-education, waveforms of desired muscle movements (from an unaffected limb) can be recorded and displayed for patients to match.
- Exclusive Blood Pressure Monitor facilitates biofeedback training for non-pharmaceutical control of hypertension.
- The BioLab's Audio and Visual Feedback are excellent with children as well as adults.
- Tape recorders, VCR's or other equipment can be activated at before or after goal attainment by the BioLab.

Optional Patient Stress Profiling Software

Optional software is available for computerized psychophysiological stress profiling of your patients. The BioLab's Stress Vector Analysis Test features automated scoring of the profile and computer generated narrative reports. The test scores are based on well-known, widely accepted, and researched assessments.
27.11 If an insulating material is used for the enclosure or part of the enclosure, the leakage current is to be measured using a metal foil with an area not exceeding 10 by 20 centimeters in contact with accessible surfaces of the insulating material. Where the accessible surface of insulating material is less than 10 by 20 centimeters, the metal foil shall be the same size as the surface. The accessible parts shall be tested individually, collectively, and from one part to another. Parts are considered accessible unless guarded by an enclosure as defined in paragraphs 4.27–4.30.

27.12 A sample of the appliance shall be tested for leakage current as indicated in paragraph 27.1. Starting with the as-received condition, the as-received condition being without prior energization except as may occur as part of production line testing, the test sequence, with reference to the measurement circuit in Figure 27.1, shall be as follows. Nonpatient equipment is tested in accordance with items A, B, and C below. Patient care equipment is tested in accordance with items B and C.

A. With switch S1 open, the appliance shall be connected to the measurement circuit. Leakage current shall be determined using both positions of switch S2, with the appliance switching devices and variable controls in all their normal operating positions, and with switch S3 in both the open and closed positions.

B. With switch S1 closed to energize the appliance, leakage current shall be determined using both positions of switch S2, with the appliance switching devices and variable controls in all their normal operating positions, and with switch S3 in both the open and closed positions.

C. Leakage current shall be monitored at sufficient intervals to determine the maximum leakage current from the time of the previous measurement to the conditions under which the normal temperature test would be terminated. Both positions of switch S2 shall be used in determining this measurement.

**FIGURE 27.1**

**LEAKAGE CURRENT MEASUREMENT CIRCUIT**

![Circuit Diagram]

Notes:
- A Separated and used as clip when measuring voltages (current) from one part of appliance excluding ground, leads, probes etc. to another
- B Probes with standard lead

SAO667  BEST COPY AVAILABLE
Patient Care Equipment

27.13 The measurement circuit for leakage current on patient care equipment is to be as follows:

A. Normally the measuring circuit is to have a resistive input impedance (R) of 1000 ohms. If, in the preliminary analysis and review mentioned in paragraph 27.9, an appliance circuit is found to have a low source impedance, it will be evaluated using a 500 ohm resistance.

B. The meter is to be average-responding and indicate rms value of a pure sine wave within an overall measuring circuit error of not more than 5 percent at indications of 10, 50, 100 and 500 microamperes (10, 50, 100 and 500 millivolts, respectively, when using a 1000 ohm resistor) at frequencies from 10 hertz to 100 kilohertz.

C. Unless the measuring circuit is being used to measure leakage current from one part of the appliance to another, the resistor and meter are to be connected between the accessible parts and the grounded supply conductor.

D. The supply voltage is to be adjusted to the test voltage as specified in paragraph 24.3.

Non-patient Equipment

27.14 The measurement circuit for leakage current from non-patient equipment is to be as follows. The ideal measurement instrument is defined in items A-C. The meter which is actually used for a measurement need only indicate the same numerical value for a particular measurement as would the ideal instrument. The meter used need not have all of the attributes of the ideal instrument.

A. The measuring circuit is to have an input impedance (Z) of 1500 ohms resistive shunted by a capacitance of 0.15 microfarad.

B. The meter is to indicate 1.11 times the average of the full-wave rectified composite wave-form of voltage across the resistor or current through the resistor.

C. Over a frequency range of 0–100 kilohertz, the measurement circuitry is to have a frequency response (ratio of indicated to actual value of current) that is equal to the ratio of the impedance of a 1500 ohm resistor shunted by a 0.15 microfarad capacitor to 1500 ohms. An indication of 0.5 milliamphere the measurement is to have an error of not more than 5 percent at any frequency within the range of 0–100 kilohertz.

D. Unless the measuring circuit is being used to measure leakage current from one part of the appliance to another, the impedance and meter are to be connected between the accessible parts and the grounded supply conductor.

E. The supply voltage is to be adjusted to the test voltage as specified in paragraph 24.3.

27.15 Generally, a peak reading voltmeter having an input impedance of one megohm or greater is to be employed in measuring the open circuit voltage between the parts in question. However, where the voltage is sinusoidal, the peak voltage can be computed from the rms or average value.

28. Applied Patient Current

28.1 The available applied patient current shall be measured for an appliance which involves the application of an electric potential to a patient (see paragraph 2.14). If the available current measured exceeds the leakage current value in Table 27.1, the appliance shall be marked in accordance with paragraph 56.1.

28.2 In making the measurement required in paragraph 28.1, the circuit is to be as described in paragraph 27.13 except that the 1000 ohm input impedance may be increased or lowered (but not less than 500 ohms) if it can be shown that maximum output would be obtained at some different level of measuring circuit input impedance.
F6, and then press the SPACE BAR. Press ALT A, and then press the SPACE BAR.

There are two exceptions to the SPACE BAR rule: if you are at the METERS or F3 DISPLAY screens, the SPACE BAR will have no effect.

2.3.16 EXIT PROGRAM, ALT N; (13) Press ALT N to exit the program. This procedure will take you back to C or A prompt. If you have entered changes in the system, you will be reminded to save these changes if you have not already done so. In most instances, you will probably not elect to save the changes.
June 23, 1989

ECLOSION CORP.

ATTN: FRANK DIMARCO

3960-A NIAGARA ST.

DENVER, CO 80207

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. This information and all correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

If your additional information is received by the Office of Device Evaluation Document Mail Center (address above), the 90-day period will begin again.

If after 30 days the requested information is not received, we will stop reviewing your submission and proceed to withdraw your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and the 90-day time period will begin again.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-8162.

Sincerely yours,

Robert I. Chissler:
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health
APRIL 10, 1989

ECLOSION CORP.
ATTN: FRANK DIMAGRO
1960-A NIAGARA ST.
DENVER, CO 80220

D.C. Number : K89C114
Received : 03-30-89
Product : ELECTRO-PHYSIO-FEEDBACK-XRIPID SYSTEM

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 the unique device 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 HFD-411
8857 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) 427-8162.

Sincerely yours,

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

Using MEDAC

WILL MEDAC work for me?

MEDAC is firmly grounded in the real-world needs of clinical practice.
MEDAC software has been used in clinical practice for over five years,
with thousands of patients. And it has been extensively upgraded as a
result of input from users in the field. Representative users and their
work include:

Professional Medicine

- Post-traumatic stress disorder (PTSD) VA Medical Ctr. Gainesville FL
- Stress profiling: Dartmouth Medical School, Hanover NH
- Myofascial pain: Tufts School of Dental Medicine, Boston, MA
- Private practice, psychological: D. Pollock, Ph.D., Winston-Salem, NC
- Private practice, psychiatric: R. T. Kramer, M.D., Torrington, CT
- Clinic: The University Psychiatric Clinic, Piner Research, NC
- Out-patient psychiatric: Beth Israel Hosp, Boston, MA
- In-patient psychiatric: University Hosp., Boston, MA
- Health Maintenance Organization: Harvard Univ Health Care, MA

Physical Medicine and Rehabilitation

- Neurovascular rehabilitation: Salem Hosp, Salem, MA
- Pain management: Scripps Memorial Hosp, La Jolla, CA
- Cardiac rehab: T. McQue, M.D., LINK, Portland, ME
- Stress tolerance assessment for head injury rehab: Rhode Island Hosp

Experimental Applications

- Athlete's performance enhancement: R. Zashkevitz, Ph.D., Boston Univ
- Psychophysiological assessment: G. Schwartz, Ph.D., Yale Univ

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The new MEDAC System

A complete system for biofeedback and stress profiling

"MEDAC is very easy to use. Allows you to spend more time with your patients. Have received outstanding support from the company. Enjoy not only working with the MEDAC System, but also the entire relationship with Davicon."

R. Perin, D.L.A.
St. Helene Hosp., Deer Park, CA

The MEDAC System is a proven performer whose reliability and clinical utility have been demonstrated in years of use. Now MEDAC features new, enhanced enhancements. And it is available for use with the new IBM Personal System/2® model 30 and the Apple Lisa™. The new MEDAC System provides increased capability and higher performance, but has the same excellent support that MEDAC users are accustomed to.

Choose MEDAC if you're looking for a powerful "turn-key" system with a full range of capabilities for stress management and relaxation. MEDAC's integrated software was designed by clinicians. For clinicians, it meets the way you do it. When you need biofeedback or stress profiling, you'll find MEDAC logical and easy to use.

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Integrated Software

For biofeedback, stress profiling, and report generation

MEDAC utilizes a bio-behavioral systems approach to stress management. Software integrates programs for stress profiling and other diagnostics, as well as clinically proven biofeedback, and full report generation. And since software is integrated, commands and procedures are consistent. This makes MEDAC easy to learn.

Unsurpassed biofeedback

MEDAC is the most sophisticated, hospital-grade biofeedback software. More complex programs are only available as software. Standard types of biofeedback programs include:
- Arterial pulse height
- Skin conductance level
- Heart rate
- EMG

MEDAC biofeedback software provides the best of both worlds. A standard mode makes operation very simple. Programs use clinically proven protocols for feedback and collect data automatically. But, prompted by on-screen instructions, you can easily modify standard protocols. You can even create and save your own protocols as a "library". This means that MEDAC is easy enough for you to use immediately, and flexible enough for you to use for years to come.

Data for all biofeedback session records are kept automatically, including mean, standard deviation, maximum, and minimum values, as well as baseline, threshold levels, and percent success.

Unique stress profiling

MEDAC is also a powerful tool for prescriptive diagnosis. It is the only system to have full stress profiling, with programs that make it possible to quantify individual stress responses. MEDAC uses a combination of self-report and physiological monitoring to assess stress responses.

Stress Audit. The Stress Audit is a 238 item Likert scale instrument that samples magnitude and types of stress experienced or expected by the respondent and assesses relative vulnerability to stress. It yields a profile that reflects three facets of stress: (1) Situational stress items, divided into seven scales, (2) Stress symptom items, organized into seven physiological scales, and (3) Vulnerability items.

Physiological Stress Analysis (PSA). These programs can detect which physiological systems are most reactive to stressors, as well as analyze over-all patterns in stress responses. Up to eight instrument channels, monitored simultaneously.

A standard protocol provides: (1) an initial or baseline period. (2) a period for the introduction of a stressor/response to stress, and (3) a recovery period. This protocol is based on the assumption that abnormal responses to stress are characterized by a high level of reactivity and/or by the length of time required to recover to baseline levels. You can easily customize this protocol to meet virtually any requirement.

Headache Questionnaire. Provides administration and scoring of a self-report diagnostic instrument. It surveys symptoms, breaking them down into seven categories, and noting specific responses that may be significant.

Automated record-keeping and reports

MEDAC automatically keeps biofeedback session records, scores and graphs. Questionnaires, and performs data acquisition for physiological stress profiling. Each patient has an individual deck on which all MEDAC data and identifying personal information are kept. You can enter comments for any session, making reviewing simpler and convenient. And you can print any portion of a patient's record at anytime. Reports are suitable for referring physicians and insurance companies.

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Using MEDAC

In your practice

How can I use stress profiling in my practice?

A stress part of your patient’s problem? Stress profiling can help you tell! And only MEDAC provides a complete stress profile with a combination of self-report and physiological monitoring to assess stress responses.

Profiling can help you to discriminate those conditions in which stress is a causative or contributing factor from those of other etiology.

How else can you use stress profiling in clinical biofeedback? Here are some ways. Biofeedback training.

- Assessing patients for biofeedback. Use the Stress Audit and PSA to help select those patients most appropriate for biofeedback training.
- Determining the optimal type of biofeedback for each patient. Use the PSA and Questionnaires before beginning training. For instance, in the case of headaches use them to evaluate the relative involvement of muscular and vascular responses.

- Establishing therapeutic house ischemes. Use the PSA and Questionnaires during the course of treatment to help set clear goals and mark progress.

- Assessing the effectiveness of training. Compare stress profiling data before, during and after the course of biofeedback training for other stress reduction therapies.

Experimental uses of stress profiling include screening psychophysiological reactivity particularly cardiovascular reactivity as a predictor of pathology.

Why is stress profiling important?

Because your time is important, MEDAC is easier to operate than any other system. This means that you can concentrate on your patient, not your equipment.

This operational simplicity has proven particularly important for hospitals and clinics. Since MEDAC requires very little training to get started, new staff members can come up to speed quickly. Also, any level of clinical personnel can operate MEDAC.

Every system claims to be easy to use. But MEDAC is self-documenting and so “user-friendly” that you can sit down and begin using it immediately, without help. If you think that is possible with any other system, try it!

Outlining information:

- Complimentary MEDAC Systems include a necessary computer equipment. For those who already own a computer or who wish to purchase and maintain their own computer equipment, Dawson also offers MEDAC “unboxed.” MEDAC 2000 for IBM PCs and MEDAC 2002 for Apple II-series computers include all instrumentation interfaces and software from the MEDAC System specifically:
  - Instrument Control: Standard measures
  - SpO2, Heart Rate, PPG, Heart Rate, Pulse, PPG, ECG, Essential (EEG, EMG).
  - All necessary sensors and cables
  - Dawson 1000 and 1000C
  - Dawson Systems

- For other applications, visit the Dawson Systems website or contact the nearest distributor for more information.

Best Copy Available.
JULY 19, 1989

ECLOSION CORP.
ATTN: FRANK DIMAURO
3960-A NIAGARA ST
DENVER, CO 80207

D.C. Number : KB932114
Received : 07-18-89
90th Day : 10-16-89
Product : ELECTRO-PHYSIO-
FEEDBACK-XRROID* SYSTEM

The additional information you have submitted has been received.

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. We intend to complete our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until after ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

All correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted as considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

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

BEST COPY AVAILABLE
To: Robert Chissler  
Premarket Notification Coordinator  
Office of Device Evaluation  
Center for Device and Radiologic Health  
FDA 510k application  
D.C. number K892114  
c: Steve Hinckley  
Re: Additional requested material basic Manual requested for 510k Application for 510k equivalency  
From: William Nelson and William Schliening  
Eclosion corp of Commerce City, Colorado  
3970 Monaco drive  
EPFX Biofeedback system  
7/10/1989  

Electro Physioloical Feedback Xrroid System  

Design for Biofeedback EPFX Device use for stress detection and stress reduction  
For Professional Biofeedback Use Only  

DISCLAIMER:  
Electro Physioloical Feedback Xrroid System EPFX  
This system is to be used as a Biofeedback multimedia system. It is designed for stress detection and stress reduction. The device does not diagnose any disease other than stress. Stress can come from many sources, this system uses many multimedia treatments to treat stress. This device also measures patients electrophysiological reactivity, which is another representation of stress.  
Only a licensed practitioner can diagnose a patient.  
This system is calibrated to measure the very fine and subtle electrical and subspace reactions to a group of biological and medical substances. The sensitivity is set so fine so as to pick up the earliest sign of disease and distress. Thus the results might be below the client recognition. The readings should be evaluated by trained staff. Use additional tests or referrals for further clarity.  
No claims other that Biofeedback Stress detection and treatment are made of the system or results.  

System Basic Design Intentions  
This system measures Electro-Physiological Reactions of the patient to applied varied electro stimulations. This is a type of
Biofeedback. This device catalogues and tabulates the complex electrophysiological reactions of your patient. This is the EPR pattern. The accuracy of the EPR pattern is limited, and as such the results cannot be treated as completely diagnostic. This device is not diagnostic of anything other than stress, the readings are meant as prediagnostic.

The doctor or practitioner then should use this data wisely and challenge the results with more standard medical measures for more accurate diagnosis within the scope of practice of the therapist. The EPFX is a computer operated energetic medicine interface that is so sophisticated most of its' functions are automatic. The autofocus system uses a link of therapy to test that is self correcting and self adjusting. The system can make corrections at speeds over one hundredth of a second. The hardest part is learning to operate the computer. It doesn't take long. In ten or so patients you will be somewhat proficient. We expect that no-one would be so presumptive as to try to treat patients the first time they use any new system. However so often new owners have all of their tough cases lined up for the first day therapy. No good results and then the system must be at fault. Any new therapy takes some time to get used to.

The Electro-Physiological-Feedback-Xrroid is a biofeedback system. The definition of biofeedback is measuring a physiological response and feeding it back to the patient. Most of the devices feedback the information primarily to the conscious and thus then to the unconscious of the patient. The EPFX-SCIO system differs in that it feeds back the information or signal to the unconscious primarily and conscious secondarily. The unconscious can then direct these autonomic processes. So our device focuses on repairing the unconscious link of mind body directly.

Feedback of electro physiological processes are given as relaxation signals to the patient. The EPFX system measures a combination of the following physiological functions, voltage potential, current potential, skin resistance, Electro Physiological Reactance, Electro Physiological Susceptance, skin temperature and Frequency. These are the raw readings made at the extremities and the head harness. (see Diagram). The EPFX system applies a variant set of signals and then measures changes in the readings. The changes determine resonance, reactivity and coherency.

The QQC is a proprietary process that does an analysis of the Polographic or voltametric three dimensional electrical pattern of a substance. This produces a substance electronic signature field. The Fields of these substances are sent into the patient via the harness. These variant patterns are of 0 Hz to 25,000 Hz and of variant wave forms. The total current is never over 5 milliamps. The patient is evaluated before and after stimulation to measure any EPR
changes that show patient reactivity. The type intensity and style of reactivity EPR offers insight into the patient health. Types of item reacting can be a link to therapy or deeper diagnosis.

The EPFX measures the Electrophysiologic Reactivity intensity of the patient to many QQC trivector voltammetry patterns. These are patterns of reactions to Sarcodes, Nosodes, Allersodes, Isodes, Nutritional, Herbals, Imponderable and Classic Homeopathics. The reaction patterns or profiles can relate disturbances of the patient. Therapies can then be arranged to develop harmonic reactions, desensitizations, biological resonance or rectification processes. All of these are applied and managed through biofeedback application. Biofeedback is the operation that allows for the cybernetic loop of systemic feedback. The only indicated use of this device and all claims related to this device are under biofeedback. The loop of measured reaction and bio-varied resonance response allow for a true feedback for self corrective Electrophysiologic therapy. Hence it is called the Electro Physiological Feedback Xrroid.

The work of Dr. Nelson in his landmark treatise ‘The PROMORPHEUS’, has broken down the science to its basic form, consciousness. The extra-Dimensional theories were tested and proven by Nelson to develop a living system model. The trivector voltammetry system measures the voltage, amperage, resistance, frequencies, etc to calculate the inductance, capacitance, resonance and conductance of the reactive system of the body over time. All done in the strict confines of biofeedback. Thus we can calculate and model the mind body connection from these multi dimensional factors. The quantic nature of the biological system allows for the interface of the digital computer.

The scientific theories behind this device are contained in the 1250 pages of the PROMORPHEUS, written in 1982.

The word doctor comes from the Latin word "EDUCTOR" or teacher. A doctor should be a teacher, thus education is a must for medicine. True medicine should be holistic medicine. Medicine is based in responsibility. Separation from a cause of disease is the responsibility of the diseased patient. If there is a cause of disease in your environment you can choose to change or reduce the cause, move to a new environment, or accept the conditions. Responsibility for healing is with the patient.

Many of the causes of disease that approach us are beneath our conscious awareness. Our unconscious is much more aware of the
disease causing factors that come at us. Our unconscious reacts with subtle energetic changes in electrical bodies. The EPFX device is the first energetic medicine device to test reactions where the patient and doctor both do not know what is being tested. Thus the unconscious of the patient causes the reactions. The reactions are not picked by the computer, not picked by the unconscious of the doctor as with point probes or kinesiology, but the results are picked by the unconscious of the patient.

WHAT IS HEALTH

Health is ease of flow.

Health is a flow of items into and out of the body. We intake nutrients, air, water, minerals, amino acids, fats, carbohydrates, thoughts, ideas, friendship, love, respect, mental stimulation, spiritual stimulation, and a host of other nutrients. We detox and excrete urine, breath exhale, stool, mucus, sweat, menses, bad feelings, fixations, addictions, Coercions, intimidations, fetishes, manias, compulsions, spiritual doubts and a host of excretions. Life is a cycle of intake, chew, absorb or reject, assimilate, produce toxins, detox, and start anew. This is the need to survive. Add to this the need to reproduce and now enters our sexual needs. All of this results in a very complex flow of energies in and out, in cycles.

The levels of the person are the body, mind, spirit, social, and environmental. It is impossible to separate these or to know where one starts and another stops. Thus these parts can not be reduced or analyzed separately.

When there is ease of flow of things in these levels the person is in health. Health is ease of flow.

FLOW OF DISEASE

Disease starts when a stressor or intrusion causes a disruption in the flow. The ease is now dis-ease. Hans Selye outlined a medical system were disease comes into the body as some sort of stressor. This produces an ALARM reaction phase as that the body is trying to deal with the incoming stress. Thus the symptom is a sign of the ALARM reaction. If we fight the symptom not the cause we stop healing. So when our child is exposed to a stress (like a bacteria from another child) a symptom presents, such as a sore throat. The symptom is sign of a disease in flow. The immune system needs help. To fight the symptom is what allopathy does. The allopathic medical doctor fights the symptom by trying to block some other flow. He uses an anti-pyretic for fever, MAO inhibitors for depression, Serotonin uptake blocker for despair, calcium blackens for heart problems, antibiotic to attack the bacteria thus weakening the immune system etc.

So our child with the sore throat might have a toxin or
nutritional deficiency as the deeper cause of the sore throat. The body is attempting to detox and stimulate the immune system with the symptom. The body is trying to cure itself and everything would be alright but, via a unfortunate twist of fate, this child is taken to an allopath. He spots the symptom right off, and prescribes an antibiotic and an anti-inflammatory. The body own attempts for healing and detox are thwarted. The disease is driven deeper. The symptom goes away but the cause lingers and another disease, more insidious than the first continues to develop. This requires another allopathic remedy, and another, till the life force and the body natural can not adapt and fight on its own. Now degenerative disease clicks in, the downward spiral disease, symptom drug, disease symptom drug continues till death stops it. The average seventy year old is on 8 drugs, the average eighty year old 10.

As the stress continues the body acclimates and goes into the ADAPTATION phase. Here the symptom goes away from familiarization. But the disease progresses deeper. We now come to an ultra important conclusion that must change medicine forever. BEING SYMPTOM FREE IS NOT A SIGN OF HEALTH. In fact you can be symptom free and quite sick. Allopathy is for crisis intervention only.

If the stressor continues the body now progresses from the ADAPTATION phase to the EXHAUSTION phase. Here organs weaken. The first form is the FUNCTIONAL phase where organs dysfunction. They make less or excess hormones, enzymes, or others. After a while they slip into the ORGANIC phase, where here the organs or organ will shrink (atrophy) or grow(hypertrophy). There now is a physical disease. If the stressor continues the last phase results which is DEATH. Cellular death, organ death, organ system death, organism death. The next diagram relates the flow of disease.

| HEALTH |
| STRESSOR (TOXIN ETC)---->>--------->>> | ADAPTATION |
| | EXHAUSTION |
| | FUNCTIONAL |
| | ORGANIC |
| | DEATH |

The causes of disease or possible stressors are:

| LACK OF AWARENESS | TOXICITY |
| STRESS | TRAUMA | INJURY |
| HEREDITY | PATHOGENS |
| ALLERGY | PERVERSE ENERGY |
Mental Factors

Deficiency or Excess of Nutrients

When these enter the body they disrupt the ease of flow. This produces the Alarm symptom. Then the body adapts, symptoms go away, but if the cause continues the disease continues. Being Symptom Free is not a sign of health. The ability to restore or heal the body is based on how much life force the body has. This has an electrical component. The life force can be suppressed or obstructed. This is the SOC index in the EPFX software.

1. Reduce or remove the cause of disease reduce the SOC index
2. Get the patient to take responsibility for their disease and their bodies, minds and spirits.
3. Try to repair the damaged organs resulting from the disease
4. Unblock the blockages to flow of energy in the body. Chiropractic, Acupuncture, and other medical arts are dedicated to unblocking unbalances of flow.
5. Reduce the symptoms with natural methods and naturopathy
6. Deal with the constitutional make up or tendencies of the patient.

This flow sheet can be set as your wallpaper by setting it from your install disk.

The EPFX medical device is a Biofeedback device. Thus it is designed to stimulate conscious awareness of our unconscious processes.

Our unconscious is aware of the initial interference in flow. And as such we all need to start our healing process with an interface with our unconscious awareness. This is the reason for the design of the EPFX.

Finally the system can help in finding ways to reduce stress thru other naturopathic means.

So the primary goal of our system is to stimulate the body to heal itself. Symptom reduction is the third priority. We try to prevent the disease from slipping further. We want true healing and long term symptom reduction.

Some patients are more aware of their unconscious. These patients are likely to feel the difference the EPFX device make and recognize the reaction patterns more easily. Others will take more time, but after several visits they will become more aware of their unconscious and feel the effects more.

Philosophy of Medicine:

The word doctor comes from the Latin word EDUCTOR which means
teacher. A doctor should be a teacher, thus education is a must for medicine. The word science is from the Latin word scio which is "to Know". A scientist seeks to know. So he must reduce variables from their natural complexity. In the real world of fractal complexity there is no way to know. This is the realization of recent science, it is a shock to science but it is true. In complex fractal situations we can not know exact results of interventions. A healer seeks to heal and thus it is secondary to know. A true healer is satisfied to heal even if he does not know how or why. A scientist wants to know more than he wants to heal. Many of our youth have grown up seeing scientist make advances in technology and they want to be like the scientists. These frustrated scientist find there is little money in science, and thus become doctors because they think that being a doctor as a form of science. When they seek to know more than they seek to heal they are not good doctors. It is important for scientist to develop and test products before they are used on patients, but then science should take a back seat to healing and education which is true healing. Healing and knowing are not the same. Healing most often takes place without conscious knowing. Healing is an unconscious process. Healing in our own bodies is maximized if we do not seek to intellectually force it.

The rules of a fractal or complex interaction such as the body human start with four simple truths,
1. Things never repeat
2. Small events can have large effects.
3. The whole is more than a sum of its' parts.
4. Analysis of the whole can be intuited or felt but not by analysis of the parts

RULES FOR THE HARNESS

1. DO NOT apply over broken skin
2. DO NOT use on patients with pacemakers
3. DO NOT use on patients with extreme electrical allergy
4. BE CAUTIOUS with patients who have had electroshock therapy
5. Wipe and clean the harness after each use (especially if contagion is suspected)
6. DO NOT try to open or tamper with the box on your harness tampering will destroy the warranty.
7. Black lead to left ankle, blue to right ankle, red to right wrist, yellow to left wrist, and head harness to forehead, or over any part of the body.

Attempting to open the box will interfere with the operation and voids any guarantees on your device.
SOFTWARE

Many energetic medicine diagnostic systems are currently on the market. There are also many therapeutic systems using energetic medicine or bio-resonance therapy. This is the first device of its kind to apply both in simultaneous operation. This allows for autofocusing of stress therapy and stress diagnosis.

Client Waiver

EPFX WELLNESS BIOFEEDBACK CONSULTATION WAIVER

1. I fully understand that the attending therapists are not allopathic doctors (M.D.'s) and do not pretend to be, but are nutritional, wellness consultants and are biofeedback specialists.

2. I fully understand the difference between the practice of allopathic medicine, nutritional wellness consulting, and Biofeedback.

3. I fully understand that the services provided by the attending therapists are not allopathic, but are nutritional, behavioral or biofeedback in nature.

4. I fully understand that the attending therapists perform their services within the parameters of a natural health care and wellness system using biofeedback and stress reduction.

5. I fully understand that the attending therapists do not offer allopathic drugs, surgery or chemical stimulants or radiation therapy. I understand that illness is not being diagnosed nor treated and that my wellness and stress are being measured.

6. I have solicited the attending, biofeedback therapists services in good faith, exercising my free will and following the dictates of my own conscience which allows me to select what I understand is most beneficial to my health.

7. I agree to consult my family medical doctor for a consultation of any risk or contraindications from biofeedback. If a medical doctor is not available, a referral for such services can be arranged.

8. I presently seek counsel, advice, opinions, biofeedback or points of view and/or programs within the scope of the attending therapists wellness and stress reduction practice.

I am aware and release the biofeedback technician to do biofeedback tests and treatments.
9. I fully understand that the services provided by the attending therapists are not generally accepted and/or recommended by allopathic doctors or other conventional health professionals. I realize that insurance payment is possible but unlikely.

Signature of patient or guardian

__________________________________________

date__________________

Your Family or personal Doctor:

__________________________________________

DEMOGRAPHICS OF PATIENT

Now you will see that several other buttons are enabled with the words in dark letters. HELP will take you to the complete help manual in Computers format.

But on some Computers computers the format might not be right so this manual might be all you can get.

You can go to the therapy program, the insurance and billing program, information if accessible, or demographics. In the normal patient program you should now go to the Demographics button and click. The cursor starts in the patient name box and you must enter a name to proceed. The name is important for the subspace operation.

You should now enter the patient name in the upper edit box. The cursor should appear in the edit box of the name when the program is started. If not, click into the box with the arrow if the cursor is not already in the edit box, and then type the correct patient name. Tabbing twice more will put you into the SOC questions.

SUPPRESSION AND OBSTRUCTION TO CURE

SOC Index:

The SCIO interview opens with a behavioral medicine interview. This is called the SOC Index. Named after the work of Samuel Hahneman the father of homeopathy, he said that the body heals itself with its innate knowledge. But the patient can suppress or obstruct the healing process with some behavior. Hahneman said that the worst way to interfere with the healing natural process was allopathy or synthetic drugs. Theses upset the natural healing process by unnatural intervention and regulation disturbance. Other ways to Suppress or Obstruct the Cure are smoking, mercury amalgams, stress, lack of water, exercise and many others. This behavioral survey then gives an index of SOC.

The scores relate to the risk of Suppression and Obstruction to the natural Cure. The higher the scores the more the Suppression
and or Obstruction. The scores of 100 or lower are ideal. The SOC index questions are: mostly based on a scanine (1-10) answer. Some answers can be more.
These questions include:
1. Number of organs removed:
2. Number of Synthetic drugs taken currently:
3. Number of cigarettes you smoke a day
4. Number of metal or amalgam fillings in the teeth during the last year:
5. Number of street drugs used per month:
6. Number of known allergies:
7. Number of unresolved mental factors:
8. Are you responsible for your body and the diseases you have:
9. Amount of fat in diet as a percent:
10. Personal stress 0-10 10 being max. Numbers can be larger than 10.
11. Number of sugar servings per day:
12. Number of exercise sessions 20 min or more per week:
13. Number of alcoholic drinks per day average:
14. Number of cups of coffee or any caffeine product:
15. Number of extreme toxic exposures last year:
16. Number of major injuries in past:
17. Number of major infections in past:
18. Number of glasses of water or natural fruit juice per day:
19. Number of pounds over weight:
20. Interpersonal stress 0-10 10 being max. Numbers can be larger than 10.
21. Job-school stress 0-10 10 being max. Numbers can be larger than 10.
22. Money stress 0-10 10 being max. Numbers can be larger than 10.
23. Sickness stress 0-10 10 being max. Numbers can be larger than 10.
24. Family stress 0-10 10 being max. Numbers can be larger than 10.
25. Desire stress 0-10 10 being max. Numbers can be larger than 10.
26. Bowel detox stress 0-10 10 being max. Numbers can be larger than 10.
27. Sweat detox stress 0-10 10 being max. Numbers can be larger than 10.
28. Urine detox stress 0-10 10 being max. Numbers can be larger than 10.
29. Mucous detox stress 0-10 10 being max. Numbers can be larger than 10.
30. Skin detox stress 0-10 10 being max. Numbers can be larger than 10.
31. Sleep stress 0-10 10 being max. Numbers can be larger than 10.
32. Number of Root canals:
Each of these questions relates a behavioral burden on the body that can create a suppression or obstruction to the curative process. Scores below 50 are very good and show little risk of suppression or obstruction. Scores above 50 and below 100 are good and show some chance of suppression or obstruction to cure. Numbers above 100 are of risk.

If the SOC has changed from the last visit, you must change it on the Demographics page. Use the “Modify Patient” button on the Patient Data screen return.

**Head electrode**

- Wipe clean harness with 20% alcohol solution
- Proper placement of the electrodes
  - Place electrodes on dry skin, loosely and gently. Thin hose can be under electrodes

**EPFX**

- Functional: Print: 
- Head: 
- Limb: 

**Computer Printer**

- DC input 6 to 10 V, 250 mA
- for external test trays or honeycombs, red out, black in
and save the new info. We hope the patient has taken responsibility and changed their behavior positively. This is reinforcing for the patient and helps the report menu.

Next we can calculate the Suppression and Obstruction to Cure Index, which can tell us the amount of available life force the patient has to recover from their disease. The computer screen has several questions on their medical history. Such as organs removed, drugs taken etc. Click onto the first edit box after the organs removed question. A none entry is equivalent to a zero. You can tab from one box to another and enter only a number. If you make a mistake and backspace the computer will give an error message. To avoid this enter the correct number after the mistake and then click in front of the correct number and backspace to remove the mistake. This will assure that there is always a number in the box once a number is inserted.

There is an impairment rating system in the report. Input any amputation, or other impairments into the report.

For body fat percentage we need to input some anthropomorphic data. Height, weight, abdomen and thigh circumference are essential. Also fat layer thickness on abdomen, and under arm tricep area are helpful. This data and the electrical harness data will allow a fat percentage rating.

If the patient is pregnant the click the pregnant box. This will allow testing of the baby in the test screen.

PREPARE NEW PATIENT OR RETRIEVE OLD PATIENT REPORT

This file allows you to start a new patient report or to find an old patients demographics file.
The demographics file you have saved on a patient can be retrieved with this screen.
After you have inputted the patient name ,sex ,and Suppression and Obstruction to Cure(SOC Index) in the Demographics file, you can add additional information such as birth date, address, phone, etc. on this screen.
If the patient you are working on is new then go to the start new file after pulling down from the File access. Then insert the birth date in the same fashion as the date is presented. You must use the date format that your Computers uses. This is different in Europe from America. Then insert any other information you want on the insert edit boxes. When you are through with entering data then save the file by clicking the 'Save Current ' button. If you wish to exit without saving click the 'Cancel' button. If you want to get an old patient demographic file the click the 'Load Old patient' button. Use Modify to change old data especially the SOC index. This will allow you to search the hard drive for an old record. The scroll bars allow you to view the records. When done use close to
BIOFEEDBACK

This program contains several programs designed to induce stress reduction and unconscious awareness of the body. The stress reduction button will start a series of relaxing images to provide a stress reducing environment.

There are guided imagery programs under the Relaxation Methods. Once selected these imagery programs will appear at the top of the screen when you click the Start Biofeedback button. This activates the system and the energetic results are displayed on the chart. On the yellow panel are relaxation numbers that indicate harmonic relaxation. Tell the patient to try to reduce these numbers.

The EPFX system measures over 10 channels every centisecond. Showing these numbers could be over-reductionistic, this is what normal traditional biofeedback does. Our idea of biofeedback differs. The goal is to help the patient. Conscious awareness might not be needed for it is most often over-reductionistic and thereby not wholistic. Rather we use an unconscious biofeedback system where we interact with the unconscious not the conscious to give the patient natural control.

There is a biofeedback game using two colored balls. If the harness is on then click the turn on game balls button and enter any of the above programs. The balls will move to the left as the patient's unconscious reduces harmonic stress. To turn off the game effect use the turn off game balls button.

Under the Biofeedback name on top of the page is also a list of other therapies. These are for a variety of issues. There is a series of treatments for the Oriental Medical concern of excess cold, heat, wind, dryness, and dampness. The EPFX will treat these deficiencies while the screen will show a multimedia program and image. The patient should sit in front of the screen for as long as you want to treat. To stop the program click on the image.

Awareness After Testing

The EPFX interface is set at natural biological electrical levels. So the therapy is most often not felt directly. But the effects are none the less dramatic even though they are below conscious perception. Still the unconscious will perceive the healing effects. This most often results in a positive change in the mood and awareness. Sensations of warmth tingling and euphoria are most often perceive. Sometimes the conscious fights the change and limits conscious perception of the healing. Increase in memory, compassion, and positivity can be demonstrated by asking questions of the patient in these areas. And realize that sometimes the conscious will
recognize these effects later that day. Some conscious minds will struggle with natural intervention and they need time to feel the effects. The goal of this medical device is to promote healing not perception of change. So be patient with such patients.

The patient should not feel the device but should feel the effects. If the water is the same temperature as the skin the person does not feel the bath but afterwards the person should feel clean. This simple awareness needs to be cultivated in our patients as they increase in self awareness and self healing.

TESTING PROCEDURE OR THE XRROID PROCESS

The “Prepare test” button allows for computer calibration. Click 't' to start. It is best to proceed with the test as soon as entering. Push the 't' key or click on the Test button once. Tell the patient to be still but not stiff. They should not talk or move and be in the same position and state of mind. The interrupt for testing will test over 1,000 items at approximately one hundredths of a second each, with a pause in between testing. There will be a click during the test and a gong at the end. If you are sensitive to noises then use your sound access on your Computers system to mute the sounds. If the patient is pregnant you can test the baby by going to the treatment button on top then to the test baby button. This can activate a filter for measuring the baby reaction patterns. If the computer can not properly filter the signals for a very young fetus it will tell you. For the fetus under 2 month there is sometimes difficulty.

Computers does not operate in real time. So to measure our patient’s reactivity we will need to interrupt Computers. The mouse will not work during this interrupt. The computer shifts to assembly language and then completes the test or therapy and when it returns it brings the data into Computers for us to review.

The total time of the test should be under 2 minutes. The mathematical calculation will start, taking about 5 to 20 seconds. During the calculation the patient can talk and move. The SOC index is in the upper left side, on the lower part there is the voltage, amperage, resistance, oxidation and hydration scores. These scores reflect results from the demographics and calibration screens. Now we can start our analysis of the patient.

Xrroid is a word for rapid testing of thousands of substances in the test kit on your harness to the electrophysiological reactivity of the patient. There are over twelve real measures of reactance variables performed on each substance. Since the reaction is an ionic reactance the test reaction take place in small time intervals allowing for the rapid test procedure called the XRROID.

The lowest scores will now appear on the top. The highest
reaction score on the top. The scores on the first screen are somewhat significant, look at them. But the most significant scores are the highest ones. To see the highest scores click on the arrow pointing to the right above the scores matrix. This takes you to the high scores. The higher the number the higher the reaction, scores above 95 are significant. The computer will shade the significant numbers in purple or red. This is not an absolute but the best mathematical estimate. The red scores are three standard deviations from the mean, purple are two SD from the mean, Yellow, one. The blue scores are in order of reactivity.

The other buttons have functions such as:

<table>
<thead>
<tr>
<th>BUTTON</th>
<th>FUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Programs</td>
<td>Accesses most of the programs</td>
</tr>
<tr>
<td>Aging</td>
<td>By adapting the work of Becker, Priori, Beardall and others, Nelson has developed a computerized system that can develop a tiny DC potential multi signal to time reverse cells. Use of techniques such as differentiation and redifferentiation into a massive set of multi signal fractals. The nonlinear analysis then can develop multi signals for deep tissue interface. This can be used to stimulate immune function, destroy pathogens, detoxify free radicals antiaging, rejuvenation.</td>
</tr>
<tr>
<td>Calibrate</td>
<td>For recalibrating</td>
</tr>
<tr>
<td>Homotoxicology</td>
<td>accesses detox and tissue stage analysis</td>
</tr>
<tr>
<td>Nutrition</td>
<td>Access nutrition and Constitutional homeopathy programs</td>
</tr>
<tr>
<td>Patient Demographics</td>
<td>For patient SOC and behavioral analysis</td>
</tr>
<tr>
<td>Risks</td>
<td>For assaying the EPR Tendencies</td>
</tr>
<tr>
<td>Adjust Anomalies</td>
<td>For adjusting the computer interface</td>
</tr>
<tr>
<td>Spinal Sarcodes</td>
<td>For testing the spine and the sarcodes</td>
</tr>
<tr>
<td>Therapy</td>
<td>Accesses many different therapy programs</td>
</tr>
<tr>
<td>Wellness</td>
<td>Use to evaluate external measures of wellness</td>
</tr>
<tr>
<td>Homeopathic Activation</td>
<td>Allows for seeing homeopathic reactivity and making homeopathic replicas</td>
</tr>
<tr>
<td>Notes</td>
<td>`For keeping notes on the patient for adding to the report</td>
</tr>
<tr>
<td>Music therapy and SUPERLEARNING</td>
<td></td>
</tr>
</tbody>
</table>
Biofeedback access

Body and Face scan for younger looking skin from stress reduction

Info

relative risk of mental, physical, spiritual, social, or environmental problem, this program can be added to by double clicking on any item in the screen it is added to the info report, go to value order if you wish to add top items

Erase Info

This will erase the info screen.

Report

goes to the report screen

Notes

This allows you to compile a note file on your patient to add to your report.

Test

resets all reactions to zero and tests all items

Retest

retains values of previous tests and tests all items

Virtual Only

Tests without harness uses subspace link

Risk Profile

Calculates general risks of 40 different areas

Set Value Order

puts all substances in order of reaction

Substance Order

Puts all substances in order of appearance

Go to No.

goes to the exact product number entered in the edit box below

Show Referrals

shows the panel with 12 ways for health(double click on it to remove) another panel shows access points for various items in the table, use the go to function to find in substance order.

Load Program

Any item added to the report with the double click will be added together for testing or treatment.

Hold:

Items are held for all tests of items (to challenge a disease, type it into the hold file and hit 'Indiv Reaction' after 10 sec the top reaction hint will appear in the goto edit. Click 'Go to' to see your hint.

Patients Unconscious Reaction Panel:

This panel asks the
patients' unconsciousness to electrically pick a cause, cure, palliation, mental fixation, and bifurcation of health points. A report of the reaction can be added with 'Make Report' button. Double clicking on an item will allow you to check or treat the item that presents.

**Retest VARHOPE:** This function is to retest the Voltage, Amperage, and etc after the test. An estimate of improvement is calculated this is all automatically added to the report.

**Edit Empty lines:** This allows the user to add items to the list by emptying the lines.

**Print table:** This allows the user to print part or all of the list of remedies.

**Test and Treat Alarm Reaction** This will test an alarm reaction and correct it if possible.

**More Research** This allows library access to the Disease Dictionary, Medical Research, and Nelson method of medicine.

When you click on an item in the table it will become highlighted. If you accidentally strike a key it might erase. Alt backspace can return the message. If you proceed to far only reinstalling the disc can reload the lost items.

When you leave the Test screen the computer remembers the last patients data. It will not erase them till the next patient is done. If you wish to edit or data to the database you may but it should only be done in the substance order of products mode. Doing an edit with the value order is dangerous to the data base. Also Please close Computers properly.

**INDIVIDUAL REACTION TEST**

This checks the reactance response of the patient to an item with multiple channels and multiple vectors. If the patient develops a headache or pain response terminate use. Individual Reaction Test just one item whatever is marked This function has been improved over the past and can also turn on an EMG, EPR, or EPR function. Since we know the proper vibration levels of the muscle we can work a EMG or other without reconnecting the harness. The coherence of the wave form connection is also rated by the computer. A long list of reaction scores is now shown but this is still only one thousandths or less of the total mathematics used. This is not meant to confuse but should improve your analysis of the reactivity. This program now is improved and compensates for entropic
variance. There is still a massive amount of mathematics used, like it takes many many signals to make a tv picture which we reductio

nistically call a tree. This program takes many signals to get a reactance. Some of the electrical vectors are shown in the first 18 values. The total reactance value is the old reductio

nistic value, it shows the total reactance.

E.P.F.X Software Instructions

INTRODUCTION

The Eclosion E.P.F.X Software system is a state of the art mouse driven biofeedback software system. If you do not have a mouse you may still run this software from the keyboard. When using a mouse just 'Point and Shoot' on any statement on the screen. You will notice one letter in every statement is red, this is-called the accellerator key. To drop a menu down press <ALT> + the red accellerator key for the menu you want. Once in a menu you may access any item on that menu by pressing a accellerator key for that item. You may also move the green highlight bar to that item and press <ENTER>. To exit this software press <ALT>-<X> from the menu system.

DEMOGRAPHICS

When you enter the demographics entry screen the date will automatically be entered on the first line for you. If this date needs to be changed you may do so at this time. To move to the next field use the <TAB> key, previous field use <SHIFT>-<TAB>. You may also use the mouse by pointing to each data area and pressing the mouse button. Move form field to field typing in the data required for each field. You do not have to enter all the information but you at least mu enter the first and last name. When you are finished entering all the data press <ENTER> or click on the OK button, the data will be saved. If you press <ALT>-<C> or click on the Clear Demographics you will clear all the demographic information. If you press <ESCAPE> or click on the Cancel button you will exit the demographics but you will not save the data.

BIOFEEDBACK SYSTEM MENU

The GSR,EMG,ECG selection will take you to the main menu of the biofeedback system. These choices will take you to general biofeedback screens with that channel active. The GSR selection will have the GSR channel active. The EMG selection will have the D.C. Amplifier active. The ECG will have the D.0 Amplifier active but more sensitive.

A. Temperature Biofeedback
The Temperature Biofeedback system will record the temperature of the body at its extremities. First put the harness on the person, headband on the head wrist bands with temperature probes on the wrist. The computer will instruct you to put the input selector in the 'harness' position. The computer will record the temperature of the head. You will then be prompted to turn the input selector to the 'left wrist' position. The computer will record the temperature of the left wrist. You will then be prompted to turn the input selector to the 'right wrist' position. The computer will record the temperature of the right wrist. You will now be instructed to remove the wrist bands form the wrist and put them on the ankles. The computer will tell you to put the input selector in the 'left wrist' position and press <INSERT>. The computer will now record the temperature of the left ankle. You will now be instructed to turn the input selector to the 'right wrist' position and press <INSERT>. The computer will now record the temperature of the right ankle. Now that the test is finished you will be asked to choose a name from the list af names given to you. Use the arrow keys to move to the name of the person you are testing and press <ENTER>. The computer may now ask you if you want to change the signal labels. If so press <2> meaning use current labels. The computer will ask you if the labels are ok press <Y>. The data will be saved to disk for later viewing. You will now be prompted to press <ALT>-<X> to exit, doing so will end the test and return you to the menu system.

B. Voltage Biofeedback

The Voltage Biofeedback system will record the voltage and resistance of the body at selected body locations. This test is preformed using the auxiliary harness and the finger wraps. Clip the two white connections of the harness to the finger wraps. Wrap the finger wraps around your fingers with the the silver-chloride contacts away from your fingers. The computer will instruct you to put the input selector in the auxiliary position, do this now. You will be touching locations on muscles. These muscles are: Tricep, Bicep, Forearm, Thigh, Hamstring and Calve. You will start on the right side and move to the left side. The computer will prompt which muscle is to be touched. When the name of the muscle appears on the screen touch that muscle. You will have about 5 seconds to get a reading. You will then see the name of the next muscle. Touch that muscle so the device can get a reading. Continue through all the muscles the computer prompts you to touch. When finished the computer will instruct you to put the wrist wraps on the ankles and instruct you to put the input selector in the 'Harness' position. Press <INSERT> to start the test. This will take resistance readings from the ankles. Now that the test is finished you will be asked to choose a name from the list of names given to you. Use the arrow keys to move to the name of the person you are testing and press <ENTER>. The computer may now ask you if you want to change the signal labels. If so press <2> meaning use current labels. The computer will ask you if the labels are ok press <Y>. The data will be saved to disk
for later viewing. You will now be prompted to press <ALT>-<X> to exit, doing so will end the test and return you to the menu system.

C. Spinal Biofeedback

The Spinal Biofeedback System will record the temperature, resistance and voltage of the back. This test is preformed using the back probe. Plug the back probe into the calibration box and plug the calibration box into the device. Calibrate the back probe following the back probe calibration instructions. Put the input selector in the auxiliary position. Apply a layer of electro-dermal gel to the area to be tested. It is a good idea to warm up the temp probes built into the spinal probes to body temperature by holding them against the person for about 30 seconds before you begin the test. Make sure you have enough cable to test the full range of the person. When the test starts the standard Biofeedback screen will appear. Note the REC-ON. You are given one 10 second screen sweep to get ready before the test taking the readings for C 1. At the top of the Biofeedback screen notice the C 1 indicator. At the end of the screen sweep the system will "BEEP" to let you know that you must move the probes to position C 2, then C3, and so forth all the way down the persons back. The last screen sweep will be labeled SAC (top row of the Biofeedback test screen). Testing is finished at the end of this screen. The system will automatically proceed the "SAVE CURRENT SESSION TO DISK" screen to store the readings that were recorded from the procedure. Now that the test is finished you will be asked to choose a name from the list of names given to you. Use the arrow keys to move to the name of the person your are testing and press <ENTER>. The computer may now ask you if you want to change the signal labels. If so press <2> meaning use current labels. The computer will ask you if the labels are ok press <Y>. The data will be saved to disk for later viewing. You will now be prompted to press <ALT>-<X> to exit, doing so will end the test and return you to the menu system.

D. Dual EMG Biofeedback

The Dual EMG Biofeedback system records the same data as the spinal biofeedback system. This test requires you to follow the same directions as the spinal biofeedback system except you will make two passes down the back on both sides of the spine. When this test is finished follow the previous directions for saving the data.
The temperature display menu will appear showing the name of the person tested with a number next to it. Type that number and press <ENTER>. The graphical display of the temperatures will appear. This screen may be printed by pressing the <PRINT-SCREEN> key. When you are finished viewing the display press <ENTER>. You will be returned to the menu system.

B. Voltage Display
The voltage display will appear when the selection is made from the menu. To get the temperature readings also you must have looked at the temperature display first.

C. Spinal Display
The spinal display menu will appear showing the name of the person tested with a number next to it. Type that number and press <ENTER>. The graphical display of the spine and its data will appear. This screen may be printed by pressing the <PRINT-SCREEN> key. When you are finished viewing the display press <ENTER>. You will be returned to the spinal display menu, type <0> and <ENTER> to exit this menu.

C. Dual EMG Display
The dual EMG display menu will appear showing the name of the person tested with a number next to it. Type that number and press <ENTER>. The graphical display of the spine and its data will appear. This screen may be printed by pressing the <PRINT-SCREEN> key. When you are finished viewing the display press <ENTER>. You will be returned to the dual EMG display menu, type <0> and <ENTER> to exit this menu.

Eclosion EPFX Mark II Manual
INTRODUCTION
This is the manual for the EPFX Mark II system using windows. Manufactured by Eclosion Corporation. This system is mouse operated and operates in the windows environment. Windows all rights reserved.
From the windows screen there are several different systems that can be manipulated and utilized for calculations for point analysis, for reports, and for data base.
1. Calculation System
2. Database Display
3. Point System
4. Report system
5. Biofeedback System
If you double click onto any icon with the mouse, you can go into any of these systems.

1. CALCULATION SYSTEM

Here on the calculation system main screen we see some of the following:
Current Client - Name of the patient that the computer is prepared to do.
Calculation selection - You may select all items or selected items.
All items: All items in the entire data base which then constitutes the Xrroid.
'Selected items: Only the items highlighted on the matrix list.
Status - 1. No data available
2. Data ready for calculation
3. Calculation complete
Tells whether we have done a calculation or not.

Matrixes list - (far right of screen) All Matrixes that can be tested. Top 100 of all can only be obtained after doing a scan and having data which then tells us the top 100 readings of all of the items that were done. Other categories that are in the data base are: All of the amino acids, bacteria, DNA, enzymes, food reactants, fungus, homeopathics, herbals and tonics, heavy metals, hormones, inhalant reactants, lipids, minerals, dental nosodes, medical nosodes, parasites, phenols, pollutants, sarcodes, supplements, vibrations, viruses, vitamins, and xenobiotics. At the bottom of the screen there are five different boxes that can be activated:

A. ABOUT - Contains copyright information and other references to the software.
B. DEMOGRAPHICS - Allows us to go into the adding of the name and putting in the basic demographics of the patient.
C. TEST - Allows us to activate the testing capacities. D. CALCULATE - Allows the computer to calculate the procedures. E. CANCEL - Allows us to cancel the program and go back to our window icon menu:

B. DEMOGRAPHICS
If we go down and click on the DEMOGRAPHICS button, (a single click will do) then the DEMOGRAPHICS box will appear. We can see that the first name appears which will be in blue and by just simply typing now, we can type in the first name of our patient. When we are done with the first name, by hitting TAB we then move to the last name. Type in the last name, when we are done, by hitting TAB we then move to the age of our patient, hitting TAB we then move to sex and the up and down arrows can move it back and forth to female and male. When we are done with the demographics we then use a single click on OK or ENTER when done. Only press ENTER when all of the demographics data is correct.

C. Test

Now when we come back to the CALCULATION SYSTEM screen we will see that the name has changed to the name that we have entered under Current Client. We will also see under STATUS that it says no data available. Our calculation selection should be moved to all items if we are going to do the total Xrroid. If we are going to SELECTED ITEM, we can go to the screen, click on whatever matrix we want or a combination of matrices by putting our arrow on matrixes, holding the left mouse button down, then moving it down. This will allow the
blue bar to bring in multiple matrixes, or we can hold on CONTROL and hit the left mouse button which allows us to select any combination of matrixes for testing. Then we need to move to the CALCULATION SYSTEM and hit SELECTED ITEMS to do just a partial test on whatever it is that we wish. If we want to the entire Xrroid we need the black ball to be on all items for CALCULATION SELECTION. The next step is to go to TEST box, click on TEST which brings us into the BIOFEEDBACK DISPLAY screen. From the BIOFEEDBACK DISPLAY screen we next need to notice that the test label at the top of the screen underneath biofeedback display says Xrroid test. From this screen we can also see the time of day at the far upper left. In the RECORD STATUS window at the far upper right. We currently see that the record is OFF. To start recording data for the test we can turn the record ON by clicking onto the record on switch on the bottom. When we do so, the computer will start to flash different items from the test tray and also from the hololinguistics screen that is being displayed at the top panel next to the RECORD STATUS window. This changing environment tells us just which items are being tested at the super Xrroid speed. In the middle we see that the number will be changing from 1 - 24 which will tell us just how many of the matrixes it has tested as the test proceeds. When the test is done, a box will appear that will be titled FILE SAVE AS. Here we can see the file name and under here should appear an abbreviated form of the patient's name followed by "BIO". This is in blue. We see DIRECTORY LABELS and DIRECTORIES, all we need to know is that we press on OK with the arrow or we hit ENTER which then allow the computer to save the mathematical data that it has encountered on the patient. We will see on the top screen that it says 'Saving Data...' which tells us what the computer is doing. We also see that the arrow has turned to an hour glass and this prohibits us from being able to operate other buttons while the saving data screen is going on. After a couple of seconds the data saving will be done, this will maneuver us back to the screen known as CALCULATION SYSTEM.

D. Calculate

Here under CLIENT, we will see the same name of the patient. We will see under STATUS that it says data ready to calculate. Now by moving the arrow to CALCULATE and clicking, the computer will now start calculating the data and making the mathematical analysis. The arrow has changed to an hour glass to prohibit us from activating other buttons. The computer will say LOADING BIOFEEDBACK DATA, PLEASE WAIT. A calculation status a pie chart will tell us how much time is left in the operation as it goes through its calculation. This pie chart will appear twice as it is reading data in a separate function. At the end of the second pie chart, we will see 100 percent will come up. Under STATUS we will see calculation complete, under CURRENT CLIENT we will see the name of the patient that we have been working on. Under the CALCULATION SYSTEM the results of our test cannot be viewed. We will now need to go down to the CANCEL BOX with our arrow and click which brings us back to the ICON MENU.
Here we have our other systems where we can look at the results. We can look at results under report system, point system, or data base display. Let's go to DATA BASE display first.

2. DATABASE DISPLAY

Clicking into DATA BASE display we go into the display program. Here we will see a list of the items, the top 10 of the products, and all the other facets of the data base. By going into the DATA BASE screen and clicking our arrow at the top of READ THE TOP 100 box, the operation comes up, says it is reading the data and then proceeds and gives us numbers of the items tested in their top 100 form starting at the top and going down to the lower. These will appear in the LIST BOX towards the left side of the screen. We can maneuver the LIST BOX screen up and down by using the scroll bar on the left side of the LIST BOX. You can maneuver the LIST BOX left and right by using the scroll bar on the bottom of the LIST BOX. This type of click allows us to read' the entire top 100 screen. To maneuver to another list we only have to go to the LIST BOX on the right side which tells us all of the different matrixes.
On this screen there are many buttons that can be activated:

A. About
B. Top 10
C. Numerical & Alphabetical
D. + and -
E. Include
F. Print

By clicking on any of those matrixes, we can bring up the scores of our test and see just what was the mathematical scores of electrical reactivity that was obtained from each item.

A. ABOUT

At the top of our screen is another ABOUT button to the far upper right which tells us about the different types of copyrights and references on our software. If we hit OK, we can get rid of that screen and then come back to the DATA BASE DISPLAY.

B. Top 10

If we click our button on the TOP 10 box, the computer will take a little bit of time and it will generate the top 10 lists of each item in each matrixes. We will not have a rating of the score but we can see the top 10 enzymes, amino acids, bacteria, DNA, or all matrixes will be contained. By using the scroll bar, we can maneuver through this list and see the top 10 matrixes on the entire report. To EXIT, we have to click on the EXIT button.

C. Numerical & Alphabetical

The system is already programmed to be able to make it's initial presentation in numerical fashion. Down at the bottom we will see two boxes; one for NUMERICAL, one for ALPHABETICAL. By clicking on the ALPHABETICAL box, the organization of the data will be presented in alphabetical form from A - Z. By clicking on the NUMERICAL box, it will be presented from the highest number down to the lowest.

D. + and -

To change the scores on any of the items in the matrixes, we have to highlight them by moving the arrow to the item, clicking on the blue bar, holding the button down to go into order, or by hitting CONTROL and the mouse button, allowing us to bring other things into the item by hitting CONTROL and by hitting the button on our mouse while any item is selected. Those highlighted items in blue can have 10 points added to the numbers by hitting the POSITIVE box next to
SCORE or subtracting ten points from them by hitting the NEGATIVE box next to SCORE. When we hit those, it will change the amount of numerical rating in front of the item. This allows the doctor to intervene with the system and to increase or decrease the numerical value of an item, whatever he feels is clinically worth while in his judgement. By continuing to click on the POSITIVE or continuing to click on the NEGATIVE we can bring any of the item's numerical rating value up or down and this allows the doctor to intervene from his own experience and to possibly correct some of the data that has been presented by the Xrroid.

It is our conclusion that the Xrroid is not always correct and that there is a statistical limitation to its data base. The correction of the system seems to be about 80%. That means that still 1 out of 5 items might be inappropriate. Here the doctor can use his technical expertise to change those scores.

E.' Include

Anything that is also highlighted can also be included into our biofeedback EDITOR by hitting the word INCLUDE. When we tap on the word INCLUDE by bringing the arrow to it and hitting the mouse button, anything that is in blue will be added to the biofeedback EDITOR.

E. PRINT

The entire item list may be printed by hitting PRINT which will then bring up the PRINT window which then tells us what type of printer we are connected to. If we hit PRINT and click OK, the print function is turned on and the items are sent to the printer. To get out of the DATA BASE DISPLAY menu, we need to move the button down to CANCEL and click out the CANCEL system.

3. REPORT SYSTEM
To go into the REPORT system from our ICON MENU. If you double click on REPORT which allows a CALCULATION STATUS box to appear, tells us about the operation in progress, and the finally brings us to the DATA REPORT system.
Here we will see numbers in front of the categories of sarcodes, nosodes, isodes, allersodes, homeopathy, nutrition, amalgam, geopathic stress, the top 100, and electrical. The numbers next to these on REPORT SELECTIONS will tell us the average score in each of these matrixes. By clicking on the SARCODE button we now bring up all of the sarcodes from top to bottom that can be viewed in our screen. These also can be maneuvered up, down, left and right by using the scroll bar on the arrow keys in the windows environment. If we move down to the ELECTRICAL box and click on it, we get a reading of our electrical parameters which include oxidation index, hydration index, resistance, amperage, voltage, watts, capacitance, inductance, and resonant frequency.
For the interpretation of the electrical parameters we need to point the doctor towards the New Biology book which describes each of these electrical functions of the body. To leave the electrical parameter screen, we need to move our arrow down to OK, click on the OK box. In our DATA REPORT SYSTEMS screen we also have NUTRITION which is a collection of all the amino acids, vitamins, lipids, minerals, and supplements screen will allow us to chart out just the complete nutritional needs of the patient. GEOPATHIC tells us about all the different vibrations in possible geopathic stress. HOMEOPATHY, we have a list of all the different homeopathics, (combination and singualrs), ALLERSODE has food and inhalant allergies, ISODES has all different types of pollutants and environmental problems, NOSODES contains all different nosodes of dental, medical, origin, virus, bacteria, and parasites, and under SARCODES we see all of the different healthy tissues of the body. Thus we can look at these quickly and easily in our DATA REPORT screen. To print the information in the DATA REPORT screen, look for the PRINT box at the bottom so that we can be able to print out our data reports generated from the patient. To leave the DATA REPORT system, we click on the CANCEL box which pulls us out.

Now we can also review our results under POINT system. 4.
By going into the POINT system we can also see the scores in any of our matrixes and maneuver through the data looking at the top 100. The operation of this system is identical to the operation of the Database System. We still have a button for the TOP 10, we also have a button for READ TOP 100, PRINT functions, PRINT SETUP, an ABOUT box which tells us about the copyrights, NUMERICAL readings, ALPHABETICAL readings on the bottom, INCLUDE function which allows us to include anything that is highlighted in the blue bar, SCORE box with plus and minus allowing us to change the items up and down in proportion, and a CANCEL screen. The beauty of the POINT system program allows us to test the patient actively in harness. To test a patient we need to maneuver the arrow to a list of items such as the TOP 100 OF ALL, ENZYMES, FOOD REACTANCE, or whatever. Put the arrow on the very top upper right arrow going up which now brings the BIOFEEDBACK DISPLAY program up on three quarters of the screen. To our right, we will see a list of the products that we are about to test and by pressing down with the mouse and moving the arrow downwards we can include any batch of items to be tested either in singular fashion or in group fashion or by pressing CONTROL and the mouse button we can bring in items that are not together and highlight them. To activate the test kit and to bring those into contact with the patient we now bring our arrow down to the box marked REACTIVITY. When go to REACTIVITY, the screen will now test the patient's initial reaction to entering those items into their electrical field. The results will appear in a couple of seconds just to the right of the REACTIVITY screen which will tell us their maximum electrical reactivity, their minimum electrical reactivity, their mean or average electrical reactivity during the test, their rise and their fall. Meaning the rise from their previous position and the total fall. The higher the numbers under reactivity, the more reaction the patient is having. The higher the rise, the more positive reaction the patient is having. The more the fall, the more negative reaction the patient is having. This allows us now to test those items and to tell if the patient is reactive. When we hit on the REACTIVITY screen, our list of products disappears and the window is turned off. To review those after testing the reactivity we have to hit ALT-T which brings back our product menu. When the product menu comes back we will see the items that we have tested. If those items are good and need to be included in the patient's profile and printshop, we move our arrow down to the small four boxes underneath the products where we see an I in one box. This allows us to click on that I and that allows the computer to include everything that is highlighted into the print screen. If we hit the minus button just above the I,
we will subtract 10 points from all of the items that are highlighted. If we hit the plus button we will add 10 points to anything that is highlighted. Thus we can add, subtract, or include the different items to be able to maneuver through the screen and determine an entire printout function for the patient. After we've added all of the information in the patient, we can bring up PRINT or PRINT SETUP function or we can hit the EDITOR from the biofeedback test screen. If we hit BIOFEEDBACK DISPLAY, with the point system matrix being done after we've included data, we click on EDITOR. This brings up the EDITOR function and allows us to look at the patient record, the date, the name of the patient, the sex and a list of all the items that we have included in the report. We can view this report by hitting the UP, DOWN, LEFT, or RIGHT arrow keys or by using the scroll bar to look at the entire data report. To print this report, we only have to click on PRINT MENU which allows us to have PRINT SETUP or PRINT FUNCTION. In PRINT FUNCTION we go into the print box and allows us to print the item if the printer is turned on. Once the printer has been turned off, the items will be returned to the screen. Thus by maneuvering through the data with the blue bar and our print function we can determine the reactivity of the patient to any different individual item and then increase or decrease the numbers and finally end at a workable homeopathic program consisting of possible nosodes, sarcodes, nutritional supplements, isodes, allersodes, and the like for patient therapeutics. With a little bit of practice, moving through the windows environment is quite easy and fun and a patient can be fully Xrroided and reactivity tested and a full therapeutic program can be charted out in 10 - 15 minutes. The purpose of the DATA BASE display, is to allow us to look at the items without being able to test them and to look at each individual matrix. This differs from the REPORT screen which allows us to look at all allersodes, nosodes, isodes, sarcodes, and nutritional items. This also differs from the POINT system which allows us to go in and test reactivity. The EPFX system also has the ability to work with an individual stylist or point probe which can also give us a system analysis.
source. Also under the PRINT menu is the PRINT FUNCTION. This will show you, first of all the printer you have selected and the print range. At this time if you have more than one page, you can select which pages you would like to print. You can also, at the bottom, select how many copies you would like to print. There is a CANCEL, OK, and SETUP. Pressing SETUP brings you to the regular printer setup window. OK actually makes the print come to the printer. The default is IBM Graphics, the print range all copies one. If you press OK, one copy of all the pages will be printed. EXIT, of course, takes you back to the main biofeedback system.

BATTERY MAINTENANCE

The EPFX Mark II Device operates with 4 AA Nicad Batteries placed permanently inside. These batteries should provide a minimum of 2 years of service with normal usage. Your batteries should last many years without problems. When your equipment arrives, please charge the batteries for 8 hours prior to use. we recommend recharging after each 20 hours of normal use. For best maintenance, disconnect harness from device and turn off power when not in use. •WARNING•: If patient connections are touching, batteries will drain faster.

To charge batteries:
1) Use device 20 hours or if battery test reads below 50% of charge.
2) Plug charger into charger input located at the back of the device.
3) Plug charger into wall outlet.
4) Allow to charge for 8 hours.
5) 'Power switch must be in the "OFF" position to charge batteries.

Unplug charger from device and wall outlet when charger is not in use.

To test batteries:
Click pointer on battery test button. The battery test screen will appear. Unplug all probes. Click on test button. Percent of battery charge is shown for each of the 4 batteries. If any battery charge is below 70%, proceed to battery charge procedure.
Probe Impedance - Point probe resistance only (Green Signal)
Probe Voltage - Point probe voltage only (Green Signal)
Harness Impedance - Wrist to wrist Resistance (Red Signal)
  Ankle to ankle Resistance (Yellow Signal)
  Finger to finger Resistance (Blue Signal)
  Voltage from head (Green Signal)
Harness Voltage - Wrist to wrist Voltage (Red Signal)
  Ankle to ankle Voltage (Yellow Signal)
  Finger to Finger Voltage (Blue Signal)
  Voltage form Head (Green Signal)

Auxiliary - Only used for battery test.
**The power switch must be On (Pushed In) for resistance reading**

The biofeedback system at the top has the name of the system which is BIOFEEDBACK DISPLAY. The next line down there are five items. There is time in the upper left hand corner, the title of test
that you are performing at the time in middle of the screen, there
is the number of trials that are going to be tested and the current
trial that is being tested. They are displayed in 0 of 0 and if
you were doing 10 trials it would be 0 of 10 and it would count
from 1 to 10 on the first number, with the second number always
staying 10. The next field over is a virtual field and usually
used for the Hololinguistic placing. The next field over is the
recording state and it will either read REC.ON or REC.OFF. Below
that is the actual biofeedback data screen. It is a black screen
with the biofeedback lines moving from left to right across it.
On both sides of the biofeedback data display area there is a
scale. On the right hand side, the scale shows four places
including a decimal point. On the left hand side the scale only
shows two places. The next area on the screen are the signals
themselves. There are four buttons, each with an outline of the color
of the signal that they are referred to. There also are four boxes
with the same colored outline showing you the actual data recorded
for each signal. Remember that the signals are color coordinated and
the data inside the color outlined box corresponds to that colored
line. Below that, there is a section on reactivity. There is a
reactivity button all the way to the left. This prepares the
biofeedback device to give a reactivity report. There must be one
full screen of data recorded. Then not only will you see the
reactivity data, which is constantly recorded next to the reactivity
button, but the maximum, minimum, mean, rise and fall of that entire
screen sweep will be displayed. In this area there is also an ABOUT
button that gives you some information about copyright and versions.
Next to that is the BATTERY TEST button. Then, we have a line that
sections off the there screen. In the left hand side of this next area there
is memory, this is a scale from 0 - 100% showing you how much of the
computer's memory is still left for you to record in. When there is
no data recorded the memory is at 100%. As the data is recorded into
memory the memory bar will drop to 0. If the memory gets below 10%,
it will prompt you that the memory is full and ask you to save the
data. Also in this area there is a TIMING button which activates the
timing screen, an EDITOR button which activates the editor, a RECORD
ON button that turns on the record state, a RECORD OFF button which
turns off the record state, and an EXIT button. Next, we'll go into
explaining what some of these buttons mean. On the SIGNAL
IDENTIFICATION buttons are the names of each of the four signals,
these are seen by a grey box with a colored outline. The name in the
center of each of the boxes is the signal name. If you go onto this
button and push it, a signal control box will pop up for that signal.

**HOW LONG, HOW OFTEN**

The most asked question on the EPFX is how long and how often
to treat. This is most often a question that requires a specific
and individual response not a generic one. But let me respond with
some ideas.

First and foremost is the question of the SOC index. how much
life force is left for the patient to heal themselves. Here is where
many of the doctors look at their shoes in embarrassment. It seems
that many persons by the EPFX device so that they need not have any
patient contact. Perhaps they made a wrong career choice, there are
several job opportunities in the food service and housecleaning
field. But to be in the health field there is a sacred unspoken oath
to try to help as much as possible without doing any harm. Education
and responsibility are important and necessary parts of the healing
process. Sometimes a patient can't talk or relate such as with pets,
but still try to take the one or two minutes it takes to input the
SOC data as much as you know.

The higher the SOC the less life force the patient will have
to cure themselves and they will need more therapy for longer times.
Under fifty SOC will not take much time and usually is asked to come
see me once or twice a month. SOC up to 100 the same unless the disease
has had dramatic organ destruction. Cases of moderate to extreme
organ destruction will take weekly visits. Nerve based and sensory
organs are harder and need more therapy. Use the timed therapies
in sarcodes. This supplies needed organ energy and awakens cellular
repair.

The danger is that the device could take over regulatory
functions in the patient's body. The device is designed to increase
awareness and to stimulate the body to heal itself. Too much and the
body can get lazy and let the system do the work. So be careful, your
end goal is helping the patient to help and balance themselves.

Another factor to consider is compliance. Does the patient like
the treatment, did they feel the effects of the device. They should
not feel the device but should feel the difference the device makes.
If they feel nothing the awareness level is probably low, another
session is helpful after a week or two. So many of my patients feel
nothing for three or four treatments but have incredible cures, so
feeling the device is not essential. Thus it should not be the goal.
The short term goals are responsibility and some light symptoms. The
long term goals are cure and self dependency of self awareness and
self fulfillment.

To get to these goals we should try to get an agreement with
our patient to a course of therapies. For simple conditions I often
agree to perhaps three visits once a month. I will terminate the need
for number three if total cure is achieved on number two. A very
chronic or life threatening disease will require more therapy. I
ask for weekly session for 8 weeks. Twice a week if crucial.

So to summarize there are many factors to consider in setting
a course of action. Let the patient and you discuss and operationalize
changes and responsibility. Please do not call me if you do not have
the SOC.
HOMOTOXICOLOGY

This program is very sophisticated and takes some skill in interpreting and using. In the basic philosophy of Homotoxicology there is the insight of how the body needs to detoxify. In an ever toxic society, our bodies need to detox more and more. Detox of stool, sinus, menses, urine, sweat, etc. Excess Detox can be seen as a symptom. Diarrhea, excess sweat, smelly urine, excess menses, sinusitis, skin rash, etc can result from excess toxicity. An if the patient is taken to an allopath the symptom can be treated. This will drive the toxin in deeper. So the field of Homotoxicology was founded. But how to know what toxin or pathogen is involved has always been the problem. Now with the EPFX device Homotoxicology is easy to learn and easier to do.

We need to know the phase of the illness, and the likely tissue it has affected. The phase is clicked on the top of the screen and the tissue types run down the page. Click on the tissue type. A green panel will appear that will have an edit box for you to input more specific tissue of an organ of concern for testing. Click the test button and the system will then test and provide two panels with information on the nature of the toxicity(isodes), the problem of pathogens(nosodes), and behaviors that interfere with detox. To treat these problems directly click on the name of the item you want to treat.

Homotoxicology has never been easier or more accurate. The patients unconscious will react to the items needed to treat.

Most of the toxins in the body are free radicals. As such they have an electrical charge. The “Detox” button will provide a magnetic electrical impulse that will shake the free radicals and increase detox. As you enter the program the system will guess what the disease state is. As you leave the panel the system will give hints, if the show hints button has not been pushed.

Also on the page is access to the lie detector, miasms, mental factors, love versus frustration from a swift Fourier analysis of the heart beat, and other functions as well.

The Homotoxicology page is perhaps the finest achievement of the EPFX system. Use it wisely.

A new set of homeopathic remedies of over two thousand has been added with the trivector voltammetry signal for each. They are tested in the big test and added to the remedy list and can be viewed by clicking the load Homeopathic Remedy list. There is a repertory report access which can improve the retesting of remedies. This program will look for an electrical compatibility to classic repertory symptoms. Input the sensations into the edit boxes. Try not to lead the patient, ask for patient responses to the questions
in the edit boxes. Get the answers in simple terms and type them into the boxes in English. Ask a question like please tell me what sensations you feel in the head. DO NOT ASK is there a pain in your head? Or any direct reference to a possible symptom

If the answer is that the area is normal then type normal. If the only answer is I am not sure then ask for the immediate or present sensations. If the patient can not talk or converse to you type N/A (for not applicable) into the edit boxes or leave all untouched. You can type 256 characters in each box.After completion Click the Load button then click the Scan button on the next panel. The computer will now scan the electrical and repertory compatibility in the homeopathic matrix, the top items will have values above 400 and appear at the bottom of the grid.Most patient are sick because they can not properly feel, express, or understand their own sensations. Patients often lie, twist or cover up some data when asked to verbally describe their sensations. The verbal area of the brain is very small and is restricted in access to the rest of the body. This makes verbal interactions weak in their ability to get to the truth of the patient's health. The EPFX device interacts with the unconscious for a deeper and truer picture. The device will now look for compatibility and allow the unconscious of the patient to chose homeopathics for their own body

Scan Potency   This program will search the patient’s reaction to potencies of a single homeopathic. First make sure he patient name is in the top edit panel. Type in the name of the homeopathic to be tested.

Start the scan. The scan will take from 1 minute to five minutes. The primary reaction or peak reaction will be displayed in the spin edit boxes. There are many other reactions that are significant. These are the harmonics of the main potency. To treat and check this potency click the 'treat' button.

Energy from Test Tray

This will allow you to make a remedy from the test tray. Put the item on the tray and click this button after loaded take the item off and the put the item to be energized on the tray, and then click start. The item energized will have the energy added to it of the item in the tray. This works equivalent to the Dermatron from Germany.

REPERTORY

This program will look for an electrical compatibility to classic repertory symptoms. Input the sensations into the edit boxes. Try not to lead the patient, ask for patient responses to the questions in the edit boxes. Get the answers in simple terms and type them into the boxes in English. Ask a question like please tell me what sensations you feel in the head. DO NOT ASK is there a pain in your head? Or any direct reference to a possible symptom

If the answer is that the area is normal then type normal. If the only answer is I am not sure then ask for the immediate or present
sensations. If the patient can not talk or converse to you type N/A (for not applicable) into the edit boxes or leave all untouched. You can type 256 characters in each box.
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**RISK PROFILE**

In the risk profile panel we can calculate the average risk of certain risk states. In the large test we can see individual reactions to individual items, where in the risk panel we average 20 items that say reflect immunity. The risk scores are then insightful for disease pattern recognition. The values that appear are the last patient's. To set the current values you must first click on the 'Load Current Patient' button This is a mathematical estimate. If there are too many red items then hit 'add 1' repeatedly till there are fewer red items this can be done till the most significant items remain. Reset will return to the beginning.
There are 40 categories. Twenty below and twenty above. Press the Information button and we also have Amino acids, Minerals, Oriental Herb, Electromagnetic static Hertzian reactions, combinations and also a switch board to our other panels. Click on calculate or hit 'u' to present the risks. The bottom 20 of 40 will appear. The top can be seen by striking the 'p' or top button. Double click on the name of a risk area and the system will put homeopathic products into the report file.

**THERAPY**

**ENERGETIC AND ELECTRO-INTERACTIVE THERAPY WITH BIORESONANCE**

The next important program is the Therapy program. Click on this button to go to the Therapy screen. As it appears there will be a suggested primary therapy mode if the computer has chosen one. This is written on the top of the screen. As that most of the primary
therapies are autofocusing the most you need to know is often how to just hit start. The autofocus system will do the rest.

There are several types of energetic therapy available and several ways to deliver them. The upper right box allows you the choice of delivery. Remove the harness for Virtual treatment. These therapies involve subspace treatments and active energetic frequencies of voltage and amperage oscillations through the parallel port through the harness. Read the harness rules in the front of this manual. The best choice is the default choice of 'Activate All'.

The power double switch on the button will activate a double signal for any function. The system will then put two wave forms together to get a double power and gain. This will still satisfy any safety levels but produces a more penetrating signal. Use when you have deep stubborn disease.

For the doctors and therapists with little experience or we have provided several automatic treatments. Since this system is interactive an automatic system is a last possible. Now the device can do BIORESONANCE therapy and evaluate the progress. It can terminate the program when the therapy has accomplished the goals and prolong or in EPR Biofeedback the therapy if required. In essence this system can make midcourse corrections in the therapy treatment. It can sense and make the required changes most compatible for the patient. Most of these autofocusing systems are so easy to operate. Just hit start. The computer does the rest. Don't complain because it is too easy. Make it look hard for your patients sake, so they respect the process.

The Panels and instructions will guide you.

The Automatic therapies are:

<table>
<thead>
<tr>
<th>THERAPY</th>
<th>GOALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auto Freq</td>
<td>Automatically treats with Rife frequencies the organs and the polarity disturbances of the patient.</td>
</tr>
<tr>
<td>AutoColor</td>
<td>Automatically treats the patient with color therapy and finally chooses the best healing color for the patient.</td>
</tr>
<tr>
<td>Auto Trivector</td>
<td>Voltammetry Automatically filters like the Bicom and Mora devices but with this cybernetic interface this system can adjust the treatment program to the best treatment capacities for maximum results.</td>
</tr>
<tr>
<td>Scaler</td>
<td>Treats the Chakras of the patient. This program can only be seen with the Autocolor screen activated. This system can develop maximum voltage, be careful with this program.</td>
</tr>
</tbody>
</table>
Mental NLP  This program allows for energetic reprogramming of mental energy follow the directions and insert the answers in the edit boxes. The device can detect personality superimposition and will alert if present. The Warning panel will allow for correction of the superimposition of personalities if detected.

Spinal  This program allows for energetic correction and detection of energetic imbalances in the spinal vertebrae. Follow instructions on screen. Sarcode, chackra, and organ reactivity is also revealed Double click on any sarcode to treat it. An Allersode test of allergy families is also provided. Difficult and reappearing concerns will need more correction and sometimes show miasmatic or inherited tendencies.

Homotoxicology  This program reveals Homotoxicology disturbances, Xenobiotics, Miasms, and mental reactions. This screen allows for a brief glimpse of the key notes or polycrests of German Homotoxicology. There are info panels on Isodes, Nosodes, Miasms, Mental factors.

Nutrition  This screen allows glimpses of nutritional disturbances and classical Homeopathy from EPR scores

Auto Frequency Modulation  This screen offers us the functions of EPR, GSR, trivector voltammetry

Auto VARHOPE  Will activate a program that will attempt electrical repair of any energetic terrain disturbance detected in the test screen. You can only use the button once. The same is activated with other programs so you can repeat.

NOTES
On every page there is notes access. This will allow you to make a special record of any observation, note, or message to put into the patient record. The first time you access this note file a warning will appear that will require you to allow the file to be created. The note file is destroyed after each patient and thus needs to be recreated with each patient. Type in any data for your report.

On the 'Report Screen' there is an 'Add Simple Notes' to add your note file to your patient report. Or use the 'Just Notes' button to see just your note file.

REPORT DATA
This will allow you to put your personal clinic data on the top of your patient reports. To access this function go to the Report screen and select the pull down Report Access menu. Click on the Report Data button. Specify your own clinic data, font
size, margins, paper size (different for American versus European), select an icon for your heading, and then save your choices. This will be the heading for your patient reports.

**REPORT**

The pull down menu on the top can be used to activate the report screen. We can make a report, save it for future reference and or print it for our records or for the patient to take home. The basic report starts with the patient name and demographics from the patient data screen. Then we add info to the report on the 'Information' button on the Test screen. Also we can take notes and add information on any screen by going to the 'Notes' button. When we first go to the 'Notes' file the computer will ask if we want to construct the notes file. Say yes because it will need to be constructed new with each new patient. Once constructed the 'Notes' file can take notes as you proceed through the total procedure. The note file can sometimes not go past 32K however. Once you have accumulated the Demographics, the Info, and the Notes, then you are ready to complete the report. Word Pad can do more.

Start the Procedure of recording a new patient visit with the New Examination Report button. This loads the current patient data. The doctor in the Report Data will be the default doctor selection if you wish to change this then click on the Doctor or Therapist name edit box.

If you want to see an old record then click on the name in the upper middle panel to see your old records. You can select the order of their appearance with the order by selection.

The choice of name and record are best completed before completing the report to avoid error messages.

The 'Report Access' on the pull down menu will have several choices for use. We can open the current file on our current patient or go to a past report for information. These are our Open choices. The current will allow us to construct our current report.

The 'Add Information' on the pull down menu will allow us to add some extra data to our report. The 'Natural Switch' has diet and health suggestions. The 'Affirmations' has some suggested affirmations. The 'Rules for taking Homeopathics' can be added. Or we can add our notes file That we have been developing during the client visit. We can also save some notes to the hard drive file that will not be added to the print function. If we want to make a note that will not be seen by the patient on his hard copy report, use the 'Add data to Hard drive not print' function.

The 'Edit Main Text File' function on the pull down menu allows us to change the style of the first lines of our reports. The Clinic heading and basic practitioner information can be changed and remembered on the 'Edit Clinic Data' function. The basic preliminary information on your report can be changed with the 'Main Text File'
function. This is the template used in the beginning page of each report. What you type here will be inserted at the front of each of your reports. If this file is blank then nothing will appear in front of your reports. A sample choice is included to begin with. It can be erased permanently if you wish, by going to the 'Edit Starting Report' Button and erase the info in the file.

The 'Report Access' on the pull down menu will have several choices for saving your report. To save the report to the hard drive click that function. To save to a floppy you must go to the print preview and use the floppy icon at eh top of the print preview page. To exit without saving anything use the appropriate function.

IF YOU WANT TO SAVE THE TOP ITEMS IN YOUR REPORT. Go to the Wellness screen, accessible from your Test screen pull down menu called 'Programs'. In Wellness then click the 'Save Significant Data to The Info File Report' button. This will add the purple items on your report or the top 250 items (which ever is smaller) to the report INFO file. They will then appear on the Info file when you load it next. You can only load the top items once per patient.

Print and Print preview can allow you to make a hard copy of your report. These are typical of Computers functions. Be sure to remember you can cut and copy from any file to your report. Be careful when saving your text files in the notepad to not lose your master templates.

IF YOU TRY TO SAVE A REPORT WITHOUT A PATIENT NAME YOU WILL GET AN ERROR OF KEY VIOLATION. Try to always have a patients' file to save to report or use save cancel to not save report.

So there are the facets of making a report and saving it. Use your word processor to prepare other styles and practice with the system. After a short time you will be abased at how well it works on the 10th time. Good Luck.

If you are having a hard time printing your reports through the EPFX device, You might need to get a Parallel port switch for the printer and device. Some printers have difficulty with complex systems like the EPFX. Purchase a parallel port switch from your local computer shop and connect it to the computer and then to the EPFX device and then to the printer. Switch to the desired setting, device for testing and printer for printing.

**HOMEOPATHIC REPERTORY**

This program is on the homeopathic activation screen.

This program will look for an electrical compatibility to classic repertory symptoms. Input the sensations into the edit boxes. Try not to lead the patient, ask for patient responses to the questions in the edit boxes. Get the answers in simple terms and type them into the boxes in English. Ask a question like please tell me what sensations you feel in the head.

DO NOT ASK is there a pain in your head? or any direct reference
to a possible symptom

If the answer is that the area is normal then type normal. If the only answer is I am not sure then ask for the immediate or present sensations. If the patient can not talk or converse to you type N/A (for not applicable) into the edit boxes or leave all untouched. You can type 256 characters in each box. After completion Click the Load button then click the Scan button on the next panel. The computer will now scan the electrical and repertory compatibility in the homeopathic matrix. The top items will have values above 400 and appear at the bottom of the grid.

Most patient are sick because they can not properly feel, express, or understand their own sensations. Patients often lie, twist or cover up some data when asked to verbally describe their sensations. The verbal area of the brain is very small and is restricted in access to the rest of the body. This makes verbal interactions weak in their ability to get to the truth of the patient's health. The EPFX device interacts with the unconscious for a deeper and truer picture. the device will look for compatibility and allow the unconscious of the patient to chose homeopathics for their own body.

**SPINAL EPR AND SARCODES**

On this panel there is access to functions of spinal analysis, allergy testing, and sarcode or organ strength. The “test and treat Trivector Voltammetry Energy Flow” this will test and treat each vertebrae. It measures the reactivity of the system to sarcode of the vertebrae while testing the flow of electrical energy thru the system. If there is a flow disturbance the computer will identify it by telling us it is not corrected, difficult (meaning chronic), or other message. The individual vertebrae can be tested and treated or the whole system can be treated multiple times.

The button “Show Sarcodes” will show us many organs and show resonant they were with the patient. The higher the number the more problem there is in the organ. An inflamed or degenerate organ will show high numbers the therapist will have to decide what was the difficulty. Healthy tissue will tend to have moderate numbers like 50 to 80. Higher numbers represent risks in the organ. The “mental foci” button will turn the organ most related to the current mental state of the patient white.

The “timed treatments” button allows us to activate therapy suggestions for specific organs or organ functions. You can set the time up to forty minutes. At the right there is activation for selections of 1. Inflamation 2. Metabolic disorder, 3. Injury, 4. Infection 5.degeneration. If you know these are present in the organ you wish to treat then click. If you are not aware then do not click these boxes. You can chose several of these check boxes but only one radio button or organ therapy at a time. The help with question will allow you to ask the patient questions to access more data. These
questions are also asked in the demographics panel under the “acu
symptom profile”, so if you have answered them on the demographic
page you do not need to enter them here they will already be in the
computer. This will make high risk organs be red on the sarcode panel.
Click on the name of the organ to treat it for a short time. Resonance
and rectified will appear on the lower right. Continue the treatments
till rectified is above 90.

Response-Reinforcing Stimulus Mechanisms in
Biofeedback Training: Operant Behavior

Neurological thinking has been largely governed by
Sherringtonian principles of stimulus-response (S-R) mechanisms
underlying motor activity and therefore behavior. There now can be
added to our neurological thinking the concept that a
"response-stimulus" mechanism plays a role in underlying motor
activity. This phrase "response-stimulus" may at first sound
nonsensical to the classical neurologist. It can, however, be made
clear by adding the qualifying adjective "reinforcing" to the word
stimulus and by rephrasing the idea as "activity-reinforcing
stimulus." It will be better understood by envisaging an actual
situation. For example, a person yawns; the activity of yawning
stretches the muscle spindles around the temporomandibular joint and
this acts as a reinforcing stimulus for a further yawn. If the subject
merely opens the mouth, letting the jaw fall passively with gravity,
there is usually insufficient stretch stimulus to cause a second
yawn. The subject has to inspire (draw in a breath) as he opens his
mouth in order to evoke adequate reinforcing stimulus to produce the
next yawn. Such inspiration is termed operative because it leads to
or enforces the subsequent activity (the second yawn). In other
words, it has operated a piece of motor activity. It is causal
behavior. In another example, a person touches a button, and the music
begins to play; the auditory stimulus of the music acts as the
reinforcing stimulus for the subject to push the button again. This,
of course, is more complex or indirect "activity-reinforcing
stimulus" situation because there is no choice or latitude in that,
if the music does not please the listener, he may not press the button
again. In similar way, however, the subject also has the choice
(albeit more limited) of not responding to the reinforcing stimulus
of the jaw by a further yawn. Whether or not the initial behavior is repeated after receiving reinforcement by the stimulus depends upon a number of variables. It is with these variables that biofeedback is concerned. It is also concerned with causing motor activity after reinforcing stimuli. Behavior which is followed by a positively reinforcing stimulus or terminates (reduces) a noxious reinforcing stimulus is termed operant behavior.

Biofeedback sometimes deals with "initial stimulus-response" mechanisms in the Sherringtonian sense, tracing the afferent-efferent pathways through the brain. On the other hand, however, it often deals with the "response-reinforcing stimulus" mechanism (or "activity-reinforcing stimulus" mechanism). In this latter type, the subject performs an action (for example, contracting a weak, partially paralyzed muscle); this causes a sound from the biofeedback instrument and the patient responds by contracting a second time in order to receive the pleasure of hearing the sound (which is sweet music to his ears because it indicates that the muscle is functioning). The fact that the muscle contracts causes summation of action potentials, and with both spatial and temporal summation more muscle fibers contract on the next occasion. This is the kind of "positive" muscle contraction mechanism used for muscle rehabilitation biofeedback when there is insufficient motor activity. Another example of the "response-reinforcing stimulus" situation is when the patient has pain from performing an action (over contracting the back muscles). This causes a high-pitched grating sound from the biofeedback instrument, and the patient responds by relaxing the muscle so that the intensity of sound goes down and at the same time the pain is less because fewer of the "Type C" fibers which carry pain sensations to the parietal cortex are stimulated. The excitatory neuronal mechanisms. In the actual practice of motor control, however, the patient does not have to be aware of the exact mechanism whereby the desired effect has been achieved. For example, an individual is not aware of the exact curling movements performed by the tongue when he speaks, until he has a neurological lesion which destroys part of the mechanism of articulation. He then has to become aware of the exact movements of the tongue in order to volitionally direct the operation. Behavior then becomes, in part, operant behavior.

There is a difference between "body-memory" or somatic memory which is not conscious and appears or rely heavily on peripheral
mechanisms, and cerebral memory which can be verbalized and is more purely central. This may be illustrated by an example of complex motor movements (complex behavior). The child prodigy violinist produced musical sounds on the violin with greater facility than the "average" child. He is not aware of the exact mechanism whereby the fingers operate on the instrument. Later in life, he may change, and for a number of reasons connected with his "psychological" status, (meaning the internal stimuli which in part caused the original motor behavior of operating the violin), he loses some of the motor skills involved with using his fingers. When he asks himself, "How did I do it?," he is only able to answer partially and incompletely. He then has to use the "response-reinforcing stimulus" mechanisms to relearn. He plays; he watches the fingers both directly and in a mirror; and when the sound is correct to his ears, he "memorizes" both in his consciousness and in his fingers (body-memory, or kinesthetic joint memory) the feeling (meaning the afferent stimulus) which leads to that particular motor response. For all these mechanisms to work, there has to be a "reward" or pleasurable sensation: and clearly the more "conscious" the subject, or in other words, the more aware of the significance of the reward to himself, the quicker will the linkage be established between the reinforcing stimulus and the response. It is in this light that one may look at behavior as a chain reaction composed of an initiating stimulus leading to a response, leading to a reinforcing-stimulus leading to a response and so on sequentially. In this way, peripheral neuronal activity is linked to cortical neuronal activity, leading to further peripheral activity and repeated again in sequence.

An analogy may be drawn regarding behavior in an interdisciplinary approach. The psychiatrist and the analyst are examining the factors operating at the "initiating stimulus" end, meaning that they study the patterns of sensation, emotion, and behavior laid down early in the organism's neurological development. The neurologist observes the present ongoing behavior, and in classical tradition the neurologist has frequently regarded the nervous system in terms of exteroceptive or interoceptive stimuli causing responses. There may now be added the dimension of the operant-orientated psychologist who examines a segment of behavior (which the patient finds sufficiently distressing to cause him to seek advice), but who disregards the cause in the distant past for that behavior. By having repetitive reinforcing stimuli linked in the
biofeedback technique to the opposite of that particular piece of motor activity, the patient comes to learn a different behavior. This new segment of motor activity is likely to cause new sensations which acquire feeling-tone, and the patient may then view himself or view the world through himself differently.

As a related neuropsychological theme, one may examine the meaning of "control-of-self" being at the basis of, or synonymous with, self-control. From the neurological point of view, it appears that subjects with poor impulse control are in some respects lacking good inhibitory mechanisms in the limbic system and, in particular, in the hypothalamus.

Thorndike (1898), who described the law of readiness also emphasized the mechanisms of stimulus-response activity. This response activity can be termed respondent activity. Under specific experimental circumstances, it can be seen as respondent conditioning. It is of interest that with special DC recording of the brain waves, the contingent negative variation or expectancy wave Grey Walter can be observed to give the electrical component of activity just prior to the operant response in classical conditioning experiments.

The whole field dealing with the role of reinforcement in the explanation of behavior is highly complex and this brief description must be regarded as an introduction to more detailed texts on reinforcement.

ALTED STATE THERAPY AND BIOFEEDBACK

Relaxation Techniques: Hypnosis, Meditation, and Imagery

Although biofeedback is an effective clinical procedure, it is not used in isolation from other therapeutic techniques. Since many of its clinical applications focus on the reduction of anxiety or physiological arousal, relaxation procedures have been used with biofeedback to maximize this effect. The patient undergoing biofeedback treatment is often introduced to a relaxation technique
prior to receiving biofeedback (Fair 1979). Clinicians using biofeedback frequently develop their own individual relaxation procedures. Most of these modified techniques are based on the progressive relaxation method originally developed by Jacobson (1958).

Standardized relaxation techniques are effective for most patients. If the patient has difficulty, the therapist must be certain that the patient's failure to relax is not due to a misconception or to therapeutic resistance. For example, some patients try too vigorously to relax, which results in increased tension. This may occur with Jacobson's technique because patients spend too much time tensing muscles and too little time relaxing. If a well-motivated patient, however, cannot adjust to the standard relaxation procedure, other methods are available. Biofeedback therapists must be familiar with alternative procedures when a standard technique fails to generate the desired response (i.e. Lowered arousal). We define arousal as it is commonly used in the field of psychology; i.e. an excess level of muscular tension and hyperactivity to stress. Current relaxation methods differ in a number of ways. Four types will be examined: hypnosis, meditation, progressive muscle relaxation, and imagery. Each of these techniques will be discussed.

Hypnosis

Historical Development

The emergence of hypnotic techniques as a recognized form of psychological therapy has paralleled the growth of biofeedback techniques in the last two decades. Although formal hypnosis predates biofeedback by about two hundred years, it has until recently, had a checkered past. The unscientific image of hypnosis has been intensified by the activities of stage hypnotists and the portrayal of hypnosis in fiction and the cinema. However, hypnosis has been extensively and scientifically studied and has become an accepted treatment procedure in certain well-defined therapeutic approaches.

The concept of animal magnetism was created by Van Helmont (1577-1644) based on Paracelus (1493-1541) theory of magnetic forces. An 18th century Viennese physician, Frenz Mesmer, used the concept of animal magnetism to develop a treatment technique based on the idea that illness was caused by an imbalance in an invisible,
magnetic fluids. Mesmer and, later, hypnosis came to be regarded as quackery and both were banned in several European countries. However naive and unusual his theory and appears today, Mesmer contributed to the development of modern clinical hypnosis because of his use of trance induction (Boring, 1950).

Mesmer's controversial theories and practises caused medical practitioners and others, to form negative opinion about hypnosis. The use of hypnotic techniques, however, by physicians such as Charcot, Liebault, and Bernheim helped maintain its importance in the mainstream of scientific inquiry (Boring 1950).

Eventually, professional associations (such as the American Society for Clinical Hypnosis and the Society for Clinical and Experimental Hypnosis) established standards for its clinical practice. Professional training programs were developed to insure that hypnosis was used ethically and responsibly. Clinical hypnosis achieved a new level of acceptance in 1956, when an American Medical Association statement described it as a "Hypnosis is a valuable therapeutic adjunct for the medical doctor" (Goleman 1977).

Theory

Everyone has a level of conditioning that is accumulated from their past. A person might be conditioned to respond to the smell of chocolate with craving. Another might see a person light up a cigarette and want one. In fact hypnosis when it is best is a deconditioning therapy that sets one free to respond openly and independent of conditioning. Hypnosis is often used to replace a conditioned response with a safer response. But deconditioning of response and freedom of response is our goal. This type of freedom of response or deconditioning hypnosis was pioneered by William Nelson in his early work.

There are several theories to account for the clinical effectiveness of hypnosis. Controversy still exists, however, over whether or not hypnosis is a special trance state. For many years it was believed that subjects under hypnosis went into a special state or trance. This is the "state" theory of practitioners such as Milton Erickson (Goleman 1977).

An alternative, and more recent, concept is referred to as the
"nonstate" theory (T X Barber 1975). Barber believes that hypnosis is not a specifically different state of consciousness, although consciousness may be somewhat altered in the process. He has demonstrated empirically that anything a subject does under a "hypnotic trance" may be duplicated by those who are not in a trance.

Even theorists who believe that hypnosis produces a special trance state cannot agree on what actually occurs. Measurements of physiological changes in subjects undergoing hypnosis have had mixed results but have generally supported the theory that the neurological status of the subject is not altered qualitatively. There have been no consistent findings of altered EEG rhythms, eye movements, pulse rate, or galvanic skin response (Barber 1975). Although hypnosis is a well-established clinical technique basic research is still needed to investigate the process (Kroger and Felzer 1976).

A thorough review of the therapeutic use of hypnosis, or hypnotherapy, is beyond the scope of this book. Researchers and therapists, who are well-versed in this technique, consider the reallocation which results from hypnosis as only one of many desirable effects of this procedure. In this chapter, only the relaxation effects of hypnosis will be discussed.

**Hypnotic Relaxation**

A variety of hypnotherapy techniques currently exist. These, however, have in common the induction of a condition (or state) where the subject becomes hyper suggestible. This allows the hypnotherapist to have significant influence over the subject's attitudes and/or behavior.

Kroger and Felzer (1976) summarize the hypnotherapeutic process which they have developed, involving what is described as a "double-bind" induction technique, based on the assumption that the subject will become automatically hypnotised. The term "double-bind" means that the subject cannot easily avoid being hypnotised. The phrase originated in the field of family therapy describing the situation of a child with schizophrenic parents, e.g. the child is given conflicting communication which causes him to be punished no matter what he does. Kroger and Fezer's induction technique involves the presentation of suggestions regarding sensations such as "warmth" or "heaviness." The subject is also given the suggestion
that he can choose to control these sensations if he wishes. One result of this induction procedure is to make the subject believe that the hypnotherapist is responsible for these sensations, instead of realizing that they are self-produced.

In addition to a standard induction techniques, patients are also "placed" into deeper states of relaxation through the use of "scene visualization," which is technique common to many types of hypnotherapy. A narration is given to the subject describing relaxing scenes with vivid, sensory experiences and colorful, elaborate visual images.

A useful technique developed by Vogt (Kroger and Felzer 1976) in the last century, is often employed to deepen the hypnotic state of relaxation. This is referred to as "fractionation" and, according to Kroger and Felzer, it involves the hypnotic presentation of sensations and images which the subject reported during previous hypnotic experiences.

After the first few sessions of hypnosis the subject is gradually introduced to "auto-hypnosis" (self-hypnosis). He learns to place himself into a deep state of relaxation through means of a conditioning process. Most therapeutic uses of hypnosis rely heavily on self-hypnosis. Indeed some theorists (e.g. Barber 1975) argue that all hypnosis is self-hypnosis since the hypnotised subject ultimately can control the situation even though he may be convinced that he cannot.

Hypnotic induction (regardless of how it is accomplished) can result in a deep state of relaxation when employed by an experienced hypnotherapist.

Although biofeedback and hypnosis are frequently applied to treat the same disorders, few studies have been undertaken which compare their relative effectiveness. Some authors suggest that hypnotherapy is more effective than biofeedback but offer little evidence to support their claim (Kroger and Felzer 1976).

Ian Wickramasekera (1976a) has conducted several experiments exploring the relationship between biofeedback and hypnosis. For example, he found the EMG training resulted in increased hypnotic susceptibility in young college males. Melzack and Perry (1976) combined alpha biofeedback training and hypnosis to teach patients control of chronic pain. They concluded that alpha biofeedback produced a marked reduction in pain only when accompanied with hypnosis and placebo effect (i.e. distraction and suggestion).
Wickramasekera (1976b) also hypothesized that biofeedback, behavior therapy techniques and hypnosis share many common elements. All three techniques arose from experimental laboratory studies, and in all three, various treatment components are specified in order that the therapist can control and predict the specific behavior of each patient. Biofeedback, behavior therapy and hypnosis all tend to focus on specific symptoms, to manipulate cognitive functioning, to focus on physiological consequences of verbal-motor events, emphasize informational feedback and reinforcement and expand the possibility of an individual to regulate his internal environment. Wickramasekera concludes that the important common element among these three types of treatment is that they strengthen the placebo response. In addition Wickramasekera believes that patients who are good candidates for biofeedback treatment.

Several biofeedback techniques have qualities similar to standard hypnotherapy, although they are not hypnotic procedures in the strict sense. One of these, "autogenic training," has become associated with biofeedback training in conjunction with thermal biofeedback in the treatment of migraine.

A German physician Johann Schultz developed autogenic training, which he considered a form of self-hypnosis. His student, Wolfgang Luthe, refined the procedure and developed a therapeutic system based on it. The technique is most often used in a simpler form when employed in biofeedback training (Schultz and Luthe, 1969).

The procedure involves the presentation of psychophysiological statements such as: "my hands feel heavy and warm" during a state of passive concentration. Although, at first, the therapist presents these statements to the subject, the latter is to practice the technique after memorizing the appropriate sequence, with frequently repeated sensory statements such as "warm" and "heavy". The repetition of such statements results in deep relaxation which often leads to peripheral vasodilatation. It is, therefore, successful treatment for vasoconstrictive disorders such as migraine and Raynaud's disease (Green and Green, 1979). Many clinicians have developed autogenic feedback techniques based on Green's original study. These can be used in conjunction with thermal training (Green and Green, 1979). After each autogenic statement the subject's average skin temperature is measured and recorded, so that the effect can be observed immediately. The measurements also allow the therapist to determine which statements best promote vasodilatation.
The patient can then use these particular phrases to control vasoconstriction in situations when he cannot go through the entire procedure, for example, when working or engaged in daily activities.

In some ways this procedure is similar to Vogt's fractionation method. In autogenic feedback, however, the subject does not verbalize what he experiences; it is indicated by the electrothermal instrument. Besides being more immediate, such information is more objective and reliable than the subject's verbal report under hypnosis.

For further information, readers are referred to Hypnosis and behavior Modification (Kroger and Felzer, 1976) and Hypnotic realities (Erickson, Rossi, and Rossi, 1976).

**Meditation**

Meditative techniques have been adopted by many biofeedback therapists to elicit deep states of relaxation.

Meditation, especially that associated with the Eastern religions, such as Zen Buddhism, has been indirectly influential in the development of biofeedback in this country. The physiological effects of various forms of meditation accomplished under empirical conditions, such as Swami Rama's demonstration of bradycardia with cardiac asystole and restitution of heartbeat as reported by Green and Green (1977), stimulated research in the conscious control of physiologic events. It became clear, however, that few people could achieve similar results, though many individuals from diverse populations can be trained in physiologic control of autonomic events (although of a less dramatic nature) through the use of biofeedback.

**Historical Development**

Although medication is often associated with the religions of the East, Christian ascetics in the West practises a form of meditation in the 4th century. These meditation techniques involved in the repetition of a single phrase from the Bible. This was later known as "Hesychasm," after a 5th century religious teacher named Hesychius.

The most popular of these techniques was the "Jesus Prayer," consisting of repeating the phrase "Lord Jesus Christ, Son of God,
have mercy on us," in the Latin "Kyrie elesion," (as such it is one of the introductory responses of the Latin Mass). Other religions developed their own forms of meditation, including the Moslem "Sufism" and the Judaic "Kabbolah".

"Transcendental Meditation" (TM) was currently popularized by Maharishi Mehesh Yogi (Benson 1975). As in every form of meditation, TM involves the use of repetitive thought which leads to a deep state of relaxation and peace of mind. This repeated thought or "mantra" apparently is derived from the Sanskrit of the Hindu religion. Many members of the Western culture have become increasingly aware of other Eastern forms of meditation such as Yoga and Zen meditation or "Zazen".

Zazen has been studied extensively by Japanese researchers, who discovered that Buddhist monks can generate an unusually "high concentration of EEG alpha rhythms" (Kasamatsu and Hirai, 1966). Interest in biofeedback in that country is keen and research on the psychophysiological correlates of Zen meditation is being conducted in Japan. At an international symposium on biofeedback in Kyoto in 1977 the results of numerous investigations of Zazen were presented and an attempt was made to synthesise the Eastern tradition of Zen meditation with the Western technique of biofeedback.

**Theory**

When examining theoretical explanations for the effectiveness of meditation, it is difficult to separate theory from religious beliefs. Meditation is commonly seen as a method where by the practitioner can achieve a closer relationship with a being or transcending experience. Altered states of consciousness are also thought to cause the physiological changes which accompany meditation.

Research on the effects of TM demonstrated that it results in "positive" changes in physiological responsiveness; positive in the sense that it lowers arousal. Herbert Benson (1975), a Harvard psychiatrist, reported that TM resulted in 10-20% lower oxygen consumption than in the normal waking state. (This decrease is greater than usually observed in sleeping subjects). Marked decreases were also observed in serum lactate levels (where as high concentrations of serum lactate have been reported in chronically anxious subjects). The most significant physiological changes with TM involved reductions in systolic and diastolic blood pressure of
individuals who regularly practises meditation (Benson, 1975).

**Meditative Relaxation**

Various meditative techniques have been developed but all involve the same factors. Benson delineated four factors: a quiet environment, concentration, a comfortable bodily position, and a passive mental attitude.

Although hypnosis and other forms of relaxation also involve the first three factors, passivity is not stressed. On the contrary, in hypnosis, the subject actively listens to the suggestions of the hypnotist and is very much aware of bodily events. This differs from meditation, where the subject is not supposed to be actively concentrating on anything. The repetition of a certain sound or single thought prevents the individual from actively engaging in distracting thought or imagery during meditation.

Benson developed a form of meditation (described in his book *The Relaxation Response*) as an efficient and economical alternative to TM. His procedure is straightforward and easy to learn; the subject is given the following six instructions:

1. Sit quietly in a comfortable position.
2. Close your eyes.
3. Deeply relax all your muscles beginning at your feet and progressing up to your face. Keep them relaxed.
4. Breathe through your nose. Become aware of your breathing. As you breathe out, say the word "ONE," silently to yourself. For example, breath IN......OUT, "ONE," IN....OUT,"ONE," etc. Breathe easily and naturally.
5. Continue for 10 to 20 minutes. You may open your eyes to check the time, but do not use an alarm. When you finish sit quietly for several minutes, at first with your eyes closed and later with your eyes opened. Do not stand up for a few minutes.
6. Do not worry about whether or not you are successful in achieving a deep level of relaxation. Maintain a passive attitude and permit relaxation to occur at its own pace. When distracting thoughts occur, try to ignore them by not dwelling on them and return to repeating "ONE." With practice the response should come with little effort. Practice this technique once or twice daily, but not within two hours.
after any meal, since the digestive process seems to interfere with the elicitation of the Relaxation Response (Benson 1975).

Patients can learn this technique prior to biofeedback treatment. Since TM has many adherents it is not unusual that a TM advocate may be referred for biofeedback treatment. It has been the authors' experience that teaching such individuals a different form of meditation or relaxation technique is counterproductive and may alienate them. Although TM may not have been effective in eliminating a specific disorder, therefore, it appears to be an adequate relaxation procedure and can be combined with biofeedback under these circumstances.

The only modification necessary is that concentration on the biofeedback signal may replace the mantra or be combined with it during the biofeedback training. Although TM purists may not favor this suggestion or insist that this antithesis of what they are attempting to achieve, many TM patients have been treated successfully using TM and biofeedback in a combined fashion.

**Progressive relaxation**

**Historical Development**

Although both hypnosis and meditation result in states of deep relaxation, that is not their primary function. Relaxation is actually a secondary effect in both techniques. Other methods have been developed specifically to foster a relaxation response, however.

Edmund Jacobson is regarded as the originator of progressive relaxation. In 1908, Jacobson began his research at Harvard on the muscular correlates of anxiety and tension. He observed that tension can be defined, physiologically, as the inappropriate contraction of muscle fibers. From this, he developed the concept that complete relaxation of all muscles may eliminate anxiety. He noted that individuals can learn to relax their muscles deeply through a process of alternately contracting and relaxing major muscle groups. This procedure was termed progressive muscle relaxation (Jacobson 1958).

His procedure consisted of approximately 50 sessions of relaxation training involving 15 muscle groups. These muscles were systematically relaxed; complete relaxation had to be accomplished
in one muscle group before the subject was permitted to concentrate on another group.

Jacobson's methods became popular in the 1950s when a variation of his technique was employed by Joseph Wolpe (1973), a psychiatrist noted for his development of "systematic desensitization".

Wolpe modified Jacobson's technique to make it more practicable; instead of the subject going through the procedure over a long period, Wolpe streamlined the method so that progressive muscle relaxation could be accomplished in one session. All of the major muscle groups were relaxed systematically in less than an hour. Although this modification does not produce all of the physiological changes described by Jacobson, it results in a relatively deep state of relaxation.

Since then, variations of Wolpe's modification have been developed, and therapists have refined the technique to meet specific therapeutic demands. Many biofeedback therapists use a version of Wolpe's method to relax subjects prior to feedback training, and a familiar one was developed by Bernstein and Borkovec (1973).

**Theory**

The theory of progressive muscle relaxation is that it counteracts the physiological effects of tension. Since a muscle cannot contract and relax simultaneously, total muscle relaxation theoretically results in complete absence of bodily tension. Since bodily tension (i.e. inappropriate excess muscle contraction) and mental states of anxiety are closely related, muscle relaxation should eventually result in the reduction of anxiety. The patient acquires this skill by learning to differentiate between sensations associated with excess muscle contraction and those associated with relaxation. This is accomplished by having the subject carefully observe physiological changes as he alternates between states of contraction and relaxation in each major muscle group.

The efficacy of progressive relaxation was documented by Gordon Paul (1969) a psychologist, at the University of Illinois, with significant decreases in heart rate, respiration rate, muscular tension and reports of anxiety in subjects undergoing relaxation. Similar results were reported earlier for Wolpe's technique and Jacobson's original method (Wolpe 1973).
The technique of progressive muscle relaxation involves the systematic contraction and relaxation of major muscle groups (usually 15 groups are used initially). As the subject learns how to relax, these groups can be combined and the entire procedure shortened. Eventually the patient should be able to relax individual muscle groups which do not have to be contracted in order to engage in certain activities.

Through a process of conditioning the patient also learns to associate physiological sensations with various words or phrases used by the therapist. After the patient has gone through the entire procedure, the therapist may ask him to sit quietly and maintain the relaxed state by repeating the word "calm". Eventually, words such as "relax" or "calm" will be associated with a deep state of relaxation and can, therefore, be used to elicit the entire relaxation effect. As was discussed in Chapter 1 with reference to Pavlov's experiment, however, a conditioned response differs in degree from the unconditioned response. Therefore, the relaxation produced by a cue word (conditioned response) would not be as deep as that produced by the entire relaxation procedure (unconditioned response).

Relaxation procedures are further described in recent texts (Basmajian 1979; Bernstein and Borkovec 1973).

After the patient has mastered the basic relaxation technique he can be introduced to the procedure of "differential relaxation." He learns to relax all muscles which do not have to be contracted in order to perform ongoing activity. For example, if he feels tense while driving a car, he can progressively relax all nonessential muscle groups such as the forehead, neck, chest, and back while allowing essential muscles such as the arms and legs to remain contracted. This procedure takes time to learn and, obviously, may be dangerous if a person cannot maintain necessary tension in task related muscles (Bernstein and Borkovec 1978).

Several taped relaxation exercises, currently available, have been developed specifically for use with biofeedback (Budzynski 1977).
Imagery

Historical Development

Compared with other relaxation methods, imagery techniques have not developed as systematically. The use of imagery for inducing relaxation training for the last century, however. Before then, imagery experiences (often artificially induced by drugs) played an important role in primitive religious rites. Artists have also used subjective imagery experiences to enhance their expression: e.g. the visual hallucinations experienced by Blake, Milton and Poe with images of heaven, hell and the supernatural.

Vivid imagery experiences have been associated with the development of many scientific hypotheses; for example, Kekule, a Belgian chemist, reportedly had a dream concerning the molecular structure of benzene. Similar imagery experiences were reported to have occurred to Descartes and Poincare (Hilgard and Atkinson 1967).

Many theorists believe that imagery experiences are influenced by activities of the right cerebral hemisphere, while mathematical and verbal concept are more dependent on left hemisphere functioning. Highly creative individuals are thought to use imagery more than others, who may be more technically or verbally orientated.

Although most patients are able to produce images, they may have difficulty maintaining them over time. Many patients are unable to produce vivid, life-like images on demand. Individuals differ in their imagery ability; some people have very few imagery experiences or perhaps, none at all. Certain patients may need training in imagery production prior to being presented with imagery therapy.

Singer (1974) recently reviewed and summarized the major therapeutic uses of imagery. Many of these techniques so far beyond the elicitation of relaxation and, therefore will not be discussed further in this chapter. Imagery techniques have been used to treat a number of disorders although they are rarely used alone. Most often imagery is combined with hypnosis or biofeedback techniques.

Theory

There are several theories concerning how imagery
facilitates memory and learning, but the mechanism whereby mental images are produced, and the reason why the production of certain images may result in deep relaxation is little understood. Concentration is a key factor in imagery, however, just as it is in hypnosis and meditation, and restful mental images produce beneficial physiological changes in many individuals.

If a patient is able to picture a tranquil scene, he will become gradually more calm and able to reduce physiological arousal. The physiologically disturbing effect of frightening images e.g. nightmares, is familiar to everyone. The goal of imagery therapy is to increase production of beneficial mental images to modify emotions and, ultimately, behavior patterns.

**Imagery Relaxation: Technique**

One technique used to produce relaxation is "scene visualization," a method often employed in hypnosis. Recollection of certain pleasant scenes can elicit relaxation; however, individuals differ in their evaluation of the pleasurable quality of images. Self-report questionnaires assist therapist in selecting the most appropriate scenes.

For example, the Reinforcement Survey Schedule (RSS) created by Tondo and Cautela (1974) contains descriptions of many images which can be developed into pleasing scenes. In taking the RSS, the patient rates those images which are most pleasurable, thereby insuring that the scene narrated by the therapist will actually please the patient.

The following episode illustrates the importance of individual differences in imagery experiences during therapy. A patient undergoing biofeedback treatment was taught to relax. She was presented with a visual image of herself lying on a beautiful white beach on a warm sunny day. Less than two minutes into this imagery experience, however, the EMG instrument registered a significant increase in frontalis muscle tension. On questioning she indicated that the scene had turned into a frightening image when she suddenly visualised the fin of a great white shark circling just off shore.

The therapist must be sensitive to changes in the patient's behavior
of physiological responses (if biofeedback is used) so as to prevent distressing imagery experiences.

In scene visualization, the therapist asks the patient to sit back comfortably, close his eyes, and concentrate on imaging the scene narrated by the therapist. Such narration is a detailed technique which depends on the style and creativity of the therapist. Colorful references to sensory experiences are stressed to make the image as life-like as possible. Whenever possible, all five senses should be involved. For example, the patient, described above, not only sees herself lying on the sandy beach, but feels the spray of the surf and the warmth of the sun, smells the ocean breeze, hears the seagulls and the gentle roar of the surf and tastes the ocean salt from the spray. Some therapists however, may feel uncomfortable with narration and, therefore, might employ a more structured relaxation technique, such as the progressive relaxation procedure presented earlier in this chapter.

**Focused Imagery**

A relaxation technique, recently developed, combines elements of all four of the major relaxation procedures discussed in this chapter (Nigl and Fischer-Williams 1980). Termed focused imagery, it is used in the treatment of psychological disorders ranging from muscle contraction (tension) headache to low back strain.

This technique involves the patient's imagining the appearance of each of the major muscle groups of the body and how they feel. Then the patient is asked to visualize the site of tension. He is then asked to visualize each muscle relaxing and to see and feel the tension slowly disappearing. The process starts with the forehead and systematically moves down to the feet. In addition, autogenic phrases are incorporated into the suggestions; emphasizing feelings of warmth and heaviness in the limbs. After the progressive relaxation is completed, the subject is asked to concentrate on the breathing process and allow it to occur as naturally as possible. Finally, meditation is used to enhance the relaxation effect using a cue word such as "calm" or "relax"; repeated subvocally with each expiration. The entire technique takes approximately 40 minutes.

In summary, relaxation techniques are important adjuncts which enhance the effect of biofeedback. It is difficult to train an
individual to reduce feedback signals without employing one or more of the techniques discussed. Certain authors have criticized biofeedback techniques because they are no often effective when used alone. For example, Orne (1975) states, "This is another instance where a new technique is introduced and found to be wanting, by itself, so it is combined with older, proved therapies." It is not uncommon in medicine and clinical psychology, however, to treat disorders with more than one technique. The fact that the two procedures (relaxation and biofeedback) may be additive increases the probability of successful treatment. Indeed, these two procedures may be synergistic, for example, EMG biofeedback combined with relaxation is more effective in treating muscle contraction headaches than either used alone (Budgynski 1978).

In summary, many techniques exist which can help individuals learn to relax, and most of these are compatible with biofeedback procedures. It is unusual for biofeedback therapists to treat patients without employing one or more of these relaxation exercises as part of the total treatment procedure. Patients must be able to reduce their physiologic arousal in order to alter the feedback signal, and without the use of one of the techniques outlined in this chapter, this would be difficult. Therefore, biofeedback therapists should be as familiar with relaxation techniques as they are with electronic instrumentation and other aspects of the biofeedback method.
--- BIBLIOGRAPHY ---

**BOOKS**


Sample of name change notification to the FDA

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Most recent past

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Kalvanya Ter 2
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Owner/Operator Number:
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We have sold part interest in the 510k to Nature, Science and You via bill of sale and contract. Nature, Science and You will be the only agent using the 510k in America.

In the past we have used the names EPFX, SCIO, and now we are notifying you as per FDA requirements http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm318796.htm. The new Name will be Eductor. Please see our clinical evaluation.

Signed

Kara Bliss Nelson