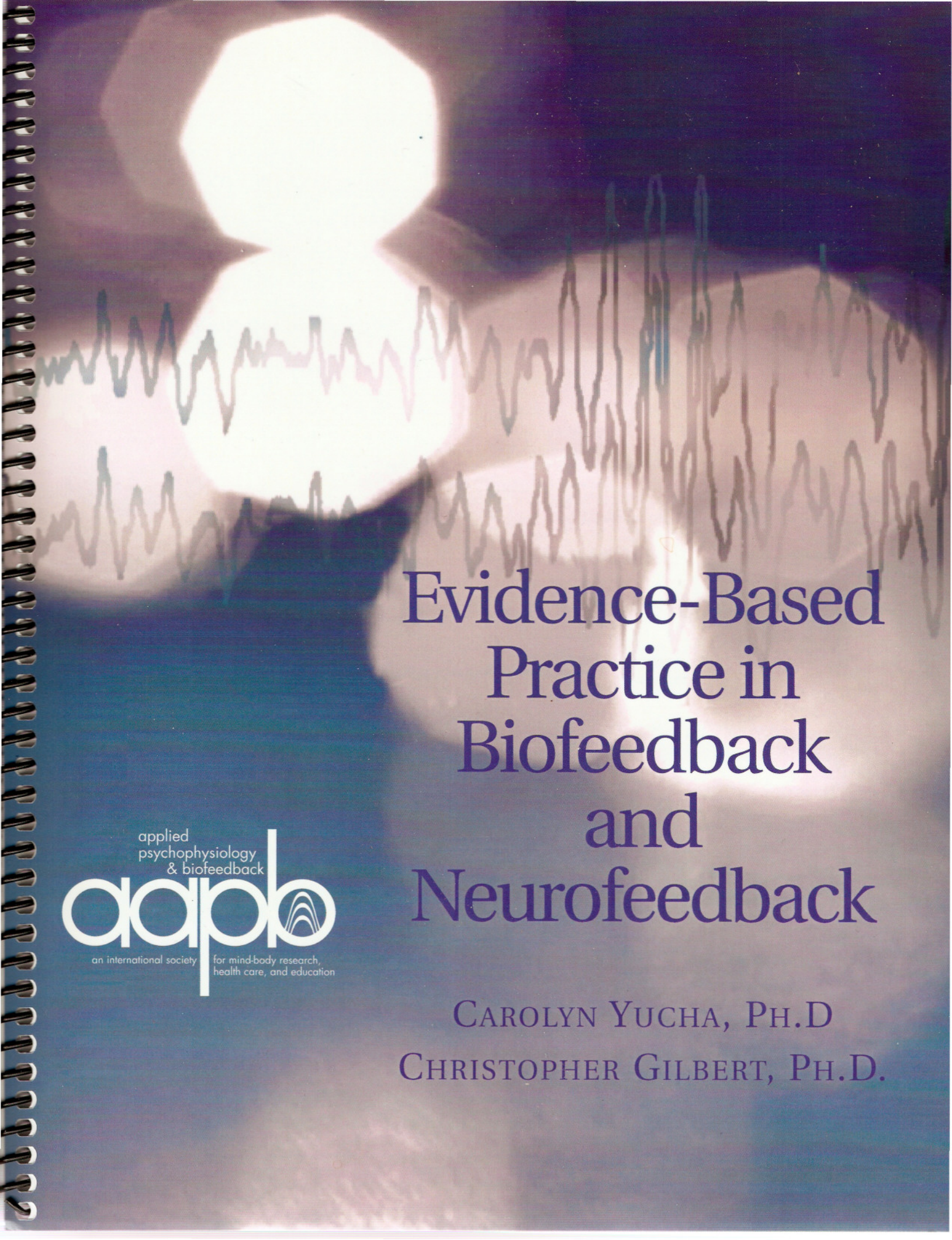

Evidence-Based Practice in Biofeedback and Neurofeedback

applied psychophysiology & biofeedback

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an international society for mind-body research, health care, and education

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Web sites for further information

Association of Applied Psychophysiology and Biofeedback	www.aapb.org
Biofeedback Certification Institute of America	www.bcia.org
Biofeedback Foundation of Europe	www.bfe.org
International Society for Neuronal Regulation	www.snr-jnt.org

Foreword:
Evidence-Based Practice in Biofeedback and Neurofeedback

Donald Moss, Ph.D., and Lynda Kirk, MA

Biofeedback and Neurofeedback

Biofeedback is a mind-body therapy using electronic instruments to help individuals gain awareness and control over psychophysiological processes (Gilbert & Moss, 2003; Moss, 2001; Schwartz & Andrasik, 2003). Biofeedback instruments measure muscle activity, skin temperature, electrodermal activity, respiration, heart rate, heart rate variability, blood pressure, brain electrical activity, and brain blood flow. Research shows that biofeedback, alone and in combination with other behavioral therapies, is effective for treating a variety of medical and psychological disorders, ranging from headache to hypertension to temporo-mandibular to attentional disorders. The present publication surveys these applications, and reviews relevant outcome research. Biofeedback is used by physicians, nurses, psychologists, counselors, physical therapists, occupational therapists, and others. Biofeedback therapies guide the individual to facilitate the learning of voluntary control over body and mind, and take a more active role in maintaining personal health and higher level mind-body wellness.

Neurofeedback is a specialty field within biofeedback, which devotes itself to training control over electro-chemical processes in the human brain (LaVaque, 2003; Evans & Abarbanel, 1999). Neurofeedback uses a feedback electroencephalogram (EEG) to show the trainee current electrical patterns in his or her cortex. Many neurological and medical disorders are accompanied by abnormal patterns of cortical activity. Neurofeedback assessment uses a baseline EEG, and sometimes a multi-site quantitative EEG (QEEG), to identify abnormal patterns (LaVaque, 2003). Clinical training with feedback EEG then enables the individual to modify those patterns, normalizing or optimizing brain activity. Neurofeedback practice is growing rapidly, with the widest acceptance for applications to attention deficit hyperactivity disorder (ADHD), learning disabilities, seizures, depression, acquired brain injuries, substance abuse, and anxiety (Clinical EEG, 2000).

Complementary and Alternative Therapies

Biofeedback and neurofeedback are ideal approaches for those individuals seeking complementary and alternative medicine (CAM) therapies (Lake & Moss, in press). The public appears to seek out therapies which: 1) give the individual a more active role in his or her own health care, 2) involve a holistic emphasis on body, mind, and spirit, 3) are non-invasive, and 4) elicit the body's own healing response (Jonas & Levin, 1999; Moss, 2003a). James Gordon, the first chairman of the federal Advisory Council of the NIH Office of Alternative Medicine, emphasizes that educating individuals in *self-care* must be at the center of the new medicine, in order to deal with the changing picture of health problems today, especially the increasing incidence of chronic conditions (Gordon, 1996). Both biofeedback and neurofeedback are holistic therapies, based on the recognition that changes in the mind and emotions affect the body, and changes in the body also influence the mind and emotions. Biofeedback and neurofeedback emphasize training individuals to self-regulate, gain awareness, increase control over their bodies, brains, and nervous systems, and improve flexibility in physiologic responding. The positive effects of feedback training enhance health, learning and performance. There are biofeedback protocols to address many of the disorders, including anxiety, depression,

and chronic pain, for which the public is using CAM therapies in high numbers (Kessler, et al, 2001; Burke, 2003; Bassman & Uellendahl, 2003).

Evidence-Based Practice

Biofeedback and neurofeedback also provide the kind of *evidence-based practice* that the health care establishment is demanding (Sackett, Straus, Richardson, Rosenberg, & Haynes, 2000; Geyman, Devon, & Ramsey, 2000). Evidence-based practice is a process of using the best evidence, preferably research findings, to guide delivery of health services. Levels of evidence range from case reports to observational studies to randomized clinical trials. From the beginning biofeedback developed as a research based approach emerging directly from laboratory research on psychophysiology and behavior therapy. The field of feedback therapies has maintained its close relationship with both pure and applied empirical research. Pure research takes place largely in laboratories, and seeks new understandings of neurophysiological mechanisms underlying disorders such as panic disorder and hypertension. Better recognition of underlying mechanisms continues to inspire new biofeedback treatment approaches. In turn, many biofeedback applications have been tested and proven both in research and practice.

Biofeedback and neurofeedback are also approaches relying on well developed professional standards and guidelines for competent practice. A national certification organization, the Biofeedback Certification Institute of America, has established a blueprint of necessary knowledge and skills, and conducts examinations qualifying individuals for certification in general biofeedback or neurofeedback (Information on certification standards is available at www.bcia.org). An additional certification is under preparation for pelvic floor disorders, such as urinary incontinence.

Efficacy and Effectiveness

The present volume fills a void in the biofeedback and neurofeedback practice world – the need for a standardized assessment of clinical efficacy and effectiveness for feedback based therapies. "Efficacy" refers to the determination of a training or treatment effect derived from a systematic evaluation obtained in a controlled clinical trial (LaVaque, et al., 2002). "Effectiveness" assesses how well a treatment works in actual clinical settings, with more typical clinical populations. Everyday clinical practice includes more individuals who suffer with sub-syndromal conditions and co-morbid disorders, and who are already participating in multiple treatments beyond the researcher's control. It is rare for the average primary care physician or behavioral health practitioner to see a patient with only one medical condition, who clearly meets diagnostic criteria, and is not involved in other therapies.

Evidence-based practice must take into account both efficacy in controlled research settings and effectiveness in the real world of clinical practice. Neither the general public nor the novice biofeedback practitioner can always assess which applications are well documented and which remain more experimental. Attending biofeedback and neurofeedback conferences, one hears discussion of many promising new approaches, and websites often claim "well-documented efficacy" for a variety of new approaches. Nevertheless, today's research climate has higher standards for "efficacy" and "effectiveness" than were current during much of the time period in which biofeedback and neurofeedback evolved. The present publication applies current standards of research methodology to biofeedback and neurofeedback practice.

Efficacy Standards

In 2001, the two professional associations in this practice area, the Association for Applied Psychophysiology and Biofeedback (AAPB) and the International Society for Neuronal Regulation (ISNR) together commissioned a Task Force to develop official standards for research methodology, establishing what kinds of research are required for each of five levels of efficacy, ranging from the lowest level – "not empirically supported" – to the highest level – "efficacious and specific." That Task Force report has been published along with a brief introduction describing the context and need for its development (LaVaque, et al., 2002; Moss & Gunkelman, 2002). The efficacy guidelines themselves can be found, with criteria for each rating, on pages 4-5 of the present document.

The Task Force has created rigorous standards, which are not easily applied to feedback-therapies. There are inherent difficulties, for example, in creating a double-blind condition for a therapy, which is founded on enhancing self-awareness of body and mind. For example, "sham feedback" has been used as a control condition in biofeedback research, that is, feedback that does not reflect the subject's actual physiological state. Yet perceptive subjects quickly perceive that the sound or light feedback doesn't fit with their perceptions of their bodies; they are not blinded as the methodology requires. There are also ethical implications today, following the international Declaration of Helsinki, published by the World Medical Association (2000), in using placebos or sham therapies, when the relative efficacy of one of the treatment conditions is already known (LaVaque, et al., 2002).

In addition, most efficacy studies in the past have compared biofeedback alone to placebo, or to currently accepted therapies. This approach attempts to isolate the specific therapeutic effects of biofeedback. In clinical practice, however, biofeedback is often most effective in combination with a wide variety of adjunctive therapies, including relaxation training, visualization, behavior therapies, client education and other strategies. James Gordon, Director of the Center for Mind-Body Medicine, has advocated that future outcome research should compare integrative packages of alternative therapies, including biofeedback, to placebo alone or to accepted therapy packages (2003).

Nevertheless it is critical to apply prevailing standards for outcome research, in order to provide a credible rating of therapeutic interventions for today's evidence-based health care sector. Not to do so exposes biofeedback and neurofeedback to the danger of being left by the wayside as irrelevant in today's best-practices focused treatment milieu.

Critiques of Biofeedback and Neurofeedback

In fact, biofeedback and neurofeedback have encountered recent critical attacks by researchers claiming that biofeedback and/or neurofeedback lack efficacy. Three examples are offered here. In 2001, the Association for the Advancement of Behavior Therapy newsletter (*The Behavior Therapist*) published an article critical of neurofeedback (Lohr, Meunier, Parker, & Kline, 2001), but overlooking key research contradicting their critique. A committee representing the *Association for Applied Psychophysiology and Biofeedback*, the *International Society for Neuronal Regulation*, and the *EEG and Clinical Neuroscience Society* responded to that critique, focusing on the use of neurofeedback for seizure disorders, and citing a large number of well

constructed studies documenting the efficacy of neurofeedback for seizure (Hammond, Sterman, LaVaque, Moore, & Lubar, 2002). Hammond (2002) also published a thoughtful well-documented response to the Lohr et al. article.

In a second incident, Reuters Health issued a press release reporting William Mullally's headache research, and his statement that biofeedback is too expensive and not effective for headache. An AAPB response to the Mullally research countered the critique, citing strong clinical and research support for the use of biofeedback in headache treatment (Moss, Andrasik, McGrady, Perry, & Baskin, 2001). Mullally generalized his conclusions from a study of one client group, with very specific conditions limiting its validity. Specifically, his study involved inpatients with chronic severe headaches, who were already receiving an intensive and comprehensive treatment package along with biofeedback. Under these conditions, adding any single additional treatment to the package would probably have produced little added benefit. Mullally also ignored a variety of empirical reports showing more positive outcomes for biofeedback in moderating headache symptoms. One meta-analysis, for example, based on over 100 empirical studies, showed a 50 % reduction in headache symptoms following biofeedback/relaxation therapy with stress management training (McGrady, Andrasik, Davies, et al, 1999)

In a third example, the *New England Journal of Medicine* published a landmark article challenging the placebo effect (Hrobjartsson, & Gotzche, 2001). In a follow up to the NEJM study, a science reporter highlighted a biofeedback hypertension study, and stated that just entering a study was as effective as biofeedback in treating hypertension. This is one more example of an author over-generalizing from an inadequate review of the literature. As the authors in the present volume make clear, there are a number of well controlled studies showing that biofeedback therapy produces significant reductions in hypertension (see pages 31-33 in the present volume). There are additional studies with little or no reduction in symptoms. The challenge remains to identify which clients are most likely to benefit from biofeedback for hypertension, and under what training conditions.

Even though the critiques of biofeedback discussed above were misguided, they demonstrate that biofeedback and neurofeedback professionals must take responsibility for rigorously assessing the efficacy of their own therapies, or else outsiders will do so, with little regard for the positive clinical experiences of long-time biofeedback practitioners. It is critical for the biofeedback and neurofeedback fields to review outcome research, and rate the efficacy of the feedback therapies for specific disorders.

The Client's Right to Know the Efficacy of a Therapy

Prospective clients also deserve to know whether a specific treatment is "not empirically supported" or "possibly efficacious." They have a right to undergo experimental treatments, but should do so with a clear knowledge of the best research available on each available therapy. Referring physicians and other referral sources also deserve and expect to have access to some rating of efficacy. The present volume reviews the best evidence to date for each biofeedback and neurofeedback application. This volume does not attempt exhaustive reviews of all research on each application. A future volume of "white papers" will attempt that more comprehensive review (Moss, LaVaque, & Hammond, in preparation). Rather this volume samples the best

available evidence and rates each application according to the official AAPB/ISNR efficacy guidelines.

Efficacy in Perspective

A lower efficacy rating does not necessarily indicate that an application is not helpful. In some cases such a rating can mean that the relevant research has not yet been conducted, in which case the authors will note that the disorder has been "insufficiently investigated." In other cases, a lower rating means that the application benefits some subjects and not others, due to wide inter-subject variability. People are not all uniform. On a group comparison basis, these selective successes may not be statistically significant.

If a prospective client cannot tolerate the available medication therapies in traditional medicine, or if the individual is averse to staying with a medication, then a "possibly efficacious" feedback therapy may be an excellent alternative.

Many of today's well-accepted medical procedures have never been subjected to the rigorous efficacy standards adopted here. Other medical therapies have been tested in random clinical trials, and show reliable but relatively small effects. In a clinical drug trial with 10,000 subjects, even a small benefit will produce a statistically significant effect. At least one recent research report on the anti-depressants, for example, showed outcomes no better than placebo (Fava et al., 1998), yet these medications are among the most frequently prescribed in most primary care clinics. Similarly, many of the widely used educational methods for assisting students with learning disabilities never received such rigorous scrutiny. A "possibly efficacious" or "probably efficacious" biofeedback or neurofeedback application may still be relatively powerful compared to the mainstream alternatives available to an individual client. These feedback therapies also provide a useful alternative for clients who show adverse effects to medications, those who fail to respond to mainstream therapies, and those who prefer more natural, self-regulation oriented treatment.

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Overview of Biofeedback

Biofeedback therapies are nonpharmacologic treatments that use scientific instruments to measure, amplify, and feed back physiological information to the patient being monitored. The information assists the patient in gaining self-regulation of the physiological process being monitored. Psychophysiological self-regulation is a primary goal of biofeedback therapies, and feedback of information facilitates learned physiological control, just as feedback facilitates learning of any skill. For example, in the treatment of hypertension, surface electrodes are used to provide the patient with information about skin temperature and muscle tension. The feedback of information from the instrument guides the patient during training as he/she learns to warm the skin (by dilating blood vessels) and relax the muscles. This is generally accompanied by a reduction in blood pressure. In this example, the instrumentation provides physiological information that would otherwise be inaccessible to the patient. ***Biofeedback therapy always involves a therapist, a patient, and a monitoring instrument capable of providing accurate physiological information.***

Modalities of biofeedback are varied. Depending on the goal of the training, biofeedback clinicians may use sensors that detect such parameters as skin temperature, muscle activity, heart rate, respiration, skin conductance, or brainwave activity. This stream of information is then presented in some form that allows the patient to perceive changes in their physiological activity in real time. Numerical or graphic displays are most common, but audio or vibratory feedback might also be used.

Biofeedback training requires that patients observe their physiological responses in detail and try to learn to alter them. This takes effort and time. For certain conditions, such as urinary incontinence, significant improvement may occur within a few sessions. In contrast, up to 50 sessions of neurotherapy (brainwave biofeedback) for attention deficit disorder may be needed before improvement is seen. Some patients are not willing to invest this time and prefer instead to take medication to control their conditions. Others are highly motivated to learn self-regulation, while some prefer to combine self-regulation with medication.

"Treatment" vs. "Training"

"Treatment" implies a passive patient receiving something therapeutic from an active practitioner. The patient's automatic healing processes may be expected to operate, but beyond that, the patient is not asked to do much more than show up for procedures or swallow pills on schedule. "Treatment" is what insurance reimbursement is traditionally designed to reimburse.

"Training," on the other hand, implies more active participation; people are trained to ride a horse, perform a job, ice-skate, etc. Learning is interactive, guided by instruction and information in order to develop a skill. Most biofeedback is done with this orientation, even though the "action" may be internal and visible only with the biofeedback instruments. Insurance policies often exclude procedures labeled "educational." The educational component in biofeedback, however, is more akin to speech therapy or rehabilitation than to a more abstract pursuit of knowledge.

A parallel can be drawn with physical therapy, which often directs a person to practice certain movements or exercises at home between sessions. This process requires active

participation but is routinely considered treatment rather than training, even though therapeutic success may rest on the thoroughness of home practice. The patient must learn to do certain movements, carry out exercises, and avoid certain injurious activities and postures. Physical therapy and rehabilitation are considered reimbursable therapeutic procedures. Is this education, training, or treatment?

An insurer would not want to cover a course of biofeedback training done strictly for self-exploration, just as an insurer would not cover weekend courses in personal development or reading self-help books. But what if biofeedback has been shown to be effective for a bona fide diagnosed disorder or if a self-control procedure is learned and then faithfully practiced? Is this now education, training, or treatment?

When biofeedback training is "prescribed" for a recognized disorder, the outcome usually depends on factors such as enhanced self-sensing, corrections in body use (changes in posture, breathing, muscle tension, or movement), relaxation, and managing emotions, all in conjunction with exposure to biofeedback signals and integrated into daily life via home practice. The biofeedback data serve as information only, like reflections from a mirror. The learner can use the information intelligently or not, and it is the use of the information, rather than exposure to it, that makes the difference.

Research Involving Behavioral Interventions

Much biofeedback research seems to assume a treatment model, as if biofeedback is a procedure "done to" a standard individual. This approach strives to standardize doses, techniques, and subject variables as much as possible. In biofeedback research this would include items such as number of sessions, type of feedback display, and behavior of the trainer. Controlling all the factors surrounding the biofeedback process is very difficult. Pursuit of experimental control often makes the research protocol too limited and standardized to represent how biofeedback is used in clinical practice.

Double-blind research is generally held in high regard because subtle expectations on the part of both subjects and practitioners are supposedly eliminated. However, the double-blind or even single-blind procedure does not make sense in biofeedback because ongoing knowledge of changes in a physiological variable is central to the learning process. Eliminating expectations by double-blinding supposedly keeps things "pure" – but expectations may be the essence of the placebo effect, which is a very interesting self-healing phenomenon, not simply a confounding factor in experiments. In biofeedback at least, such an effect is something to be maximized and mastered, not eliminated.

Tailoring the biofeedback learning process to the individual may be more effective clinically, but it introduces uncontrolled variability, the bane of research designs. Although keeping subjects passive and standardizing the protocol might keep things tidy for research purposes, it works against the success of biofeedback as well as other self-regulation methods.

Instead of considering biofeedback research as "inconclusive" because it does not follow the double-blind model of pharmaceutical research, a different model should be considered in which self-regulation is the active ingredient. The training model is most applicable to biofeedback applications. The "training" concept involves active participation and individualizing of the biofeedback situation to fit the individual learner. For instance, one person

may learn best with continuous exposure to the feedback signal, while another person may learn best while using imagery with minimal feedback. The very factors that would introduce unwanted variability into most "treatment" research constitute the essence of active learning. Wait-list controls, controlled case studies, and other clinical research methods are more appropriate for studying biofeedback than standardized clinical trials.

"Training to criterion" refers to the subject/trainee/patient practicing a certain mode of control until a criterion, which represents meaningful change, is reached: for instance, a particular level of muscle tension or hand temperature. Without demonstrating the ability to alter one's physiologic responses, a subject in a biofeedback experiment cannot be said to be receiving the intended "treatment." This would be comparable to a subject not taking the prescribed medication in a drug effectiveness study. Yet training to criterion is often ignored in biofeedback studies.

It follows that exposing someone to a course of biofeedback does not necessarily constitute an adequate intervention, any more than filling a prescription is adequate. Just as the pills must actually be swallowed, the person's active attention must be engaged. Even if the necessary control (blood pressure for instance) has been learned well in the laboratory, the application of that control in real life will vary. Adherence to the prescribed self-regulation regimen, including periodic relaxation, altered breathing, and cognitive changes, will be applied with varying degrees of diligence, depending on amount of commitment, belief, suffering, and conflicting demands on attention and time. This variability is not easily controlled, and is comparable to drug research subjects taking the prescribed drugs in widely varying doses and concentrations, at varying times from day to day, and sometimes skipping days.

Understanding and applying the biofeedback information is certainly more complicated than swallowing a pill, but it constitutes the essence of the treatment, and must be accommodated in the research design and accepted by those who evaluate biofeedback research. Bearing in mind these limitations, this monograph is a summary of the research findings, mostly over the past 20 years, examining the efficacy of biofeedback for various disorders.

Clinical Efficacy of Biofeedback Therapy: Explanation of Efficacy Levels

Biofeedback therapy has matured over the last 30 years, and today there are myriad disorders for which biofeedback therapy has been used. Large research grants have funded prospective studies on biofeedback therapy for a variety of disorders, such as headache (migraine, mixed, and tension), essential hypertension, and urinary incontinence. These studies consistently report positive results.

On the other hand, several reports of unsuccessful biofeedback training have appeared in the research literature since the inception of biofeedback training three decades ago. Many of the unsuccessful studies conducted in the early development of the field reflect failure to thoroughly train patients. For example, some unsuccessful studies provided only minimal training with the biofeedback instrumentation (often 1-4 sessions of short duration), provided little coaching, involved no home practice, and failed to train to clinical criteria.

In 2001, a Task Force of the Association for Applied Psychophysiology and Biofeedback and the Society for Neuronal Regulation developed guidelines for the evaluation of the clinical efficacy of psychophysiological interventions (Moss & Gunkelman, 2002). The Board of Directors of both organizations subsequently approved these guidelines without revision. ***These Criteria for Levels of Evidence of Efficacy, described below, were used to assign efficacy levels for the vast number of conditions for which biofeedback has been used.***

Level 1: Not empirically supported
Supported only by anecdotal reports and/or case studies in non-peer reviewed venues. Not empirically supported.

Level 2: Possibly Efficacious
At least one study of sufficient statistical power with well identified outcome measures, but lacking randomized assignment to a control condition internal to the study.

Level 3: Probably Efficacious
Multiple observational studies, clinical studies, wait list controlled studies, and within subject and intrasubject replication studies that demonstrate efficacy.

Level 4: Efficacious

a. In a comparison with a no-treatment control group, alternative treatment group, or sham (placebo) control utilizing randomized assignment, the investigational treatment is shown to be statistically significantly superior to the control condition or the investigational treatment is equivalent to a treatment of established efficacy in a study with sufficient power to detect moderate differences, and
b. The studies have been conducted with a population treated for a specific problem, for whom inclusion criteria are delineated in a reliable, operationally defined manner, and
c. The study used valid and clearly specified outcome measures related to the problem being treated, and
d. The data are subjected to appropriate data analysis, and
e. The diagnostic and treatment variables and procedures are clearly defined in a manner that permits replication of the study by independent researchers, and

f. The superiority or equivalence of the investigational treatment has been shown in at least two independent research settings.

Level 5: Efficacious and specific
The investigational treatment has been shown to be statistically superior to credible sham therapy, pill, or alternative bona fide treatment in at least two independent research settings.

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Note: This document is also available on line at www.aapb.org and www.snr-jnt.org.

Conditions for Which Biofeedback Has Been Used

The following review is not meant to be an exhaustive review of the literature, but rather an overview of the state of the evidence for biofeedback. The following process was used to select citations. First, a comprehensive literature search was done (PsychInfo and PubMed) with the help of a librarian to find clinical research and systematic review articles mentioning biofeedback or neurofeedback between 1993 and the present. A 10-year interval was selected because the last publication addressing efficacy was published by AAPB in 1994.

Reports studying only normal subjects were excluded. Remaining articles were sorted as to treatment condition and the most pertinent ones were summarized briefly. Separate more specific literature searches were done on those conditions with few citations in order to expand the evidence and these were incorporated into the document. This draft was sent to AAPB's Board of Directors and those listed in the acknowledgements for comments. These persons were asked to identify unlisted studies, if any, that might alter the efficacy levels. Certain classic studies were then added to the citations. It must again be emphasized that this book is NOT a comprehensive review of the field and many important studies were not included. However, the authors feel confident that these studies would not alter the efficacy levels as reported here. Although this is not a comprehensive review of the field, the authors feel the studies reported represent the current status of research in the field.

Alcoholism/Substance Abuse

Level 3 Efficacy (Probably Efficacious)

Researchers have used both biofeedback assisted relaxation training and neurofeedback (alpha-theta brainwave feedback) to deal with alcoholism and its accompanying symptoms (e.g., depression). In comparison to a control group, thermal biofeedback increased drinking related locus of control in a study of adolescent alcoholics (Sharp, Hurford, Allison, Sparks, & Cameron, 1997). Alpha-theta brainwave training was accompanied by significant decreases in certain factors measured using the Millon Clinical Multiaxial Inventory (schizoid, avoidant, passive-aggression, schizotypal, borderline, paranoid, anxiety, somatoform, dysthymia, alcohol abuse, psychotic thinking, psychotic depression and psychotic delusional) in comparison to those receiving traditional medical treatment (Peniston & Kulkosky, 1990). Taub and his colleagues (1994) studied 118 chronic alcoholics randomly assigned to 1 of 4 treatment conditions: 1) routine treatment of Alcoholics Anonymous and counseling (RTT), 2) RTT plus transcendental meditation, 3) RTT plus EMG biofeedback, and 4) RTT plus neurotherapy. Self-report of abstinence for the four groups were 25%, 65%, 55%, and 28%, respectively. This study suggests that the addition of meditation or EMG biofeedback enhances RTT, while neurotherapy does not.

A number of case studies and uncontrolled studies show benefit of neurofeedback for treating alcoholic depression (Kumano et al., 1996; Waldkoetter & Sanders, 1997). A few controlled neurofeedback studies (Peniston & Kulkosky, 1989; Saxby & Peniston, 1995) provided further evidence for this reduction in depression and reported sustained prevention of relapse at 21-month follow-up in alcoholics who had completed the training (Saxby & Peniston, 1995). Another showed that 6 of 10 alcohol-dependent males had not relapsed 4 months post self-regulation of slow cortical potentials (Schneider et al., 1993). These studies demonstrate promise in altering alcoholic behavior via alpha-theta brainwave feedback. Results are less

promising for crack cocaine treatment (Richard, Montoya, Nelson, & Spence, 1995), but the studies are insufficient to conclude this.

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Anxiety
Level 4 Efficacy (Efficacious)

Very few well-controlled, randomized studies have shown biofeedback to be superior to other relaxation and self-control methods for reducing anxiety. Most show biofeedback (EMG, GSR, thermal, or neurofeedback) to be roughly equivalent to progressive relaxation or meditation. This may be because anxiety is less a disorder of physiology than of attention and cognition, and biofeedback monitors physiological changes. Lehrer, Carr, Sargunaraj, and Woolfolk (1994) evaluated the hypothesis that biofeedback is most effective when applied in the same modality as the disorder (autonomic feedback for ANS disorders, EMG feedback for muscular, etc.). Self-relaxation techniques have in common the process of using conscious intent to calm oneself, and for anxiety reduction it may matter little which modality is used, because the central component is the cognitively-based conscious intent.

Two studies showed biofeedback's efficacy in reducing anxiety without making comparisons with other relaxation techniques. Hurley and Meminger (1992) used frontal EMG biofeedback with 40 subjects trained to criterion and assessed anxiety over time using the State-Trait Anxiety Inventory (STAI). State anxiety improved more than trait anxiety. Wenck, Leu, and D'Amato (1996) trained 150 7^{th} and 8^{th}-graders with thermal and EMG feedback, and found significant reduction in state and trait anxiety.

Roome and Romney (1985) compared progressive muscle relaxation to EMG biofeedback training with 30 children and found an advantage for biofeedback; Scandrett, Bean, Breeden, & Powell (1986) found some advantage of progressive muscle relaxation over EMG biofeedback in reducing anxiety in adult psychiatric inpatients and outpatients. Vanathy, Sharma, and Kumar (1998), applying EEG biofeedback to generalized anxiety disorder, compared increased alpha with increased theta. The two procedures were both effective in decreasing symptoms.

Rice, Blanchard, and Purcell (1994) studied reduction in generalized anxiety by comparing groups given EMG frontal feedback, EEG alpha-increase feedback, EEG alpha-decrease feedback, a pseudo-meditation condition, and a wait-list control. All treatment groups had comparable and significant decreases in the STAI as well as drops in Psychosomatic Symptom Checklist. Similar results were obtained by Sarkar, Rathee, and Neera (1999) by comparing the generalized anxiety disorder response to pharmacotherapy and to biofeedback; the two treatments had similar effects on symptom reduction. Hawkins, Doell, Lindseth, Jeffers, and Skaggs (1980), concluded from a study with 40 hospitalized schizophrenics that thermal biofeedback and relaxation instructions had equivalent effect on anxiety reduction. However, Fehring (1983) found that adding GSR biofeedback to a Benson-type relaxation technique reduced anxiety symptoms more than relaxation alone.

In conclusion, biofeedback of various modalities is effective for anxiety reduction; it is not specific, but shares characteristics with other relaxation techniques.

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Arthritis
Level 3 Efficacy (Probably Efficacious)

Both thermal and EMG biofeedback have been used to teach relaxation techniques to adults with chronic arthritis. A recent meta-analysis of 25 randomized controlled studies demonstrated significant pooled effect sizes post-intervention for pain, functional disability, psychological status, coping, and self efficacy (Astin, Becker, Soeken, Hochberg, & Berman, 2002). Thermal bio feedback coupled with cognitive behavioral therapy decreased pain behaviors, self-reports of pain intensity, and rheumatoid factor titer (a measure of disease activity), in comparison to control subjects and those receiving social support only (Bradley, 1985; Bradley et al., 1987). This intervention was associated with a reduction in rheumatoid arthritis related clinic visits and days hospitalized, thereby decreasing medical costs (Young, Bradley, & Turner, 1995). EMG biofeedback also reduced duration, intensity and quality of pain in comparison to control groups (Flor, Gunther, Turk, & Koehler, 1983) and these beneficial effects were maintained 2.5 years later (Flor, Gunther, & Turk, 1986). Finally, a small, randomized study of 6-17 years old with juvenile rheumatoid arthritis showed modest support for relaxation training (Lavigne, Ross, Berry, & Hayford, 1992).

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Asthma

Level 2 Efficacy (Possibly Efficacious, research done with mixed results)

A review of all randomized controlled research on relaxation techniques to affect asthma (Huntley, White, & Ernst, 2002) failed to find convincing evidence of efficacy as measured by pulmonary function testing or symptom change. Biofeedback studies were included, mostly using EMG. A study examining the effect of EMG feedback on immune system components found changes in neutrophils and basophils, suggestive of reduced inflammation, along with some improvement in asthma symptoms (Kern-Buell, McGrady, Conran, & Nelson, 2000). Respiratory sinus arrhythmia training (self-regulation of breathing for maximum heart-rate variability) seems to produce beneficial changes in asthma symptoms and reductions in respiratory impedance (Lehrer et al., 1997; Lehrer, Smetankin, & Potapova, 2000) although randomized controlled trials assessing clinical improvement have not yet been done.

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Attention Deficit (ADD) & Hyperactivity (ADHD) Disorder

Level 4 Efficacy (Efficacious)

Studies on ADD and ADHD are difficult to interpret because they use a variety of training protocols and a variety of outcome measures. Nevertheless, numerous case studies

demonstrate the efficacy of neurofeedback in treating ADD and ADHD (Ramos, 1998; Wadhwani, Radvanski, & Carmody, 1998).

Uncontrolled studies using neurofeedback contingent on decreasing slow wave activity and increasing fast wave activity show that persons with attention deficit disorder (ADD) improved in ADD symptoms, intelligence score, and academic performance (Grin'-Yatsenko et al., 2001; Lubar, Swartwood, Swartwood, & O'Donnell, 1995; Thompson & Thompson, 1998;). Only those individuals who significantly reduced theta over the training sessions also showed a 12-point increase in WISC-R IQ, improved Test of Variables of Attention (TOVA), and ADDES rating score (Lubar, Swartwood, Swartwood, & O'Donnell, 1995). One large multi - center study (1,089 participants, aged 5-67 years) showed that sensorimotor - beta neurofeedback training led to significant improvement in attentiveness, impulse control, and response variability as measured on the TOVA (Kaiser & Othmer, 2000) in those with moderate pre-training deficits. EEG biofeedback training has also been used successfully in the school setting (Boyd & Campbell, 1998).

A few controlled studies have also been done that compare neurofeedback to other treatments. The first of these was a study done with 4 hyperkinetic children under six conditions 1) no drug, 2) drug only, 3) drug and sensory motor rhythm (SMR) training, 4) drug and SMR reversal training, 5) drug and SMR training II, and 6) no drug and SMR training (Shouse & Lubar, 1979). Combining medication and SMR training resulted in substantial improvements in behavioral indices that exceeded the effects of drugs alone and were sustained with SMR training after medication was withdrawn. These changes were absent in the one highly distractible child who failed to acquire the SMR task.

In comparison to a waiting list control, Carmody and colleagues (2001) report conflicting outcomes as measured by the TOVA and teacher reports. One small (n=18) controlled study showed that enhancing beta wave activity and suppressing theta wave activity increased intelligence scores and reduced inattentive behaviors as rated by parents in comparison to the waiting list control (Linden, Habib, & Radojevic, 1996). A 15 session EEG neural training procedure led to improvements in the Wechsler Individual Achievement Tests and Child Behavior Checklist and Profiles in the experimental but not the waiting list control group (Patrick, 1996). Two studies, done in different laboratories comparing treatment with EEG biofeedback to stimulants (i.e., methylphenidate, Ritalin), demonstrated that both groups improved on measures of inattention, impulsivity, information processing, and variability as measured by the TOVA (Rossiter & La Vaque, 1995; Fuchs, Birbaumer, et al, 2003). In addition, Fuchs et al (2003) showed comparable improvement on the speed and accuracy measures of the d2 attention endurance test and on behaviors related to the disorder as rated by both teachers and parents for both neurofeedback and methylphenidate.

Others have shown that after 30 sessions of neurofeedback, 16 of 24 patients taking medications were able to lower their dose or discontinue medication totally (Alhambra, Fowler, & Alhambra, 1995). Finally, Monastra, Monastra and George studied 100 children with ADD/ADHD receiving Ritalin, parent counseling and academic support at school. Based on parent preference, 50 children also received EEG biofeedback. While children improved on the TOVA and an ADD evaluation scale while taking Ritalin, only those who had EEG biofeedback sustained these improvements without Ritalin.

In summary, these studies suggest the neurofeedback is better than no treatment and equivalent or better to medication. However, to be effective, at least 20 sessions of neurofeedback must be provided, with some clinicians providing 40 – 50 sessions. Rossiter (1998) tested patient-directed neurotherapy. A therapist provided up to 10 treatment sessions to train patients or parents of younger children to use the equipment, to monitor treatment, and to make changes in the treatment protocol, as necessary. Fifty sessions were then conducted at home using inexpensive, easy to operate systems. Results from the initial 6 patients showed marked improvement on the TOVA, suggesting that home neurofeedback may be an effective and cheaper alternative to therapist-directed treatment for many ADHD patients.

Taken together, these studies suggest that neurofeedback is an effective treatment for ADHD. Further studies are needed to examine long-term effects of training sessions and whether or not refresher sessions are needed to maintain the effects.

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Autism
Level 1 Efficacy (Not sufficiently investigated)

One case study of an 8-year-old boy with mild autism reported the effect of neurofeedback. After 31 sessions, the boy showed positive changes in all the diagnostic dimensions defining autism in the Mental Disorders-III-Revised (Sichel, Fehmi, & Goldstein, 1995).

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Cancer and HIV, Effect on Immune Function
Level 2 Efficacy (Possibly efficacious, not sufficiently investigated)

A small study on 13 stage 1 breast cancer post mastectomy patients showed improvements in immune function (natural killer cell activity, mixed lymphocyte responsiveness, cancavalin A responsiveness, and the number of peripheral blood lymphocytes (Gruber et al., 1993). Another small study (n=10) examining the effects of relaxation training including EMG biofeedback in HIV positive men showed significant improvement on anxiety, mood, self-esteem, and T-cell count in comparison to a control group (Taylor, 1995). Finally, a study of 42 HIV patients showed no treatment effects on immune function, but those treated with massage and biofeedback showed significant differences in quality of life assessment in health care utilization and health perceptions (Birk, McGrady, MacArthur, & Khuder, 2000).

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Cerebral Palsy
Level 2 Efficacy – Possibly Efficacious (Not sufficiently investigated)

There are few studies examining the efficacy of EMG biofeedback to improve posture (Metherall, Dymond, & Gravell, 1996) and walking in children with cerebral palsy. Biofeedback of the triceps surae muscle group in the leg improved gait symmetry in comparison to physical therapy alone (Colbourne, Wright, & Naumann, 1994). Portable EMG units to help train ankle dorsiflexor recruitment improved ankle function as evaluated through tapping ability (Toner, Cook, & Elder, 1998).

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Chronic Obstructive Pulmonary Disease
Level 2 Efficacy (Possibly Efficacious, Not Sufficiently Investigated)

A small randomized study demonstrated that those persons receiving breathing pattern training had a 22% increase in FEV1 and 19% increase in FVC, but no significant increases in the control group (Esteve, Blanc-Gras, Gallego, & Benchetrit, 1996).

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Chronic Pain
Level 3 Efficacy (Probably Efficacious)

Chronic pain can arise from just one or two sites or it can be pervasive and widespread. Most research studies focus on pain from a particular site, but since chronic pain regardless of its source may involve non-specific factors such as neural sensitization, altered neurotransmitter

levels, inflammation, and muscle guarding, there is some logic to also treating chronic pain as a unitary condition regardless of its site and supposed generating mechanism.

A comprehensive literature review of "biopsychosocial" approaches to chronic pain (Neilson & Weir, 2001) examined many single and combined treatments and found that EMG biofeedback had at least moderate support as a separate treatment. The bulk of the studies and the three systematic reviews covered mostly back pain, the most common focus for research.

Humphrey and Gevirtz (2000) studied "recurrent abdominal pain" in 64 children and teenagers, using thermal biofeedback alone or in combination with cognitive-behavioral treatment. Results for pain relief were significantly above an inactive treatment (fiber only) control group.

Vlaeyen and colleagues (1995) studied response to EMG biofeedback training in 71 chronic back-pain patients in comparison with a cognitive-training group. The groups had comparable positive outcomes, as compared to wait-list control and an operant-conditioning only treatment. Newton-John, Spence, & Schotte (1995) compared cognitive therapy with EMG biofeedback in chronic back patients and obtained similar beneficial effects with both, as compared to a wait-list control group. Effects persisted at a 6-month follow-up.

Flor and Birbaumer (1993) studied both EMG biofeedback and cognitive therapy for both back pain and temporomandibular joint pain. In this study biofeedback had the strongest effect on many aspects of pain, and the effects were still present at a 24-month follow-up. The apparent equivalence between cognitive-behavioral and biofeedback approaches makes the time ripe for a study of the effects of each compared with the combined effect of both.

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Cystic Fibrosis
Level 2 Efficacy (Possibly Efficacious, Not Sufficiently Investigated)

Respiratory muscle biofeedback coupled with breathing retraining produced significant improvement in FEV1 and FVC in comparison to a control group that received biofeedback assisted (hand warming) relaxation training (Delk, Gevirtz, Hicks, Carden, & Rucker, 1994).

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Depressive disorders
Level 2 Efficacy (Possibly Efficacious, Not Sufficiently Investigated)

Preliminary case studies (Kumano et al., 1996; Rosenfeld, 2000) and pilot studies (Waldkoetter & Sanders, 1997) show that neurofeedback may decrease depressive symptoms. One study compared biofeedback assisted relaxation to a wait list control on depression in chronic pain patients and found improved scores on the Beck depression index (Corrado & Gottlieg, 1999).

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Diabetes Mellitus
Level 2 Efficacy (Possibly Efficacious, Not Sufficiently Investigated)

The efficacy of biofeedback for diabetes depends on the outcome of interest. Biofeedback assisted relaxation training appears to have no effect on diabetic control as measured by glucose tolerance, fasting blood glucose, two-hour postprandial blood glucose and fructosamine (Jablon, Naliboff, Gilmore, & Rosenthal, 1997) or on glycosylated hemoglobin (Lane, McCaskill, Ross, Feinglos, & Surwit, 1993). Mood (e.g., depression, anxiety) may impact this lack of response (McGrady & Horner, 1999).

On the other hand, thermal biofeedback to increase peripheral blood flow, improved healing to foot ulcers in a randomized controlled study or 32 patients with chronic nonhealing ulcers; 87.5% of ulcers healed in the experimental group in contrast to 43.8% in the control group (Rice, Kalker, Schindler, & Dixon, 2001). Biofeedback of body center of gravity was shown to reduce the number of falls and force of the fall in elderly patients with diabetic sensory neuropathy in comparison to those who did not receive the biofeedback training (Wu, 1997). Finally, audio biofeedback on weight bearing of persons with transtibial amputation may help patients learn to ambulate correctly using a prosthesis (Chow & Cheng, 2000).

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Eating Disorders

Level 1 Efficacy (Not Sufficiently Investigated)

One study of 76 obese and 27 anorexic girls showed benefits of a multimodal program including biofeedback relaxation based on electrodermal response (EDR), with better results for anorectic girls (Pop Jordanova, 2000).

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Epilepsy
Level 3 Efficacy (Probably Efficacious)

Early studies testing neurofeedback for epilepsy showed promise in reducing seizure activity. A double blind cross-over study showed that seizure activity increased during non-contingent reinforcement and decreased by about 50% when persons with epilepsy were reinforced for increasing sensorimotor rhythm or other frequencies that normally inhibit seizures (Lubar, Shabsin, Natelson, et al, 1981). The reduction in seizure activity was accompanied by decreases in nocturnal 4-7Hz activity and increase in 8-11 Hz activity (Whitsett, Lubar, Holder, et al, 1982). More recent studies build on these findings and demonstrate that self-regulation of slow cortical potentials using EEG feedback decreases seizure activity in drug resistant epilepsy when compared to pre-training (Kotchoubey, Schneider, et al., 1996; Kotchoubey, Strehl, et al., 1999; Sterman, 1986; Swingle, 1998). This effect was sustained for at least 6 months after therapy (Kotchoubey, Blankenhorn, Froscher, Strehl, & Birbaumer, 1997). A five consecutive day neurobehavioral treatment protocol resulted in 79% of patients being able to achieve seizure control (Joy Andrews, Reiter, Schonfeld, Kastl, & Denning, 2000). Kotchoubey and colleagues studied patients with refractory epilepsy in a controlled clinical trial comparing an anticonvulsive drug plus psychosocial counseling (drug), a group which learned to control breathing (control), and a group learning self regulation of slow cortical potentials (experimental). The experimental and drug groups showed a significant decrease of seizure frequency, but the control group did not (Kotchoubey, Strehl, Uhlmann, et al., 2001).

A review of 18 studies reporting clinical findings in the treatment of seizure disorders with EEG feedback was completed by Sterman (2000). Of a total of 174 patients treated, 82% demonstrated significant (greater than 30%) seizure reduction, with an average reduction exceeding 50%. Many of the studies also reported reductions in seizure severity and 5% of patients experienced complete control for periods of tabulation up to one year. Although every study reported significant clinical benefits exceeding expected placebo effects, none were designed to be randomized clinical trials. This led a Cochrane Database Systematic Review to conclude that there is no reliable evidence to support the use of EEG biofeedback in the treatment of epilepsy because of methodological deficiencies and limited number of patients studied (Ramaratnam, Baker, & Goldstein, 2001). More randomized controlled clinical studies are needed in this area.

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Fecal Elimination Disorders
Level 3 Efficacy – Probably Efficacious

Literature on biofeedback for fecal incontinence and constipation is difficult to interpret. Most studies include patients with a variety of conditions and lack control groups. A recent critical review of the literature concludes that biofeedback results in 67 % - 74% success in treating fecal incontinence, but states that quality control is lacking in many of the studies reviewed (Heymen, Jones, Ringel, Scarlett, & Whitehead, 2001).

Children: Biofeedback has been used for fecal incontinence in children and for that occurring after surgery for anorectal malformations and results in clinical improvement in children with fecal incontinence (Iwai, Iwata, Kimura, & Yanagihara, 1997; van Ginkel et al., 2000). Biofeedback has also improved constipation (encopresis) in 44% - 80% of children studied (Iwai et al., 1997; van Ginkel et al., 2000). A controlled study of biofeedback versus conventional therapy in 49 children with chronic idiopathic constipation was reported recently (Sunic-Omejc, Mihanovic, Bilic, Jurcic, Restek-Petrovic, et al, 2002). Biofeedback was shown to be an effective method of treatment for childhood constipation because rectal sensation threshold, critical volume and recto-anal inhibitory reflex volume were significantly higher and the prevalence of abnormal defecation dynamics was significantly lower after treatment in those receiving biofeedback training.

Adults: In adults, biofeedback has been used to treat chronic fecal incontinence and that following childbirth, and anorectal surgery. It has resulted in improvement in fecal incontinence in 60% to 92% of those studied (Chiarioni et al., 2002; Ko et al., 1997; Ryn, Morren, Hallbook, & Sjodahl, 2000), but does not seem to be effective to correct incontinence after surgery for rectal prolapse (Hamalainen, Raivio, Antila, Palmu, & Mecklin, 1996). Fecal incontinence after obstetric trauma was also improved with biofeedback (Fynes et al., 1999). Long-term efficacy of biofeedback for fecal incontinence has been demonstrated (Enck, Daublin, Lubke, & Strohmeyer, 1994; Guillomot et al, 1995; Ryn et al., 2000). Biofeedback has led to significant improvement in those with constipation (Heymen, Wexner, 1999; Ko et al., 1997; Pucciani, et al., 1998).

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Fibromyalgia
Level 2 Efficacy (Possibly Efficacious, Research Done with Mixed Results)

This poorly understood disorder has often been the subject of clinical trials involving several simultaneous interventions. The rationale for this scattershot approach is usually that it is a multidimensional disorder, and therefore calls for multiple approaches in combination. Biofeedback is often included as part of a treatment package including physical exercise and cognitive-behavioral therapy. EMG is the most common modality, but EEG feedback has been used also. Separate reviews (Hadhazy, Ezzo, Creamer, & Berman, 2000; Sim & Adams, 1999) of mind-body approaches to fibromyalgia, examining mostly randomized controlled studies, concluded that there was no clear superiority of any mind-body approach including biofeedback, but that collectively they seemed to help in conjunction with physical exercise. Berman & Swyers (1999) concluded, "The strongest data exist for the use of mind-body techniques (e.g., biofeedback, hypnosis, cognitive behavioural therapy), particularly when utilized as part of a multidisciplinary approach to treatment." Several uncontrolled trials have shown improvement from EMG biofeedback alone (Mur, Drexler, Gruber, Hartig, & Gunther 1999; Sarnoch Adler, & Scholz, 1997). "Improvement" may include quality of sleep, self-efficacy, pain threshold, and emotional adjustment.

Donaldson, Sella & Mueller (1998) included biofeedback with other therapies and found improvement in symptoms along with normalization of the EEG. Mueller, Donaldson, Nelson, & Layman (2001) improved fibromyalgia symptoms using EEG-driven stimulation. Though neither study used clinical controls, this promising CNS-normalization approach seems to address a particular biological characteristic of fibromyalgia. EMG biofeedback offers at most a partial role, perhaps interchangeable with other "mind-body" approaches, in the treatment of fibromyalgia's diverse symptoms.

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Foot Ulcers
Level 2 Efficacy (Possibly Efficacious, Not Sufficiently Investigated)

Thermal biofeedback to increase peripheral blood flow, improved healing to foot ulcers in a randomized controlled study or 32 patients with chronic nonhealing ulcers; 87.5% of ulcers healed in the experimental group in contrast to 43.8% in the control group (Rice, Kalker, Schindler, & Dixon, 2001).

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Hand Dystonia
Level 2 Efficacy (Possibly Efficacious, Not Sufficiently Investigated)

EMG biofeedback improved the clinical and electromyographic picture in 9 out of 10 patients with hand dystonia (writer's cramp) who showed EMG overactivity of proximal muscles during writing (Deepak & Behari, 1999).

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Headache - Pediatric Migraine
Level 3 Efficacy (Probably Efficacious)

The research support for childhood migraine using biofeedback as an intervention is more plentiful than for adult migraine. Research support for migraine in general, both child and adult, is stronger than that for mixed and tension-type headache.

A recent review article (Hermann & Blanchard, 2002) summarized headache/biofeedback research to date in children and concluded, "With few exceptions…thermal biofeedback has been proven to be highly successful in alleviating headache activity in children. In fact, in most studies more than two thirds of the children could be classified as treatment successes based on

the widely accepted criterion of a 50% symptom reduction." (p. 145). Studies using a credible placebo condition for comparison so far have not been done.

A minority of studies used EMG biofeedback from the frontal area instead of or in addition to hand-warming biofeedback. Most protocols use 10 sessions or fewer and included home practice; some involved the parents also. For example, five children with tension-type headaches (Arndorfer & Allen, 2001) participated in a multiple-baseline, time-lagged, within-subject design using thermal biofeedback. All learned the handwarming technique and showed significant clinical improvement, and six months afterward, 80% were headache-free. Labbe (1995) compared thermal biofeedback-assisted autogenic training to autogenic training only, with a wait-list control group, in 30 migrainous children. Eighty percent of the first group had significant improvement; 50% of the second group, and none in the third group.

Headache – Adult
Level 4 Efficacy (Efficacious)

Adult headache, tension, whether tension, migraine, or mixed, has been the focus of much research. For example, Arena, Bruno, Hannah, & Meader (1995) compared biofeedback training from the forehead and trapezius muscles, with a non-feedback progressive muscle relaxation control group, in 26 tension-headache patients. Clinical improvement was strongest for the trapezius group. Silberstein (2000) published a review of migraine treatment on behalf of the American Academy of Neurology – U.S. Consortium, and concluded that thermal and muscle biofeedback, in a general context of relaxation training, was generally effective and recommended as a treatment option. McGrady, Wauquier, McNeil, & Gerard, (1994) and also Vasudeva, Claggett, Tietjen, & McGrady (2003) found superior clinical results for biofeedback-assisted relaxation as compared to self-directed relaxation, and this conclusion was supported by measurement of cerebral flood flow using trans-cranial Doppler monitoring.

Rokicki et al (1997) found a significant drop in headaches following a six-session EMG biofeedback protocol, compared with a control group which showed no improvement. Improvement correlated most with greater sense of self-efficacy rather than with EMG levels. A meta-analysis of research by McCrory, Penszien, & Rains (1996) determined that EMG biofeedback was "modestly effective" for tension-type headaches compared to wait-list controls, but was not significantly different in effect size from cognitive therapy, relaxation training, or hypnosis. Isolating biofeedback as the active element from factors such as general relaxation, emotional improvement, and enhanced self-efficacy has not been very successful so far, but it may facilitate a synergistic effect.

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Hypertension
Level 4 Efficacy – Efficacious

A meta-analysis of 23 studies completed between 1975 and 1996 compared biofeedback based training with active interventions (those thought to be effective, such as relaxation and meditation) and with inactive interventions (those representing a control group, such as clinic BP measurement or sham biofeedback). While both biofeedback and other active treatments resulted in a reduction in BP, there were no differences in the magnitude of the reduction in either SBP or DBP when biofeedback was compared with active treatment. However, when biofeedback was compared to inactive control treatments, there was a significantly greater reduction in both SBP (6.7 mmHg) and DBP (4.8 mmHg) (Yucha, Clark, et al., 2001). A second meta-analysis of 22 randomized controlled studies (comprising a total of 905 essential hypertensive persons) published between 1966 and 2001 supported these findings (Nakao, Yano, Nomura, & Kuboki, 2003). In comparison with non-intervention controls, biofeedback resulted in significantly greater reductions in SBP (7.3 mmHg) and DBP (5.8 mmHg). Compared with other behavioral interventions, the net reductions in SBP and DBP were not statistically different.

More recent studies show similar findings in comparison to control groups (Nakao et al., 1997). Biofeedback appears to work just as well for those with white coat hypertension as those with essential hypertension (Nakao, Nomura, Shimosawa, Fujita, & Kuboki, 2000) and for those with and without organ damage secondary to their hypertension (Nakao et al., 1999). Laboratory training followed by home training appears to be particularly effective (Henderson, Hart, Lal, & Hunyor, 1998).

Unfortunately, the degree or response to biofeedback training has varied widely for hypertension. This may be due to the starting level of BP (the higher the initial level, the better the response), the variety of modalities used (thermal, EMG, heart rate, BP biofeedback), the length of the training (4-20 sessions), and the ability of the subject to actually learn and incorporate the techniques into his/her lifestyle (Yucha, 2002). While, it is difficult to predict which hypertensives will be helped to reduce or even eliminate their antihypertensive medications with training, those with high resting sympathetic activity (low skin temperature, high heart rate, high BP) appear to benefit more with biofeedback-assisted relaxation training (Weaver & McGrady, 1996).

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Insomnia
Level 3 Efficacy – Probably Efficacious

In 1996, an NIH Technology Assessment Panel examined existing research and concluded that several non-pharmacological techniques, particularly relaxation and biofeedback, produce improvements in some aspects of sleep, but questioned whether the magnitude of the improvement in sleep onset and total sleep time were clinically significant.

In 1998, the American Academy of Sleep Medicine recommended biofeedback along with progressive muscle relaxation for insomnia after reviewing the quality of research, using American Psychological Association research criteria. Biofeedback was rated "probably efficacious" along with sleep restriction and cognitive-behavioral therapy. (Morin et al., 1998)

(Progressive muscle relaxation, stimulus control, and paradoxical intent were rated even higher.)

The assignment of specific biofeedback procedures to particular subjects based on personal characteristics such as presence of tension and anxiety was examined by Hauri, Percy, Hellekson, Hartmann, and Russ (1982) using theta and SMR EEG. Nicassio, Boylan, and McCabe (1982) highlighted the importance of expectancy and found no correlation between achieved muscle relaxation and quality of sleep.

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Irritable Bowel Syndrome

Level 2 Efficacy (Possibly Efficacious, Research Done with Mixed Results)

Studies of biofeedback to reduce irritable bowel syndrome (IBS) symptomatology are mixed. Earlier studies showed benefits with effects lasting 4 years posttreatment (Schwarz, Taylor, Scharff, & Blanchard, 1990). Two controlled comparisons of a previously validated multicomponent (relaxation, thermal biofeedback and cognitive therapy) treatment for IBS showed no different in comparison to an attention-placebo control group or a symptom monitoring control group (Blanchard et al., 1992). A recent study tested the effect of computerized biofeedback games for teaching relaxation (monitored by electrodermal activity) to patients with IBS. Training reduced the global and bowel symptom score and 50% of patients continued to use the technique to induce relaxation (Leahy, Clayman, Mason, Lloyd, & Epstein 1998).

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Mechanical Ventilation
Level 2 Efficacy (Possibly Efficacious, Not Sufficiently Investigated)

Relaxation training using EMG biofeedback and breathing retraining using tidal volume biofeedback may help patients to be weaned from mechanical ventilation (Jacovone & Young, 1998). Only one randomized trial showed those receiving biofeedback were weaned from their ventilator in 20.6 days in comparison to those in the control group who were weaned in 32.6 days (Holliday & Hyers, 1990).

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Motion Sickness
Level 2 Efficacy (Possibly Efficacious, Randomized Clinical Trials Not Done)

The rationale for biofeedback relies on an assumed correlation between ability to control the autonomic precursors of motion sickness (rise in skin conductance, drop in skin temperature, high heart rate) and resistance to sickness due to induced motion, such as a chair movable in three directions, as is done with NASA research.

Promethazine is commonly prescribed for motion sickness in astronauts, with variable effectiveness. The strongest study on this application was by Cowings and Toscano (2000) where promethazine injections were compared to autogenic feedback training, including skin temperature and conductance, with superior results for the latter. Control groups included a saline-placebo injection and no treatment. Four 30-minute sessions of autogenic training resulted in significantly more tolerance of the rotating chair, in comparison with the two levels of intramuscular promethazine and placebo. Decreased variability of skin conductance plus lower HR was evident in the autogenic feedback groups.

Two other studies investigated the correlation between physiological change and success in reducing symptoms of motion sickness (Graybiel & Lackner, 1980; Jozsvai & Pigeau, 1996). These showed little correlation. Thus the logic of this approach can be called into question.

Scattered studies in the past 25 years have tried autogenic training assisted by biofeedback of temperature, skin conductance, and heart rate, sometimes including cognitive therapy.

Desensitization *in vivo* has been the basic clinical model for intervention. Yet it is difficult to reproduce the conditions of a spaceship free of gravity. Also, the stimulus context of a chair spinning in three dimensions is more drastic than the usual context of a moving vehicle or boat. So generalizing from this experimental context to a more universal, non-astronaut situation is open to question in spite of the study's design, so far unreplicated. The best approach, based on the research to date seems to be training GSR control, first in isolation and then while exposed to a condition expected to induce motion sickness.

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Multiple Sclerosis

Level 1 Efficacy – Not sufficiently investigated

Biofeedback retraining appears to be an effective treatment for constipation and fecal incontinence in some patients with multiple sclerosis (Wiesel et al., 2000). It does not appear to enhance the effect of behavioral modification, medication, and pelvic floor training (Klarskov, Heely, Nyholdt, Rottensten, & Nordenbo, 1994).

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Myocardial Infarction
Level 2 Efficacy (Possibly Efficacious, Not Sufficiently Investigated)

Survivors of out-of-hospital ventricular fibrillation or asystole were randomized into two groups, a control group and a group receiving psychosocial therapy consisting of physiological relaxation with biofeedback focused on altering autonomic tone, cognitive behavioral therapy and cardiovascular health education. Risk of cardiovascular death was significantly reduced 86% and all cause mortality was reduced by 62% in those receiving psychosocial therapy (Cowan, Pike, & Budzynski, 2001).

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Post-Traumatic Stress Disorder
Level 2 Efficacy (Possibly Efficacious, Not Sufficiently Investigated)

Several small studies incorporating biofeedback into multi-component therapy (including eye movement desensitization and reprocessing [EMDR]) reveal some improvement in self-report, psychometric, and standardized interview measures after therapy (Carlson, Chemtob, Rusnak, Hedlund, & Muraoka, 1998; Silver, Brooks, & Obenchain, 1995). A study of Vietnam veterans with combat-related post-traumatic stress disorder compared traditional medical treatment with 30 sessions of alpha-theta brain-wave neurofeedback (Peniston & Kulkosky, 1991). Neurofeedback resulted in decreases in MMPI scores on clinical scales labeled Hypochondriasis, Depression, Hysteria, Psychopathic Deviate, Masculinity-Femininity, Paranoia, Psychasthenia, Schizophrenia, Hypomania, and Social Introversion-Extraversion in comparison to the traditional care group who showed decreases only on the scale labeled Schizophrenia. A 30-month follow-up showed that all traditional care patients had relapsed, in contrast to only 3 of 15 neurofeedback patients. More studies are needed in this area.

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Raynaud's Disease
Level 2 Efficacy (Possibly Efficacious, Research Done with Mixed Results)

Several brief, relatively uncontrolled studies seem to confirm the rationale underlying biofeedback treatment of Raynaud's disease. Peterson and Vorhies (1983) studied thermal biofeedback-trained Raynaud's patients, observing the speed of hand temperature return to baseline after hand immersion in ice water, which was six to seven times as fast after biofeedback training (6 minutes average after training vs. 40 minutes before). Jobe, Sampson, Roberts, and Kelly (1986) compared hand temperature responses to whole-body chilling before and after either classical or standard biofeedback ("operant") biofeedback training, and found that both approaches were effective. When Guglielmi, Roberts, and Patterson (1982) compared thermal biofeedback with EMG biofeedback and controls, with a double-blind procedure, all three groups had comparable improvements, suggesting a role of non-specific factors. Keefe, Surwit, and Pilon (1980) found similar results, in which other behavioral control methods performed as well as thermal biofeedback. However, Freedman et al (1988) compared simple thermal biofeedback with autogenic training and found the former more effective.

The largest study to date of Raynaud's involving biofeedback compared use of a calcium-channel blocker (nifedipine) with thermal biofeedback, EMG feedback, and a placebo (Raynaud's Treatment Study Investigators, 2000). In this study of 313 subjects with primary Raynaud's disease, nifedipine seemed to be the superior agent for reducing symptoms. Problems with training the thermal biofeedback subjects to an adequate level of skill, however, (Middaugh et al., 2001) mitigated the final results.

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Repetitive Strain Injury
Level 2 Efficacy (Possibly Efficacious, Not Sufficiently Investigated)

A randomized controlled study of 30 patients with upper extremity repetitive strain injury showed that those receiving thermal biofeedback and autogenic relaxation had significantly higher reductions in pain in comparison to the waiting list condition (Moore & Weisner, 1996).

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Spinal Cord Injury
Level 1 Efficacy (Not Sufficiently Investigated)

There are limited studies on biofeedback post spinal cord injury and they involve different treatment protocols and outcome measures. However, patients with long-term cervical spine injury were able to increase triceps EMG activity after one biofeedback treatment and further increases occurred after additional treatment sessions (Brucker & Bulaeva, 1996). A small study (n=10) studied patients in a daily therapy program lasting 2 months including muscle strengthening and gait training. Half the subjects received biofeedback for 30 minutes a day; half used an ambulatory device to receive continuous biofeedback every time they walked. After 2 months, those undergoing clinical therapy showed a 50% reduction in hip drop; those using the home training device showed almost normal gait (Petrofsky, 2001).

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Stroke
Level 2 Efficacy (Possibly Efficacious, Research Done with Mixed Results)

Four meta-analyses on the effect of biofeedback for rehabilitation after stroke show conflicting results. The first included 8 studies (total of 192 patients) and examined functional

outcome of EMG biofeedback. They found a significant effect size (0.81), concluding that EMG biofeedback is useful for neuromuscular reeducation in the hemiplegic stroke patient (Schleenbaker & Mainous, 1993). The second meta-analysis compared the effects of EMG biofeedback and physical therapy on upper extremity function and found no significant differences (Moreland & Thomson, 1994). The third meta-analysis included studies with an outcome of change in range of joint motion of a paretic limb. The results of pooling 8 studies did not support the efficacy of biofeedback in restoring upper or lower extremity range of motion of hemiparetic joints (Glanz et al., 1995). The fourth meta-analysis examined the efficacy of EMG biofeedback compared with conventional physical therapy for improving lower extremity function. EMG biofeedback was superior to physical therapy for improving ankle dorsiflexion muscle strength, but not for improving gait quality, ankle range of motion, ankle angle during gait, stride length, or gait speed (Moreland, Thomson, & Fuoco, 1998). Thus it appears that when functional measures related to lower extremity are the outcome, biofeedback is effective; when functional measures related to the upper extremity or change in range of joint motion is the outcome, biofeedback is not effective.

More recent studies show benefits of a standing biofeedback trainer (including a height-adjustable work table, weight bearing sensors, and a real-time visual and auditory feedback system) to increase stance symmetry (Cheng, Wu, Liaw, Wong, & Tang, 2001; Wong, Lee, Kuo, & Tang, 1997). Visual feedback incorporated into physical therapy also improves stand symmetry and sway (Sackley & Lincoln, 1997).

Finally, a case study describing neurotherapy one-year post left-side CVA resulted in improvement in speech fluency, word finding, balance and coordination, attention, and concentration (Rozelle & Budzinski, 1995). Depression, anxiety, and tinnitus were greatly reduced.

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Temporomandibular Disorders (TMD)
Level 4 Efficacy – Efficacious

Used alone, biofeedback improves pain, pain-related disability, and mandibular functioning (Gardea, Gatchel, & Mishra, 2001). When used in combination with other treatments, such as intraoral appliances (Turk, Zaki, & Rudy, 1993), and cognitive-behavioral skills training (Gardea et al., 2001), the effect is enhanced (Turk, Rudy, Kubinski, Zaki, & Greco 1996). A recent meta-analysis of 13 studies of EMG biofeedback treatment showed that biofeedback was superior to no treatment or psychological placebo control for patient pain reports, clinical exam findings, and or ratings of global improvement (Crider & Glaros, 1999).

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Tinnitus
Level 2 Efficacy (Possibly Efficacious, Not Sufficiently Investigated)

EMG biofeedback and neurofeedback have been used in the treatment of tinnitus. Biofeedback appears to be of greatest benefit in reducing tinnitus for certain subgroups of patients (Erlandsson, Rubinstein, & Carlsson, 1991). For example, EMG biofeedback is most effective when muscle tension and mental distress accompany the tinnitus (Ogata, Sekitani, Moriya, & Watanabe, 1993). EEG biofeedback to upregulate the amplitude of alpha activity and downregulate the amplitude of beta-activity, during muscle relaxation and acoustic orientation, led to a significant reduction in the score on a tinnitus questionnaire, in comparison to a control group that did not receive neurofeedback (Gosepath, Nafe, Ziegler, & Mann, 2001).

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Traumatic Brain Injury
Level 3 Efficacy (Probably Efficacious)

EEG biofeedback appears to improve memory in persons with brain injury (Thornton, 2000). It also improves attention and response accuracy of a performance task and decreases errors in a problem solving task (Tinius & Tinius, 2000). Walker, Norman, & Weber (2002) found that 88% of mild head injury patients showed more than 50% improvement in qEEG coherence scores and that all patients who had been employed prior to injury reported being able to return to work following the treatment. One small controlled study (n=12) demonstrated that EEG-based therapy results in improvement of some measures of cognitive function as well as participants' reports of depression and fatigue (Schoenberger, Shif, Esty, Ochs, & Matheis, 2001). Another controlled study demonstrated significant improvement in attention deficits in those receiving feedback of beta activity in comparison with a matched control group (Keller, 2001). More controlled studies are needed in this area.

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Urinary Incontinence in Females
Level 5 Efficacy (Efficacious and Specific)

Numerous studies demonstrate levels 4 and 5 efficacy of biofeedback for urinary incontinence in females. It is better than no treatment (i.e., control) (Burgio et al., 1998; Burns et al., 1993; Dougherty et al., 2002; McDowell et al., 1999), better than or equal to other behavioral treatments (e.g., pelvic floor exercises) (Burns et al., 1993; Glavind, Nohr, & Walter, 1996; Sherman, Davis, & Wong, 1997; Sung, Hong, Choi Baik, Yoon, 2000; Weatherall, 1999; Wyman, Fantl, McClish, & Bump, 1998) and better than drug (i.e., oxybutynin chloride) treatment (Burgio et al., 1998) in both young and old females. Combining drug and behavioral therapy in a stepped program can produce added benefit for those not satisfied with the outcome of single treatment (Burgio, Locher, & Goode, 2000).

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Urinary Incontinence in Males
Level 4 Efficacy (Efficacious)

Most studies testing the effect of biofeedback on male incontinence have been done on males after prostatectomy, many of whom were not incontinent. In this population, biofeedback for urinary incontinence was not effective (Bales et al., 2000; Franke et al., 2000; Mathewson-Chapman, 1997). However, studies in men who were incontinent after prostatectomy, demonstrate that biofeedback was better than no treatment (control) (Van Kampen et al., 2000) and equal to pelvic floor exercises (Floratos et al., 2002).

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Urinary Incontinence in Children
Level 2 Efficacy (Possibly Efficacious, Randomized Clinical Trials Not Done)

Studies of biofeedback efficacy in children who are incontinent of urine lack control groups. However, three studies show improvement in urinary incontinence in 80-90% of children treated (Combs, Glassberg, Gerdes, & Horowitz, 1998; Hoekx, Wyndaele, & Vermandel, 1998; McKenna, Herndon, Connery, & Ferrer, 1999).

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Vulvar Vestibulitis
Level 3 Efficacy – Probably Efficacious

EMG biofeedback and pelvic floor exercises have been used to treat women with vulvar vestibulitis. A randomized study comparing biofeedback, with cognitive behavioral therapy, and with vestibulectomy demonstrated that all three groups reported statistically significant reductions in pain and improvements in sexual function and psychological adjustment (Bergeron et al., 2001). Although the vestibulectomy group was more successful than the two other groups in regard to pain reduction, some of the patients assigned to this group refused the intervention. The benefit of EMG biofeedback and pelvic floor exercises also been demonstrated in two uncontrolled studies, with patients showing reductions in pain and about 70% able to resume sexual activity without discomfort (Glazer, Rodke, Swencionis, Hertz, & Young, 1995; McKay et al, 2001).

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Sample Protocols

General EMG Training

The principle of EMG training is normally to provide the learner with enhanced information about his/her muscle tension in a particular area, hoping that this will facilitate learning control of the muscle. Relaxation of excess and inappropriate tension is the usual goal. Sensors are attached to the skin over the muscle being targeted for change. Muscles may be targeted anywhere on the body, including the forehead, neck, shoulders, back, jaws, arm, legs. Insertable pelvic sensors are used to target pelvic muscles. Tiny electrical signals emitted by muscles, proportional to degree of contraction, and amplified and fed to a visual display or an audio signal. The visual display may be digits, polygraph-style lines, or changes in colors or patterns. The audio tone may indicate changes in muscle tension by a rising or falling tone, or by a change in frequency of a beep. Most biofeedback systems allow for recording average muscle tension over a specified time interval.

After some instruction, the learner is allowed quiet practice time during which he/she attempts to lower the measured muscle tension, using the biofeedback signal as an external guide. The trainer suggests various ways to relax, helps deal with obstacles to learning, keeps track of progress, and generally facilitates the learning process. Home practice is usually prescribed, since the goal is to learn better control of the muscles without the aid of biofeedback monitoring. One or more criteria are usually set as goals of training: for instance, staying below two microvolts for the upper shoulder. Speed of recovery from contraction is another common criterion, and also keeping muscle tension lower during movement.

Frequency of sessions varies, and may be twice per week or less often. The biofeedback is considered a temporary learning aid, and as the learner becomes more sensitive to internal sensations and learns to read his/her body better, the biofeedback become less necessary. The duration of this learning process varies from person to person, but might typically take one to three months. Duration is best determined by achieving the criteria rather than by number of sessions. Symptoms are usually tracked with home diaries, and this helps the learner understand which activities and situations increase muscle tension. Self-regulation eventually begins to become habitual: goals such as keeping the shoulders low or the jaw loose require less and less conscious involvement.

Temperature Training

The goal of temperature training is to teach the learner to warm their peripheral extremities. While core temperature is 98.6^{o}F (37.0^{o}C), skin temperature is much lower, ranging from 75-95^{o}F. In order to raise skin temperature, one must relax skeletal muscles as well as the muscles within the walls of the blood vessels. This latter effect is believed to result in better blood flow to the skin and therefore a rise in skin temperature.

A thermal sensor, called a thermistor, is taped to the skin, usually on the palmar surface of one of the fingers. The temperature of the skin changes the resistance of the thermistor, thereby altering the electrical signal in proportion to the temperature. The signal is displayed visually and/or through a tone that changes in response to changes in temperature. The visual display may be digits, polygraph-style lines, or changes in colors or patterns. Commonly, the learner's skin temperature is displayed on a thermometer.

After some instruction, the learner is allowed quiet practice time during which he/she attempts to raise the skin temperature. The trainer suggests various ways to do this, using the biofeedback signal as a guide. For example training in slow deep breathing usually helps the learner to relax. The learner may repeat autogenic phrases, such as "My hands feel warm and heavy" or imagine lying on the beach feeling the sun's warmth on the hands. Home practice is prescribed and the learner may be given a simple handheld thermometer to monitor progress. On subsequent training sessions, the thermistor may be moved from one hand to the other or to a foot. This helps the learner to generalize the skin temperature warming to areas beyond the hands. One or more criteria are set as goals of training. Typically learners are asked to raise hand temperature to 90 – 95^{o}F and foot temperature to 90^{o}F.

Thermal training sessions are typically held weekly. The biofeedback is considered a temporary learning aid and as the learner becomes more sensitive to internal sensations of stress, the biofeedback becomes less necessary. The duration of this learning process varies from person to person, but typically requires 4 to 8 sessions, accompanied by home practice.

Thermal training is typically combined with other biofeedback modalities to train learners in general relaxation. It is also used in a number of disorders such as Raynaud's Disease, hypertension, migraine headaches, and anxiety. More recently it has been used to increase blood flow to wounds, thereby promoting healing.

Skin Conductance Training

Skin conductance feedback provides information about sweat gland activity on the hand, which is closely correlated with sympathetic nervous system activity. This variable is called SCA (skin conductance activity), EDA (electrodermal activity), or the more classic term GSR (galvanic skin response). Sensors are attached to two fingers or two sites on the palm, and feedback is provided in various ways: a changing audio tone, changes in colors on a display, numerical change, meter deflection, or a moving line via video feedback. Response time is less than two seconds, making it very sensitive to transient changes in emotion.

Self-calming by physical or cognitive means tends to lower skin conductance, while negative emotions such as fear, worry, or anger usually raise it, as will a startle response. Any disorder which would benefit from emotional calming may respond to GSR biofeedback, provided the learner is able to generalize from the feedback situation to real life. For example, GSR feedback is often employed in treatment of phobias and anxiety attacks, and has been used as one element in modifying hypertension and bowel disorders which are exacerbated by emotional upset.

In learning to reliably lower one's GSR, one learns to resist distractions which disrupt attention and to maintain a state of mind which is neutral or pleasant. Relaxation techniques such as slow breathing, imagery, or meditation can help keep the attention steady and the emotions calm. This tends to stabilize the autonomic nervous system. Time needed to learn the skill varies from days to months. Practice between biofeedback sessions facilitates mastery of the skill, and is practical since home-trainer GSR devices are available for less than $100.

EEG Training or Neurofeedback

The goal of neurofeedback is to teach learners to modify their EEG. There are many applications of EEG training. One of these includes teaching the learner to maintain a relaxed,

alert, and focused mental state while carrying out cognitive tasks. Another application of EEG training includes teaching the learner to increase slower frequency brain waves to achieve deeper levels of psychophysiological relaxation or to access calmer mental states. Other applications use EEG training to treat such disorders as depression, anxiety, epilepsy, sleep disorders, fibromyalgia, pain, alcoholism and other addictions. EEG training is also used in the rehabilitation of brain injury and stroke.

These applications are done by training learners to alter their brain waves. Historically, there are four types of brain waves identified according to their frequency, or bandwidth. They are known as delta (0.5-4 Hertz), theta (4-8 Hertz), alpha (8-12 Hertz), and beta (13-20^{+} Hertz), differing according to their frequency. Each person has an individual pattern of brain wave activity, but there are certain "signatures" of brain wave frequencies that are associated with specific symptoms or dysfunction. For example, people with Attention Deficit Disorder tend to have greater ratios of slower EEG activity (delta, theta, or even alpha) compared to faster beta activity. In this example, the goal of training for individuals with ADD is to decrease the amplitude of slow wave activity (delta, theta, and/or alpha) while increasing the amplitude of faster wave activity (beta).

In neurofeedback training, surface sensors are placed on selected areas of the head and ears. The number and location of these sensors is determined by the specific application and goal of the EEG training. Typically, the number of sensors used varies between three and six. The EEG signal is displayed visually and/or through auditory tones that vary as the EEG changes. Brain wave changes in the desired direction are rewarded with visual and/or auditory feedback. The visual signal may be graphs, digits, waveforms, changes in colors or patterns, or even animations.

Neurofeedback training typically requires 40 or more fifty-minute sessions, usually held twice or more weekly. EEG training may be accompanied by cognitive or other therapies. For example, those with ADD may receive coaching in learning strategies, while those with alcoholism may receive coaching in alcohol avoidance.

Neurofeedback may be combined with other biofeedback modalities such as EMG, EDR, temperature, HRV or other biofeedback modalities to train learners in general relaxation.

Heart Rate Variability

HRV stands for Heart Rate Variability. The term RSA (Respiratory Sinus Arrhythmia) predates the term HRV, and referred to the rise and fall of heart rate synchronized with each breath (faster on the inhale, slower on the exhale). The magnitude of this systematic variability seems to reflect a healthy alternation between two autonomic influences on the heart beat: sympathetic and parasympathetic. Lack of this variation reflects an imbalance between the two aspects of the ANS, most likely deficient parasympathetic influence, and is a sign of poor cardiovascular health. By calming one's emotional state and by making the breathing slower and more regular, the HRV can be increased, at least temporarily.

The biofeedback setup for HRV involves monitoring either heart rate alone or heart rate plus respiration. Heart rate may be detected from plethysmographic sensors on the finger or earlobe, or via EKG monitors. Most commonly, a trace reflecting cyclic variations in heart rate is displayed on a video screen. The mean heart rate per minute is not important; the variability of heart rate is the variable of interest. The trainee observes the trace (or a derived graphic display)

and uses it as feedback for regulating the breath and/or the emotional state. The heart beat variability is maximized at a particular "resonant frequency" (breathing rate per minute) and this rate, usually around six per minute, can be determined for each individual by observation and experimentation.

The time to achieve an improved HRV while assisted by biofeedback might average four to ten sessions. Learning time varies as with any biofeedback procedure. Generalization to the everyday environment, away from the biofeedback monitoring, takes longer than achieving success within the biofeedback context. Practicing with HRV biofeedback provides a model for real-life self-regulation; the goal is to develop awareness of one's breathing and of one's emotional state, both of which interact and influence the autonomic balance. This balance in turn has been found helpful for several disorders involving chronic maladjustment of the autonomic nervous system.

Biofeedback Foundation of Europe

The Biofeedback Foundation of Europe (BFE) was founded to promote a greater awareness of biofeedback among European health professionals and, through training workshops, to educate clinicians in the use of biofeedback techniques and technology. BFE has compiled a series of clinical protocols developed by major contributors in the field of biofeedback and physical therapy, in an effort to improve knowledge in the use of electromyography as an effective tool for physiotherapy. These describe assessment and biofeedback training technique. Protocols for the following conditions can be found on their website (http://www.bfe.org/library.html - click on BFE protocols).

Patella Femoral Pain Syndrome
The Unstable Shoulder
Post Operative Knee
Urinary and Fecal Incontinence
Phantom Limb Pain
Oral Pharyngeal Dysphagia
Myofacial Pain and TMJ
Chronic Tension Headache
Repetitive Strain Injury
Effortless Diaphragmatic Breathing
Vulvovaginal Pain Disorders
Peak Performance Training with Electrodermal Biofeedback
Towards an Integrated Approach of sEMG Utilization: Quantitative Protocols of Assessment and Biofeedback

The Biofeedback Certification Institute of America

The Biofeedback Certification Institute of America (BCIA) was created in January 1981 to establish and oversee standards for practitioners who use biofeedback and to certify those who meet these standards. BCIA is an autonomous nonprofit corporation. The primary mission of BCIA is to protect the public welfare by certifying the competence of biofeedback practitioners. BCIA policies and procedures are set by an independent board of directors, which is comprised of a rotating group of distinguished biofeedback clinicians, researchers, and educators. Two certification programs are currently offered: 1) General Biofeedback covers EMG and thermal modalities and provides the basics of biofeedback, and 2) the EEG Biofeedback program deals with neurobiofeedback and brainwave modalities.

In 1996 the Board of Directors of the Biofeedback Certification Institute of America and the Academy of Certified Neurotherapists collaborated to develop a specialty certification in EEG Biofeedback to be managed and administered by BCIA. The opportunity to certify through the grandparenting process ended on December 31, 1997. Since 1998 the formal certification program in EEG Biofeedback has been available.

BCIA certification is the mark of distinction for providers of biofeedback services. Certification recognizes health care providers who have demonstrated competence in the use of biofeedback and self-regulation treatment methods. Recertification at four year intervals indicates providers have undergone continuous peer review of ethical practice and have continued to acquire knowledge of recent developments in the field. Names of certified practitioners may be found on the BCIA Web site. A BCIA certified practitioner must have met the following qualifications:

1. Prerequisite educational degree of a BA/BS or higher from a regionally accredited academic institution in a BCIA accepted clinical health care field such as: psychology, medicine, nursing, therapy, social work, or counseling. Credentialed special education teachers and counselors may also become certified in EEG Biofeedback to work in school environments.
2. Didactic training by completing a three semester-hour university course or its equivalent or completing a BCIA accredited training program.
3. Evidence of a human anatomy, human physiology or human biology course from a regionally accredited academic institution or from a BCIA accredited program.
4. Supervised biofeedback training must be provided by a BCIA approved supervisor in the categories of personal biofeedback, case conference, and patient/client treatment hours under direct clinical supervision.
5. Written certification exams covering the blueprint areas are required of all candidates.
6. BCIA certification establishes that the individual has met entry-level requirements for the clinical practice of biofeedback. However, BCIA certification is not a substitute for a state sanctioned license or other credential to practice one's profession. Candidates for BCIA certification who do not hold a professional license or its equivalent must stipulate that they practice under the supervision of a licensed provider.

BCIA hosts a website at www.bcia.org where the public or other interested professionals may read about certification requirements or search for a practitioner. Further information about certification in biofeedback is also available from their office:

10200 W. 44th Avenue, Suite 310,Wheat Ridge, CO 80033
(303) 420-2902 ? Fax: (303) 422-8894 ? Email: BCIA@resourcenter.com

Association for Applied Psychophysiology and Biofeedback (AAPB)
Code of Ethics

Members of the Association for Applied Psychophysiology and Biofeedback are expected to comply with the organization's Ethical Principles. These principles cover such areas as responsibility, competence, standards, public statements, confidentiality, protection of client rights and welfare, professional relationships, and research with humans and animals. A copy of these can be found on the organization's website at:

http://www.aapb.org/public/articles/details.cfm?id=277

Answers to Common Questions about Biofeedback Treatment

What is a normal amount of time for a visit? If it takes longer, is it customary to bill per 1/4 hour increments or is it usually one lump sum?

Biofeedback sessions commonly range from 45 minutes to 90 minutes. Shorter or longer sessions may be justified under unusual situations (e.g., shorter for a brief, uncomplicated follow-up or practice session; longer for EEG training for epilepsy or treatment of a multiplicity of symptoms). It is customary to bill either by length of session in 1/4 hour increments or a fixed amount per session regardless of length, depending on the profession and setting or the person doing the therapy.

What are general guidelines for number of sessions for major diagnoses of migraine headaches, hypertension, tension headaches, Raynaud's disease, anxiety, irritable bowel syndrome?

Eight to twenty sessions is a reasonable length of treatment for each of the disorders listed when there is good patient adherence and no other disorder present. Follow-up interviews are advisable at three, six, and nine months after the end of treatment.

What are reasonable fees for biofeedback therapy?

Fees vary among professions (psychologist, physician, master's level counselor, nurse, social worker, physical or occupational therapist, etc.) and between geographical regions, but are not dependent on the physiological system being addressed in biofeedback therapy. Fees range from $50 to $200 per hour for biofeedback therapy. There should be little difference in fees between modalities of biofeedback therapy, except that EEG therapy will customarily be higher because further specialized training is required.

Is it customary to break down the psychotherapy bill separately?

Although some biofeedback providers bill separately for biofeedback therapy and psychotherapy in the same session, it may not be necessary to do so. In addition to the use of biofeedback instrumentation, the clinical protocols in biofeedback therapies customarily involve two or three modalities of biofeedback and a variety of therapeutic procedures. Examples are autogenic training, imagery, symptom charting, assessment of life stressors, cognitive behavior therapies, strategies for generalization from the clinic to every-day life, and application of skills outside the therapy session, assignment and review of homework, and adherence management.

In some cases biofeedback therapy may be considered a subcategory of psychotherapy, as is done by the World Health Organization in ICD-9CM. The factor that defines biofeedback therapy is the use of instrumentation for teaching physiological self-regulation. When biofeedback instrumentation is not part of assessment or treatment, the procedure is not biofeedback therapy and should not be billed as such.

In some states, biofeedback therapy is not considered a form of psychotherapy and is not billed as such. Biofeedback providers should check with the ethical codes of regulatory and professional agencies in their local region for the appropriate diagnostic code. Suggested CPT codes are provided on pages 47-48.

For what diagnoses is biofeedback a treatment of choice?

Biofeedback therapy is a treatment of choice for certain types of fecal incontinence and urinary incontinence. It is a treatment of choice for tension-type headaches, migraine headaches, other chronic pain syndromes, irritable bowel syndrome, essential hypertension, asthma, Raynaud's disease/ syndrome, and a variety of neuromuscular disorders, especially during rehabilitation. EEG biofeedback therapy is a treatment of choice for certain selected patients with epilepsy or attention deficit disorder.

What treatments should be tried prior to biofeedback?

We recommend a behavioral "step-care" approach to treatment prior to biofeedback therapy. This approach would include for example, diet change, exercise or environmental restructuring. If a disorder is life threatening, it must be stabilized before biofeedback therapy is initiated. For example, the treatment of essential hypertension might include medication to bring blood pressure down and to maintain it at a safe level until the person develops self-regulation skills with biofeedback therapy. Also, when a person has psychological issues that interfere with learning self-regulation or with changing or eliminating a symptom, then psychotherapy may be needed before biofeedback therapy can be effective.

Please list any suggestions or ideas on why extended periods of time longer than 15-20 sessions might be necessary?

Many factors may contribute to an extended period of biofeedback therapy. Examples are the number and chronicity of symptoms, the number and type of additional medical or psychological diagnoses, the amount and type of medication and psychosocial factors such as motivation, multiplicity of life stressors, secondary gains, and intrafamily dynamics. Chronic pain of long duration, seizure disorders, and neuromuscular rehabilitation customarily take longer than 20 sessions.

Where can I get more information about biofeedback?

The Association for Applied Psychophysiology and Biofeedback has a website with further up-to-date information. For answers to the following, visit www.aapb.org and click on About Biofeedback.

What is Biofeedback?
What is Neurofeedback?
What is Psychophysiology?
What kinds of problems can biofeedback help?
Where can I find somebody to help me with biofeedback?
Facts for Insurance Decision Makers

Conclusion

The diversity of applications of biofeedback therapies reflects the commonality of underlying factors in many behavioral and psychophysiologic disorders such as emotional and cognitive stressors, the stress response, and failure to maintain healthy homeostasis. That biofeedback therapies are effective with a variety of symptoms is no mystery. Theoretically, any physiological process that responds to stress will respond to stress reduction. Biofeedback therapies incorporate a solid core of behavioral, cognitive, and physiological self-regulation techniques that are used by the patient to alleviate the underlying causes of the disorder. Biofeedback therapies have broad applications because they give the patient skills that facilitate the natural tendency of the body to return to healthy homeostasis as well as skills for enhanced well-being and prevention of disease.

Treatment Codes

(compiled by Robert P. Whitehouse, EdD, March 2003)

The treatment codes for biofeedback therapy used by practitioners and third party payors in the United States are established by the Current Procedural Treatment (CPT) Code committee of the American Medical Association.

Health and Behavior Assessment/Intervention	
96150	Health & behavior assessment (e.g., health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; initial assessment
96151	Re-assessment
96152	Health & behavioral intervention, each 15 minutes, face-to-face; individual
96153	Health & behavioral intervention, each 15 minutes, face-to-face; group (2 or more patients)
96154	Health & behavioral intervention, each 15 minutes, face-to-face; family (with the patient present)
96155	Health & behavioral intervention, each 15 minutes, face-to-face; family (without the patient present)
Biofeedback	
90901	**Biofeedback training by any modality**
90911	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG &/or manometry
Psychiatric Therapeutic Procedures	
90875	Individual psychophysiology therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); approximately 20-30 minutes
90876	Individual psychophysiology therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); approximately 40-45 minutes
Other Codes, which might be useable, if approved by third party payors	
94010	Spirometry, including graphic record, total & timed vital capacity, expiratory flow rate measurement(s), with or without maximal voluntary ventilation
94400	Breathing response to CO_2 (CO_2 response curve)
96002	Dynamic surface electromyography, during walking or other functional activities, 1-12 muscles
95957	Digital analysis of electroencephalogram (EEG) (e.g., for epileptic spike analysis)
90806	Individual psychotherapy. Insight oriented, behavior modifying &/or supportive, in an office or outpatient facility, approximately 45-50 minutes, face-to-face with the patients

ABC CAM Codes

Five character codes have been developed by the Alternative Link for over 4000 procedures "that describe the patient encounter with nursing, complementary and alternative medicine (CAM), and indigenous medicine services. Laws governing such providers differ by state and are available at 877-621-LINK.

CDAAP	Biofeedback, counseling, mental health services, practice specialties. Assisting the client to modify a body function using feedback from instrumentation.