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THE DESIGN AND TESTING OF A MAGNETIC BIOSTIMULATOR

By

Bruce Ian Rapley.

A thesis presented in partial fulfilment of
the requirements for the degree of
Master of Philosophy.

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ABSTRACT

A commercial pulsed electromagnetic field therapy unit, typical of those used in current medical practice, is evaluated. The principle of operation is determined, and the magnetic field output quantified. The unit is trialed on a human subject to verify the manufacturer's claims regarding the physiological responses of both vasoconstriction and vasodilation. The results to not confirm the manufacturer's claims.

A programmable magnetic biostimulator is designed and tested. This approach is unique, featuring a transconductance amplifier to drive the stimulation coil. Significant increases in performance are obtained in comparison to standard voltage feedback amplifiers, particularly with rapid rise-time waveforms, such as square waves.

The magnetic biostimulator is trialed in a clinical setting on four experimental subjects to determine the claimed vasodilation response of pulsed magnetic fields. Two subjects are normal, healthy individuals, and two have been diagnosed as having Primary Raynaud's Disease, a disorder of peripheral circulation. Various responses are recorded and discussed in the text.

The magnetic biostimulator is trialed in a laboratory situation in order to determine the effect of magnetic fields on the cytogenetics of the broad bean, *Vicia faba*. No significant differences in the number of chromosome or chromatid breaks are recorded between the control and test groups. Significant differences at the 95% probability level between the control and test groups are recorded, however, for various stages of the cell cycle. This finding may imply that various forms of exogenous magnetic fields may affect the cellular mechanisms involved in mitosis.

The clinical and laboratory trials verify the effectiveness and practicality of the chosen design. In reviewing the performance of the magnetic biostimulator, suggestions for future implementations are discussed.

To Anne-Marie

Without her constant help, support and love,

the completion of this thesis would

never have been possible.

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~

"Men are deplorably ignorant with respect to natural things, and modern philosophers,as though dreaming in the darkness, must be aroused and taught the uses of things, the dealing with things; they must be made to quit the sort of learning that comes only from books, and that rests on vain arguments from probability and upon conjectures."

William Gilbert, "On the Loadstone".

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1

INTRODUCTION

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1.1 STATEMENT OF OBJECTIVES

1 To design and construct a multi-function biomagnetic stimulator which may be used to determine the effects of applied electromagnetic fields on various living systems.

2 To clinically trial the magnetic biostimulator by attempting to evaluate the potential use of pulsed electromagnetic fields as a vasodilator.

3 To trial the magnetic biostimulator in a laboratory setting to evaluate the cytogenetic effects of alternating magnetic fields on the Broad Bean: *Vicia faba*.

4 To evaluate the effectiveness of the magnetic biostimulator as a potential research and clinical tool.

1.2 HISTORICAL PERSPECTIVE

It has long been thought that magnetic fields have curative properties. The ancient Greeks are known to have mined magnetite (a magnetic form of iron oxide, Fe_3O_4) in the province of Magnesia in Asia Minor (now modern Turkey) as far back as 1000 B.C. The first Greek scientist, Thales of Miletus (624 - 565 B.C.), believed that loadstone (magnetite) was 'alive', attracting metal by 'animating' (exciting) it.

William Gilbert, 1545 - 1603, physician to Queen Elizabeth I, proclaimed that the Earth was a giant magnet. He compared magnetic forces with life forces.

Anton Mesmer, 1733 - 1815, an Austrian physician developed his theory of Animal Magnetism around 1770 based on the Greek notion that magnets were alive. Mesmer was the first researcher in modern times to develop a comprehensive model of the interaction of magnetic fields and living organisms. He postulated that a subtle, imperceptible 'fluid' flowed through the human body, the smooth uninterrupted flow of which constitutes health - blockage causing disease. His 'magnetic' therapy sessions became famous throughout Europe and were highly sought after.

Along with the discovery that rubbing magnets over the body often proved to be beneficial, Mesmer also invented 'group therapy' and discovered the placebo effect.

Magnetic therapy fell into disrepute following a vicious attack on Mesmer by the French Royal Academy of Sciences who hired such eminent people as Benjamin Franklin (then the American ambassador to France) and Antoine Lavoisier (considered to be the Father of Modern Chemistry). This austere commission declared Mesmer to be a quack, creating a cloud which persists to this day.

In the 20th century such scientists as Nicola Tesla and Lakhovsky persisted with experiments investigating the effects of magnetic fields on plants and animals, including humans. In particular Lakhovsky had great success in treating people with cancer, recording a number of spectacular 'cures' (Brown[13]). Tesla attributed his long life to his practice of taking daily 'electrical baths' inside one of his giant solenoids (Cheney[14]). However magnetic fields were still not generally accepted by the medical fraternity as legitimate forms of therapy due to the lack of a known scientific mechanism of action in the human body.

A mechanism began to emerge in 1957 with the publication of a paper by Fukuda[1], which showed that hydrated, living bone exhibited the piezo electric effect. This paper formed the basis of a theory which eventually lead to the clinical application of magnetic fields to treat bone non-union.

In the 1970's Robert O. Becker, then an orthopaedic surgeon at the Veteran's Administration Hospital in Syracuse, New York, developed the first modern treatment involving magnetic fields. This treatment is used today to treat recalcitrant fractures, (fractures which will not heal), and is to be found in most modern hospitals.

Research into further medical uses for magnetic field therapy is expanding exponentially world-wide. Considerable hope is held for new therapies which will treat soft tissue disorders as well as organic diseases such as cancer and A.I.D.S.

Parallel to the development of medical treatments using magnetic fields is the equally important research into the possible harmful effects of similar fields. Numerous publications relating potential dangers have literally flooded the literature (Carstensen[15], Polk & Postow[16], Wertheimer & Leeper[17], Feychting & Ahlbom[18], Olsen[19], Floderus[20]). Not restricted to scientific journals, the deluge receives much attention in the popular press, magazines and newspapers. Such publication of often ill researched findings has only led to great public confusion, and in some cases - panic.

1.3 Potential Applications of Magnetic Field Therapy

1.3.1 Potential Benefits of Pulsed Electromagnetic Fields

The reported effects of electromagnetic fields are manifold. Since Fukuda's[1] landmark paper of 1957 detailing the piezo electric effect in hydrated living bone, research world-wide has embarked on an exponential growth curve. Contemporary research includes such diverse experiments as: "The effect of magnetic treated water on the growth, flowering and fruiting of glasshouse grown tomatoes", Pavlov[2] et al., 1983; "The effect of alternating magnetic fields (60 - 100 gauss, 60 Hz) on *Tetrahymena pyreformis*," Tabrah[3], et at. 1978; and Pulsing electromagnetic fields induce cellular transcription, Goodman[4], 1983.

Electromagnetic fields are now commonly used to stimulate enzyme activity in recalcitrant seeds, e.g. "Effects of magnetic seed treatment on yields of barley, wheat, and oats in Southern Alberta", Pittman[5], 1977; and "Effects of magnetic seed treatment on amylolytic activity of quiescent and germinating barley and wheat seeds," Pittman[6], 1979. While the use of various electromagnetic fields on seeds and plants offers considerable commercial opportunity, this thesis focuses on two studies: a) the effects of such fields on humans, with the emphasis on beneficial medical applications with respect to Raynaud's disease; and b) the effects of such fields on the DNA of beans.

All experimentation involves potential risk. In the experiments involving humans discussed in this thesis, every effort has been made to minimise the actual risk to subjects. Field exposures have been kept within the I.R.P.A. /

I.N.I.R.C.[21] established guide-lines, (also Appendix Four) and are generally similar to other experiments currently undertaken around the world. In all cases, the subjects involved in the experiments discussed in this thesis have been appropriately informed, are participating voluntarily without obligation, (having the option of discontinuing the experiments at any time for any reason,) and have signed a consent form detailing their involvement and understanding of the experimental protocol. Although the human experiments were conducted prior to the commencement date of this masterate, the author sought independent assessment of the protocols, presenting a proposal to the Human Ethics Committee at Massey University. The guide-lines suggested by the committee were adhered to. Subsequently a formal proposal was passed in principle by the Massey University Human Ethics Committee, although further experiments and have been conducted since the commencement of the this thesis.

It is now well established that electromagnetic fields modify the behaviour of calcium in calcified and non calcified tissues: "Pulsing electromagnetic fields: A new method to modify cell behaviour in calcified and noncalcified tissues", Bassett[7], 1982. To quote Bassett directly;

During the past 20 years, great strides have been made in defining bioelectric phenomena in the skeletal system. As a result, it is possible to treat, clinically, disordered function in these tissues. The success of these efforts and a rapidly expanding base of fundamental data suggest that many important advances can be made as new research endeavours characterise effects of weak pulsing electric currents on cell behaviour. Future endeavours will involve investigators versed in biochemical, biophysical, developmental, endocrinological, physical-chemical, and physiological aspects of the skeletal and other systems. Unfortunately, few of these individuals are equipped by past experience or training to deal easily with the principles and techniques of electricity or electromagnetism. In such an environment, confusion of concepts and terminology is an ever present and real danger.

Of particular importance is Bassett's warning. Since 1982 hundreds of papers have been produced world-wide, many of which are of dubious quality. The technical descriptions are so poor and lacking in detail that duplication is virtually impossible in all but a few instances. Carstensen15 (pp237-251) tabulates 116 clinical trials concerning the effects of extremely low frequency magnetic fields on plants and animals. Of these, only 18 experiments have been replicated to date. Ten with positive results confirming the original finding, and 8 negative results questioning the original findings.

Despite this plethora of inferior papers, significant breakthroughs have been accomplished. The treatment of recalcitrant fractures with alternating electromagnetic fields is now commonplace in many western hospitals. The groundwork for such therapies was laid by such researchers as Becker and Bassett, e.g. Modification of fracture repair with selected pulsing electromagnetic fields, Bassett[8], et al. 1982. Bassett recounts a spectacular cure of osteonecrosis of the hips in a 30 year old mother in "Biomedical implications of pulsing electromagnetic fields", in Surgical Rounds, 1982.

Unfortunately the success of such innovative treatments has sparked the production of a number of dubious magnetic field treatment devices. It is claimed that such units claim to beneficial in the treatment of: arthritis; arthrosis; bronchitis; bruising; burns; diabetes; fractures; migraine; myosistis and prostatitis; nephritis and gastritis; neuralgia, both brachial and intercostal;

osteoporosis; retinitis; rheumatism; sinusitis; sleep disorders; spondylitis and Scheurmanns disease; tonsilitis; tooth extraction; ulcers, including chronic, gastric and varicose; and be useful in generally aiding wound healing.

Extravagant claims are supported by such statements as: "...based on clinical evidence..."; "...one of the most advanced and effective units available"; "Russian cosmonauts have proved that men cannot remain in space away from the earth's magnetic field (9.6 Hz) for more than 250 days without permanent damage to the intricate biological function of the human body". All too often such claims are not referenced to any specific scientific literature. Where references are provided, in many cases they do not directly relate to the kind of stimulation which the unit is capable of providing. A list of manufacturers appears in Appendix One.

While the various diseases and disorders listed above may one day submit to treatment using electromagnetic fields, the case is far from decided. Clinical trials conducted scientifically with adequate control conditions as well as adequate control over the electromagnetic variables need to be undertaken before public announcements are made. Researchers in this field may be spurred on by the results of Becker, Bassett, Pilla, and Smith.

One area of potential enquiry worth pursuing is that relating to the redistribution of microcirculation patterns in the human body. Warnke, in a seminal paper entitled: "The possible role of pulsating magnetic fields in the reduction of pain", (published in Pain Therapy, 1983 Elsevier Biomedical Press), recounts the widening of blood vessels as registered by 5 and 12 μm thermography under the influence of pulsed magnetic fields in the range of 500 μT - 2 mT. Essentially Warnke used a 200 Hz carrier wave modulating this between 5 - 25 Hz for optimal stimulation. He does however report increases in skin temperatures with a 50 Hz carrier modulated at 30 Hz at 1.5 mT. There are two points worth noting from Warnke's paper: a) both large vessels and capillaries dilate under the influence of the applied magnetic field; b) pulsating magnetic fields applied to the head need the lowest induction intensity in order to achieve a reaction.

Warnke's paper is a milestone in that he was able to show a similar response in both humans and horses, thus avoiding the placebo effect. In addition, the increase in peripheral blood flow was accompanied by an increase in oxygen in the tissues which was indexed by the amount of oxygen diffusing out through the surface layers of the skin. It is without doubt that his experiments showed a genuine increase in oxygen in the tissues. Obviously this would be of use when attempting to treat ischaemic pain (pain caused through lack of oxygen in the tissues).

Warnke proposes a mechanism to explain his results: hyperpolarisation of the nerves of the sympathetic system thus causing a reduction in information. He believes that the eddy currents generated across the various cell membranes as a result of the pulsed magnetic fields, while insufficient in themselves to directly cause hyperpolarisation, are able to cause an 'adding-up' of electrical potential across the membrane. In this way, sufficient polarisation may be achieved by the adding up of stored electrical potential in the form of differential concentrations of ions across the membrane. He is quick to point out that this response is obviously time dependent.

His theory relies upon the fact that the time constants of the pre and post-synaptic membranes of the alpha receptors of the sympathetic nervous system are sufficiently long for pulsed magnetic fields of the order of 200 Hz modulated at 5 - 25 Hz to effect a response. The time constants of the beta receptor system are considerably shorter and have a tendency to be influenced only by metabolic stimulation, so it is unlikely that they would be affected by similar electromagnetic stimulation. Warnke concludes that the hyperpolarisation of the alpha receptors influence the rate of action potentials delivered to the muscles surrounding the blood vessels, (arteries and metarterioles). This reduced muscle tone allows the vessels to expand under normal blood pressure, thus delivering more oxygenated blood to the tissues. As a result, not only does the surface temperature of the skin increase, but the amount of oxygen diffusing out thought the skin surface increases.

This thesis will investigate the potential application of the magnetic biostimulator in clinical trials in an attempt to determine the possible use of pulsed electromagnetic fields as vasodilators which could then be used in the treatment of Raynaud's disease.

1.3.2 Potential Dangers of Pulsed Electromagnetic Fields.

Not all of the reported effects can be regarded as beneficial. Garcia-Sagredo and Monteagudo[11], 1991, report that the waveforms generally used to enhance bone regeneration caused an increase in chromosome breakages which were statistically significant. It is important to note that these increased aberrations occurred at the 4.0 mT level. No increased effects above the normal were observed with field strengths of 1.0, 2.0 or 3.0 mT. A significant point concerning the geometry of the applied field is that all four exposure levels were obtained by placing the test tube in a predetermined position within a pair of Helmholtz coils. While the author states that the peak readings were, 1.0, 2.0, 3.0 and 4.0 mT respectively, the exact location of the test tube within the coil would not only determine the peak flux density, but also the orientation of the field in space. The resultant vectors would be considerably different for each location which might tend to nullify the results as each treatment would have two different variables rather than the single stated one: field strength.

Khalil and Qassem[12], 1991, exposed human lymphocytes to a 10 ms pulse with a repetition rate of 50 Hz producing a duty cycle 1.0. A pair of Helmholtz coils produced the applied field at 1.05 mT. They discovered that cell cultures exposed for 72 hours exhibited a significant reduction in cell proliferation rate and an increase in sister chromatid exchanges. They conclude that exposure to pulsed electromagnetic fields may induce a type of DNA lesion that could lead to chromosomal aberrations and death. Such lesions do not seem to increase the number of sister chromatid exchanges.

The literature contains numerous papers discussing the potential harmful effects of electromagnetic fields, particularly those associated with power distribution, i.e. 50 - 60 Hz. A list of such papers is to be found in the bibliography. To date, there has been no compelling evidence to prove beyond reasonable doubt that such fields are harmful. Epidemiological studies tend to suggest some correlation between exposure to magnetic fields from high voltage overhead power lines and various types of cancer.

1.3.3 Evaluation of the Effect of Some Alternating Magnetic Fields

In order to test the biomagnetic stimulator it was decided to attempt to evaluate the effect of electromagnetic fields on two biological systems.

The first involves the use of the biomagnetic stimulator as a medically therapeutic device. (The current uses of magnetic fields in medical treatment have been discussed in brief in Section 1.2, Historical Perspective, and Section 1.3, Potential Applications of magnetic field therapy.) This study focuses on the claim that certain electromagnetic fields cause vasodilation which in turn cause an increase in skin surface temperature, (as shown by Warnke, 1983).

In brief, alternating electromagnetic fields are applied to the base of the skull via a short solenoid. Skin temperatures recorded by a computer are analysed to determine if the applied fields caused an increase in temperature. If successful, this technique could be used to treat sufferers of Raynaud's disease. (See Chapter Five.)

The second approach involves investigating the effects of various alternating magnetic fields on DNA during mitosis (cell division). The Broad Bean, *Vicia faba*, was chosen because of the relatively small number of large chromosomes. Growing beans were subjected to various alternating magnetic fields for three days after which the root tips were excised and prepared for microscopic analysis. Essentially, the chromosomes were examined in Metaphase for any visible aberrations such as breaks and bridges. In addition, the ratios of cells in each stage of the cell cycle were determined in both control and test plants in order to determine if the applied fields affect the rate of cell division. The results of these experiments are presented in Chapter Six.

1.4 SUMMARY OF THE THESIS

Chapter Two:

Chapter two details the analysis of a typical medical biostimulator, using the Magnafield 990 Multi-Rhythm treatment unit. This unit representative of devices currently on the market. Firstly an electronic analysis is undertaken by determining the exact type of magnetic field produced. This is achieved by using a storage oscilloscope to examine the output of a magnetic flux meter the probe of which is placed near the induction coil. An example of the output is displayed in Plate 2.4.

The Magnafield 990 is then tested in two clinical experiments to determine the physiological response of a human subject. Two trials are conducted, first one to determine if the unit can produce a vasodilation response, the second to determine if a vasoconstriction response can be initiated. The results do not support the claims made by Magnacare for the Magnafield 990. This leads to conjecture over the clinical efficacy of such treatment devices.

Chapter Three:

Chapter three details the design and construction of the biostimulator modules including: timebase generator; timebase generator computer interface; simple analogue switch; zero-crossing switch; pseudo random analogue switch; programmable analogue switch and transconductance amplifier. In addition the design of a low-pass filter is discussed, as this is required for later analysis. Full circuits diagrams and the printed circuit layout, where applicable, are detailed.

Chapter Four:

The valuation of the magnetic biostimulator designed in Chapter Three is outlined in Chapter four. The devices tested include: timebase generator; simple analog switch; zero-crossing switch; pseudo random switch; low-pass filter and transconductance amplifier. Due to the inability to source some integrated circuits in New Zealand, the computer interface for the timebase generator was not completed, hence its actual operation could not be evaluated within the time constraints of this project.

Chapter Five:

In order to evaluate the clinical efficacy of the magnetic biostimulator it was decided to test the unit by attempting to stimulate a vasodilation response in human subjects. In order to determine if vasodilation occurred, it was necessary to devise some non in-invasive procedure. The measurement of surface skin temperature was chosen. Chapter Five details some mathematical modelling based on the work of Hertzman5-16. A generally held belief is that skin surface temperature and sub-cutaneous blood flow are linearly correlated between 25C and 35C. The results of the mathematical modelling provide a more complex answer in the form of a second order differential equation.

A brief discussion of Raynaud's Disease is undertaken as an introduction to the clinical trials. The thesis is to test the effect of pulsed low frequency magnetic fields on normal subjects, and compare these results with those obtained from subjects who have been diagnosed as having impaired physiological temperature control.

The magnetic biostimulator was clinically trialed on four volunteer subjects, two who suffered from Raynaud's Disease, and two normal, healthy controls. Some interesting results were obtained which may be suggestive of a magnetically induced vasodilation response in the normal subjects. The response of the Raynaud's sufferers is however more complex, and cannot be investigated further within the bounds of this project. The topic is worthy of further investigation.

Chapter Six:

To test the magnetic biostimulator in a scientific laboratory setting, it was decided to investigate the effect of various magnetic fields on the chromosomes of *Vicia faba*, the broad bean. The rationale for using *Vicia faba* is that it has a large genome (24.3 picograms of DNA in a 2C nucleus). It has a diploid number of 12 chromosomes which are large and morphologically distinct. Thus *Vicia faba* is an ideal organism to use for studying cytological events. The stages of mitosis are easily identifiable and any chromosome breakages can be readily detected. Furthermore this species can be easily cultivated under standard glasshouse conditions.

Chapter Six begins with a review of current theories of interaction between living systems and low frequency magnetic fields. The experimental protocol chosen involves detecting possibly harmful effects of various magnetic fields by examining the number of chromosome and chromatid breaks at metaphase. In addition, the number of cells in each stage of the cell cycle is determined for five experimental conditions. This procedure would enable any changes in the rate of cell division to be determined, as the number of cells in each phase is proportional to the time spent in each phase.

While no significant differences in the number of chromosome or chromatid breaks is evident between the various experimental treatments, the time taken in each phase of the cell cycle appears to be significantly different for the different treatments. A number of different avenues for future research are discussed.

Chapter Six also details an evaluation of the biomagnetic stimulator as a scientific research tool and outlines possible future improvements.

Chapter Seven:

Chapter Seven contains a brief resume of conclusions which includes the following sections:

Analysis of a typical magnetic biostimulator;

The magnetic biostimulator as a clinical tool;

Pulsed magnetic fields as a human vasodilator;

The magnetic biostimulator as a scientific research tool;

The effect of magnetic fields on chromosomes;

The effect of magnetic fields on the cell cycle.

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