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**A Breakthrough from an unexpected Corner:
Turning an old technology into a Paradigm Shift.**

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ABSTRACT

This Paper elucidates the history, the design philosophy of innovation and the transformation of an old process-technology into a breakthrough, evidence-based therapy with international medical acceptance, verification of effectiveness as well as the strategic business model employed to promote the efficacy of the new technology medical device.

The history of application of Pulsed Electro Magnetic treatment goes back to the first experiments with electro-magnetic devices for therapeutic purposes but where no scientific evidence was found for the efficacy of such treatments. Pulsed Electro Magnetic Field Therapy (PEMFT) was not medically acceptable and was, until recently, in disrepute, professionally-speaking.

A re-visiting of the technology with reference to the partially inconsistent, yet positive anecdotal results obtained, gave rise to in-depth analysis as well as scientific research conducted by independent institutions. This resulted in the identification of the key physical interaction which influenced the physiological parameters and which in turn could be related to a significant improvement of pathologies.

The effect of PEMFT on the physiological self-regulation ability of organisms, for example was demonstrated to be quantifiable, repeatable and consistent. By applying and promoting a systems approach as practiced by engineers who were involved in complex multi-disciplinary projects for many years, a different perspective on the innovative development of PEMF Therapy was established.

The medical impact of the new generation PEMF treatment, now re-named Physiological Regulation Therapy, is elucidated briefly. The practical resistance to an innovative breakthrough technology process from a previously unproven technology is discussed in terms of professional culture and the underlying paradigmatic shift.

The innovative, process-based therapy working mainly at cellular and self-regulation level was a classic Kuhn-like [1] paradigmatic departure from the indication-based therapy as applied to pharmaceutical therapy. Over the past 10 years exceptional breakthroughs of the non-symptom based therapy have been documented through clinical trials, scientific medical investigations and the publication of relevant literature.

The turn-around of the old and insufficiently understood technology into an innovative, significant, scientific breakthrough-technology, requires this paradigm shift. It is surmised that the paradigm shift will strongly influence medical schools and practitioners over the next 5 to 10 years. The first ripples are indeed visible already.

The authors, as “outsiders” to the medical discipline, bring an engineering perspective to bear on the development of innovative but system-integrated medical devices which can promote the medical device industry and bring system engineering approaches into the realm of medical technology and therapy. The authors, both involved in Systems Research, are trained as professional engineers with years of experience and with considerable interest in system integration and product

design. Both are active internationally and one of the authors has been closely related to the PEMF therapy device under consideration.

Both authors have presented a number of Papers at International Conferences individually and in partnership on the topics of Strategic Business Leadership and Business Transformation, System Engineering and Holistic Management Model Development for High Technology Companies.

This background and thinking is now applied in charting the development of a paradigmatic quantum jump medical device which represents a breakthrough from an unexpected corner.

INTRODUCTION

As an aeronautical engineer specialized in supersonic aerodynamics and an Academic in Mechanical and System Engineering respectively, the authors got involved in the field of medical therapy devices very hesitantly. However, after 10 years of intimate and intellectual shoulder rubbing with product manufactures, research scientists and medical practitioners some noteworthy insights and possible contributions were made.

Interdisciplinary research has become an almost indispensable factor in scientific progress. Just about all scientific endeavors, including medical research, has become highly organized and specialized. Kuhn [1] showed that although science normally progresses continuously and in gradual steps this happens within the prevailing professional paradigm of the day. Occasionally a paradigmatic quantum jump forward is considered revolutionary, but considered highly suspicious and by its very nature, uneven. Usually it occurs only when contradictions that have arisen out of normal professional activities can no longer be accommodated.

To get professionally involved in a process-based therapy where the previous generation technology led only to inconsistent results which could not be explained scientifically, was not initially convincing nor attractive.

But in the course of time the authors' interest in innovative product development and system technology overcame their

BRIEF HISTORY

The history of application of Pulsed Electro Magnetic treatment goes back to the first experiments with electro-magnetic devices for therapeutic purposes but where no scientific evidence was found for the

hesitancy. This paper is an attempt to show the history and initial technological assumptions, the design approach and the transformation of an insufficient technology into a breakthrough, scientifically verifiable, evidence-based therapy which may now require a paradigm shift in the medical profession with regard to this type of therapy.

The objective of this paper is to demonstrate that an old, established, yet unconvincing, technology, properly analyzed and understood can be turned around in an innovative fashion and become a breakthrough process. The institutionalized accreditation for a new technology device is relatively easy to accomplish if it withstands scientific scrutiny. However, to change the paradigm of the individual practitioner is more difficult to realize. The paper attempts to show the process as well as the difficulties encountered during the development of the device and gives an indication why professional re-assessment of the now new and verifiable technology is difficult to achieve.

A Strategic Approach for successfully introducing the new technology to medical professionals is briefly presented which might help the breakthrough technology to be accepted in paradigmatic terms. The scope of the paper is unusual in that it looks at product development, medical efficacy and branding strategy in a holistic fashion, i.e. from a system perspective. The paper tries, as it were, "to connect the diverse dots into a coherent line".

The paper is organized under 5 headings which describe the following:

- Brief History: the old technology with its lack of credibility and poor consistency, medically speaking.
- Design Considerations and Research in the development of the new Device.
- Medical Impact of the new technology embedded in the new device,
- Strategic Business Model: the strategy on how to change the medical paradigm with respect to this new application of technology.
- Discussions and Conclusion.

efficacy of such treatments. Pulsed Electro Magnetic Field Therapy (PEMFT) was not medically acceptable and was, until recently, in disrepute, professionally-speaking.

A re-visiting of the technology with reference to the partially inconsistent, yet positive anecdotal results obtained, gave rise during the mid nineties to in-depth analysis as well as scientific research conducted by independent institutions. This resulted in the identification of key physiological parameters which in turn could be related to a significant improvement of pathologies. The effect of PEMFT on the physiological self-regulation ability of organisms, manifested especially in the improvement of macro- and micro circulation, partial oxygen pressure improvement amongst other parameters, was demonstrated to be quantifiable, repeatable and consistent. By applying and promoting a systems approach as practiced by engineers who were involved in complex multi-disciplinary projects for many years, a different perspective on the innovative development of PEMF Therapy was established.

The basic objective of PEMF therapy is to influence the ion-based regulation mechanisms of the organism (human body) through appropriate magnetic fields so that self-regulatory physiological parameters which contribute to the healing process will be improved measurably, consistently and with significant levels of improved pathologies.

Prior to 1995, the old technology devices did show some improvements in combating ailments and diseases but could not always be correlated, as these studies were seldom conducted under strict and Good Clinical Practice (GCP) standards. Most of the success reports came from non-medical laypeople and were often based on scientifically inadequate and partially unreliable information. Although some significant healing effects were well known and scientifically documented, for example Rubin et al [2], Stiller et al [3] and Ieran et al [4] there was a noticeable lack of confidence in the therapy from Medical School trained physicians. There seemed to be no coherent theory, no proper measurements of the parameters under investigation and a poor description of the experiments.

This was the stage set until the fundamental work of Kafka [5] [6], and Michaelis [7] [8] established the scientific and medical veracity of the process. Later Bohn [9], Klopp [10] and others corroborated the underlying soundness of the therapy through the practical results obtained by medical practitioners and Clinical

Institutions who used the new technology PEMF Therapy Device.

For the purpose of briefly elucidating the therapy the following basic system considerations are stated:

A living organism,

- Is self-regulating
- It is networked as a complex system
- It is continuously optimizing resources and optimizing for system performance
- It is self-healing
- Consists of cells which are different in function but in principle similar in bio-chemical aspects, supplied by the circulatory system with oxygen, nutrients and ensures removal of toxins and waste products
- A large enough number of dys-functioning cells within the same organ determine the symptoms of the ailment

Electro magnetic energy

- is a form of energy that can be transferred, accepted and utilized at some bio-chemical and/or physiological level by the organism.
- can be converted to chemical energy e.g. ATP at cellular level
- is an essential, but not sufficient form of energy for living organisms (on this planet)
- Maxwell's equations form the basis for the description of electro magnetic processes; ie it has a direct influence on electrically charged atoms and molecules in the organism.

The design and innovative thinking with regard to an old technology, with new scientific insights and instrumentation led to a re-visiting of the PEMF Therapy credibility problem.

DESIGN CONSIDERATIONS AND RESEARCH

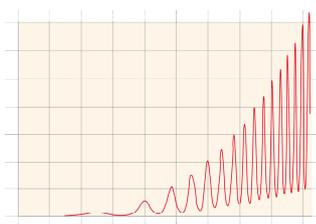
“Different ways of thinking about problems are the beginning of the scientific process” is a quote according to Popper [11]. Kuhn [1] corroborates by saying that “the importance of problems are the conditions they create for changing paradigms”.

Kafka [5] investigated the physical and physiological interactions of existing PEMF devices and found considerable discrepancies between existing devices of poor efficacy and especially a lack of consistency in results. Kafka looked at the available data from various researchers and device manufacturers but found little credible scientific causes for their success or non-success. Some of these old technology PEMF devices were commercially available for many years and some for a few decades already. Claims were being made which were never scientifically scrutinized and could not easily be tested for accuracy.

Kafka took a different approach: By taking into account the laws of physics applied to atomic, molecular and ionic physical-chemical interaction and reaction, Kafka looked at the effects of magnetic fields on physiological parameters occurring at submicroscopic level. It is those effects that determine the complex interaction between the various physiological body functions and to keep system optimization, performance, vitality and health viable for survival.

Kafka found that the successful therapy attained with conventional (old technology) PEMF systems can be traced to stimulations with arbitrary and empirically chosen frequencies which produced stimulations to activate certain molecular interactions. However, measured against the conceivably larger numbers of different molecular interactive physiological systems regulating physical body functions, only a relatively small number of molecules can be activated by individual frequencies. Stimulations with signal waveforms characterized by a wide spectrum of frequencies such as square and trapezoidal signals, should therefore extend and improve the success of the therapy. In this, the pulse repetition rate of the signal also seemed to play a leading role in effectiveness.

By means of using discrete spectral Fourier Analysis, Kafka optimized the time-varying signal in the form of a dc-pulse. He investigated where the physiological chemistry would be influenced to such an extent that the body's own regulation mechanisms can become more effective. Kafka determined that the subtle influence on the physiological mechanisms improved when applying as wide a range of frequencies with a compound signal that would be even better than a traditional square, triangular or exponentially- formed variation of magnetic flux. Through this mathematical optimization process, Kafka invented the BEMER pulse which is depicted in the adjacent graph:



$$y = k(x) * x^a * e^{(\sin x * b)}$$

a = 3, b = 3, k(x) = 1

PEMF therapy seemed more successful in the extremely low range of frequencies of time varying dc-fields. By making the intensity of the magnetic field in the order of magnitude of the geo-magnetic field, Kafka achieved measurable physiological data and a very high level of consistency for the first time.

From these basic considerations Kafka, Michaelis, Bohn and others like Jelinek [13], Blaha [14] and Möbes [15], conducted numerous studies during the years around the new millennium; some in medically supervised User Studies and some very specific empirical work in the laboratory at Universities and Institutions in various countries. The results from Jelinek, Blaha and Möbus looked promising as they covered diverse physiological effects in connection with diverse applications: sport injuries and performance enhancement, stress protein release for the protection of cell damage and the effect of the new generation PEMFT on tumour tissue. In the final analysis these, albeit positive, contributions are not sufficient quantitatively and did not constitute proof with respect to pronouncing general healing and attributing it to the treatment.

However, by the years 2003 there were already a number of scientific publications and tentative scientific research results available which indicated consistency and reliability in the physiological parameters that were affected by the new technology approach. Better understanding and conformance to the internationally accepted Evidence Based Guidelines (EBG), which include meta-analysis, risk-benefit analysis and some randomized controlled trials contributed greatly to the astounding results in terms of multi-morbidity, speed of recovery and again, consistency that were found in medical practitioner's practices.

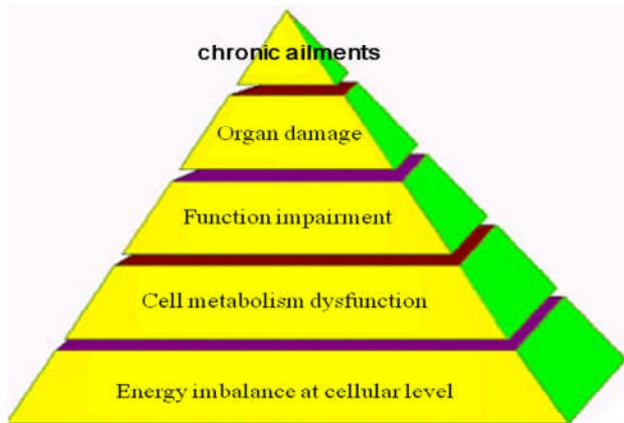
Note that just about everything about the PEMF Therapy was explained at molecular level and in a physics-chemistry framework. Cellular biology considerations were not initially part of the design picture. That was also about to change as some of the significant effects of the pulsating magnetic field on the physiology of the body could only be explained at bio-chemical / cellular level.

Michaelis [7] [8] investigated the new device from a different angle: Michaelis studied the effect of the new technology PEMF Therapy on the macro- and micro-

circulation, the effect on the immune system, the gas exchange at alveoli level (oxygenation), the effect on cellular metabolism and the general effect on the regeneration proteins which enable healing processes. The results showed a direct correlation between the application of the new technology PEMF and the improvement of the physiological parameters under observation.

From those results the new Therapy was developed and the therapy was seen to be successful in a wide spectrum of indications. This was not easily acceptable by the current medical paradigm which is indication-based, ie symptom related. To be able to treat a diversity of conditions with different symptomatic exhibits with such a high success rate, was not previously possible and therefore incredulous.

Michaelis [8] suggested a paradigm which can be illustrated with a cause-pyramid as shown:



The PEMF treatment effectively addresses the energy shortage at cellular level which is after all the underlying cause to sense-able symptoms. By interaction at the biochemistry level (actually at atomic, molecular and ion level) the pulsed magnetic energy transfer improves the cellular metabolism of virtually all cells, it improves the microcirculation by a chemical interaction (releasing NO gas) and thus dilating the blood vessels. Furthermore the effect on the blood viscosity, and oxygen absorption capacity of the erythrocytes provides a complete physiological regulation picture which is positively applicable to almost all ailment conditions.

There have been no negative side-effects observed in millions of applications of the therapy. The treatment seems to address the real cause of symptoms, not by treating the ailment but by improving the physiological self-regulation of the body.

After 10 years in use with medical accreditation in most of over 50 countries by their respective Health Ministries and Medical Institutions, the new technology device known by the acronym B.E.M.E.R. (Bio-Electro-Magnetic-Energy-Regulation), has achieved previously unheard of success rates in the treatment of chronic ailments, wound healing, recovery from surgery and sport science to mention but a few. The key-effect of BEMER treatment is however on the physiological self-regulation level. The significant improvement of a diverse range of ailment conditions is a secondary effect as the physiological parameters are improved and the body is enabled to correct its dys-functions mainly by improved ATP production.

The process-based BEMER Therapy is now well established in most western countries and is based on state of the art ongoing fundamental as well as medical research.

As the treatment is not indication-based it does not fall under the chemical protocol type validation. A treatment that is non-invasive, non-ingestive and completely without negative side-effects will have to be validated differently to pharmaceutical products. However, if claims of healing for specific indications are made other protocols have to be applied.

MEDICAL IMPACT

In practice the new technology was applied by numerous medical practitioners in many countries and used in conjunction with other therapies or as stand-alone therapy with excellent results. While such results are strictly speaking anecdotal, they certainly fall within the realm of Evidence based Individual Decision-making Medicine (EBID) [16]. It is important to note that almost all medical practitioners see the BEMER as a welcome supplementary tool in the treatment of very therapy-resistant cases, especially the chronically ill and the elderly. But the therapy also shows high efficacy for acute cases, injuries (edemas and hematomas) as well as maintenance of vitality and

performance through the direct influence of the cellular metabolism and blood circulation.

By 2004, Kafka [6], Michaelis [8], Bohn [9] and a group of other researchers, had made considerable impact in the area of alternative and natural medicine practitioners. This was quickly taken up by university trained medical practitioners and other researchers internationally and tested in practice.

It is here where Dr Rainer Klopp made considerable inroads into the verification of the physiological changes with respect to microcirculatory flow initiated by the BEMER specific PEMF treatment.

This seminal work by Klopp [10] on the theoretical aspect of human micro circulation and the empirical work covering pharmaceutical substances as well as PEMF treatment of the new technology has a wealth of information elucidating in detail the reasons for the success of such treatment in a diversity of conditions.

The work that was carried out until recently (2009) was all done under the conditions of ethical and GCP (Good Clinical Practice) standards. Klopp describes in excellent style, technical accuracy and scientific detail the measurement techniques and the analysis of all data so obtained.

Klopp is the leader in this field as evidenced by his prolific output on the subject of the significant and beneficial influence of the BEMER Signal on micro-circulation and its secondary effects. He pushed the new generation PEMFT credibility to a new level.

The treatment is suitable for almost all ailments and conditions for people of any age and any situation which can only be understood in a new cellular-dynamics improvement paradigm alluded to above. The conventional wisdom defines that specific situation A can only be treated with the best possible solution X and condition B with the state of the art solution Y. The new paradigm could make the possibly dangerous assumption that a proper diagnosis is not necessary as the body's self-regulation ability to optimize the body for optimum performance and vitality will correct all non-ideal situations (ill-health). That is not what we advocate. However, it is very unnerving in medical circles when an ailment / disease or illness can be treated with something as simple, something as profound, something as safe and something as effective as the new generation PEMFT with the BEMER Signal now has been proven to be.

It is here where the last aspect of the paradigm shift comes into significance: How to convince the individual medical practitioner that the principles by which this new generation technology can help to promote individual health care in contrast to sickness management.

This is even more vexing when the actual treatment is as easy as lying down and pressing some buttons on the digital control box that generates the BEMER Signal and adjusts its intensity according to treatment requirements. The treatment lasts between 8 and 30 minutes in total, cannot be overdosed and is completely without side effects.

Its efficacy in terms of pain alleviation, wound and fracture healing and in the treatment of chronic ailments including such ailments as diabetes 2, rheumatism and arthritis which are after all lifestyle diseases, is remarkable to say the least.

In the final analysis the treatment must be further investigated by many other independent researches to confirm or reject the observations made over the last 10 years in as a diverse a field of medical specialization as possible. That is clear. But as the treatment attacks any medical problem at a more fundamental level – cellular, circulatory and self regulatory – the process-based approach reminds us of the hand-washing process of the Hungarian Medicine Professor Ignaz Semmelweis in 1861. [17]

Despite various publications of results where hand-washing reduced mortality below 1%, Semmelweis' observations conflicted with the established scientific and medical opinions of the time.

Semmelweis' practice only earned widespread acceptance years after his death as the paradigm in the medical profession of his day could not accept a Kuhn-like paradigm shift.

STRATEGIC BUSINESS MODEL

To be able to distribute a medical device of such far-reaching positive and relatively simple application requires at least nine key-considerations:

1. Registration as a medical device
2. Accreditation at Medical Association Level
3. Providing credible information to medical practitioners
4. Providing CPD accredited education to medical practitioners
5. Providing training on the medical device for all users
6. Convincing individual practitioners to incorporate the new technology into their practices
7. Building a medical niche for the new technology
8. Building a reliable network of practitioners
9. Working in close co-operation with medical practitioners, research organizations and users.

The first five points are relatively easy if the professional work of accreditation, correct and clear information and ethical as well as practical considerations are met satisfactorily. This has

already been accomplished in most of the 50 countries where the BEMER Device is available.

Point 6, of overcoming the natural skepticism of the PEMF therapy with the old PEMF treatment discredited and not ever taught at medical school, is analogous to marketing an alien concept in a different culture to your own. The practical overcoming of the Kuhn – Semelweis Paradigm shift problem.

Only a mind-set change can accommodate the treatment of a patient with a specific set of conditions with an universal process. Whilst this is understandable, it is paramount that the new technology be introduced with the necessary sensibility and professionalism, with convincing scientific arguments and practical results but also with the necessary energy and determination.

Advances in a therapy that has been largely dismissed as medically ineffective, or rather unverified after 20 years or more is very difficult to achieve. Yet, during CPD (Continuous Professional Development) approved seminars and at hospitals the soundness of the research and the scientifically presented information usually provides some openness to the new paradigm of process-based treatment.

Aspects 6 to 9 deal with promoting and building a niche and a level of medical acceptance on the new technology product which has tremendous possibilities of home care and home treatment.

It is in these last areas where pertinent aspects of the management model developed by Winzker [18] have been used.

The selected anchors of the management model considered in the implementation are:

1. Professional empathy (paradigmatic situation)
2. The time-space aspect in which most medical practitioners find themselves currently
3. The integrated or system thinking aspect of the new paradigm
4. The continuously applied re-assessment of results observed and their fit in the new paradigm
5. The introduction of the new paradigm in this particular context of PEMFT to Medical Schools on a scientific basis
6. Education for the general public and medical practitioners as to the advantages, benefits and effects of the new generation PEMFT technology.

These anchors have been applied for the last 8 years to different degrees and with varying competence by the authors through public and medical seminars, workshops and interactions with medical practitioners, medical insurance institutions, hospitals and other medically and sport related

bodies. Cause for optimism is getting better and better as the new generation's physiological effectiveness and the resultant significant improvement of a diversity of ailments and conditions have improved.[19] [20]

DISCUSSION AND CONCLUSION

PEMF Therapy is at least 50 years old and was applied rather sporadically in practice. The medical results were not rigorously verified and regarded as unreliable. Only during the last decade has the technology been revisited and brought to a standard of understanding and application which provides quantifiable, repeatable and consistent results.

The decision to invest in the development, accreditation and commercialization depends on the acceptance of the various medical practitioners that could use the treatment as yet another tool in the medical toolbox.

The challenges related to changing a paradigm in the profession are considerable on the individual practitioner level, if not at the institutionalized level. Researchers and Medical Associations tend to be more open for a revisiting of an old technology traded as a medical treatment and discovering that the new technology keeps all the promises and more.

Convincing a medical professional of the acceptance of a contrary paradigm, a paradigm that goes against the principle of symptom-based treatment as the sole model for medical treatment is akin to operating a business in a foreign culture where all the aspects pertaining to culture have to be addressed in the day to day interactions with individuals. The management model developed for a holistic approach to the multi-disciplinary complex engineering systems has been adapted to this task and so far it is showing good results.

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