RITM SCENAR®

scenar health usa

The solution to affordable, effective pain management for all Americans

---

A position paper

For more information please contact
Helen Gracie 1800 680 6394
email: admin@scenarhealth.us

FDA Cleared

510K CLEARANCE No.
K092117

Health Canada

Medical Device Bureau
Licence No. 86149

This position paper is intended to provide information on the technology, use, safety and effectiveness of Self Controlled Energo-Neuro Adaptive Regulator: RITM SCENAR®

Introduction

RITM SCENAR® is an advanced form of electrotherapy and is effective and may be used in treating acute ,chronic pain and post operative. RITM SCENAR® therapy functions on two physiological principles: that the body has its own healing capabilities and that it is continually employing processes of self-regulation to maintain health.

The RITM SCENAR® device is a small, hand-held device with transdermal electroneuro-stimulator, graphic display (Professional models), light emitting diodes (models for home use) and audible indications. It delivers non-invasive, computer-modulated therapeutic electro-stimulation via a patient's skin and involves high amplitude, short-duration waveforms with little discomfort to patients. Due to this device's high amplitude, small unmyelinated 'C' fibres can be stimulated to a higher degree than with other forms of electrotherapy. When sufficiently stimulated 'C' fibres trigger neuro- and regulative-peptide release with resultant pain relief and healing. The RITM SCENAR® impulse is carried via afferent nerve fibres to regulatory centres in the brain which in turn responds via efferent nerve fibres. RITM SCENAR® interprets this response and, via computer modulation, results in its next impulse being modified accordingly which further provides information back to the brain to either amplify or dampen the pathological signals initiating pain, ultimately leading to homeostasis. RITM SCENAR® therapy protocols include rating of pain, measurement of range of movement and testing of movement related to functional impairment.

The RITM SCENAR® device is small, portable, user-friendly, safe, and is relatively low-cost. Patients may benefit from faster recovery times, versatility and no concurrent medication interactions. The RITM SCENAR® has been cleared for marketing by the FDA and Health Canada for use in treating Chronic & Acute Pain.

RITM SCENAR®

Definition

RITM SCENAR® is an acronym for Self Controlled Energo-Neuro Adaptive Regulator.
SC - Self-Controlled The RITM SCENAR® device establishes a biofeedback link with the body when in use, constantly changing the properties of the applied electric impulses, depending on the measured reaction from the body.
EN – Energo-Neuro The effect of RITM SCENAR® is based on electric impulses of a specific shape; patterned after the natural nervous discharges of the human body.
AR – Adaptive Regulator The RITM SCENAR® device not only provides direct therapeutic effect, but also activates the natural defences of the body [1] [2]. The effect is achieved through the stimulation of reflective zones and acupuncture points on the skin surface.

[1] Gorodetskyi I G, Gorodnichenko A I, Tursin P S, Reshetnyak V K, Uskov, O N: Non-invasive interactive Neurostimulation in the post-operative recovery of patients with a trochanteric fracture of the femur. J Bone Joint Surg [Br]2007;89-B:1488-94.
[2] G. Gorodetskyi et al, The effects of non-invasive, interactive Neurostimulation on pain and edema during post-surgical rehabilitation following internal fixation of unstable bi-malleolar ankle fractures, Presented as a poster by Dr James Dillard at the IASP 2008, Glasgow, Scotland. Accepted for publication Dec 2009, Journal of Foot and Ankle Surgery

Overall, RITM SCENAR® is an effective, non-invasive medical technology, which works by stimulating the body's inherent self-healing mechanisms. Its direct effect is several times stronger than other physiotherapeutic devices, with no undesirable side effects. [3] [4] [5] [6] [7] [8].

Brief History: from TENS to RITM SCENAR®

An early form of electro analgesia (or reduction of pain by electrical stimulation) dates as far back as Ancient Rome 46AD where Scribonius Largus used the shock of a torpedo ray to manage headache and gout. Over the centuries, and with the advent of electricity, electro analgesia in many forms has been proposed. The transcutaneous electrical nerve stimulator (TENS), introduced in the 1970's as an alternative therapy to pharmacological treatments to chronic pain, was acknowledged as a viable method of pain management by America's Food and Drug Administration, and several companies began the development of TENS devices. Although TENS provided electrical stimulation through a harmless electrical impulse via electrodes placed over the intact skin surface, the pain suppression was short-lived.

The development of RITM SCENAR® devices and RITM SCENAR® therapy is closely connected with RITM OKB ZAO, established in 1980. RITM OKB ZAO participated in the Russian National Program of space research during the 80's. The main task of RITM OKB ZAO was the development of methods and means of correction of the psycho physiological state of healthy people (astronauts, pilots, elite athletes, etc.)

One of their projects was to develop a device that was small, portable and economical (as in the TENS device) but to still be effective at maintaining the overall health of astronauts. A team of researchers from RITM OKB ZAO set out to design one universal non-invasive device that would not only provide long-lasting pain relief but could also correct the adaptive mechanisms of the body, thereby restoring homeostasis and health. The leading engineer Alexander Karasev started out by modifying the electrical impulse (as used in TENS) so that

---

[3] Lee KH, Chung JM, Willis WD. Inhibition of primate spinothalamic tract cells by TENS. J Neurosurg. 1985; 62: 276-287

[4] Linda S. Chesterton, Nadine E. Foster, Christine C. Wright, G. David Baxter and Panos Barlas
Effects of TENS frequency, intensity and stimulation site parameter manipulation on pressure pain thresholds in healthy human subjects
Pain, Volume 106, Issues 1-2, November 2003, Pages 73-80

[5] Garrison DW, Foreman RD: Effects of prolonged transcutaneous electrical nerve stimulation (TENS) and variation of stimulation variables on dorsal horn cell activity, Eur J Phys Med Rehabil 6:87-94, 1997

[6] Reilly JP, Applied Bioelectricity: From Electrical Stimulation to Electropathology, 1998 Springer-Verlag NY. pg 130 and 233

[7] Christie Q. Huang, Robert K. Shepherd Reduction in excitability of the auditory nerve following electrical stimulation at high stimulus rates: Varying Effects of electrode surface area Hearing Research 146 (2000) 57-71

[8] Pyne-Geithman G, Clark J F, InterX elicits significantly greater physiological response than TENS: Lymphocyte metabolism and Cytokine production. Presented as a poster at IASP 2010, Montreal, Canada. Aug. 29th 2010.

this new device could correct the body's adaptive mechanisms resulting in homeostasis and health. However, two criteria had to be met: the device had to have biofeedback and the signal had to be identical to the body's neural impulses (i.e. compact, short, with high amplitude and with no habituation).

The first RITM SCENAR® prototype was manufactured in 1976 by RITM OKB ZAO. which could be manipulated over the body (as opposed to the TENS device) enabling the device operator to compare the body's responses in order to choose the best zones for treatment.

A team of doctors and scientists including Alexander Revenko and Yuri Gorfinkel were involved in formulating the treatment methodology of RITM SCENAR®. They discovered that all local reactions in the treatment zones in RITM SCENAR® therapy were indicative of the general dynamics of the whole body. The treatment method involved the operator choosing the optimal treatment zone according to the body's reactions to RITM SCENAR® therapy. These optimal reactions were termed the Small Asymmetry.

In 1990 the USSR Health Care Ministry permitted serial production of RITM SCENAR® devices and officially accepted the technology to be used in the national health care system.

In 1999 RITM OKB ZAO established a joint venture in the Netherlands – Intermediate Services BV to manufacture RITM SCENAR® devices for the European market.

Following ISO 9001, ISO 13485 and the CE Mark in 2006, RITM SCENAR® devices become available worldwide including Australia.

RITM Australia was established in 2006 as a branch office of RITM OB ZAO with the aim of enabling affordable and easy access to RITM SCENAR® therapy in the Asia-Pacific region.

The FDA cleared RITM SCENAR® in May 2011 for the treatment of acute, chronic and post operative pain.

Canada health approved RITM SCENAR® for pain management on May 18th 2011.

RITM America & RITM Canada were established in 2011 to import & distribute RITM SCENAR® to the USA & Canadian Markets.

Scenar ® Technology

RITM SCENAR® technology relies on the body's mechanism of adaptation ensuring dynamic equilibrium or, homeostasis. Regulation of the body's vital functions is achieved through close connection and interaction of the nervous and endocrine systems. The effects of these

systems results in the release of biologically active chemical modulators called neuromediators. Examples of these are acetylcholine, adrenaline and nor-adrenaline. Amino acids are another type of chemical modulators. These are important in activation of the thickly myelinated A- and B-neural fibres. Examples of this modulator include glutamine and asparagine. The largest group of chemical modulators are the neuromediators and includes endorphins (the *'feel good'* chemical modulator), enkephalins and bradykinin.

In RITM SCENAR® therapy the most important chemical modulators are neuropeptides. These are the main modulators of neural activity of the thin non-myelinated, 'difficult-to-excite' C-fibres. These neuropeptide-producing nerve fibres make up more than 70% of the body's neural tracts. C-fibre's specific properties enable the production of a powerful analgesic effect, which is brought about by the release of neuropeptides, once the C-fibre is activated.

The main goal of RITM SCENAR® therapy is to activate maximum number of C-fibres to induce the secretion of a sufficient amount of neuropeptides. This is achieved by active feedback, bipolar electric impulse and individually dosed influence.

Active feedback

The most unique characteristic of RITM SCENAR® is that it can induce changes in the parameters of its impulse automatically and in accordance with the body's response to the device. While conventional therapeutic devices are passive, RITM SCENAR® involves active reflex biofeedback, which means that the device communicates actively with the processes that are happening in the body. The RITM SCENAR® device does this by monitoring the skin's impedance and then changes the electric impulse it is sending out in accordance with the changes in the skin's impedance. Therefore active reflex biofeedback means that maximal therapeutic effectiveness can be achieved.

Bipolar electric impulses

The characteristics of the RITM SCENAR® impulse are such that the probability of excitation of the thin neuropeptide-secreting C-fibres is higher than conventional methods of electrotherapy [9] [10] [11]. RITM SCENAR® enables a maximal part of the nervous tissue to be activated. This is necessary for the achievement of an optimal response from the patient's body. Furthermore, RITM SCENAR® is a system of monitoring and response. The body creates electromagnetic and acoustic fields. In a pathological state these fields are modified. It is these signals that are detected by RITM SCENAR® and are used to form the therapeutic impulses from RITM SCENAR®. RITM SCENAR® therefore enables a unique interaction between it and the patient's body.

The electrical signals generated by the RITM SCENAR® device are similar in form to the body's own endogenous neurological impulses. In this way the body does not recognize them as

[9] Somers D, Clemente F R, TENS for the management of neuropathic pain: The effects of frequency and electrode position on prevention of allodynia in a rat model of CRPS type II, Phys Ther, Vol. 86, no.5, 2006: pg 698-709

[10] Han J S, Acupuncture: neuropeptide release produced by electrical stimulation of different frequencies. Trends in Neurosciences, Vol. 26, No.1, January 2003

[11] Hamza, M.A. et al. (1999) Effect of the frequency of transcutaneous electrical nerve stimulation on the postoperative opioid analgesic requirement and recovery profile. Anesthesiology 91, 1232–1238

alien or invasive therefore negative side effects as a result of the therapy are virtually non-existent.

An important and unique characteristic of RITM SCENAR® is that it is independent of any other devices. It is physically controlled by a trained therapist who observes the treatment process and ensures the device's function. In this way the patient, the device and the therapist create a 'treatment triangle'. This treatment triangle is essential for *correcting* the disturbed function of the body and for *completing* the adaptive reactions of the body, resulting in the restoration of homeostasis.

Individually dosed influence

RITM SCENAR® can be used regardless of the type of diagnosis and is therefore a non-specific approach. However depending on the complaint or ailment of the patient the therapist can choose the dosage of RITM SCENAR® or the direction in which RITM SCENAR® is applied. In this instance the therapist is only a facilitator of RITM SCENAR® therapy with the body-device interaction being responsible for healing.

Clinical experience with this device has further indicated that the optimal therapeutic effect is achieved when there is a maximal variability of the impulse during treatment [12] [13] [14]. The optimum therapeutic results are always dependent upon the patient's body's response and therefore individual to each patient. As the RITM SCENAR® device monitors and evaluates treatment results it independently delivers the correct impulse without the possibility of overdosing and hence little or no side effects. Please refer to section discussing *Safety of* RITM SCENAR® for full breakdown of indications, contraindications, cautions and side effects.

RITM SCENAR® Device

RITM SCENAR®is an original treatment device whose design and function is based on 25 years of clinical research. RITM SCENAR® devices stimulate the skin surface with electrical impulses that are based on the natural patterns of the nervous system.

[12] Melzack R: Prolonged relief of pain by brief, intense transcutaneous somatic stimulation. Pain. 1975;1: 357-373.

[13] Chandran P, Sluka KA. Development of opioid tolerance with repeated transcutaneous electrical nerve stimulation administration. Pain. 2003;102:195–201

[14] Josimari M. DeSantana, PhD, Valter J. Santana-Filho, MSc, Kathleen A. Sluka, PhD: Modulation Between High- and Low-Frequency Transcutaneous Electric Nerve Stimulation Delays the Development of Analgesic Tolerance in Arthritic Rats Arch Phys Med Rehabil Vol 89, April 2008: pg 754-760

Hand-held device for professional therapists

The RITM SCENAR® Professional series devices are designed for medical and health care practitioners to complement their treatments or to provide specialist RITM SCENAR® therapy.

The RITM SCENAR® Professional series devices measure the electrical activity of the body (skin impedance) and display the information on a LCD screen. This allows the practitioner to view current readings and choose the most appropriate mode of operation and zone of treatment.

The RITM SCENAR® Professional series devices can be set up with various amplitude modulations depending on the stage of the complaint process, treatment area and the individual response of the body.

Five Damping modes are used according to the complaint phase, skin sensitivity and body response.

The practitioner can control and modify the complex electrical waveforms and frequencies of the RITM SCENAR® device such as impulse intensity, duration of gaps between impulses, power influence and other parameters of the device to achieve optimal treatment results.

Different Frequencies can be utilized for treating degenerative processes or for treating inflammatory processes.

RITM SCENAR® Pro: the entry-level Professional RITM SCENAR® device has a subjective, Non-diagnostic mode (Diag 0), as well as an objective diagnostic mode – Diag1, enabling the practitioner to localize the most optimal treatment zone and time.

RITM SCENAR® Expert device supports two more diagnostic modes: Diag 1 and Diag 2 and one Screening mode – Diag 3, plus an unique feature - BEE Mode, suitable for emergency situations. The Expert device with its robust casing design is also suitable for Veterinarians or mobile practitioners treating in the field.

RITM SCENAR® Pro+ is the most multifunctional and advanced model and is designed for advanced users providing specialist RITM SCENAR® therapy.

RITM SCENAR® device for home users

Simplified and easy to use versions of RITM SCENAR® Professional models are available for home users.

These models are designed for individuals to use as a home use product or for support during professional RITM SCENAR® treatment. They provide simple and effective pain relief treatment. Available by prescription only.

RITM SCENAR® Therapy

Scientific and technological research exists to advance human knowledge with the aim of improving comfort and our health and well being. Being an original scientific development RITM SCENAR® devices and treatment methods are based on 25 years of ongoing clinical research. The RITM SCENAR® device, produced by RITM OKB ZAO, offers general therapeutic non-invasive treatment to the body's physiological systems, via the skin, in order to relieve pain. The basis of RITM SCENAR® function is dependent on the communication systems within the body during health and disease. These systems and their function in relation to RITM SCENAR® will be addressed.

Principles of RITM SCENAR® Therapy

Any living creature constantly regulates its internal processes in accordance with its own requirements and in response to environmental conditions. This self-regulation, which is necessary for the survival of all organisms, is dependent on a constant flow of information being delivered to the brain from the nervous, endocrine and circulatory systems. Of these systems the quickest is the nervous system which delivers its information via electric impulses. This vital biological system, its components and the way RITM SCENAR® is hypothesized to interact with it, are discussed next.

Biological foundations of RITM SCENAR®

The nervous system provides the principal function of a living organism and is composed of both central (brain and spinal cord) and peripheral components with the latter having both somatic and autonomic (parasympathetic and sympathetic) subdivisions. The central nervous system's major function is to receive, process, and send out information. To accomplish this, the brain, which is composed of inter-related but specialized areas of function, carefully coordinates all incoming and outgoing signals through these areas via a network of connections. Because of these specialized areas that interrelate, any interruptions (no matter how minor) that occur in any part can disrupt certain functions or behaviours.

Although difficult to separate because of their overlapping effects, changes in the nervous system can be classified as:

Structural: these are changes affecting the structure of the nervous system such as the number of neurons or synapses;

Biochemical/metabolic: this includes changes in neurotransmitters affecting cerebral metabolism;

Functional: changes here can affect the electrical activity of the nerves or the motor, sensory and cognitive processes (Timiras, 1994).

The peripheral nervous system which links the brain with the skin, muscles and internal organs, via the spinal cord, orchestrates the processes that are not under conscious control. The central nervous system is either attenuated or stimulated via the parasympathetic and sympathetic subdivisions, respectively, depending upon the stimulus. This is carried out through the secretion of neuro modulators (via the nervous systems) and hormones (via the endocrine system) which act quickly to re-establish homeostasis or to shift the equilibrium point for adaptation to the new environmental conditions. In this way the body is able to constantly monitor changes within its environment enabling the body to survive and even resist disease and injury. However, the body and its systems can be placed under levels of duress from which the body may not be able to spontaneously recover. This can result in disease, injury and/or dysfunction. It is then necessary to seek medical attention which can involve conventional, modern or traditional healing practices.

The methodologies of many traditional healing practices such as acupuncture and acupressure are based on the fact that the skin and nervous system have the same embryological origin. The skin, which is a large sensory organ, remains linked throughout adulthood to the nervous system. It plays a unique role in providing a protective barrier to the body. Stimulating nerve endings within the skin at particular points are believed to effect changes in internal organs. Similarly, stimulating active points on the skin via electric impulses which follow the pattern of those of the central nervous system are hypothesized to stimulate and optimize the regulatory functions of the nervous system restoring health.

RITM SCENAR®, which is a therapeutic electrotherapy delivered via the skin, is hypothesized to produce both local effects (by stimulating the skin, muscle and blood vessels) as well as a general influence (by influencing nervous and endocrine systems). It is further hypothesized that the pattern of RITM SCENAR® impulses stimulates nervous pathways via active points in the skin in an effort to restore and to improve the regulation of the disease-affected organs and tissues. The RITM SCENAR® device is aimed at stimulating the skin surface with specifically shaped impulses. Constant measurement of electric skin parameters enables an intelligent feedback mechanism (via a patented modulation algorithm). This involves the patient (who senses the stimulation), the device (which measures the skin parameters monitoring dose duration and intensity of impulse), and the operator (who applies the device in the appropriate location for the necessary amount of time).

Initial observations

The use of RITM SCENAR® is governed by the *primary* and *secondary* signs of the patient's body and these are as follows:

Primary Signs

The label *primary* signs refer to the patient's complaints or discomforts. These can include pain, swelling and loss of sensation. Other primary signs are wounds, rashes, ulcers, scars and discoloration observed on the skin prior to RITM SCENAR® treatment.

Secondary Signs

The *secondary* signs are observations made during treatment; they are the patient's response to treatment and can indicate the areas that are most sensitive to RITM SCENAR®

treatment. Such effects can be any localized changes taking place during or immediately following treatment. These can include skin becoming paler (or redder), or an increase in pain or itching or loss of skin sensitivity. These effects can be observed in the area directly being treated or in other areas of the body.

Secondary signs can also be observed emanating directly from the device, or as a result of contact with the patient, and can include the appearance (or disappearance) of a humming sound, the presence of 'stickiness' or indeed smoother movement of the electrode as it is being used, meaning that these zones may require a shorter treatment time.

An overall general response of the patient can be described as taking place either during or directly after treatment, where the patient may experience sudden sleepiness, or conversely, an energized sensation. The patient may also feel warmth and sweating. This generalized patient response is an indication that a shift in the energy balance has been achieved and can further indicate that the treatment session has been completed.

Observed Clinical Effects of RITM SCENAR® therapy

- Pain Relief:
- Autonomic responses from the patient:
  Sympathetic – in some cases patients may begin to perspire, heart beat and blood pressure increases slightly, patient feels warm
  Parasympathetic – after 10 to 15 minutes of RITM SCENAR® treatment, most patients become relaxed, heartbeat slightly decreases, and blood pressure normalizes;
- Post treatment – most patients report having prolonged deep sleep 'first time in years'
- Range of motion increases due to muscular relaxation;
- Microcirculation – increased – directly under the RITM SCENAR® electrode one can see erythema after a few minutes of application;
- Feeling of well-being, lightness, relaxed, sleepy, but not tired;

Note:

Under the conditions of the licences both in USA and Canada we can only claim the benefit of pain relief until further research is conducted to allow further claims.

Safety of RITM SCENAR® therapy

Indications

The FDA and Health Canada have cleared RITM SCENAR® Devices for treatment of chronic and acute pain.

Contraindications

There are specific contraindications and this includes patients who have any type of cardiac pacemaker, patients who are prone to seizures, e.g. epileptic seizures, pregnant women or intoxicated individuals.

Also contraindicated is placement of a RITM SCENAR® electrode over malignant tumours or open wounds.

It is important to note however that RITM SCENAR® is *not* contraindicated for patients who have metallic implants such as pins, plates, and screws nor is it contraindicated for patients who have had joint replacements.

Cautions

RITM SCENAR® electrodes should not come in contact with wet skin. Natural body secretions such as sweat are acceptable however. It is also recommended that jewellery be removed prior to treatment with RITM SCENAR®.

Particular caution should be taken when RITM SCENAR® electrodes are placed over areas associated with phlebitis and thrombophlebitis as these conditions have increased change of blood clot formation which could become dislodged during RITM SCENAR®treatment.

It is important to note that treatment sessions with RITM SCENAR® should not exceed 20 minutes to any specific area of the body and that there should be a minimum of two hours between treatment sessions to avoid skin irritation.

RITM SCENAR® Therapy Safety Studies

Between 1988 and 2004 studies were conducted in the following institutions:

- The P.Anokhin Normal Physiology Research Institute, USSR Academy of Medical Science 1988.
- The N.Burdenko Institute of Neurosurgery, USSR Academy of Medical Science 1990.
- The Central Research Institute of Reflexotherapy of the USSR Ministry of Public Health 1991.
- The N.Priorov Central Research Institute of Traumatology and Orthopedics, Ministry of Public Health of the USSR (RF) 1991, 1997.
- The Research Institute of Paediatrics and Children's Surgery, Ministry of Public Health of the RSFSR (RF) 1991,1997.

- The 7th Central Military Aviation Research Hospital, Ministry of Defence of the USSR 1991.
- The I.Sechenov Moscow Medical Academy 1997, 2001.
- Moscow State Medical and Stomatological University 2001, 2003, 2004.
- The Research-and-Production Centre of Traditional Medicine and Homeopathy, Ministry of Public Health of the Russian Federation 2001.
- The Federal Scientific Clinical and Experimental Centre of Traditional Diagnostic and Treatment Methods, Ministry of Public Health of the Russian Federation 2003, 2004.
- Russian Medical Academy of Post-Graduate Education, 2003, 2004.

The objective of research was assessment of the safety and tolerability of the impact of RITM SCENAR® treatments. This research illustrates that RITM SCENAR® treatments are safe and will be tolerated without any side effects or adverse reactions.

Use of RITM SCENAR® therapy

General methodology

From the stage of embryogenesis the skin and nervous system arise from the same layer in the embryo, the ectoderm. These same origins mean that the nervous system and the body's organs and activities are interlinked and the nervous system therefore plays an important role in regulating the body's activities. RITM SCENAR® therapy methodology, which is applied via the skin, works via the nervous system to benefit organs within the body.

The functioning body creates electromagnetic acoustic fields, which form the body's general spectrum of impulses. In a pathological state the body creates unique physiological impulses. It is these signals, which are perceived and used to form the therapeutic impulses of the RITM SCENAR® device. The RITM SCENAR® impulse is at the same level as the body's own physiological signals so it is not detected as foreign.

Zones of treatment

A planned treatment course, which is a pre-set algorithm aimed at healing, consists of general, local and additional zones.

Local Zones are the surface projections of affected organs where the primary signs are observed. Treatment of the local zones restores any disruptions between the affected organ and the body's regulatory systems.

General Zones influence the regulation centres and aid in achieving the shortest path to homeostasis. Treating the General Zones in any complaint or condition usually achieves a good result hence these zones are treated in every session of the treatment course. The General Zones include the spinal pathways, (the 3 Pathways and 6 Points) the neck and shoulder area (the Collar zone), the abdomen and the 'Palm' (gynaecological zone).

Additional Zones are those responsible for the function of major blood vessels, lymph nodes, the liver, adrenal glands, ovaries, scrotum, tongue, ears and immune system sensitive zones.

Also treated is 'Su Jok' hand and foot zones. According to Su Jok practice there are active points on the hands and feet linked to various organs and body parts which when stimulated, such as with massage or acupuncture, can result in treating or preventing diseases in organs linked to those active points.

For patients who have numerous health complaints the treatment begins with RITM SCENAR® treatment of general zones, progresses to local zones where primary areas are treated as well as any secondary effects of these areas. If pain is localized to a single area then treatment starts locally followed by general zones and then additional zones.

Asymmetry

As mentioned earlier, RITM SCENAR® uses active reflex biofeedback as a way of virtually communicating with the body, detecting the impulses the body is emitting and conversely modifying the signal that the RITM SCENAR® device applies. During this interaction the RITM SCENAR® may come across 'asymmetries'.

Asymmetries are areas where it is believed that the cells and tissues of the body respond more actively than others. This can be detected by the therapist when the device becomes '*sticky' on the skin or by digital readings of the* RITM SCENAR® *device if using diagnostic mode*. The sensation of 'stickiness' implies that the therapist will sense that the device feels as if it is magnetically attracted to the skin when dragged across it. This can cause reddening, numbness or increased sensitivity of the skin.

Conditions treated with RITM SCENAR® therapy

RITM SCENAR® therapy can help to treat acute and chronic pain.

Further treatment can be performed to the painful area after the initial treatment. This can take place up to several times per day (with a minimum of two hours between each session) in particular if new complaints arise.

Certificates

International Certificates

RITM OKB ZAO has received test reports certifying that RITM SCENAR® was tested and found to be in conformity with IEC 60601-2-10:2001 + A1: 2001 and IEC 60601-1:1988 + A1: 1991 + A2: 1995 and EMC: IEC 60601-1-2:2001 (ed. 2) international safety standards, ISO 9001 and ISO 13485 international quality management system standards.

Local Certificates

Australian TGA – No: 140659, 164651
U.S. Food and Drug Administration – No: K092117
Europe: EC Directive 93/42/EEC
Korea FDA

Canada: Health Canada – DL# 86149

Conclusions

RITM SCENAR® therapy follows the basic principles of medicine in that it views the living organism as a whole, harmonising the body's tasks for optimum function of the physiological processes. The goal of RITM SCENAR® therapy is not to cure a given ailment but to promote self-regulation to a stage where the organism heals itself. Furthermore, 25 years of clinical experience and anecdotal evidence indicate that RITM SCENAR® therapy on its own can be sufficient for the treatment of pain.

References

Chernov, JN et al (2004). Advantages of RITM SCENAR® therapy in treating chronic adnexitis. RITM SCENAR®-therapy and RITM SCENAR®-expertise. Issue 9-10, Taganrog. Collection of Articles, Unpublished study.

Coleman, S. The Combination Of RITM SCENAR® And Activity Based Program For The Rehabilitation Of Individuals Affected By Paralysis. Unpublished study.

Juully Lyons, Overview of RITM SCENAR® therapy and its application to physiotherapy practice. Unpublished article

Klimova LV et al. RITM SCENAR®-therapy effect on the state of the blood plasma redox balance in patients with organ ischemic injury. Emergency Department, Rostov State Medical University (Rostov-on-Don) Clinical Trials Department, RITM OKB ZAO (Taganrog) Emergency Hospital №2 (Rostov-on-Don). Unpublished study.

Kulizhskiy BP, et al. RITM SCENAR®-therapy in Ischemic Stroke Rehabilitation, Collection of Articles. Unpublished study.

Lipkova, M. Three Case studies: Treatment Of Alopecia, Burns and Psoriasis In Bioregeneration RITM SCENAR®-Centre Slovakia. Unpublished study.

Lishnevski SA (2002). Biocontrollable electrostimulation of clinics in nervous diseases. Likarska Sprava;(7):68-70. Kiev, Ukraine.

Maklesova et al 2002. Influence of RITM SCENAR® therapy on GABA content, antioxidant and epileptic activities. European Neuropsychopharmacology: 12(3); 426.

Maljushko OA, et al. RITM SCENAR® AND ANTIHOMOTOXIC MEDICATIONS IN THE PREMENSTRUAL SYNDROM THERAPY. RITM SCENAR®-therapy and RITM SCENAR®-expertise. Issue 9-10, Taganrog. Collection of Articles, Unpublished study.

Moiseev, SV. RITM SCENAR® Technology and Sports Medicine publication, translation from Russian to English, Unpublished study.

Morse SA, et al (2010). RITM SCENAR® results from G & G Holistic Addiction Treatment Summary Report.

Mortensen, C (2009). Ritm Scenar Institute RITM SCENAR® Sport/Home Training Handbook.

Mortensen, C. (2009) Ritm Scenar Institute Level 1 RITM SCENAR® Training Handbook.

Petrov JA et al (2004). TREATING LACTATIONAL MASTITIS WITH RITM SCENAR®-THERAPY. RITM SCENAR®-therapy and RITM SCENAR®-expertise. Issue 9-10, Taganrog. Collection of Articles. Unpublished study

Sokurenko VN et al (2004). RITM SCENAR®-THERAPY IN TREATING STERILITY RITM SCENAR®-therapy and RITM SCENAR®-expertise. Issue 9-10, Taganrog,. Collection of Articles. Unpublished study.

Tarakanov AV, et al (2006). Activation of antimicrobial endogenous protection in patients with pyogenic surgical pathology. Current problems in surgery, Abstracts from the II Conference of the Department of surgical diseases, State Medical University of Rostov Rostov, Russia. Unpublished study.

Tarakanov AV et al (2009). Effect of Artrofoon and RITM SCENAR® Therapy on Parameters of LPO and Antioxidant System of the Blood in Patients with Peritonitis in Postoperative Period. Translated from *Byulleten' Eksperimental'noi Biologii i Meditsiny*, Vol. 148, Suppl. 1, pp. 136-139.

Tarakanov AV et al (2007). RITM SCENAR® in therapy of chronic insomnia and neurocirculatory asthenia in emergency doctors. Translated from Non-drug Medicine journal. Academic and research journal. №1 – 2007 - pp.37-41.

Tarakanov et al (2009). The dependence of the oxidative stress on the number of strokes in early postinfarction angina pectoris. Skoraya Meditsinskaya Pomosch (Emergency) journal.№ 2 – pp. 62-65.

Tarakanov AV, et al (2005). Multifactor mechanism of RITM SCENAR®-analgesia. Reflexology Journal, Issue No: 3 (7), Moscow, Russia.

Timiras, P. (1994). Physiological basis of aging and geriatrics, 2nd ed. CRC Press, Boca Raton.

Trembach GA, et al. Using the Method of Non-Specific Stress-Resistance Improvement for Treating the Irritable Bowel Syndrome. Russian Centre of Functional Surgical Gastroenterology, Krasnodar; RITM OKB ZAO, Taganrog. Unpublished study.

Tsimmerman IaS, Kochurova IA, Vladimirskii EV (2006). Physiotherapy of gastric ulcer and duodenal ulcer. Klinicheskaia Medicina, 7/2003, Perm, 2006, Russia

S. A. Lishnevski (2002). Biocontrollable electrostimulation in clinics of nervous diseases. Likarska Sprava 2002;(7):68-70, Kiev, Ukraine

U.U. Starovoinov, U.I. Perfiliev, A.A. Krammarenko (2007). Book General RITM SCENAR® Therapy for personal and home use.

Zaidiner B et al, (2006). Analgesia with device for sensory restoration. Support Care Cancer 14: Pp 654.

Zaidiner B et al, (2007). RITM SCENAR®-technology for chemotherapy-induced neurotoxicity. Support Care Cancer 15: Pp753.

Disclaimer:

The purpose of this position paper is to describe the technology, use, safety and effectiveness of RITM SCENAR® *therapy. While every effort has been made to ensure the accuracy of information RITM OKB ZAO and RITM Australia Pty Ltd who authored this paper disclaims any responsibility for any results of the application. No information is intended or should be used as a substitute for professional medical advice. The information contained in this position paper is based on research and anecdotal experience carried out by Russian*

scientists and the founders of RITM SCENAR® *therapy, Y. Gorfinkel, A. Revenko, and Y. Grinberg et al.*

