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# The Transcutaneous Vagus Nerve Stimulation Device of the Nu-Calm-Solace Lifesciences Gives an Output Signal that is a Multifractal : Is there a Support in the Treatment of the Atrial Fibrillation ?

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**Abstract**

The transcutaneous Vagus Nerve Device of the Solace Life-Sciences has been conceived to give a reduction or remission of a number of psychological disorders. However, it has been found by us that it has an output signal that is a multifractal. The pathophysiology of Heart Failure (HF) is characterized by hemodynamic abnormalities that result in neurohormonal activation and autonomic imbalance with increase in sympathetic activity and withdrawal of vagal activity. In normal subjects, in particular, a multifractal structure has been identified in heart rate dynamics and HRV. The pathology usually reduces or can disrupt this fractal or multifractal dynamics resulting in the alteration of its fractal properties. Atrial Fibrillation (AF) is a common cardiac arrhythmia. In previous experimental studies, the investigators found that Low-Level Vagus Nerve (VN) Stimulation (LLVNS), at voltages substantially below that which slowed the sinus rate, significantly suppressed AF inducibility and decreased AF duration. Since the above mentioned device produces a multifractal with an high multifractal strength, we encourage the researchers to experience it in their clinical cardiologic studies, and in particular, in atrial fibrillation.

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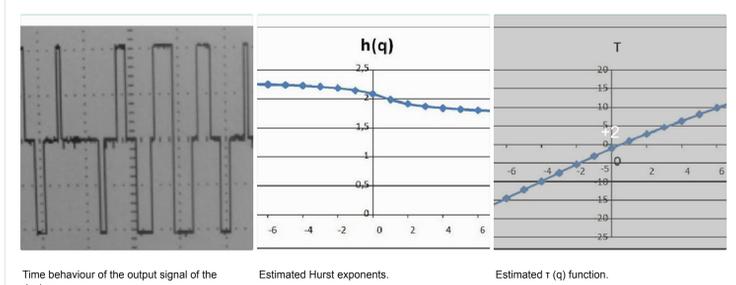
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# The Transcutaneous Vagus Nerve Stimulation Device of the Nu-Calm-Solace Lifesciences Gives an Output Signal that is a Multifractal: Is there a Support in the Treatment of the Atrial Fibrillation?

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**Introduction**

Autonomic Nervous System (ANS) is a highly complex system that affects every physiological system with an highly complex anatomy, control, and physiological influence and Autonomic Neuroscience (AN) is becoming a new advanced discipline that studies function and dysfunction of the (ANS). Dysfunction of autonomic function leads to a variety of clinical problems that can be highly at risk for subjects. One basic feature is that the cardiac rhythm is modulated by the two limbs of the (ANS), the sympathetic and parasympathetic, which exert antagonistic effects. The Sympathetic (SNS) and Parasympathetic (PNS) branches of (ANS) are known to have strong influence on the pace maker cells of the heart. Heart Rate Variability (HRV) is used to quantify activity of the autonomic nervous system. The pathophysiology of Heart Failure (HF) is characterized by hemodynamic abnormalities that result in neurohormonal activation and autonomic imbalance with increase in sympathetic activity and withdrawal of vagal activity. While dominance of sympathetic modulation characterizes several pathophysiological conditions, the appropriate vagal modulation induces normal heart rate dynamics and the correct its intrinsic variability.

Presently, electrical Stimulation of the Vagus Nerve (VNS) is an FDA-approved treatment. The important tool is that (VNS) has emerged also as a promising therapeutic approach for cardiac

diseases [1,2]. A new non-invasive stimulating procedure, called transcutaneous Vagus Nerve Stimulation (tVNS), has been developed [1]. Consequently, it becomes of fundamental importance to analyze in detail such innovating procedure under the technical as well as clinical profiles. In our studies we used the NuCalm device (<http://www.nucalm.com/>). This device applies two gel electrode patches to the neck below the ear lobe (right and left) for transcutaneous stimulation of the afferent Auricular Branch of the Vagus Nerve (ABVN). The device received FDA approval, satisfying essential health and safety requirements. Transcutaneous Vagus Nerve Stimulation (tVNS) targets the cutaneous receptive field of the ABVN at the outer ear [3]. Ear lobe vagal stimulation does not create adverse effects [4], but it does induce modulating effects on heart rate, blood pressure, or peripheral microcirculation during the stimulation procedure. The use of applied electrodes near both right and left ear lobes assures afferent and efferent induction since the right vagus nerve has efferent fibers to the heart. Of course, the use of the device is not recommended in the case of pregnancy, and is contraindicated for persons with metal in the body, such as pacemaker and ventricular assist devices or brain and cochlear implants. Actually, the whole NuCalm arrangement has been designed as a combined system of components that work together in reducing psychological disorders as anxiety, depression and stress. First the subject applies a NuCalm topical cream that has been designed to induce relax by counteracting

**Abstract**

The transcutaneous Vagus Nerve Device of the Solace Life-Sciences has been conceived to give a reduction or remission of a number of psychological disorders. However, it has been found by us that it has an output signal that is a multifractal. The pathophysiology of Heart Failure (HF) is characterized by hemodynamic abnormalities that result in neurohormonal activation and autonomic imbalance with increase in sympathetic activity and withdrawal of vagal activity. In normal subjects, in particular, a multifractal structure has been identified in heart rate dynamics and HRV. The pathology usually reduces or can disrupt this fractal or multifractal dynamics resulting in the alteration of its fractal properties. Atrial Fibrillation (AF) is a common cardiac arrhythmia. In previous experimental studies, the investigators found that Low-Level Vagus Nerve (VN) Stimulation (LLVNS), at voltages substantially below that which slowed the sinus rate, significantly suppressed AF inducibility and decreased AF duration. Since the above mentioned device produces a multifractal with an high multifractal strength, we encourage the researchers to experience it in their clinical cardiologic studies, and in particular, in atrial fibrillation.

**Keywords:** Transcutaneous vagus nerve stimulation; Heart rate variability; Multifractals; Atrial fibrillation; Autonomic imbalance; Heart failure

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... designed with the purpose to treat subjects affected by depression, anxiety, stress. The whole system consists of four components that leverage biochemistry, neurophysiology, and physics to obtain and maintain parasympathetic nervous system dominance. Previously, we have performed an HRV analysis just on tVNS only [1,2,3,4] ...

... As the second, the system uses the microcurrent stimulation patches, a tVNS system that is placed behind each ear at the Mastoid Process. Research has shown that this device induces an increase of parasympathetic response [1,2,3,4]. Next, a noise-dampening headphones are used to deliver proprietary non linear oscillating neuroacoustic software to bring the brain wave pace to the presleep stages (12Hz -4Hz) via brain entrainment. Finally, Light-blocking eye masks are used to negate visual stimuli. ...

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## Recommendations

<p><b>Project</b></p> <p><b>Complexity in Architecture</b></p> <p>Nicoletta Sala · Gabriele Cappellato</p> <p>The aim of the project is to study how the concept of complexity can appear in architecture and design.</p> <p><a href="#">View project</a></p>	<p><b>Project</b></p> <p><b>Riemann wave background</b></p> <p>Daniilo Merlini · Massimo Sala · Nicoletta Sala</p> <p><a href="#">View project</a></p>
<p><b>Project</b></p> <p><b>A meta-model of human change.</b></p> <p>Franco Orsucci · Chiara Moceani · Wolfgang Tschacher · Giulio de Felice</p> <p>This meta-model of change would combine in a nonlinear system dynamics / complexity science framework, our knowledge of common factors of change in psychology and social sciences. The model should ... <a href="#">[more]</a></p> <p><a href="#">View project</a></p>	<p><b>Article</b></p> <p><b>Model the fractal component in heart rate variability as a dyadic bounded cascade</b></p> <p>November 2011 · <i>Fractals</i></p> <p>D C Lin</p> <p>The fractal component in the long-term heart rate variability (HRV) in health and in certain heart disease conditions were studied in the framework of dyadic [1]. Consequently, it becomes of fundamental importance to analyze in detail such innovating procedure under the technical as well as clinical profiles. In our studies we used the NuCalm device (<a href="http://www.nucalm.com/">http://www.nucalm.com/</a>). This device applies two gel electrode patches to the neck below the ear lobe (right and left) for transcutaneous stimulation of the afferent Auricular Branch of the Vagus Nerve (ABVN). The device received FDA approval, satisfying essential health and safety requirements. Transcutaneous Vagus Nerve Stimulation (tVNS) targets the cutaneous receptive field of the ABVN at the outer ear [3]. Ear lobe vagal stimulation does not create adverse effects [4], but it does induce modulating effects on heart rate, blood pressure, or peripheral microcirculation during the stimulation procedure. The use of applied electrodes near both right and left ear lobes assures afferent and efferent induction since the right vagus nerve has efferent fibers to the heart. Of course, the use of the device is not recommended in the case of pregnancy, and is contraindicated for persons with metal in the body, such as pacemaker and ventricular assist devices or brain and cochlear implants. Actually, the whole NuCalm arrangement has been designed as a combined system of components that work together in reducing psychological disorders as anxiety, depression and stress. First the subject applies a NuCalm topical cream that has been designed to induce relax by counteracting</p> <p><a href="#">Read more</a></p>
<p><b>Article</b>   <a href="#">Full-text available</a></p> <p><b>ENCAINIDE REDUCES HEART RATE VARIABILITY FRACTAL DIMENSION AMONG ARRHYTHMIC PATIENTS WHO SUFFERED AC...</b></p> <p>January 2005</p> <p>Jose Luis Hernandez Caceres · Eduardo Tejera · Kiria Valdés Crespo · Luis Garcia Dominguez</p> <p><b>ABSTRACT</b> The Autoregressive Dimensional Index (ARDI) was measured in a subset of R-R recordings corresponding to 257 patients from the Cardiac Arrhythmia Suppression Trial (CAST) study, both before, and during treatment with the anti-arrhythmic drug Encainide (E). Encainide induced an average ARDI increase of 47% (P&lt;0.001, paired t-test). =&gt; A similar analysis with 127 patients treated with ... <a href="#">[Show full abstract]</a></p> <p><a href="#">View full-text</a></p>	<p><b>Article</b></p> <p><b>The { {Chaos Theory} } and Nonlinear Dynamics in Heart Rate Variability Analysis: Does it Work in Shor...</b></p> <p>June 2007 · <i>Annals of Nonlinear Electrocardiology</i></p> <p>Goran Krstacic · A. Krstacic · F.E.S.C. Anton Smalcevic M.D · Mirjana Jembrek-Gostovic M.D</p> <p><b>Background:</b> Dynamic analysis techniques may quantify abnormalities in heart rate variability (HRV) based on nonlinear and fractal analysis (chaos theory). The article emphasizes clinical and prognostic significance of dynamic changes in short-time series applied on patients with coronary heart disease (CHD) during the exercise electrocardiograph (ECG) test. Methods: The subjects were included ... <a href="#">[Show full abstract]</a></p> <p><a href="#">Read more</a></p>
<p><b>Article</b></p> <p><b>Heart rate variability, multifractal multiscale patterns and their assessment criteria</b></p> <p>October 2018 · <i>Physiological Measurement</i></p> <p>Dorota Kokosinska · Jan Jakub Gieraltowski · Jan Zebrowski · Rafal Baranowski</p> <p><b>Objective:</b> Both the central nervous system and the autonomic nervous system are complex physiological networks which modulate the heart rate. They are spatially extended, have built-in delays and work on many time scales simultaneously-nonhomogeneous networks with multifractal dynamics. The object of our research was the analysis of human heart rate variability (HRV) using the non-linear ... <a href="#">[Show full abstract]</a></p> <p><a href="#">Read more</a></p>	<p><b>Conference Paper</b>   <a href="#">Full-text available</a></p> <p><b>Heartbeat Dynamics from a Microcanonical Multifractal Approach</b></p> <p>September 2011</p> <p>Oriol Pont · Michel Haissaguerre · Hussein Yahia · Méléze Hocini</p> <p>Heartbeat dynamics is a complex system. To characterize it properly, advanced nonlinear signal-processing methods are needed. In this context, recent developments on reconstructible signals and multiscale information content have led to the Microcanonical Multifractal Formalism (MMF). The MMF provides signal-analysis techniques particularly suited to heartbeat dynamics. In particular, ... <a href="#">[Show full abstract]</a></p> <p><a href="#">View full-text</a></p>

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