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## Contents

Introduction	3
physio <b>key</b> Technology	4
Biological Foundations	5
physio <b>key</b> Therapy	6
Observed Clinical Effects of physio <b>key</b> Therapy	7
Intended Use	7
Contraindications	7

## Introduction

The **physiokey** is the latest development in neurostimulation technology, being the next step in hand held pain relief devices which have a history going back to the Russian SCENAR device. The nature of the **physiokey**'s feedback-controlled stimulation allows for a unique evidenced based application that optimises certain treatment parameters and thus achieves consistently good results across a broad range of conditions, both acute and chronic in nature.

The **physiokey** not only provides direct therapeutic effect, but also activates the natural defences of the body<sup>1 2</sup>. The effect is achieved through the stimulation of trigger points and acupuncture points on the skin surface.

Overall, the **physiokey** device is an effective, non-invasive, advanced form of electrotherapy and may be effective in treating acute and chronic pain. By stimulating the body's inherent self-healing mechanisms, its direct effect is several times stronger than that of other physiotherapeutic devices, with no undesirable side effects<sup>3 4 5 6 7 8</sup>

The **physiokey** delivers a damped, bi-phasic, sinusoidal impulse delivered through two fixed concentric electrodes. The device adjusts its output in response to changes in skin resistance or impedance. This means the **physiokey** is applied *without the need for conductive gels*, directly onto the patient's skin. This advancement in treatment has a significant impact on the way neurostimulation can be delivered and subsequently on the results that can be achieved in the clinical setting.

Every **physiokey** treatment is designed to optimise the main aspects of any neurostimulation treatment to ensure better and lasting results. Research has shown that the optimisation of various treatment parameters

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<sup>2</sup> G. Gorodetskyi et al, The effects of non-invasive, interactive Neurostimulation on pain and oedema 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.

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

<sup>4</sup> 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

<sup>5</sup> 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

<sup>6</sup> Reilly JP, Applied Bioelectricity: From Electrical Stimulation to Electropathology, 1998 Springer-Verlag NY. pg 130 and 233

<sup>7</sup> 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

<sup>8</sup> 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.

can significantly increase the effectiveness of neurostimulation across a broad range of painful conditions<sup>9</sup>  
<sup>10 11</sup>.

The correct application of the **physiokey** ensures all of these parameters are optimised and offers the practitioner a way to scientifically apply neurostimulation with evidence-based protocols and achieve excellent results.

## physiokey technology

**physiokey** technology relies on the body's mechanism of adaptation ensuring dynamic equilibrium and 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 result in the release of biologically active chemical modulators, called neuromediators. Examples of these neuromediators:

- amine: acetylcholine, noradrenalin, adrenalin, dopamine, serotonin epinephrine, norepinephrine, histamine
- amino acids: glycine, glutamic, aspartic and gammaaminobutyric acid.
- purine nucleotides: adenosine, cytidine, guanosine, thymidine
- neuropeptides: enkephalin, neuropeptide Y, cholecystokinin, substance P, neurotensin.

During **physiokey** therapy it is the neuropeptides that are the most important chemical modulators. Neuropeptide-producing nerve fibres make up more than 70% of the body's neural tracts and can therefore be stimulated from many areas of the skin. The main goal of **physiokey** therapy is to induce the secretion of a sufficient amount of neuropeptides to relieve pain and initiate a healing response. This is achieved by active feedback mechanisms, damped, bi-phasic, sinusoidal impulses and individualised treatment<sup>12</sup>.

The most unique characteristic of **physiokey** 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 physiotherapeutic devices are passive, **physiokey** involves active feedback; the device has a changing base of processing. The **physiokey** device does this by monitoring the skin's impedance and then changes the electrical impulse it emits accordingly.

The characteristics of the **physiokey** impulse are such that the probability of excitation of the thin neuropeptide-secreting neural fibres is higher than conventional methods of electrotherapy<sup>13 14 15</sup>.

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<sup>9</sup> Jan Magnus Bjordal, Mark I. Johnson, Anne Elisabeth Ljunggreen; Transcutaneous electrical nerve stimulation (TENS) can reduce postoperative analgesic consumption. A meta-analysis with assessment of optimal treatment parameters for postoperative pain. *European Journal of Pain* 7 (2003) 181–188

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<sup>14</sup> Hamza MA, White PF, Ahmed HE, Ghoname EA: Effect of the frequency of transcutaneous electrical nerve stimulation on the postoperative opioid analgesic requirement and recovery profile. *Anesthesiology*. 1999 Nov; 91(5): 1232-8.

<sup>15</sup> Heidland A et al.: Neuromuscular electro stimulation techniques: historical aspects and current possibilities in treatment of pain and muscle wasting. *Clinical Nephrology*, Vol. 79 - No. Suppl. 1/2013, p12-23

## biological foundations

physio**key** therapy functions on two physiological principles: that the body has its own healing capabilities and that we can promote this ability to heal by stimulation of the areas of the brain responsible for regulation of the autonomic nervous system and homeostasis. physio**key** technology, which is a therapeutic electrotherapy delivered via the skin, is hypothesised to produce both local effects - by stimulating the skin, muscle and blood vessels - as well as a general influence - by an effect on nervous and endocrine systems.

It is further hypothesised that the pattern of physio**key** impulses stimulates nervous pathways via 'keypoints' on the skin in an effort to restore and to improve the regulation of the disease-affected organs and tissues. The physio**key** device function 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.

The physio**key** device is a small, hand-held transdermal neurostimulator, delivering non-invasive, computer-modulated therapeutic neurostimulation via the patient's skin and involves damped, bi-phasic, sinusoidal impulses with little discomfort to the patient. These impulses stimulate both the A delta fibres, responsible for the quick, shallow first pain, and the C fibres, known to maintain the state of hyper-excitability of the painful area and the spread of the hyperalgesic state to nearby neurons.

It has been shown that an electrical stimulus activates C fibres when an intensity higher than the threshold for A fibres is used. Due to the device's delivery of high amplitude oscillating waveforms in millisecond dosages, small unmyelinated C fibres can be stimulated to a higher degree than with other forms of electrotherapy. Stimulation of 'C' fibres has been shown to activate the right and left anterior insula and the frontal operculum of the brain. The anterior insula are responsible for perception of pain and the maintenance of homeostasis within the body<sup>16</sup>.

When sufficiently stimulated, 'C' fibres also trigger local neuro- and regulative-peptide release with resultant pain relief and healing. The physio**key** impulse is carried via afferent nerve fibres to regulatory centres in the brain which in turn responds via efferent nerve fibres. The physio**key** 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.

physio**key** technology relies on the body's mechanism of adaptation ensuring dynamic equilibrium or, homeostasis. This regulation is achieved through close connection and interaction of the nervous, endocrine and immune systems. These systems communicate through the release of biologically active chemical modulators called neuromediators. Peripheral electrical stimulation promotes the release of endogenous opioid peptides such as enkephalins, endorphins, and dynorphins<sup>17</sup> and sensory neuropeptides such as Substance P and Calcitonin Gene-Related Peptide<sup>18</sup>

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<sup>16</sup> Weiss, Thomas et al (2008) "Brain activation upon selective stimulation of cutaneous C- and A $\delta$  -fibres" *NeuroImage* 41:pp1372-1381

<sup>17</sup> J-S Han and Q Wang Mobilization of Specific Neuropeptides by Peripheral Stimulation of Identified Frequencies. *Physiology* August 1, 1992 vol. 7 no. 4 176-180

<sup>18</sup> Burssens P, Forsyth R, et al Influence of burst TENS stimulation on the healing of Achilles tendon suture in man. *Acta orthopaedica Belgica* (impact factor: 0.4). 01/2004; 69(6):528-32.

## physiokey therapy

Every physiokey treatment is designed to optimise four main aspects of any neurostimulation treatment to ensure better and lasting results. Research has shown that the optimisation of various treatment parameters can significantly increase the effectiveness of neurostimulation across a broad range of painful conditions. Missing any one of these parameters could significantly reduce or even negate any clinical benefit from the treatment<sup>19 20</sup>.

**Optimal Treatment Points.** The physiokey identifies areas of low impedance. These areas of low skin impedance relate to major nerve branches, trigger points, acupuncture points, and localised areas of sympathetic skin response. Research has shown that targeting these points gets a better clinical result<sup>21 22 23 24</sup>.

**High Amplitude Stimulation.** The physiokey delivers safely and comfortably a much higher amplitude signal than would normally cause muscle contraction with a TENS or interferential. This is made possible by the feedback controlled stimulation and the fixed electrode head - the practitioner is able to deliver direct stimulation without uncomfortable muscle contraction<sup>25 26 27 28 29 30 31 32</sup>.

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<sup>19</sup> Breit R, Van der Wall H, Transcutaneous Electrical Nerve Stimulation for Postoperative Pain Relief After Total Knee Arthroplasty, *The Journal of Arthroplasty* Vol. 19 No. 1 2004

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<sup>27</sup> 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

<sup>28</sup> 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

<sup>29</sup> Reilly JP, *Applied Bioelectricity: From Electrical Stimulation to Electropathology*, 1998 Springer-Verlag NY. pg 130 and 23

<sup>30</sup> 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

<sup>31</sup> G 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.

<sup>32</sup> Carbonario F, Matsutani LA, Yuan SL, Marques AP. Effectiveness of high-frequency transcutaneous electrical nerve stimulation at tender points as adjuvant therapy for patients with fibromyalgia. *Eur J Phys Rehabil Med.* Apr 2013; 49(2): 197-204.

**Varying Frequency.** A range of analgesic mechanisms are activated when varying frequencies are used. The physiokey has a frequency range from 5 - 460Hz. All physiokey protocols ensure that a broad range of frequencies are delivered in every single treatment<sup>33 34</sup>

**Prevent Accommodation.** Research has shown that treating too often, treating too long, and treating in fixed frequencies causes the body to stop responding to neurostimulation after a period of time, sometimes as little as four 20-minute treatments<sup>35 36</sup>. physiokey protocols focus on delivering short infrequent treatments to multiple treatment points that change in every treatment, and by using a wide range of frequencies, the physiokey ensures patients continue to respond to treatment over the full treatment course.

## Observed Clinical Effects of Therapy

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

## Intended use

- Acute and chronic pain
- Increased blood circulation
- Passive muscle stimulation
- Improvement and recovery of function.
- ARTG identifier 230724

## Contraindications

- Patients who have on-demand-type cardiac pacemaker or other electrically powered implant.
- Electrode placement over malignant tumours.
- Use over open wounds.
- Patients prone to seizures.
- Alcohol intoxication.
- Pregnancy.

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