

Revolutionary Concept in the Treatment of Pain & Depression

Exploring the neurophysiological impact
of music on the human nervous system

.....in the Beginning



.....in the Beginning



HALF-MIS

High Amplitude Low Frequency Music Impulse Stimulation

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About MUSIC

- A multitude of waves (appr. 20-20.000Hz) as a function of time
- Means for transmitting emotion from the composer/ musician to a listener
- Means for coordinating and focusing brain activity
- Perception: The sense of hearing + of vibration

The system of the Pacini corpuscles

- Physiological properties, frequency optimum
- Distribution and purposes.....*WHY???* – THE CLOU
- Cortical representation of vibrotactile stimuli =
- Cortical representation of painful stimuli

Neuroanatomy of the Pacini System

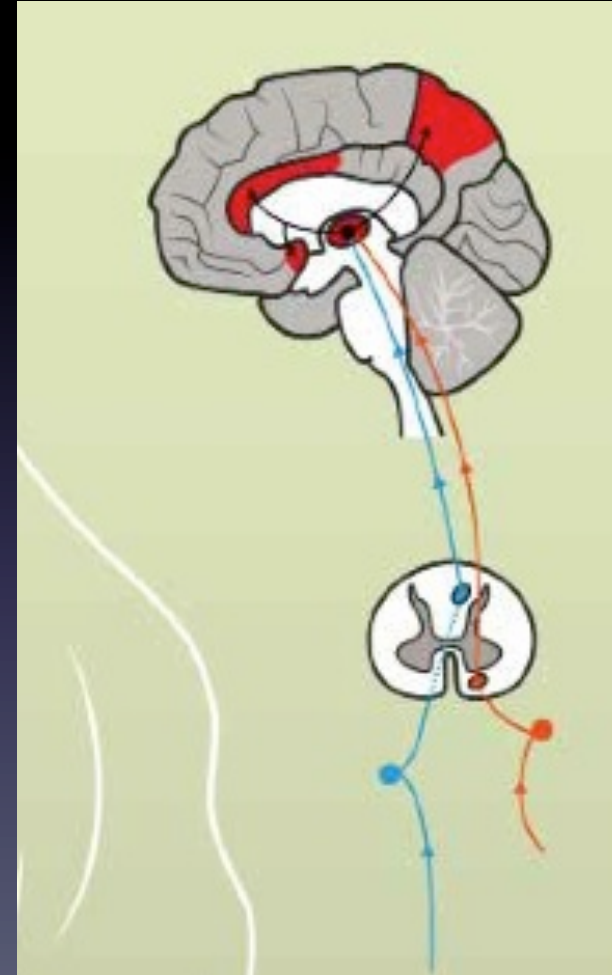
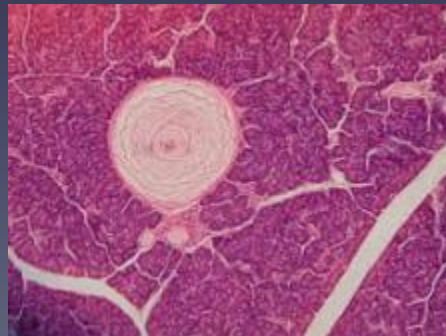
All vibrotactile input relayed in VPL

All painful stimuli, in VPL of Thalamus

Projections to the parietal lobe, S1&2

To the Limbic system

To the Brain Stem



Neuroanatomy of the Pacini System

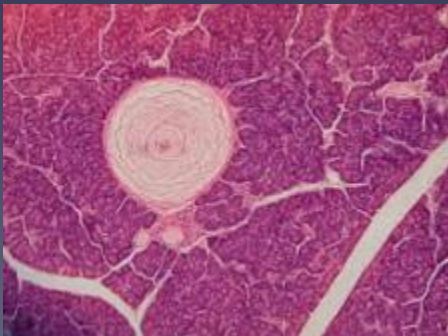
The Vagus Nerve Pathway

Afferents to Nucleus Tractus Solitarius

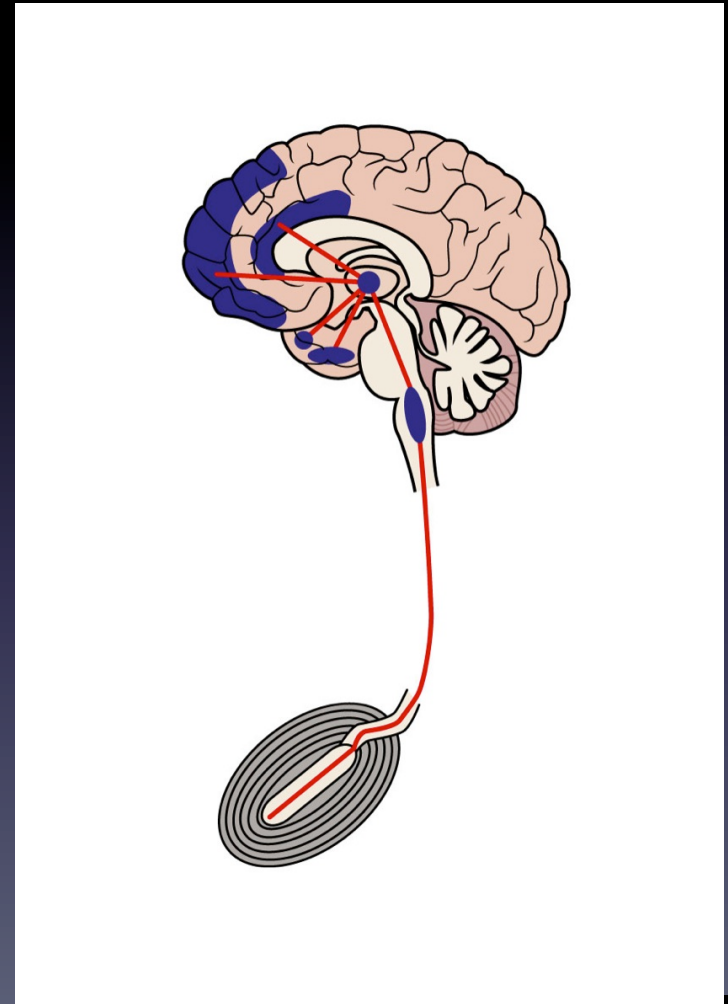
Viscero-Sensory stimuli, to VML of Thalamus

Projections to the frontal lobe, prefront.

To the Limbic system



The Pacinian Corpuscle



HYPOTHESIS

- “A High Amplitude, Low Frequency Sound Impulse Stimulation is perceived by the abdominal Pacini corpuscles”
- “This activation of the visceral vibro-tactile system results in a reduced perception of pain”

Scientific background

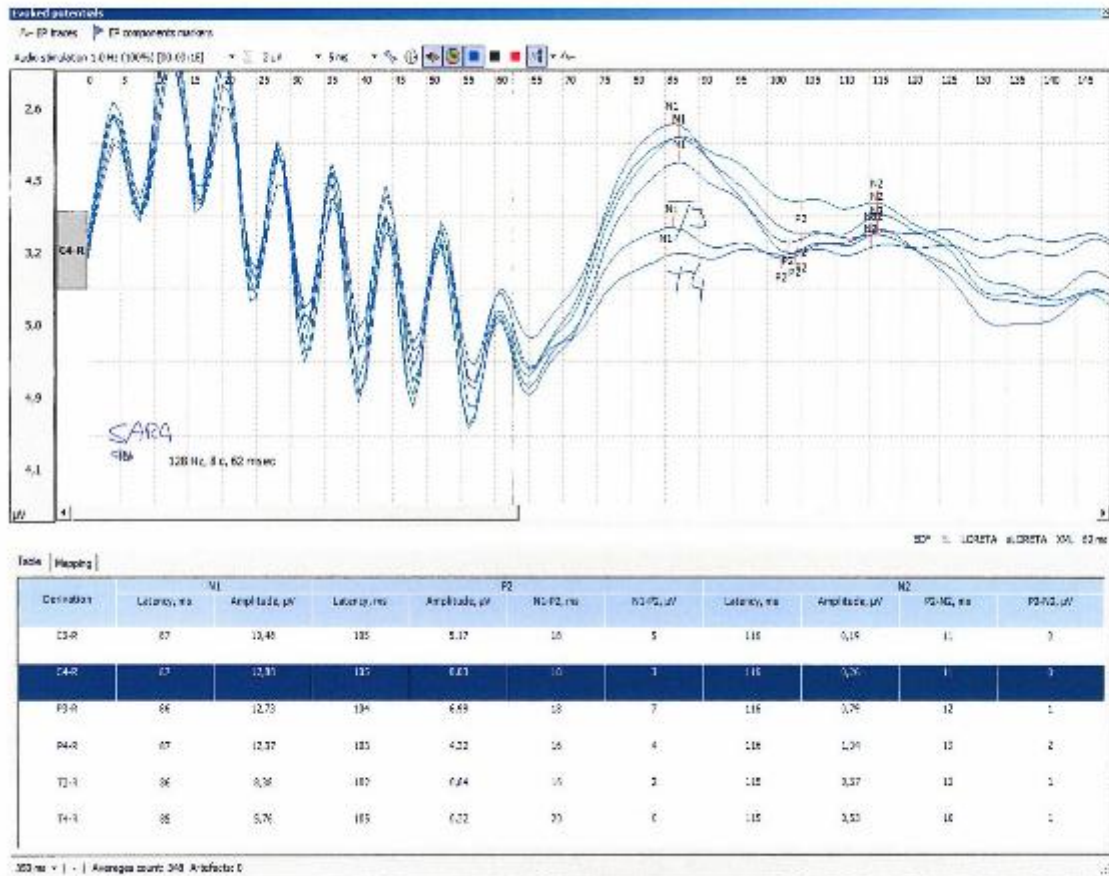
- Amassian, 1952: Double simultaneous stimulation of N. Ulnaris and Nn. Splanchnici
- Coghill et al.: Functional MRI, cortical representation of vibrotactile and painful stimuli
- About ELEPHANTS, subsonic communication
- Gate control theory and theory of neuroplasticity
- Vagus Nerve Stimulation – treatment modality

Scientific Development

Proof-of-concept & optimizing the treatment modality

- Development of the VISEP modality
- VISEP in healthy volunteers, SCI, born deafs
- Double simultaneous stimulation, SSEP/VISEP
- HALF-MIS' effect on pain threshold
- fMRI/PET brain mapping of HALF-MIS
- Clinical trials: Depression, PDPN, CPSP, pruritus, epilepsy
- Implementing HALF-MIS as a Vagus Nerve Stimulator
- The Concept of HALF-MIS Home Treatment

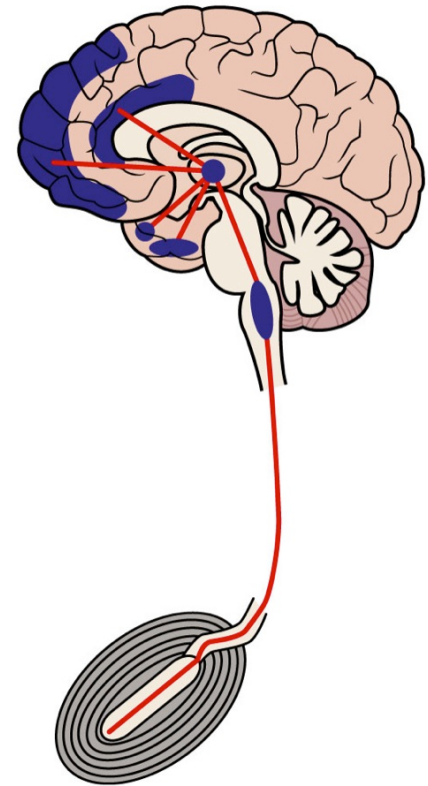
VISEP — Viscero-Sensory Evoked Potentials



VNS

Vagus Nerve Stimulation, the evidence

- Evidence-based guideline, AAN, 2013
- VNS for partial seizures, Cochrane
- VNS for treatment resistant depression
- VNS in migraine and headaches
- VNS in tinnitus
- VNS in drug addiction
- VNS in chronic pain



HALF-MIS in the treatment of Epilepsy

Implementing the VNS properties

- Xong et al.: VNS' effect - vagal outer ear branch
- VNS in ESES children – HALF-MIS is safe
- Protocol: HALF-MIS in treatment resistant epilepsy
- Protocol: HALF-MIS in ESES
- Protocol: HALF-MIS as VNS – PET & fMRI proof

HALF-MIS in the Psychiatry

Pending Protocols:

- Wang, Sigurdadottir et al.: Depression
- Precht et al.: ADHD
- Nielsen et al.: Drug abuse

HALF-MIS, RCT in Depression

Results, Protocol completed:

Treatm/Hamil	Ham17Start	Ham17Slut	Ham6Start	Ham6Slut
HALF-MIS	20.77	15,22*	11,11	7,88*
CONTROL	19,65	18,05*	10,35	9,60

* = Statistically significant

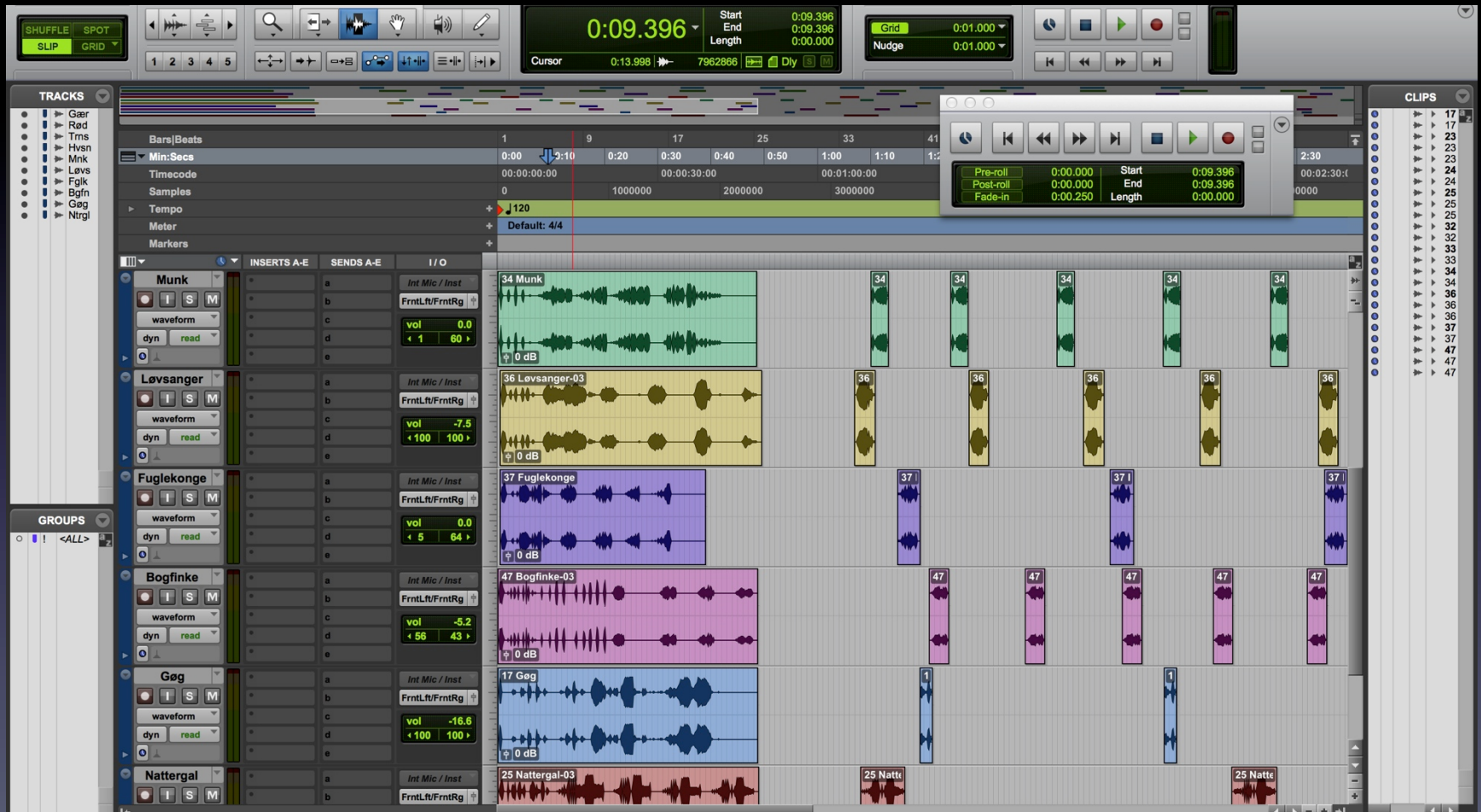
Results in Table 2 do show results for both Hamilton17 and Hamilton6. For the Halfmis group the difference for Hamilton17 at start and end 5.55 (highly significant with $p=0.001$) and for the control group 1.60 (also significant with $p=0.019$).

The difference in Hamilton6 for the Halfmis group is 3.12 (significant with $p=0.004$) and for the control group 0.75 (non-significant with $p=0.121$)

Technology of the Music and empiric evidence

- Properties of the music, rhythm, enhancing beauty
- The music development group: Palle Mikkelsen, Chris Minh Doky, Niels Lan Doky, Bernhard Lewkovitch, Niels Eje et al.
- Digital production enabling sound design of HALF-MIS
- Math. designed bass tracks – effect parameter control
- Subwoofer versus high power vibratory technology

Technology of the Music, the programming interface & environment



Product Development

The Prototype for Home Treatment

- The “vibro-generator”
- The HALF-MIS sensors –
- Transmission of patient data
- The iPad – downloading APPs
- Algorithms for optimizing
- The catalogue of music
- Measuring the effect



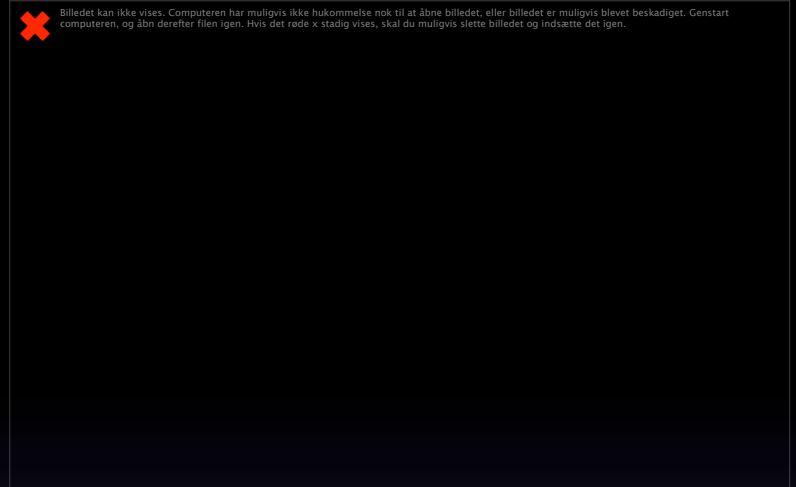
Product Development

The Prototype for Home Treatment

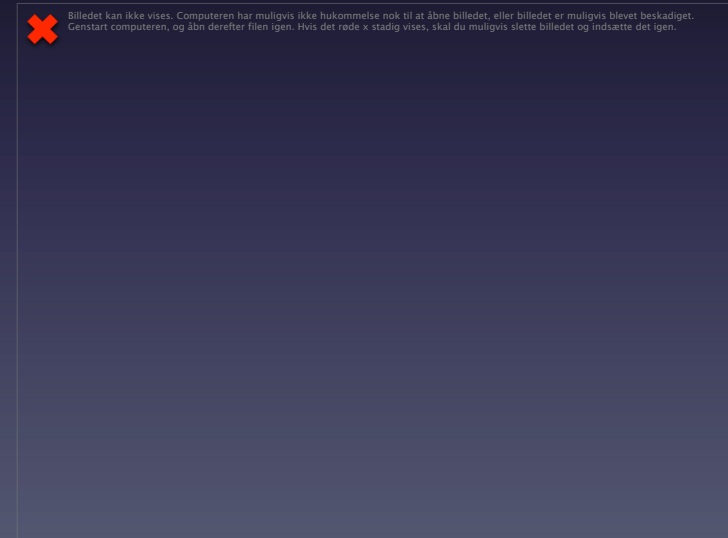


The Treatment Session

*The Patient's side/
The Doctor's side*



- The Patient is “mounted” in the chair
- The Patient starts and controls the Session
- The Evaluation
- The Doctor defines the treatment course
- Monitoring and storing the biometric data



Safety

HALF-MIS is absolutely safe!

- Non-pharmaceutical, non-invasive, non-electrical
- Earlier experience (evidence) with VAT (Vibro-Acoustic Therapy) and VAM
- Own experience – dose related uncomfotabilities
- Proof of safety according to ISO 2163
- The biosignal feed-back and patient control protection system
- The cumulated G force monitoring system – the “Nielsen”-unit
- The system of regulatory approval in the developed countries

HALF-MIS

Visions of the possibilities

- An efficient, innovative, evidence based pain treatment system
- NO side effects – NON-INVASIVE - NON-PHARMACEUTICAL
- The system is easily applicable for pain treatment at home
- ADD-ON to medical treatment
- HALF-MIS may prevent the development of neurogenic pain
- All types of pain are relieved
- Symptoms of depression and anxiety are proven to be relieved
- In severe depression ECT may be replaced by HALF-MIS
- HALF-MIS as a VNS provides a new treatment for epilepsy and migraine

Case Stories

excerpts from the HALF-SIS logs:

- Tension Type Headache
- Spinal Cord Injury
- Spasticity, CPSP & Depression
- Central Post Stroke Pain
- ADHD
- Whip Lash trauma
- CRPS (Complex Regional Pain Syndrome)
- Dercum's disease

Thank you!
And feel free to try it yourself!!!



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