EXECUTIVE SUMMARY

Neural-Cell Technology

and

Its application in medical filed

The Super-High Resolution Electrocardiograph

*SHR-EKG*

www.vsholding.com

Electronic Design & Research Inc
7331 Intermodal Drive, Louisville KY 40258
info@vsholding.com
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Introduction I (medical)

Surface EKG recordings, reflecting cardiac muscles activities, have been an invaluable diagnostic and investigational tool for the clinical scientist for more than 70 years. As it shown on the below picture, an initial electrical signal (pulse) created in the SA node (located in the right atrium) stimulates the atria to contract. Then the signal travels to the atrioventricular (AV node). After a small delay (about 42 ms), the electrical signal diverges through the left and right bundles of His to the respective Purkinje fiber for each side of the heart, as well as to the endocardium at the apex of the heart, then finally to the ventricular epicardium, causing its contraction. These signals are generating rhythmically, which in turn results in the coordinated rhythmic contraction and relaxation of the heart.

A widely used surface EKG recording does not contain any important information about electrical activities of the conduction system of the heart. Nevertheless, it has been vitally important to have knowledge of any abnormalities in the conduction system for diagnostic of an abnormal heart’s activities and installing a pacemaker in the proper location.

When someone’s heart does not beat normally, a cardiologist assigns an electrophysiological study (EPS) to find out why. Electrical signals usually travel through the heart in a regular pattern. Heart attacks, aging and high blood pressure may cause scarring of the heart. This may cause the heart to beat in an irregular (uneven) pattern. Extra abnormal electrical pathways found in certain congenital heart defects can also cause arrhythmias. During EPS, doctors insert a thin tube called a catheter into a blood vessel that leads to your heart. A specialized electrode catheter designed for EP studies allows them to send electrical signals from your heart and record its electrical activity.

Heart, its conduction system, standard recording with a signal from a catheter, and depicted recording of the conduction system and timing signal, such as the SA node, the AV node, Bundle His, and the QRS complex

ANATOMY OF THE CONDUCTION SYSTEM

Heart, its conduction system, standard recording with a signal from a catheter, and depicted recording of the conduction system and timing signal, such as the SA node, the AV node, Bundle His, and the QRS complex
Samples of recordings from three different patients, including recordings obtained with the Neural-type signal enhancer

On the left side (top) is a standard EKG recording with a surface bit-by-bit, real time recording of a His bundle signal (SHBE). There was no recording from a catheter presented for verification, because it was taken from a healthy volunteer.

Recordings in the middle and bottom were obtained from two different patients during an electrophysiological study in a cat lab. Patients EKG recordings are indicating conduction blocks, which supported by both IHBE and SHBE recordings.

1. The SHBE is recording from a His bundle enhancer using the 4-channel based signal processor,
2. The IHBE is recording from a catheter, placed nearby the His bundle fibers
3. The I, aVr, and V2 are standard EKG recordings
Introduction II (technology)

The neural-cell technology (NeuTAC) is the most powerful signal or information processing technological known to humanity. The uniqueness of the NeuTAC technique based on parallel rather than a serial architecture, and its ability to process analog and digital information simultaneously rather than just digital or analog alone. The NeuTAC significantly enhances signal-to-noise ratio by “intelligently” analyzing all input channels and forming a weighted spatial average output. Only chosen weighted channels, which satisfy the algorithm’s requirements, are contributing to the output result. V. A. Shvartsman inventions in the field of Neural Network and AI are incorporating in a new technology by introducing a new type of feedback, feed-forward feedback (FFF), to the family of positive and negative feedback. The feed-forward control opens an extra dimension to how information can be processed, controlled and presented.

The sample recordings made by 5-channel neural-cell processor

1- An output signal is from a very low noise preamplifier. There is no recognizable deflection between P and QRS waves.

2- Recording from the processor Noise is greatly suppressed and the Bundle His signal is easy to read.

The sample of simultaneous recording performed in a cathlab. The top recording is a regular ECG signal (V2 leads). The middle is a recording (IHBE) obtained from a catheter (endocardial recording) and the bottom is a recording (SHBE) from the body surface after a neural type multichannel processor had processed it.
A block-diagram of the 4-channel noise reduction processor

The first 4-channel signal processor utilized the Multiple Parallel Input Noise Reduction System, U.S. Patent No. 4300101. It was able to record a signal below a noise level and provided the pass for a better solution. The second generation of a 5-channel system built and thus greatly improved His bundle signal recordings. Another U.S. Patent No. 4,692,709 secured the improvements. A mathematical investigation provided support for a more advance noise reduction algorithm by using an 8-channel noise reduction processor.

A block diagram of an n-channel signal-to-noise enhancement processor
Block-diagram of the 8-channel Super-Low Level Signal Processor based on the neural-cell technology

Presently, we do not have a ready to run 8-channel system, though some components of it is assembled and working properly.
**BUDGET (3 years project)**

(USD in thousands)

The project is to build four of SHR-EKG devices utilizing eight (8) new channels analog/logic congruent algorithm, four of 8 channels EKG simulators, ten of 8-prons electrodes, and creating a doctor’s testing/education laboratory.

<table>
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<th>Phase I</th>
<th>Building an 8-channel SHR-EKG (prototype)</th>
<th>$856</th>
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<tr>
<td>Phase II</td>
<td>Building an 8-channel field-ready SHR-EKGs</td>
<td>$1,745</td>
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<tr>
<td>Subcontract Material/Labor</td>
<td>$285</td>
<td></td>
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<tr>
<td>Special Equipment</td>
<td>$416</td>
<td></td>
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<tr>
<td>Devising and manufacturing an 8-channel EKG signal simulator with 8 independent random noise generators</td>
<td>$100</td>
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<tr>
<td>Production of four 8-channel EKG simulator (4 x $25,000)</td>
<td>$100</td>
<td></td>
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<tr>
<td>Development and production of 8-prone sensing electrodes (10 x $10,000)</td>
<td>$100</td>
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<tr>
<td>Direct Labor for developing software for recording, transmitting, and displaying collected information</td>
<td>$901</td>
<td></td>
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<tr>
<td>Travel</td>
<td>$46</td>
<td></td>
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<tr>
<td>Publications</td>
<td>$30</td>
<td></td>
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<tr>
<td>Other direct cost (rent, utility, etc.)</td>
<td>$125</td>
<td></td>
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<tr>
<td><strong>Sub total</strong></td>
<td><strong>$4,705</strong></td>
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Phase III Build three additional SHR-EKG devices (3 x $950,000) $2,850

| Direct Expenses to set the first testing lab | $1,850 |
| Direct Labor | $150 |
| Supply | $30 |
| Publications (printing, mailing, etc) | $40 |
| **Sub Total** | **$2,070** |

| Direct Expenses to set a doctor’s teaching/training lab | $500 |
| Direct Labor | $180 |
| Supply | $25 |
| Publications (printing, mailing, etc) | $40 |
| **Sub Total** | **$745** |

Miscellaneous expenses $100

**Total Direct Cost** $9,470

General & Administrative Expenses (35% of $9,470) $3,314

**Total cost of the Project** $12,784

Fee/Contingency (10%) $1,278

**Total Estimated cost** $14,062
Principal’s CV and his inventions

Dr. VLADIMIR A. SHVARTSMAN, Ph.
V_shvartsman@vsholding.com

7331 Intermodal Drive, Louisville, Kentucky 40258
Cell: (502) 415-4229; Office: (502) 933-8660
Children: One - Andrew Anthony Shvartsman - Born 1/25/86
Citizenship: Resident since 1977, U.S. Citizen from 1985

EDUCATION:
1952-1960 Primary and Secondary school
1960-1962 Vocational School and high school;
1962-1964 University of Jdanov, Department of Electronics;
1964-1967 Military Service
1967-1969 University of Jdanov, Department of Electronics, BSES in Industrial Electronics
1969-1974 University of Leningrad, Department of Biomedical Cybernetics, MS
1978-1981 University of Louisville, Speed School, Kentucky Microcomputer Experimental Design

1983- President & CEO VS Holding LLC
Electronic Design and Research Inc

RESPONSIBILITIES: Corporate management, basic research, R&D management, analyzing findings, designer, writing technical articles and proposals, etc
Biomedical related Research: Automatic arrhythmia detection,
Optical analysis of exhaled air,
Non-invasive analysis and monitoring of ICP,
Real-time evoked potential detection and analysis,
Real-time non-invasive detection of the Bundle of His, Communication (frequency-hopping, telemetry),
Analog data compression,
Localization of the Ventricular Ectopic focus and its Elimination using laser beam irradiation,
Hospital/industrial security and communication systems, Etc.

1978-1983 Biomedical Engineer/Research Associate, University of Louisville Dept. of Medicine, Division Of Cardiology, Louisville, Kentucky, USA
RESPONSIBILITIES: Supervised a team working on a theory for a multichannel signal processor; assigned to develop and supervise the cardiology research laboratory; engineering developments, conduct experimenting and perform heart catheterization, data collection, processing and interpretation, preparation, and writing scientific articles. Guiding technique for precise laser interventions applied to the myocardium; New signal processing technique for non-invasive detection of His-Parkinje activities; Technique (micro-heat) for accurate closed chest experimental infarct (on animal model); Study of the electrical activities of His Bundle area.

1975-1977 Senior Biomedical Engineer/Research Associate, Research Institute of Pathology and Therapeutics of Physiology and Pathology of Higher Nervous Activity, USSR
RESPONSIBILITIES: Supervised engineering/technical staff, conducted research. Studying "The influence of stress conditions on processing of information by the cerebral"; Studied the ability of the selective part of cerebral to a new function; developed, assembled and operated multichannel telemetry system and analog/digital analyzer to perform that research.

1969-1975 Electronic Engineer/Research Associate, Leningrad Research Institute of Nuclear Physics, Department of Molecular Biology, USSR.
RESPONSIBILITIES: Development, assembling and operating sophisticated scientific instruments while investigating Biochemical protection against radiation poison. Devised, assembled and operated a very highly sensitive paramagnetic resonance spectrometer; Developed, designed and assembled a device to measure the quadruple movements of long molecular compounds.

INVENTIONS:

1987 Fundamental And Harmonic Pulse-Width Discriminator, U.S. Patent No. 4692710
1989 Personal Warning System, Patent Pending
1989 Universal Personal Tag, Patent pending
1990 Rapid evaluation of R-R interval, Patent pending file No. 625506
1991 Noninvasive monitoring intracranial pressure, Patent pending file No. 14637
1991 Highly Compressed time-variable recording; patent pending
1992 Sequential analog data compressor; patent pending

1993 - Time-variant digital/analog data processing and retrieval, Patent pending file No. 0624.014638

1994 - Time-Variant, Ideal High-Pass Filter; patent pending

1997 - High-resolution F-to-V converter; patent pending

2007 - Intelligent solid-state relay/breaker, U.S. Patent No. 7304828

2010 - Very low power consumption solid-state relay, U.S. Patent No. 7755414

2020 - Self-protected, intelligent power control module, U.S. Patent No. 7742273


2012 - Micro-power pulse controller for magnetic latch solenoid, relays, and valves, U.S. Patent No. 8125754

AWARDS

Co-investigator:

NIH ROI HL 19768-04 (06/80-12/82), Recording and Analysis of Low Level Cardiac Signals" $265,450

KY Heart Association (27/80-27/81); "Creation and Localization of Artificial Ectopic Cardiac Foci" $1,726.00

Principal Investigator:

U.S. AMRDC DAMD-7-84-C-4034 (11/83-5/84); "The Multichannel Signal Processing Technique Based on Logical Cleansing." $49,476.00

NIH 1 R43-HL33059; (8/84-5/85); "Time-Variant Data Compression and Retrieval" $50,000.00

U.S. AMRDC; DAMD17-85-G-5030; (11/84-5/85); Computer Graphics Control System" $29,640.00
PUBLICATIONS portray to the subject


2. Flowers, NC, Shvartsman, VA, Horan, LG, “His-Parkinje Signals as Part of the Surface Electrocardiogram”, Proceedings of the 11th InterAmerican Congress of Cardiology, San Juan, Puerto Rico, 1980


