

EXECUTIVE SUMMARY

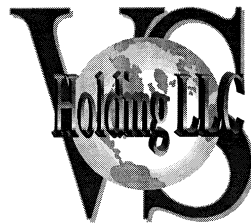
Neural-Cell Technology

and

Its application in medical filed

The
Super-High Resolution Electrocardiograph

SHR-EKG



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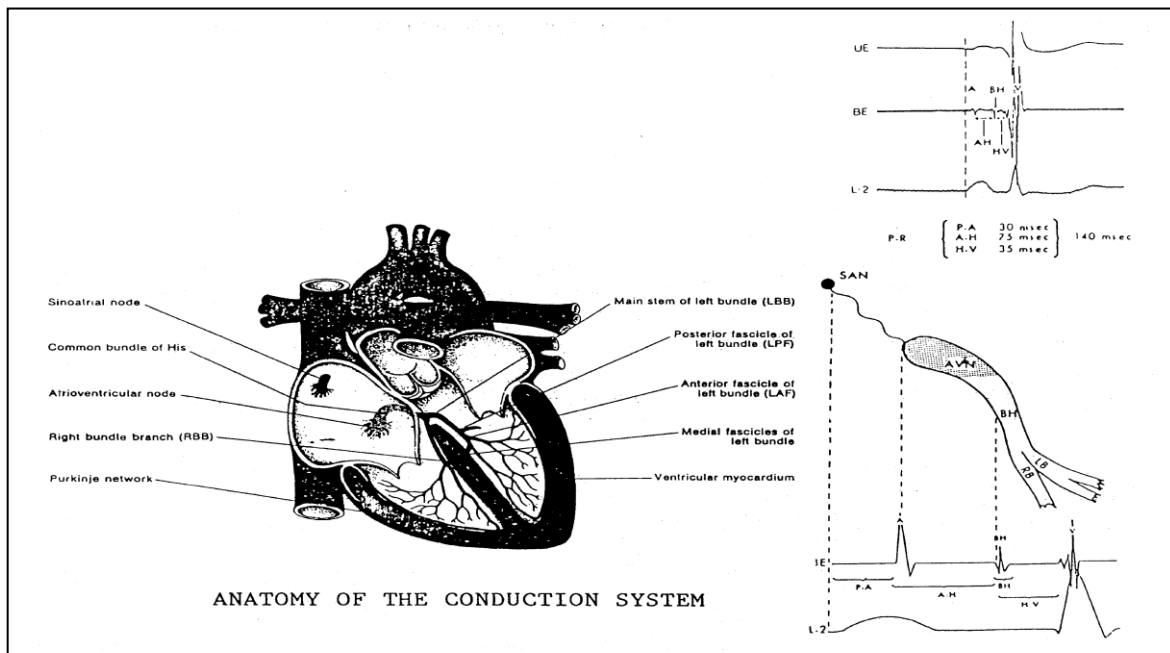
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Introduction I (medical)

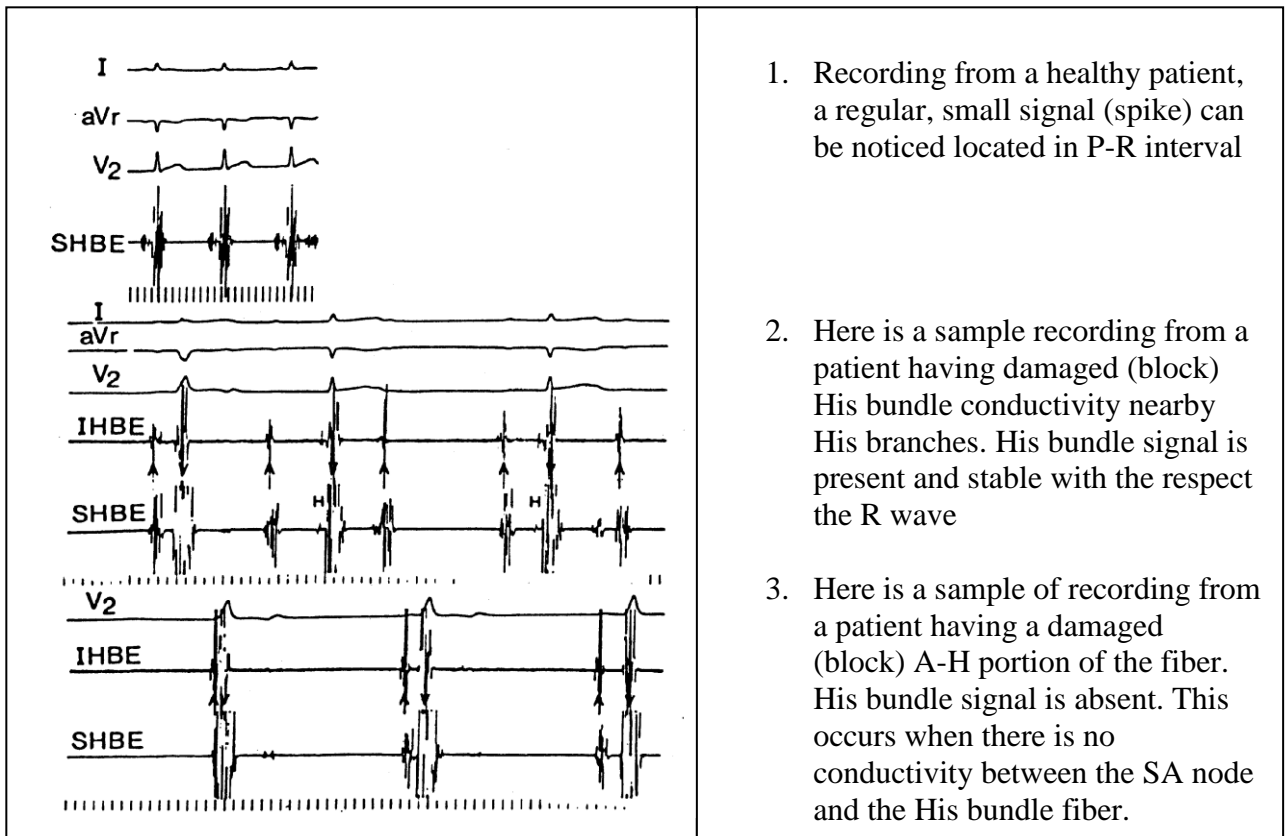
Surface EKG recordings, reflecting cardiac muscles activities, have been an invaluable diagnostic and investigational tool for the clinical scientist for more than 70 years. As it shown on the below picture, an initial electrical signal (pulse) created in the SA node (located in the right atrium) stimulates 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



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.

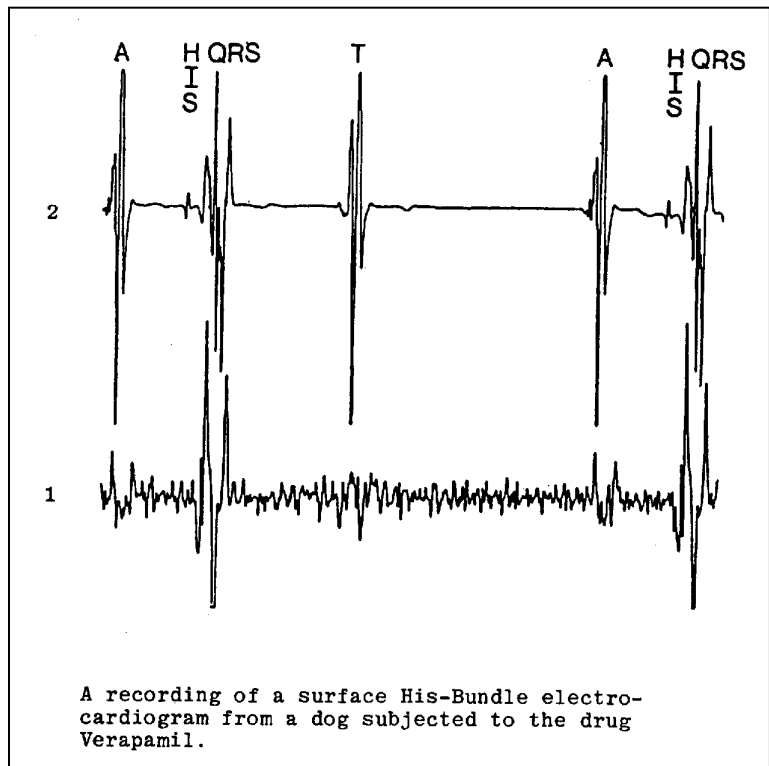
1. The SHBE is recording from a His bundle enhancer using the 4-channel based signal processor,
2. The IHBE is recording from a catheter, placed nearby the His bundle fibers
3. The I, aVr, and V2 are standard EKG recordings

Introduction II (technology)

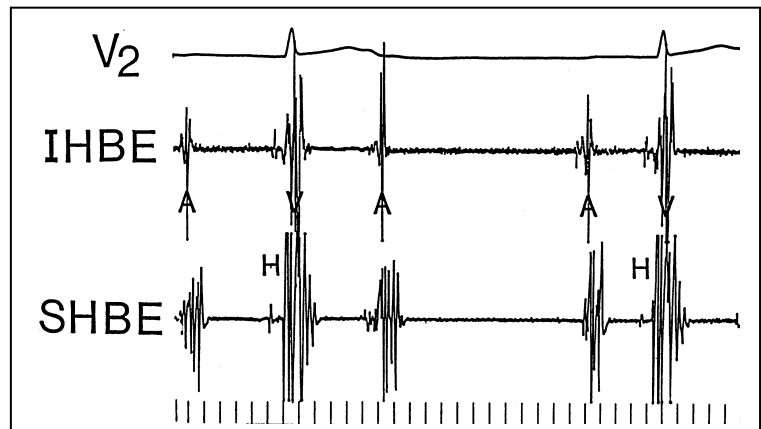
The neural-cell technology (NeuTAC) is the most powerful signal or information processing technological known to humanity. The uniqueness of the NeuTAC technique based on parallel rather than a serial architecture, and its ability to process analog and digital information simultaneously rather than just 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.

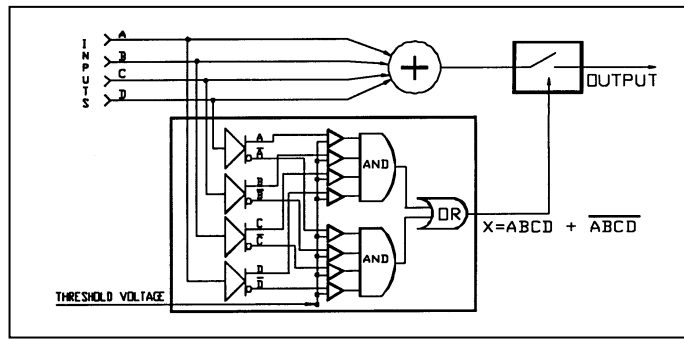
The sample recordings made by 5-channel neural-cell processor

- 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



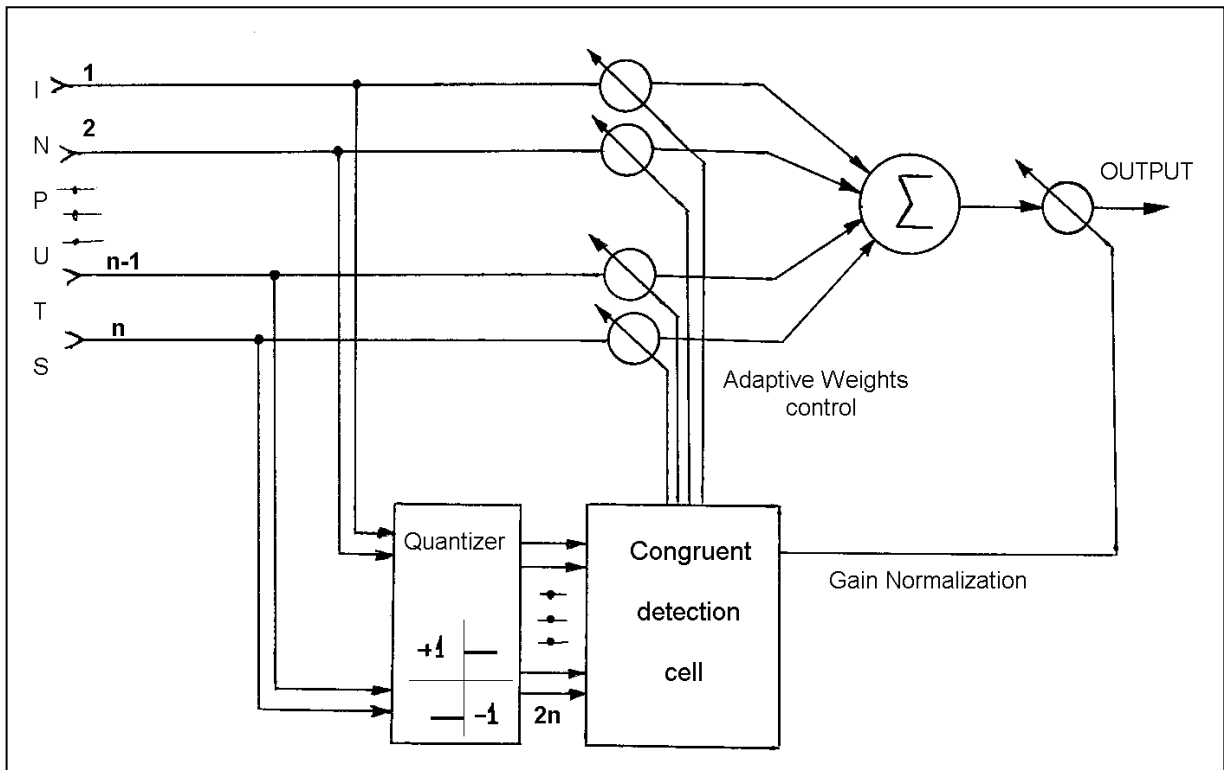
The sample of simultaneous recording performed in a cathlab. The top recording is a regular ECG signal (V2 leads). The middle is a recording (IHBE) obtained from a catheter (endocardial recording) and the bottom is a recording (SHBE) from the body surface after a neural type multichannel processor had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





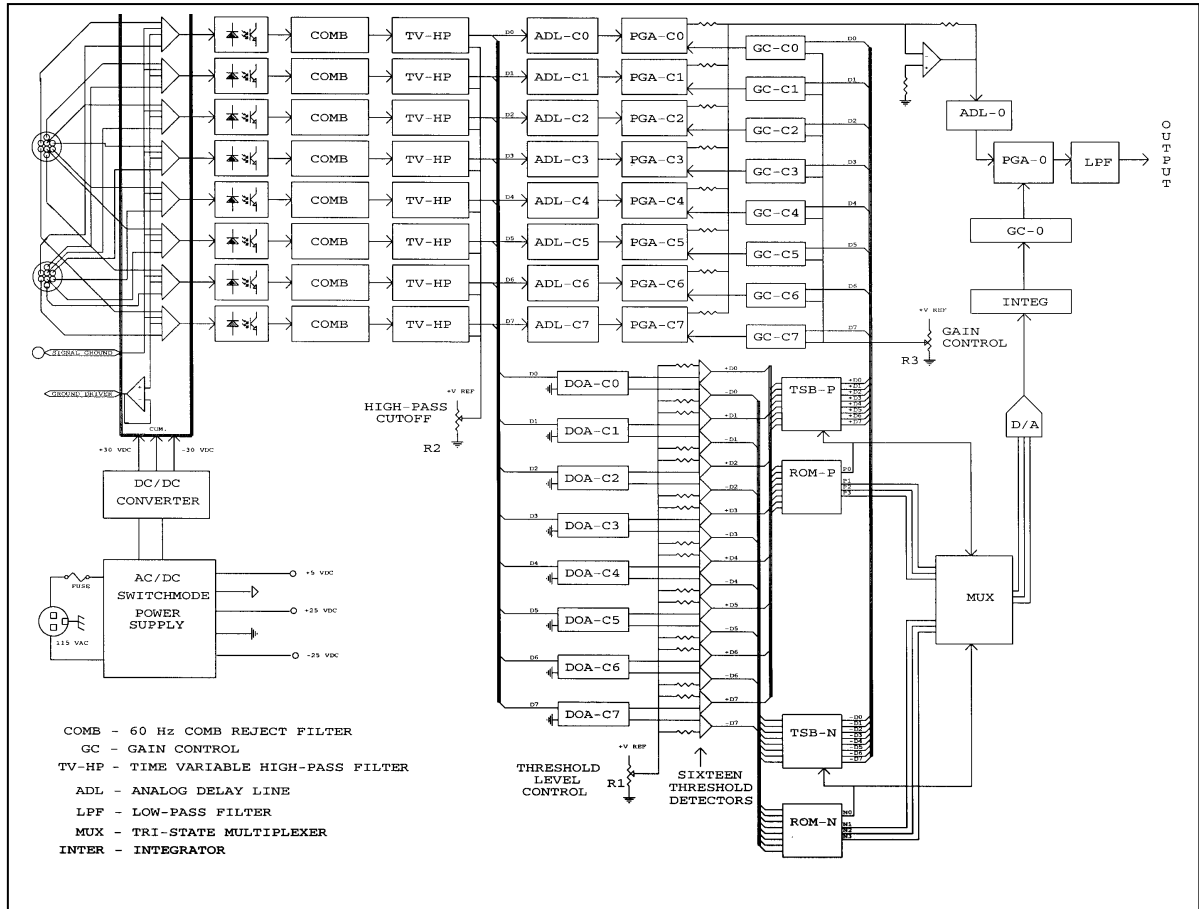
A block-diagram of the 4-channel noise reduction processor

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.

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



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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
1974-1975 Postgraduate - Jdanov Memorial University Ph.D. in Biophysics, Thesis: "Study of an Evoked Potential Work of a Single Active Neuron in Cerebral Cortex on Non-restrained Animal via Telemetry System"
1974-1976
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-Parkinson 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 (r) 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:

1982 Multiple Parallel Input Noise Reduction System, U.S. Patent No. 4300101
1987 Fundamental And Harmonic Pulse-Width Discriminator,
U.S. Patent No. 4692710
1987 Parallel Input Signal Processor For low-level Signal, High Noise Environments,
U.S. Patent No. 4692709
1988 Telemetry Tracking And Monitoring Security System, Patent pending
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

- 1992 - EKG + H-bundle cardiac recorder,
Patent pending File No. 0624.014636
- 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
- 2011 - High efficiency charge-and-add adjustable DC-DC converter, U.S. Patent
No. 8358520
- 2012 - High Efficiency All-Electrical Vehicle Propulsion System,
U.S. Patent No. 201202680401A1
- 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

1. Flowers, NC, Shvartsman, VA, Horan, LG, “Beat-By-Beat Recording of His-Parkinje Wave Without Digital Averaging”, Proc. of the 22nd Annual Meeting of the Association of University Cardiologists, Phoenix, Arizona, January 1980.
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
3. Flowers, NC, Shvartsman, VA, Sohi, GS, Kennelly, BM, Horan, LG, “The Addition of His-Parkinje Waveforms to the P, QRS, and T on an Every Beat Basis,” Presented at the 53rd Scientific Session of the American Heart Association, 1980, Circulation, Volume 62, Suppl. III, October 1980
4. Flowers, NC, Shvartsman, VA, Kennelly, BM, Sohi, GS, and Horan, LG, “Surface Recording of His-Parkinje Activity on an Every Beat Basis Without Digital Averaging”, Circulation, pp.948-952, Vol. 63, No 4, April 1981.
5. Flowers, NC, Shvartsman, VA, Sohi, GS, Horan, LG, “Signal Averaging Versus Beat-By-Beat Recording of Surface His-Parkinje Potentials”, Proceedings of the International Symposium of Signal Averaging in Clinic. Card., Cologne, Germany, pp. 329-349, May 7-9, 1981.
6. Flowers, NC, Shvartsman, VA, Sohi, GS, Horan, LG, “Routine Surface Identification of His Bundle Activity: Another Case of Lag Between Discovery and Application”, Proceedings of the Association of University Cardiologists, Phoenix, Arizona, 1982.
7. Shvartsman, VA, Barnes, GS, Shvartsman, L., Flowers, NC, “Multichannel Signal Processing Based on Logic Averaging”, IEEE Transaction on Biomedical Engineering, Vol. BME-29, #7, pp. 531-536, July, 1982.
8. Flowers, NC, Shvartsman, VA, Horan, LG, “On Line Beat-By-Beat Body Surface Detection of His-Parkinje Potential”, Proceedings of the International Symposium on Body Surface Mapping, pp.281-287, 1982.
9. Flowers, NC, Shvartsman, VA, Horan, LG, Sohi, GS, Sridharan, MR, “Early Studies on Patients with Abnormalities of the Conduction System Using Surface His Bundle Recordings”, Journal of the American College of Cardiology, 1982.
10. Flowers, NC, Horan, LG, Shvartsman, VA, Sohi, GS, Sridharan, MR, “Surface His Bundle Electrocardiography,” Japanese Heart Journal, Vol. 23, 1982.
11. Flowers, NC, Shvartsman, VA, Horan, LG, Sohi, GS, Sridharan, MR, “Every Beat Human Surface His Bundle Recordings, Conduction and Arrhythmia,” Circulation, Vol. 66, (Suppl. II), Pg. 11-17, October 1982.
12. Flowers, NC, Shvartsman, VA, Palakurthy, PR, Horan, LG, Sohi, GS, Sridharan, MR, “Relationship of Surface and Catheter Recorded AH and HV Intervals in Normal Subjects,” Circulation, Vol. 66 (Suppl. II), Pg. 11-129, October 1982
13. Flowers, NC, Shvartsman, VA, Horan, LG, Palakurthy, P., Sohi, GS, Sridharan, MR, “Analysis of PR Subintervals in Normal Subjects and Early Studies in Patients with Abnormalities of the Conduction System Using Surface His Bundle Recordings,” JCC, pp. 939-946, Vol. 1, No. 5, November, 1983.
14. Shvartsman, VA, Flowers, NC, “Response to Comments on multichannel Signal Processor Based on Logic Averaging,” Vol. BME-31, Vol. #6, pp. 484-486, IEEE Trans. on Biomedical Eng., June, 1984.

15. Shvartsman, VA, Barnes, GR, "Noninvasive His Bundle Measurement," AAMI 20th Annual Meeting, pp. 81, May 6-8, 1985.
16. Shvartsman, VA, Barnes, GR, "Noninvasive His-Bundle Measurements," Proc. of the MD & DI Conference/Exp., pp. 38-43, June 1985.
17. Shvartsman, VA, and Barnes, GR, "An Improved Adaptive Parallel Processor," Proc. of the 7th Annual Confer. IEEE/EMBS, pp. 752-755, September 1985.
18. Shvartsman, VA, and Barnes, GR, "Adaptive Parallel Processor," Proc. of the Mathematics in Signal Processing, Univ. of Bath, the IMA, Oxford Univ. pp. 120-124, September 17-19, 1985.