

Bioresearch Funding Group

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February 21, 2006

Joseph Shen, MD
Premier Heart, LLC
14 Vanderverter Avenue
Port Washington, NY 11050-3757

Dear Dr. Shen:

This is to summarize my role in clinical trials that were conducted in Germany and in several countries in Asia. The purpose of the trials was to determine the accuracy of diagnosis of regional or global ischemic heart disease due to coronary artery disease using 3DMP interpretations, a Premier Heart diagnostic program of 3DMP digital ECG data, by comparing them to clinical catheterization (angiogram) results.

The 3DMP diagnoses performed at Premier Heart were blinded to responsible physicians until coronary angiographic reports were sent to me. Conversely, angiographic reports were blinded to Dr. Shen and to staff at Premier Heart until I received and verified that matching 3DMP reports existed. The comparative analyses are based on the results obtained from Premier Heart and the participating physicians prior to the data exchange.

The 3DMP results for any patient were not seen by the responsible physician nor were catheterization reports seen by Dr. Shen or any Premier Heart staff until I performed this verification. I certify that these trials were conducted in a strictly double-blind manner.

Sincerely,



Alan Berson, PhD

CURRICULUM VITAE

Alan Berson
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EDUCATION

Georgetown University; PhD, Physiology & Biophysics
George Washington University; MSE, Engineering Science
City College of New York; BEE, Electronic Engineering

POSITIONS

Director of Research, Bioresearch Funding Group; 2000 to present
Leader, Bioengineering Research Group, and Deputy Chief, Devices & Technology
Branch, National Heart, Lung & Blood Institute, NIH; 1978-2000
Chief, Instrumentation & Data Processing, Research Center for Cardiovascular Data
Processing, VA Medical Center, Washington, DC; 1961-78
Research Professor, Dept of Clinical Engineering, School of Medicine, George
Washington University Medical Center; 1971-79

PROFESSIONAL SOCIETIES & ACTIVITIES

Member, American Heart Association (AHA) Committee on Computers &
Electrocardiography; 1984-90
Member, AHA Committee on Cardiac Monitoring; 1987-89
Member, AHA Committee on Ambulatory Monitoring; 1985-86
Member, AHA Committee on Electrocardiography; 1963-76
Fellow, Stroke Council, AHA; 1984-present
Chairman, Committees on Diagnostic ECG, Cardiac Monitors, and
Sphygmomanometers, Association for Advancement of Medical Instrumentation
(AAMI); 1980-2000
Chairman, AAMI standards Board; 1986-95
President, AAMI; 1991-92
Editorial Board, Biomedical Instrumentation & Technology; 1989-95; Journal of Clinical
Engineering; 1986-97
Board of Directors, International Society for Computerized Electrocardiology; 1988-90
Member, Office of Personnel management Rating Panel, NIH; 1987-98
Member, Data & Safety Monitoring Board, PEM Naviscan, 2005

PUBLISHED PAPERS AND REPORTS
(partial list)

Kossmann, CE,Berson, AS, ... Recommendations for standardization of leads and of specifications for instruments in electrocardiography and vectorcardiography. *Circulation* 35: 583, 1967.

Ishikawa, K, Berson, A et al: ECG changes due to cardiac enlargement. *Amer Heart J* 81:635, 1971.

Berson, A et al: Direct conversion of FM magnetic tape into digital form. *IEEE Trans Biomed Eng* 18: 281, 1971.

Pipberger, HV, Berson, A et al: Diagnostic classification of orthogonal ECGs and VCGs in Vectorcardiography 2; Proc of XI International Symposium on VCG, Hamby and Glassman, eds., Amsterdam, North-Holland Pub Co, 1971.

Berson A et al: Errors caused by electrode displacement in Frank and McFee lead systems, *Ibid*, p. 468.

Berson, A: Resistivity & dielectric constant of cardiac muscle and lung in the dog. *Proc 25th Ann Cong Eng in Med & Biol*, 1972.

Manoach M, Grosman E, Varon D, Gitter S, Ripberger HV, Ishikawa K, Berson AS. Influence of conductivity of intraventricular mass on QRS amplitude in different vertebrates. *Am Heart J*. 1972 Oct;84(4):576-80.

Pipberger HV, Ishikawa K, Berson AS. QRS amplitude changes during heart filling and digitalization. *Am Heart J*. 1972 Feb;83(2):292-7.

Pipberger, HV, Arzbaecher, R, Berson, A et al: Report of Committee on Electrocardiography, AHA, Safety and Electrical Shock hazards. *Circulation* 46: 1, 1972, and *IEEE Trans Biomed Eng* 20: 140, 1973.

Berson, A: Analog to digital conversion, in *Proc of International Fed for Information Processing, Computer Application for ECG and VCG analysis*, Zywiets and Schneider, eds., Hannover, Germany, North-Holland Pub Co., 1973, p. 57.

Berson, A: Telephone transmission of electrocardiograms. *Ibid*, p. 83.

Pipberger, HV, ...and Berson, A: Clinical application of a second generation ECG computer program. *Amer J Cardiol* 35: 597, 1975.

Pipberger, HV, Dunn, RA, and Berson, A: Computer methods in electrocardiography. *Ann Rev Biophysics & Bioengin* 4: 15, 1975.

Pipberger, HV, Arzbaecher, RC, Berson, A et al: Recommendations for standardization of leads and of specifications for instruments in ECG and VCG. Report of Committee on Electrocardiography, AHA. *Circulation* 52: 11, 1975.

Toole, JF and Berson, A: Multicenter trial for assessment of B-mode ultrasound imaging, in *Clinical Diagnosis of Atherosclerosis*, Bond et al, eds., Springer-Verlag, NY, 1982.

Berson A: Preface, in *Cardiac Monitoring in a Complex Patient Care Environment*, AAMI, Arlington, VA, 1982.

Berson, A: An overview. *Ibid*, p. 8.

Berson, A and Briller, SA: Ventricular fibrillation waveforms. *Ibid*, p. 63.

Schmitt, OH and Berson, A: Epilogue. *Ibid*, p. 81.

Berson, A: The present and future computer ECG cart and the ideal cart, in *Computerized Interpretation of the ECG*, Engineering Foundation, NY, 1982.

Berson, A: Ultrasound B-scan assessment program, in *Atherosclerosis Reviews*, R. Hegyeli, ed., Raven Press, NY, 1982.

Mock MB, Powell RS, Watson JT, Berson AS. Non-invasive methods in the diagnosis of cardiovascular diseases - general review. *Kardiol Pol.* 1982;25(10-11):829-38.

Berson, A: Magnetic control and powering of surgically implanted instrumentation. *IEEE Trans Magnetics* 19: 2157, 1983.

Berson A et al: Diagnostic electrocardiographic devices. American National Standard, AAMI, Arlington, VA, 1983.

Berson A et al: Cardiac monitors, heart rate meters and alarms. American National Standard, AAMI, Arlington, VA, 1983.

Barnes, R, Berson, A et al: Report of workshop on detection and treatment of renovascular disease. *Hypertension* 7: 452, 1985.

Sheffield, LT, Berson, A et al: Recommendations for standards of instrumentation and practice in the use of ambulatory electrocardiography. *Circulation* 71: 626A, 1985.

Berson A: ECG instrumentation - State of the Art and recommendations, in *Computer ECG Analysis: Towards Standardization*, Willems, et al, eds., North-Holland Pub Co., Amsterdam, 1986.

Berson, A et al: Non-automated sphygmomanometers. American National Standard, AAMI, Arlington, VA, 1986.

Berson, A: Bandwidth, sampling, and quantizing for ECG, in *Computerized Interpretation of the ECG*, Engineering Foundation, NY, 1986.

Berson, A et al: Electronic or automated sphygmomanometers. American National Standard, AAMI, Arlington, VA, 1987.

Bailey, JJ, Berson, A et al: Recommendations for standardization and specifications in automated ECG: Bandwidth and digital signal processing. Report from the Committee on Computers and Electrocardiography, American Heart Association. *Circulation* 81: 730, 1990.

Dunn, RA and Berson, A: Left ventricular assist system reliability testing. *Proc of Computers in Cardiology*, 1990.

Bond, MG, Berson, A, and Bryan, FA: Ultrasound imaging of atherosclerotic lesions in arteries of animals: Validity and reproducibility, in *Atherosclerotic Plaques - Advances in Imaging for Sequential Quantitative Evaluation*, RW Wissler, ed., Plenum Press, NY and London, 1991.

White WB, Berson AS, Robbins C, Jamieson MJ, Prisant LM, Roccella E, Sheps SG. National standard for measurement of resting and ambulatory blood pressures with automated sphygmomanometers. *Hypertension* 1993 Apr;21(4):504-9.

Laks, MM, ... and Berson, A: Will relaxing safe current limits for electromedical equipment increase hazards to patients? *Circulation* 89: 909, 1994.

Anderson ST, Pahlm O, Selvester RH, Bailey JJ, Berson AS, Barold SS, Clemmensen P, Dower GE, Elko PP, Galen P, et al. Panoramic display of the orderly sequenced 12-lead ECG. *J Electrocardiol.* 1994 Oct;27(4):347-52.

Laks, MM and Berson, A: Electrical safety measures for physicians using electromedical equipment. *Seminars in Neurology* 15: 311, 1995.

Prisant LM, Alpert BS, Robbins CB, Berson AS, Hayes M, Cohen ML, Sheps SG. American National Standard for nonautomated sphygmomanometers. Summary report. *Am J Hypertens.* 1995 Feb;8(2):210-3.

Laks, MM, ... and Berson, A: Recommendations for safe current limits for electrocardiographs. From the Committee on Electrocardiography, American Heart Association. *Circulation* 93: 837, 1996.

Berson, A: Imaging structure and function in medicine and biology, in *Quantitative nondestructive evaluation*, DO Thompson and DE Chimenti, eds., Plenum Press, NY and London, 1997.

Wickline, S, and Berson, A: NHLBI/FDA conference on thrombosis and infections with cardiovascular devices. *J Biomed Materials Res* 42: 341, 1998.

Budinger, TF, Berson, A et al: Cardiac MR imaging. *Radiology* 208: 573, 1998.

Pantalos, GM, Altieri, F, Berson, A et al: Long-term mechanical circulatory support system. Reliability recommendation. *Amer Soc for Artificial Internal Organs. Ann. Thorac Surg* 66: 1852, 1998.

Norman JE, Bailey JJ, Berson AS et al. NHLBI workshop on the utilization of ECG databases: preservation and use of existing ECG databases and development of future resources. *J Electrocardiol.* 1998 Apr;31(2):83-9.

PRESENTATIONS/PARTICIPATION AT SCIENTIFIC MEETINGS

(Partial list)

Chairman, Instrumentation Session, IEEE Conf Eng Med & Biol; Atlanta, 1978.

Digital ECG Systems. IEEE Conference; Atlanta, 1978.

Organizer, NHLBI/NIH Workshop on Noninvasive Techniques for Assessment of Atherosclerosis in Peripheral, Carotid, and Coronary Arteries; Bethesda, 1980.

Lead Systems and Electrodes. NHLBI/NIH Workshop on Ambulatory ECG Recording; Bethesda, 1981.

Performance Criteria; Ibid.

Chairman, Ambulatory Monitoring Session, AAMI National Meeting; Washington, DC, 1982.

Session Chairman, 7th Meeting of Computerized Interpretation of ECGs, Engineering Foundation; Santa Barbara, 1982.

Chairman and Organizer, AAMI Conference on Cardiac Monitoring; Washington, DC, 1981.

Ventricular Fibrillation, Ibid.

US multicenter Trial to Evaluate B-scan Imaging, US/Italy Joint Symposium on Noninvasive Diagnosis in Cardiovascular Disease; Bethesda, 1981.

NHLBI-supported Research on Minimally Invasive Systems for Assessment of Atherosclerosis. Special presentation, International Organization of Legal Metrology; Rostov, USSR, 1983.

NHLBI-supported Research. Special presentation, Karolinska Hospital; Stockholm, 1983.

Chairman, Computer Assistance in Imaging Cardiovascular Structures, SCAMC Meeting on Computer Applications in Medical Care; Baltimore, 1983.

Chairman, Magnetics in Medicine, International Magnetics Conference; Philadelphia, 1983.

Magnetic Control and Powering of Surgically Implanted Instrumentation; Ibid.

NIH/NHLBI Research. Special presentation, Dedication of Second University of Rome; Rome, Italy, 1983.

NHLBI Research Opportunities. Special presentation. Marquette Electronics; Milwaukee, WI, 1984.

Chairman, Scientific Sessions, AAMI Annual Meeting; Washington, DC, 1991.

Organizer, NHLBI/NIH Workshop on Cardiovascular Imaging; Bethesda, 1992.

Organizer, NHLBI/NIH Workshop on Cardiac MR Imaging; Bethesda, 1996.

Imaging Structure and Function in Medicine and Biology. Keynote Speaker. Review of Progress in Quantitative Nondestructive Evaluation; Brunswick, Maine, 1996.

Organizer, NHLBI/FDA Conference on Thrombosis and Infections with Cardiovascular Devices; Bethesda, 1997.

Organizer, NIH Bioengineering Symposium; Bethesda, 1998 and 1999.

Organizer, NHLBI Workshop on Nanoinstrumentation and Biosensors; San Diego, 1999.