

## **George E. Yanulis**

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### **PROFESSIONAL ACTIVITIES**

**06/2014–Present:** *MEDICAL DEVICE CONSULTING LLC-President/Principal Engineer, Ft Myers, FL - Clinical Engineering/Medical Device Consultant Expert* - including consulting on heart bypass systems and involved in the research & development of a heart failure therapy monitoring system

**01/2015–12/2017:** *Temple University - Adjunct Professor, Bioengineering Engineering Department*

**03/2014–Present:** *B. H. Barkalow & Associates - Clinical Engineering Consultant, Newaygo, MI*

**11/2010–Present:** *Laughlin Engineering Firm, LLC - Senior Medical Device Consultant*

**08/2009–12/2013:** *College of Staten Island, Adjunct Faculty, Engineering and Physics Department*

**10/2008–3/2009:** *Cleve Med (Cleveland Medical Devices Inc.), Consultant* on a NIH design Grant related to ECG electrode design

**08/2005–08/2008:** *Cleveland Clinic Foundation, Doctoral Student in Applied Biomedical Engineering, Pre- and Post-Doctoral Associate and Research Assistant - Doctorate in Engineering, Cleveland State University/Cleveland Clinic, 8/2008*

**08/2000–07/2002:** *University of Pittsburgh, Pittsburgh, PA Graduate Student and Research Assistant/Teaching Assistant - Master of Science (Bioengineering), University of Pittsburgh, 5/2002*

**05/1999–06/2000:** *University of Pennsylvania Health System, Philadelphia, PA, Clinical Engineering Consultant*

**08/1997–08/2000:** *Drexel University, Graduate Student in Biomedical Engineering and Teaching Assistant*

**10/1996–05/1997:** *James A. Haley Veterans Hospital, Tampa, Florida Research Assistant* - conducted pulse oximetry research under the direction of John E. Scharf, MD

**08/1990–08/1994:** *University of Alabama at Birmingham-Research Assistant & Graduate Student in Biomedical Engineering*

**04/1989–08/1990:** *SUNY at Upstate, Syracuse, NY, Research Assistant*

**10/1987–03/1989:** *Malcolm F Grow AFB, MD, USAF Active Reserves, 1<sup>st</sup> Lt & Clinical Engineer, Received Honorable Discharge*

**05/1986–10/1987:** *RCA-Moorestown Logistics Engineer, Moorestown, NJ*

**05/1985–05/1986:** *Philadelphia Naval Shipyard, US Naval Logistics Engineer*

**08/1983-3/1984:** *Matriculated as Osteopathic Medical Student, Chicago, IL*

**05/1982-8/1983:** *US patent and Trademark Office - Assistant Patent Examiner, US Patent and Trademark Office*

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### EDUCATION

<b>Doctorate in Engineering</b> Biomedical Engineering	<b>Cleveland State University/Cleveland Clinic</b> Cleveland, OH	2008
<b>Master of Science</b> Bioengineering	<b>University of Pittsburgh</b> Pittsburgh, PA	2002
<b>Master of Engineering</b> Biomedical Engineering	<b>University of Virginia</b> Charlottesville, VA	1981
<b>Bachelor of Arts</b> Premedical Studies/Chemistry	<b>Syracuse University</b> Syracuse, NY	1977

### HEART FAILURE THERAPY/LVAD RESEARCH & DEVELOPMENT EXPERTISE

- Involved and continue to be involved in the R&D of ventricular assist devices and bridge to transplantation & destination devices for both adult and pediatric patients (2016 – present).
- Have and continue to be involved as a Medical Device Consultant/ Expert Witness (written over 30 Expert Reports and have been deposed on 6 different occasions).
- Extensive expertise in cardiac device implant and ablation device product design and design and execution of animal studies, including over 200 implants and 500 physiological monitoring studies (canine model).
- Have Performed ECG signal detection & cardiac pressure/volume analysis (canine model) 2005 – 2008 – Cleveland Clinic Foundation
- Provided all engineering analysis and fabrication including participating in the implants in the OR (Cleveland Clinic Foundation– 2005-2008)
- Expert witness for a Heart Bypass System (2017- 2018)
- Reviewed Design History Files for Cardiac Perfusion Systems
- Reviewed Quality Assurance Testing and Results for atrial fibrillation (AF) therapy and other heart failure (HF) devices
- I have been Expert Witness on both cardiac pacemaker and implantable cardioverter-

defibrillator (ICD) devices for Medtronic; St Jude Medical/Abbott; and Boston Scientific (BSCI) and 2 tertiary health systems (over 25 to date)

- Evaluated cardiac pacing and ICD lead/system failures
- Reviewed cardiac pacing and ICD monitoring sessions
- Expertise in the use radio frequency ablation systems for cardiac ablation therapy systems as a Consultant (for a health care system) and has part of my doctoral research at the Cleveland Clinic
- Review of materials related to BSCI cardiac ablation therapy system
- Participated in Ablation Therapy Devices/cardiac pacemaker devices being tested on the canine model as a doctoral student (Cleveland Clinic 2005-2009) --Doctoral Dissertation Link: **Yanulis GE**. A novel cardiac pacing paradigm for atrial fibrillation and heart failure patients [dissertation]. [Cleveland (OH)]: Cleveland State University; 2008 May. 106 p.
- Served as a Device Consultant for a startup venture involved in the R&D of an Ablation Therapy System as far as the (2018)
- Had evaluated clinical users' needs been satisfied in view of specific end user requirements for US and United Kingdom medical device start-up firms, patients, and the clinician.

#### MEDICAL DEVICE EXPERT WITNESS EXPERIENCES

- Performed several Human Factors Analysis on both cardiovascular and orthopedic devices (2014-Present)
- Expertise in technical file review including the following for atrial ablation therapy system (2015); several cardiac pacemaker device cases; ICDs (2014-2016); heart bypass systems (2017-2018)
- Have been involved in the review of several design history files for cardiac device implants
- Evaluated design verification and validation protocols and reports for over 40 different medical devices (2014-Present)
- Have reviewed over 1000 MAUDE database (refer to separate attachment of selected devices which I have served as an Expert Witness/Medical Device Consultant (2011-Present)

- Have Reviewed several MDR(s), Complaint Investigations, CAPA(s), Non-conformance(S) and Change Control(s) for all types of cardiac device and cardiac imaging systems (2011-Present)
- Expertise in developing Final Evaluation Report(s) related to their current validation and verification tasks and provided recommendations as part of their submission to the FDA subsequent to an FDA site visit which had been approved by & Development and Quality Review Divisions at BSCI, Therakos, Inc, St. Jude/Abbott, and Medtronic (2012-Present).

**ADDITIONAL HEART FAILURE (HF) THERAPY DEVICE PATIENT EXPERTISE**

- Co-Investigated the implementation of coupled pacing (CP) (a novel pacing paradigm) for controlling the ventricular rate of mechanical contraction (VRMC) – 2005 -2008 - Study Results demonstrated that acute application of CP resulted in both a negative chronotropic (mechanical not electrical rate) and a positive inotropic response during acutely induced atrial fibrillation (AF)  
[https://www.annalsthoracicsurgery.org/article/S0003-4975\(08\)00735-2/fulltext](https://www.annalsthoracicsurgery.org/article/S0003-4975(08)00735-2/fulltext)
- Performed Preclinical Device Trials on cardiac pacing algorithms (Cleveland Clinic, 2005-2008)

**ADDITIONAL RESEARCH & DEVELOPMENT EXPERIENCES RELATED TO LEFT VENTRICULAR FUNCTION STUDIES**

- After inducing AF by rapid pacing in six dogs, we applied the following pacing modalities: rapid right ventricular (RV) pacing, rapid CRT, CRT with an additional RV paced beat (CP) at a specific delay (CRT + CP), and CRT with vagal stimulation (CRT-VS).
- Obtained Left ventricular (LV) pressure recordings and echocardiography for 2D strain analysis were performed. CRT + CP reduced the ventricular response rate and increased the LV systolic pressure and cardiac output compared with CRT alone (Cleveland Clinic, 2005-2008).  
<https://academic.oup.com/europace/article/12/3/430/476248>
- Mentored and Taught over 200 undergraduate bioengineering students at Temple University (2015-2017) in two cardiac systems/physiology coursework in:
  - Systems Physiology- BIOE 5500
    - Cardiovascular Anatomy & Physiology (materials presented)

- Cardiovascular Control
- Flow in cardiovascular system
- Cardiac Devices- BIOE 4287 (materials presented)
  - The Cardiac Conduction System
  - Cardiac Pacing and Defibrillation
  - Cardiopulmonary Bypass and Cardioplegia
  - Animal Models for Cardiac Research
  - Clinical Trials Formulation
  - End-Stage Congestive Heart Failure: Ventricular Assist Devices
  - CADs related to the design of cardiac valves
  - FDA cardiac regulated expertise
- Reviewed a Heart Bypass Template Risk Analysis and Risk Management Materials (2017-2018)
- Reviewed System's Perfusion Bypass Records
- Vascular prostheses, artificial hearts/ventricular assist devices, and extracorporeal/intravenous oxygenators
- Expertise in biocompatibility of cardiac devices and orthopedic devices

**HARDWARE/SOFTWARE INTERFACE EXPERTISE/EXPERIENCES**

- The Philips IntelliVue MX800 Patient Monitor for monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics, and neonates in hospital environments by trained health care professionals.
- The Philips M3001A Multi-Measurement Module (MMS)
- Echocardiographic acquisitions performed with a Vivid 7 machine (GE Healthcare)
- cSound 2.0 software beamforming technology used in Vivid 7 machine systems
- PDP 11 assembly programming
- Collaborated with Data Science Corporation (DSI) on several projects that included advanced ECG signal detection and pressure-volume loop analysis (Cleveland Clinic 2018-2009)
- Expertise in the R&D of Positron-emission tomography (PET) generators and PET imaging systems, Radio frequency ablation and mapping systems

- Expertise in Image Reconstruction Techniques for Computerized Tomographic (CT) Coronary Artery Calcium Quantification, Reconstruction methods used in helical and multi-slice CT
- Expertise in Fourier Analysis of Discrete-Time Signals – Fast-Fourier Transform and Discrete Filter Design, Sampling and Discrete-Time Signal Analysis
- Continuous Time Signal and Non-Continuous Time Signal Analysis

**IMAGING SYSTEMS RELATED COUSEWORK TAKEN**

- Biomedical Signal Processing
- Computation and Modeling in Biomedical Engineering
- Cardiovascular systems and dynamic modeling
- Computer applications/techniques used in medicine

**IMAGING SYSTEMS & CARDIAC DEVICE COUSE WORK TAUGHT (TEMPLE UNIVERSITY – 2015-2017)**

- Biomedical Signal Processing
- Cardiac Systems Course

**MEDICAL DEVICE EXPERT WITNESS EXPERIENCES INTELLECTUAL PROPERTY EXPERTISE**

- I have written Three (3) Invalidity Reports and Two Infringement Analysis Reports for two medical devices.
- I have been employed as an Assistant Patent Examiner at the U.S. Patent and Trademark Office. In that capacity, I examined patent applications for potential novel applications in the medical infusion and sharp systems area for such applicants as Baxter Travenol Laboratories, Abbott Labs, and other patent applicants (1982-1983). I was enrolled in the USPTO's Patent Examiner's Training Program and received the USPTO's Superior Achievement Award (May, 1983).

**DEPOSITIONS GIVEN BY DR. GEORGE YANULIS AS OF 4/27/2020**

<b>Case Name</b>	<b>Court</b>	<b>Date Filed</b>	<b>Party Affiliation</b>
Hitachi Medical Systems v. South West Mississippi Anesthesia, P.A.	United States District Court Middle District of Louisiana Civil	July 31, 2013	South West Mississippi Anesthesia, P.A.

	Action No. 12-273BAJ-SCR		
Robert Bowie and Susan Bowie v. Arthrex, Inc. and Surgical Systems, Inc.	Superior Court of Maine Androscoggin County Civil Action No. CV2014-74	April 25, 2014	Robert Bowie and Susan Bowie
Thomas R. Ruxlow v. DuPuy Orthopedics, Inc. and Johnson & Johnson	United States District Court Southern District of Iowa Central Division Civil Action 4:13-CV-428	October 8, 2013	Thomas Ruxlow
George Koulas v. DuPuy Orthopedics, Inc	United States District Court District of Hawaii Civil No. 13-00713 BMK	Dec 27, 2013	George Koulas
Theotis Latimore v. Botsford Hospital, John Parmely, D.O., John Parmely, D.O., P.C., Specialist in General Surgery, Harun Zekirovski, D.O, Covidien LP and/or Covidien PLC, formerly known as Covidien LTD, and Medtronic, Inc., successor corp.	STATE OF MICHIGAN IN THE CIRCUIT COURT FOR THE COUNTY OF OAKLAND  Case No. 14-138209-NH	October 30, 2014	Theotis Latimore
Jake Lovato, Individually Lovato and as Personal Representative of the Wrongful Death Estate of Altagracia Gloria Lovato (Plaintiffs),  vs.  Board of Regents of the University of New Mexico Board of regents of The University of New Mexico, Defendants.	First Judicial District Court County of Santa Fe State of New Mexico No. D-101-CV-201301167	April 24, 2013	Board of Regents of the University of New Mexico

**PUBLICATIONS (PEER REVIEW PUBLICATIONS)**

Lim P, **Yanulis GE**, Verhaert D, Greenberg NL, Grimm RA, Tchou PJ, Lellouche N, Wallick DW. Coupled pacing improves left ventricular function during simulated atrial fibrillation without mechanical dyssynchrony. *Europace*. 2010 Mar;12(3):430-6. doi: 10.1093/europace/eup440

**Yanulis GE**, Lim P, Ahmad A, Popović ZB, Wallick DW. Coupled pacing reverses the effects of persistent atrial fibrillation on the left ventricle. *Ann Thorac Surg*. 2008 Sep;86(3):984-7. doi: 10.1016/j.athoracsur.2008.03.085

**Yanulis GE.** A novel cardiac pacing paradigm for atrial fibrillation and heart failure patients [dissertation]. [Cleveland (OH)]: Cleveland State University; 2008 May, 106 p.

Cingoz F, **Yanulis GE**, Ching E, Fukamachi K, Wallick DW. Use of conventional dual chamber pacemakers with custom lead adapters to induce atrial fibrillation or heart failure in dogs. *Ann Thorac Surg.* 2007 May;83(5):1858-62.

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### ABSTRACTS

- Two abstracts presented on heart failure research at American College of Cardiology meeting
  - March 2008

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### PRESENTATIONS

- Rutgers Medical School, Cardiology Department
  - March 2013
- Rutgers College of Engineering, Biomedical Engineering
  - 2012
- Cleveland State University
  - April 2008

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### HONORS / AWARDS

- Cleveland Clinic Research Innovation Award
  - September 2008
- Cleveland Clinic Research Innovation Award
  - October 2007
- Honorable Discharge, USAF Medical Service Corp, 1<sup>st</sup>
  - March 1989
- Superior Achievement Award, United States Patent Office
  - 1983
- Member of Tau Beta Pi Engineering Honorary

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### PROFESSIONAL AFFILIATIONS / SOCIETIES

- Association for the Advancement of Medical Instrumentation
- Heart Rhythm Society
- IEEE Engineering in Medicine & Biology