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# Albert Vangura

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## Summary

- Engineering professional with nearly forty years of experience in product design, development, manufacturing, and testing with twenty-five of those years in medical devices.
- Extensive background in developing products including: AiresMINI Ventilator, RHYNO Windshield Cutter products, medical devices for Respirationics, Hill-Rom, Alung, Oberg and CardiacAssist, military aircraft for Sikorsky Aircraft, Boeing Defense and Space and the International Space Station at NASA, athletic products for Reebok, Adidas and the U.S. Olympic Biathlon team, childhood products for Velcro and the US Consumer Product Safety Commission.
- Twenty years as a forensic expert in biomechanics, bioengineering, and product development.
- M.S. Degree in Bioengineering; B.S. Degree in Exercise and Sports Science, and A.S. Degree in Mechanical Engineering Technology.
- Grew up in a machine shop with years of hands-on experience developing and creating physical prototypes, parts, and assemblies.
- Holder of multiple US and World Patents.

## Education & Certifications

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| University of Pittsburgh – Pittsburgh, PA<br>Doctoral Student in Bioengineering (finished coursework)                      | inactive |
| University of Pittsburgh – Pittsburgh, PA<br>Master of Science in Bioengineering   | 2000     |
| The Pennsylvania State University – University Park, PA<br>Bachelor of Science, Exercise and Sports Science: Biomechanics, | 1992     |
| The Pennsylvania State University – University Park, PA<br>Associate of Science in Mechanical Engineering Technology       | 1991     |

## Professional Experience

**We Cut the Glass, LLC – Gibsonia, PA** **May 2011 – Present**  
**President, Founder**

- Designed, developed, manufactured, and marketed the RHYNO Windshield Cutter™ - a novel battery-powered, hand tool used by rescue workers and law enforcement to cut laminated glass to gain access to injured motor vehicle occupants and buildings.
- RHYNO is patented in 27 countries – 120 distributors in 75+ countries.
- Developed products for manufacturability, usability, and safety using the latest in product development protocols and standards for design, human factors, lean manufacturing while meeting UL, CE, PSE, KC, and other safety certifications.

- Developed working prototypes, finished design, design documentation, test protocols and reports, manufacturing documentation and quality assurance/control documentation in support of regulatory body submissions. Sourced and managed suppliers, materials, and manufacturing. Developed CAPA procedures and managed complaint system.

**Biomechanics / Bioengineering / Product Development Consultant**

**May 2003 – Present**

- Specialist in impact biomechanics, injury biomechanics and the analysis of accidents involving: Medical Devices, Falls, Motor Vehicle Crashes, Machine Guarding, Human/machine Interface, Sports & Recreation Equipment, Manufacturability, Usability, Human Factors and Playgrounds.
- Provide industry consultations for product development, electro-mechanical test beds, biomechanics, manufacturing, usability, regulation & standards compliance.

**Aires Medical, Inc. – Mooresville, NC**

**March 2021 – March 2022**

**Director of Engineering**

- Lead a team to develop, manufacture, test and release to market novel, wearable non-invasive ventilators with portable oxygen concentrator and nebulizer.
- Develop the necessary testing for safety and efficacy for submittal and regulatory approval from FDA, CE and others for global expansion.
- Manage a diverse engineering team of 20+ Mechanical Designers, Human Factors Engineers, Hardware Engineers, Software Engineers, Regulatory and Quality Control/Assurance Engineers.
- Maintain financial accountability for budgeting and tracking.
- Apply and/or develop highly advanced technologies, scientific principles, theories and concepts that are new to the industry.
- Develop intellectual property towards Patent Applications in US and World.

**Philips/Respironics – Monroeville, PA**

**Apr 2019 – March 2021**

**Design Quality Engineer / Senior Consultant**

- Review designs, documents, records, for compliance to internal Quality Management Systems (QMS) procedures and regulations. Using SAP for document control for PDM/PLM.
- Ensure proper justification of statistical analysis and hypothesis testing.
- Participate in device risk management activities in accordance with ISO13485 and ISO 14971, support in establishing proper statistical controls in development and transfer to manufacturing processes, verify data integrity, electronic data storage and data sheet validations.
- Review and coordinate with Validation for all test method and design validation, review activities related to Design Verification and Design Transfer of Medical Devices.
- Ensure work product meets regulations.
- Support scientific, complaint, and test failure investigations.
- Participate in phase reviews, write Quality Procedures.

**Respironics – Monroeville, PA**

**Oct 2018 – Dec 2018**

**Systems Engineer / Senior Consultant**

- Review, evaluate and mitigate EU- MDR gap assessments.
- Develop written rationale for EU-MDR and FDA requirements.

**Lead Test Engineer / Senior Consultant**

- Project and systems engineering, manufacturing and planning, preparation and execution of the CH-53K Static Test Article, Drop Test Article and Fatigue Test Article qualification tests.
- Test loads development, fixture design and development.
- Prepared test plans.
- Documentation control using DOORS.
- Coordinated design and construction of a complex electro-mechanical test program using dozens of hydraulic actuators, hundreds of strain gages and string potentiometers to apply simulated flight, ground, handling, taxi and take-off loading scenarios for envelope expansion and 1st Flight.
- Prepared presentation materials for the US Navy (NAVAIR).
- Prepared formal internal and government reports and presentations.

**Oberg Industries – Pittsburgh, PA**

**2007 – 2008**

**Consultant - Senior Bioengineer**

- Coordinated the design and development of a series of electro-mechanical machine cells used to manufacture proprietary aerospace and medical device products.
- Developed the manufacturing validation and verification protocols for diabetic pumps and associated needles (IQ, OQ, PQ).

**ALung Technologies, Inc. – Pittsburgh, PA**

**2007**

**Project Manager / Senior Bioengineer / Consultant.**

- Packaging design, development, and manufacturing for a novel electro-mechanical extracorporeal blood oxygenation device.
- Assisted with product development, verification and validation, biocompatibility testing, human factors, usability, packaging of a novel, proprietary disposable hemodynamic oxygen exchange device.

**Respironics, Inc. – Pittsburgh, PA**

**2002 – 2003**

**Project Manager / Senior Bioengineer/ Systems Engineer**

- Developed wearable medical devices to treat sleep disorders.
- Developed working prototypes for human factors and marketing comparisons.
- Worked inside cross-functional teams to define the specifications for mechanical packaging, electronics, software, materials, human factors, disposables, user manuals, regulatory submittals, clinical trials, usability, quality control/assurance, manufacturing, and shelf packaging.

**CardiacAssist, Inc. – Pittsburgh, PA**

**1999 – 2002**

**Project Manager/Senior Bioengineer/Systems Engineer**

- Designed and developed transcatheter and implantable heart pumps.
- Directed development of mechanical specifications for electro-mechanical drive mechanisms, blood contacting materials, manufacturing processes, human factors, quality processes and clinical applications.
- Assisted with preparation of documents in support of regulatory submissions and quality system compliance.

**Marshall Space Flight Center – Huntsville, AL**

**1999**

**Structural Test Engineer**

- Project planning, preparation of the International Space Station Static Test Article qualification tests.
- Test loads development, electro-mechanical test fixture design and development.
- Prepared test plans.
- Coordinated design and construction of a complex electro-mechanical test program using 37 hydraulic actuators, hundreds of strain gages and string potentiometers to apply simulated flight, ground, handling, taxi and take-off loading scenarios for envelope expansion and 1st Flight.

**Musculoskeletal Research Center – Pittsburgh, PA**

**1999 - 2000**

**Research Associate**

- Soft-tissue Biomechanics.
- Developed and executed soft-tissue and joint biomechanical studies to evaluate and characterize the mechanical/structural properties and kinetics/kinematics.
- Designed and developed electro-mechanical test systems and utilized tensile test machines and electro-mechanical test beds.
- Cadaver dissection.
- Prepared manuscripts for publishing in peer-review journals, technical book chapters and national conferences.

**Human Engineering Research Laboratories / VA Medical Center – Pittsburgh, PA**

**1998**

**Research Associate**

- Developed and executed biomechanical wheelchair studies, wheelchair performance and reliability testing of wheelchairs utilizing electro-mechanical test systems including ergometers, specially-designed test fixtures.
- Incorporated biomechanical and human factors principles for usability and human/machine interface. Prepared grant proposals.

**Hill-Rom Company – Batesville, IN**

**1997**

**Mechanical Test Engineer**

- Developed electro-mechanical test fixtures to perform reliability testing of critical care hospital beds and equipment.
- Analyzed human factors, usability/performance, and developed test mannequins.
- Test program planning.
- Investment proposal writing.

**Boeing Defense & Space Group / Rotorcraft Division – Ridley Park, PA**

**1993 – 1997**

**Structural Test Engineer**

- Project planning, preparation and execution of the V-22 Static Test Article, Drop Test Article and Fatigue Test Article qualification tests.
- Test loads development, fixture design, development and manufacturing.
- Prepared test plans.
- Coordinated design and construction of a complex electro-mechanical test program using 72 hydraulic actuators, 1,200 strain gages and over 500 string potentiometers to apply simulated flight, ground, handling, taxi and take-off loading scenarios for envelope expansion and 1st Flight.

- Prepared presentation materials for the US Navy (NAVAIR).
- Prepared formal internal and government reports and presentations.

**Reebok International – Randolph, MA**

**1993 - 1994**

**Biomechanical Test Engineer.**

- Developed three electro-mechanical test machines to evaluate torsion, rotation and flexion characteristics of athletic shoe performance.
- Planned, prepared and executed tests on athletic shoes.
- Performed materials testing, data acquisition and statistical analysis.

**Leonard Associates – Mohnton, PA**

**1993 - 1994**

**Biomechanical Test Engineer**

- Developed a carbon fiber, road-racing bicycle front fork.
- Prepared a line-item cost analysis for a start-up, developmental machine shop.

**Exeter Research – Brentwood, NH**

**1992**

**Biomechanical Test Engineer**

- Developed electro-mechanical test machines.
- Prepared and executed sports equipment component tests.
- Material properties testing for athletic equipment.
- Report and technical documentation preparation.
- Supported a computer-based, foot-impact evaluation system in nine retail sporting good stores for Adidas.

**Vangura Tool Incorporated – Clairton, PA**

**1982 - 1992**

**Machinist**

- Tool design, fixture design, quality assurance, milling (CNC, manual), turning, welding, sawing, drilling, grinding, EDM, and benchwork.

**Biomechanics Laboratory / Pennsylvania State University – University Park, PA**

**1990 - 1992**

**Research and Teaching Assistant / Mechanical Engineering Aide.**

- Prepared and executed biomechanical and sports equipment studies in baseball, golf, hockey, football, tennis, boxing, volleyball, cross-country skiing.
- Material properties testing.
- Assisted in development of electro-mechanical, computer-based test systems.
- Coordinated, instructed a biomechanics seminar.

**Patents**

- A Hand-held Tool For Breeching Laminated Glass, Tempered Glass and Film-covered Glass and Method For Using Same. Serial #: 62/333,389 Filed: 5/9/2016
- A Hand-held Tool for Cutting Laminated Glass and Film-covered Glass and Method for Using Same, U.S. Patent: 9,409,813. Inventors: A. Vangura.
- Wheelchair Hand Rim, Patent #: 6,276,705 Issued August 21, 2001. Inventors: Mark Baldwin, MS, Rory A. Cooper, Ph.D., Michael L. Boninger, MD, Albert Vangura, MS, and James Ster