XAVIER ZEKE ARAMBULA

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 - Portfolio: https://xavierarambula.online
- Introductory Loom Video: * Exploring Medical Device and Orthopedics (Spine) Opportunities

PROFILE

• Early-career Biomechanical Engineer with experience in 3D-printed orthopedic implants (fixtures) and project engineering (Class 2 Powered Wheelchair). Strong background in anatomy, physiology, and orthopedics, with a passion for the spine market. Seeking a full-time role in medical device design, quality, or product management.

EDUCATION

5/24

San Diego State University, San Diego, CA

- B.S. in Mechanical Engineering (Bioengineering)
 - Relevant Coursework: Biomechanics, Computer-Aided Design, Fluids Engineering, Human Anatomy, Human Physiology, Mechanical Components, Mechanics of Materials, Mechatronics Laboratory, Molecular Biology, Nanobiotechnology, Scalable Manufacturing, Sensor Technology, Thermodynamics

EXPERIENCE

9/24 - present 9/24 - present Substitute Teacher, BCSD & SDUSD, Bakersfield & San Diego, CA

Engineer 1, CTLS (Cervical, Thoracic, Lumbar, Sacral), Bakersfield, CA

- Design and 3D-print patient-specific spinal and extremity (PETG) implants using SolidWorks and a Bambu Lab P1S (FDM) 3D Printer. Use pre-op case parameters on LinkedIn (dimensioned CT scans) for each design input. Implants cover a variety of approaches (anterior, posterior, lateral) as well as styles (fusion, fixation). For spinal fusion cases, implants are to be used with pedicle screws. For trauma and extremity cases, implants are designed for stabilization or replacement.
- Conduct ASTM-compliant mechanical testing (F2077, F1717) using an Instron machine at a local university; test and validate
 performance characteristics of each implant. Furthermore, develop data analyses, perioperative surgical guides, and technical
 drawings (GD&T ASME Y14.5 compliant) to communicate the manufacturing and perioperative intent of each implant.
- Implement ISO 13485:2016 and ISO 14971:2019 standards for design control documentation purposes. Define technical risks
 and opportunities, including risk cubes, master records, and quality inspection plans, for each implant to ensure patient safety.
 Perform engineering studies on fabricated materials to facilitate further analysis; incorporate orthopedic surgeon feedback.
- 3D-print translucent PLA models (of the spine, pelvis, knee, and foot) to validate the anatomical fit of each implant.
 Project Engineer (Senior Capstone), Quality of Life Plus (QL+), San Diego, CA

9/23 - 8/24

- Led a 4-person team of Mechanical Engineers that developed and delivered a Class 2 Medical Device: a self-propelled beach wheelchair capable of transporting adaptive surfers with paraplegia or quadriplegia to and from the beach shore safely.
- Managed project logistics such as: budget, team meetings, timeline, material procurement, vendor and stakeholder communication, an Integrated Master Schedule (Gantt Chart via TeamGantt), and Engineering Change Orders for compliance.
- Modeled and assembled the final system design of the all-terrain wheelchair in SolidWorks; conducted FEA to verify load-bearing capacity (300-1000 lb). Created the Final Bill of Materials in an engineering drawing following GD&T ASME Y14.5.
- Integrated an NVIDIA Jetson Nano microcontroller with a ZED 2i stereo camera to enable semi-autonomous features (e.g, spatial mapping, object detection) to the chair via machine learning (PyTorch and Ultralytics YOLO). To enable obstacle avoidance in conjunction with the wheelchair's motor controller (AC/DC connections), an emergency stop function was created. The chair is maneuverable via a joystick for use by adaptive surfers and also automatically stops to avoid any objects upon detection.
- Assisted with fabrication (welding) of chair and leg rest hardware made from 304 Stainless Steel (ASTM-A554 Mill Finish).
 Conducted validation and testing procedures to ensure compliance with safety and technical parameters outlined in the Preliminary Design Report (PDR); incorporated continuous stakeholder feedback throughout the design process.
- The final working prototype was received successfully by the sponsor (QL+) and industry at the Senior Design Day Expo in May; the wheelchair was delivered to the client (AmpSurf) in August (couldn't be delivered earlier due to the client's prior obligations). From May to August, was responsible for equipment maintenance and ensuring the prototype retained all working functions.

Hard Skills: Anatomical Modeling, ASTM & ISO Standards, Automation, Biocompatibility, Biomaterials, Cadaver Labs, Continuous Improvement, Design Control, Finite Element Analysis (FEA), Gage R&R, Mechanical Testing (Instron, MTS), Medical Instrumentation, Patient-Specific Design, Medical Device Documentation (DHF, DHR, DMR, QMS, 510(k)), Medical Device File, Medical Device Regulations (21 CFR 820, EU MDR), Medical Imaging Integration (CT, MRI), Rapid Prototyping, Test Protocols, Tolerance Stack-Up Analysis, Verification and Validation (V&V)

Design: ANSYS, Autodesk Inventor, CATIA, Fusion 360, PTC Creo (Windchill), Siemens NX, SolidWorks (PDM)

Software: Linux Terminal, Minitab, Materialise (3-Matic, Mimics, Orthoview), Microsoft (MS) Office, ZED SDK

Programming: Arduino IDE, C++, Git, Java, MATLAB, NVIDIA Jetson, Python, SQL, VBA, Machine Learning (PyTorch, Ultralytics YOLO)

Manufacturing: 3D Printing (FDM, SLA, SLS), DFM, DOE, GMP, Lathe, Mill, Polymers, Power Tools, Resin, Soldering, Turn, Welding (TIG, MIG)

Training: Certified SOLIDWORKS Associate (CSWA), GD&T (Advanced Applications, Fundamentals, Inspection - Engineer Essentials LLC), Lean Six Sigma Green Belt (Six Sigma Global Institute), Print Reading and Tolerances (Engineer Essentials LLC), SDSU Machine Shop Training

Soft Skills: Adaptability, Cross-Functional Collaboration, Design Reviews, GTM Strategy, Material Selection, Process Optimization, Regulatory Compliance, Risk Management (FMEA, CAPA), Root Cause Analysis, Statistical Analysis, Stakeholder Management, Technical Documentation

Languages: English, Spanish