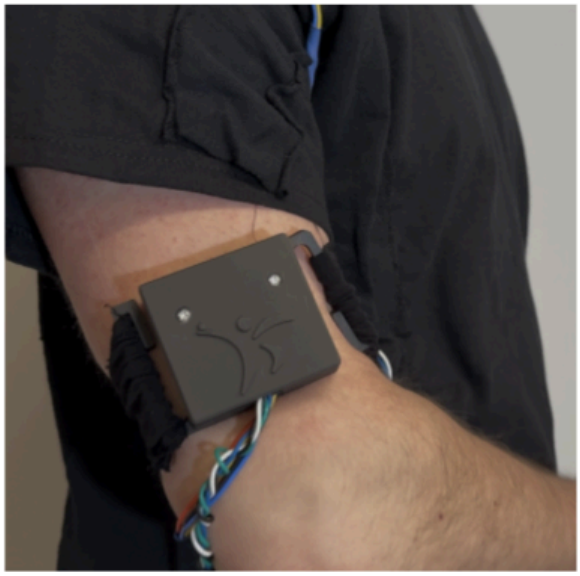
Axio Recovery

A Non-Invasive Valgus Elbow Torque Tracker for Real Time and User-Friendly Assessment of UCL Stress



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Submission Video: https://www.youtube.com/watch?v=kjjIC4S8IDw

CORNELL DEBUT BIOMEDICAL ENGINEERING PROJECT TEAM

Axio Recovery
The Real-TIme Elbow Torque Tracker

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I. Executive Summary (Abstract)

Ulnar collateral ligament (UCL) injuries represent a growing challenge in baseball; from 2010 to 2019, reconstruction surgeries surged 40%, with 54% of reported injuries occurring in athletes aged 15–19. Occurring during critical recruiting and development years, these injuries can delay or derail advancement to collegiate and professional competition. For Major League Baseball (MLB) pitchers undergoing UCL reconstruction, returning to MLB games requires an average of 20.5 months. (Solomito et al.) (Erikson et al.) Despite lengthy rehabilitation timelines, quantitative rehabilitation monitoring remains largely confined to motion-capture laboratories and medical imaging facilities (Trasolini et al.). *Axio Recovery* addresses this gap with a novel wearable rehabilitation tool that combines surface electromyography (sEMG) and inertial measurement unit (IMU) data to estimate elbow torque and track recovery progress throughout the return-to-throw process. The system leverages a patient-specific Hills musculoskeletal model calibrated using individualized muscle activation and motion data, reducing reliance on generalized biomechanical models and laboratory-based motion capture. Requiring only a one-time calibration, *Axio Recovery* enables continuous, non-invasive monitoring during rehabilitation exercises and on-field throwing activities using low-cost wearable sensors. In one representative trial, *Axio Recovery* estimated a peak torque of 55.6 N*m against the ground truth metric of 54.2 N*m from a motion-capture studio, yielding 2.58% error. Future development will integrate all sensing components into a single adjustable arm sleeve and extend the platform to UCL rehabilitation across multiple sports. The underlying sensing and modeling framework may also be adapted for injury monitoring and rehabilitation of other hinge joints.

II. Description of Problem

Ulnar collateral ligament (UCL) injuries are a growing challenge among overhead athletes such as baseball pitchers, javelin throwers, and tennis players. In New York State alone, UCL reconstruction procedures increased by 343% between 2003 and 2014, with 88.5% occurring in adolescents and young adults aged 15–24, driven by factors including overuse, early sports specialization, and poor throwing mechanics. Considering these injuries disproportionately affect athletes during critical development and recruiting years, effective rehabilitation and return-to-play monitoring are essential for long-term athletic success. (Solomito et al.) In addition to adolescents, MLB athletes are an extreme risk group experiencing a significant increase (40% increase from 2010 to 2019) in UCL reconstruction surgery (UCL-R, Tommy John surgery) to correct attenuation due to continuous, high-intensity overuse. Even after Tommy John surgery, MLB pitchers experience reduced performance in addition to lengthy recovery periods (~600 days) that impact careers and delay return-to-play.

Current methods for characterizing UCL-related stress, such as consumer-oriented wearable diagnostics, in-person MRI consultations, or camera-based motion capture, remain limited. The consumer-oriented market consists of products that are accessible but biomechanically inaccurate; the leading product, Driveline's *Pulse,* has an estimated 38.7% error (Boddy et al.). MRI consultations can diagnose ligament damage but cannot continuously assess elbow loading during throwing and rehabilitation activities. Motion-capture studios, such as Kinitrax's *Hawkeye*, are streamlined but expensive (>$1,000,000), limiting use to artificial

labs, and require physical simplifications of muscle engagement . Our surveys of 10+ customer stakeholders (clinical staff specializing in biomechanics and college-level D1 athletes) additionally demonstrate an underdeveloped market for managing UCL-based physical therapy. Right now, no device delivers accurate, personalized, non-invasive, and low-cost UCL-stress analysis for players in the field.

III. Project Objective

Axio Recovery is an in-field wearable system that estimates valgus elbow torque during rehabilitation following UCL reconstruction. Our innovation lies in translating the patient-specific Hill's musculoskeletal model into a wearable, field-deployable rehabilitation system using personalized surface electromyography (sEMG) and inertial measurement unit (IMU) measurements, giving continuous, accessible biomechanical monitoring. The platform consists of wearable sensor bands, a portable datalogger, and physician-facing analysis software, allowing data-driven rehabilitation and return-to-play decisions.

We leverage the Hills Musculoskeletal Model (HMM) to estimate elbow torque from muscle activation and limb kinematics. Unlike current systems that rely on generalized biomechanical assumptions and specialized facilities, the model is calibrated to each athlete and can be deployed during routine rehabilitation and training. We apply the HMM as a generalization of torque, where force is the contraction of the target muscle group, and radius is the distance from the muscle head to the elbow joint. The Hills-Musculoskeletal Model is a widely used model for elbow torque prediction in clinical settings, and recent advancements in sensor technology for surface electromyography (sEMG) and estimated positional/rotational sensors streamline integration into the *Axio Recovery* device. By targeting the major muscle groups contributing towards elbow torque (i.e., biceps brachii long head, triceps brachii long head, triceps brachii short head). This information provides in-field correlation between elbow torque for pitch types and elbow torque that directly informs physician decision-making on specialized physical therapy regimens and recovery timeline. With *Axio Recovery*, athletes are provided with a consumer-grade diagnostic that non-invasively characterizes UCL stress with elbow torque metrics in a streamlined, easy-to-wear sleeve.

IV. Documentation of Design

Software Analysis Methods

Our proprietary musculoskeletal software serves as one of leading novel methods for elbow muscle torque prediction, originating from Hu et. al, "An Improved EMG-Driven Neuromusculoskeletal Model for Elbow Joint Muscle Torque Estimation" (Hu et al.). Multiple kinematics and physiological models are synthesized with the Hill-Musculoskeletal Model to simplify inputs required for elbow torque computations. Throughout the development process, the software is coded with Python, stored in an ISO-compliant GitLab coding stack, and launched through a cloud-hosting platform on our website (*www.axiorecoverytracker.com*).

The net resultant muscle moment, referred to previously as elbow torque, follows the basic model for torque according to the elbow joint kinematic model (where

$\tau(\theta, t) = \Sigma\,(r(\theta, t) * F(\theta, t))$. From a high-level perspective, the radius component of elbow torque represents the distance of the muscle head relative to the elbow joint, and the force component represents the contraction of the target muscle. This sets the outline for the two data inputs (and sensors) required for estimating elbow torque: muscle head location (IMUs) and muscle contraction force (sEMG). While the muscle head radius model requires basic tendon and ligament information to determine kinematics in the end user, the muscle contraction model extrapolates force response metrics from preexisting literature. Additionally, calibration factors are integrated to specify the musculoskeletal model for the specific end user, which is instructed through a user manual for the prescribing physicians. This includes procedures such as range-of-motion exercises and high-repetition training while equipped with the wearable *Axio Recovery* sensor bands.

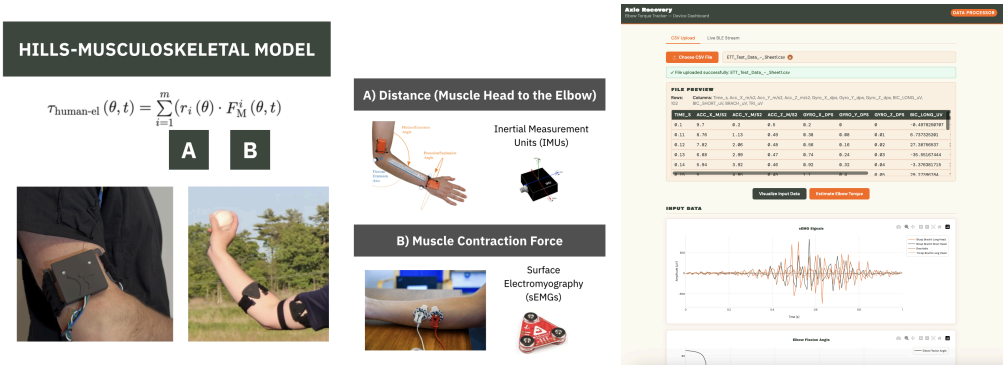

Figure 1 & 2: Figure 1 (left) represents the basic Hill's Musculoskeletal Model shown for elbow torque computation. Hill's model involved computing individual force elements of the target muscle, computed with the user interface. Figure 2 (right) represents the physician software.

Design for In-Field Equipment

Our physical product consists of wearable sensor bands and a training session datalogger given to the end user for storing biometrics. The design remains consistent across iterations, inspired by the experimental design from the Human Robotics Group at the University of Alicante (Garcia et al.). Stock sEMGs (*MyoWare 2.0*) and IMUs (*LGD320 9DOF*) are encased in ABS plastic on a nylon compression band that easily slides up the arm. These are directly connected to a WROOM Sparkfun ESP32 microcontroller in a waist-worn datalogger design via I2C (IMUs) and Analog (sEMGs). Our custom PCBs include basic analog filters, USB-C charging, and I2C multiplexers for sensors. The ESP32 is coded in C++ for signal processing (bandpass filtering & smoothing), compiling data, and optimizing packing for low-latency data sampling of ~10 kHz. The ESP32 is microSD card compatible and flexible for future expansion into wireless transmission via Low-Range Radio (LoRa) or Bluetooth (BLE).

Our project specifically targets the biceps brachii long head, the triceps brachii long head, and the pronator-teres muscles for elbow torque estimation. In-person market research from athletic immersion with baseball and tennis players highlighted the wearability of devices

over accuracy. As such, our team conducted extensive experimentation and noted that these target muscle groups are dominant sources of UCL stress (>10%) for elbow torque estimation.

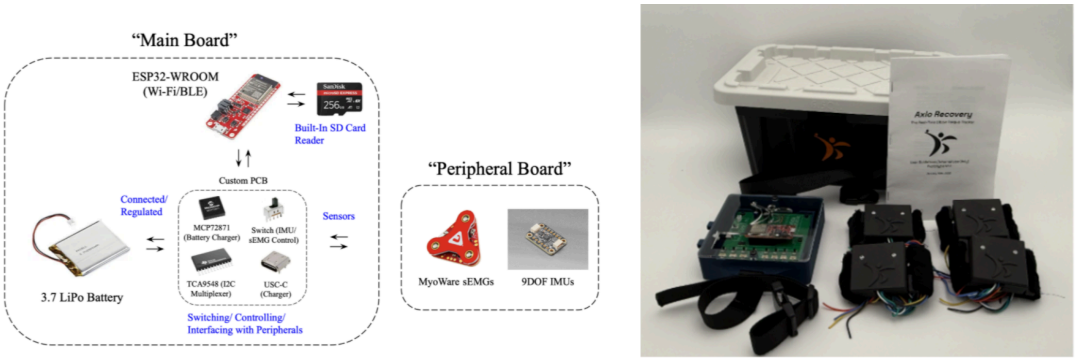

Figure 3 & 4: Figure 3 (left) represents the general electromechanical design for the physical product (including wearable sensor bands and datalogger). Figure 4 (right) includes all components provided in the entire workflow for prototype V2.0.

V. Final Prototype and Functionality

Verification Testing

Verification testing for the physical *Axio Recovery* V2.0 encompassed qualitative wearability assessment and quantitative confirmation of key design features. During pitching regimens (n = 6), participants completed baseball pitching exercises without observable restriction in range of motion; a demonstration of a member using the device is in the attached video. The sensor arm bands and datalogger are designed to avoid pinching, and no electrical dropouts or sensor migration were observed during an 8-hour trial wearing and testing the device. This trial additionally confirmed no issues with range-of-motion (ROM) while actively using the device. From shorter-duration durability testing, one participant (1 of 6) reported mild contact dermatitis from EKG pad exposure, which has been identified for future improvement.

Verification testing confirmed that the final prototype satisfied all user-defined design requirements. Our testing established that we have +3 hours of datalogging capabilities (the length of a typical training session), a sensor band mass < 75 g and < 40 C surface temperature for devices (for user comfort). For the software testing, edge case assessments including biceps curls and side-to-side waving were conducted. This included basic throws with low-muscle engagement, which provided valid <5% error in motion-detection for arm kinematics.

Initial Validation Testing

Axio Recovery has undergone preliminary validation testing in an OptiTrack motion capture studio at Cornell University. Low-intensity overhand throws (~20 mph) were recorded simultaneously with the *Axio Recovery* device and the *OptiTrack* system, and elbow torque was estimated with various post-processing methods. For *Axio Recovery*, elbow torque is estimated and downloaded as a .CSV from the Hill-Musculoskeletal pipeline on the main website. For the

reference standard for validation, the *OptiTrack* motion capture system, elbow torque is extrapolated from the motion dataset with the Upper Extremity Dynamic Model in OpenSim, an open-source platform for simulating human movement. As recommended, additional MATLAB processing utilizes user metrics (weight, height, forearm/ upper arm length) to better tune signals before computing the inverse kinematics. As shown in Figures 5 and 6, in one representative trial, *Axio Recovery* estimated a peak torque of 55.6 N*m against the ground truth metric of 54.2 N*m from the OpenSim pipeline, yielded 2.58% error. These results demonstrate that the wearable system can reproduce laboratory-derived torque measurements while operating outside a motion-capture environment. This is a fraction compared to the 38.7% error reported from Driveline's *Pulse* device currently in the field. From this, *Axio Recovery* achieves research-grade accuracy in a streamlined design, thus closing the gap in UCL rehabilitation management.

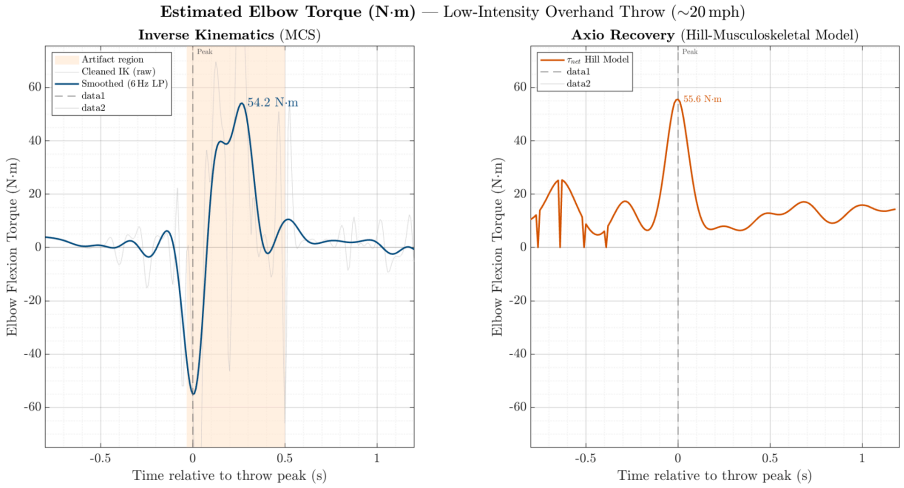

Figure 5 & 6: Side-by-side comparison of torque from inverse kinematics in the motion capture studio (*OptiTrack, left*) and the Hill Model (*Axio Recovery, right*) device. Specifically, prototype V2.0 is worn underneath the motion capture equipment during trials.

Future Improvement

Two priorities for the next iteration include wireless data streaming for the sensor arm bands and a digitized calibration workflow for physicians. Sensors are currently wired to the PCB-shield via Molex connectors, which is not ideal for athlete comfort. Our team continues to experiment with common wireless methods in consumer wearables such as Low Range Radio (LoRa) and Bluetooth Low Energy (BLE) as wireless alternatives for low-cost alternatives. Additionally, the current IFU-guided calibration protocol will be transitioned into a digital walkthrough controlled through a 2.7" LCD touchscreen integrated into the datalogger. These refinements converge on the V2.0 form factor with slimmer components and an interactive on-device interface, completing the development phase before an official comparative effectiveness study (CER) validation testing with overhand throwing athletes being processed for IRB approval from Cornell University.

VI. Patentability

Axio Recovery enters the market as a novel diagnostic tool leveraging patient-specific muscle biomarkers as opposed to trained musculoskeletal models.Current methods for characterizing UCL stress, disregarding in-person consultations with physicians, involve either wearables or generalized motion capture models. While wearables are simple and low-cost, they are incredibly inaccurate or invasive. Pulse's *Driveline* (US 10,314,536 B2) filed October 2017 dominates the market as a non-invasive diagnostic device for estimated elbow torque and other throwing metrics, however, experiences significant, 38.7%, error. Other on-market products use standard or infrared cameras to track arm movements and map these motions to generalized models for muscle engagement. For athletic-specific applications, KinaTrax's *Hawkeye* system (US 10,445,930) is a markerless, machine learning motion capture system for biomechanical information. Hawkeye is popular for controlled pitching environments but requires intensive training data and high up-front costs (~$1,000,000 installation fee) (Verducci). For general applications, OptiTrack's *Flex3* camera (US 9,100,587) and *Motive* software (US 9,019,349) is a lower-cost motion-capture system in academic biomechanics settings. While more accessible, these require external musculoskeletal modeling software such as OpenSim. As a result, data processing and interpretation remain dependent on biomechanics specialists, reducing accessibility for athletes and clinicians. Finally, similar nonprovisional (utility) patents use sEMG and IMUs to target gesture control (US9299248B2) and robotic training methods (US9278453B2), but not explicitly for musculoskeletal modelling methods.

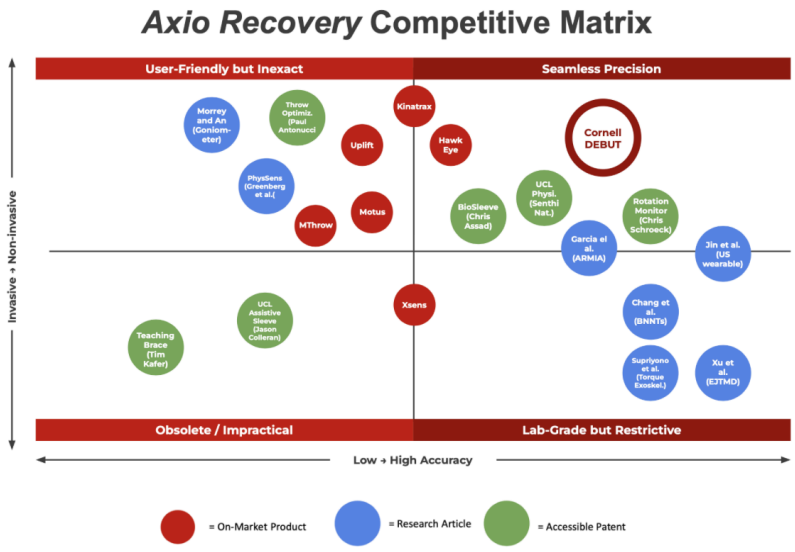

Figure 7: Competitor analysis of the on-market, research-based, and patented products

VII. Regulatory Pathway

Axio Recovery is a Physical Medicine Diagnostic Electromyography device under regulation 21 CFR 890.1375, and would be submitted through a traditional 510(k) Premarket Notification as a Class II device. The predicate device is the *Comprehensive Muscular Activity*

Profiler Pro (CMAP ProTM) from Medical Technologies Unlimited Inc. (MED-TEK) under K113074. *Axio Recovery* is a prescription, wearable sEMG and limb-position monitoring device. This is patient-worn and prescribed by sports medicine trainers to record and display upper-arm muscle activity and motion during athletic applications in support of the patient's clinical assessment. As a sEMG-based system used to provide neuromuscular characterization of a user's condition with physician supervision, *Axio Recovery* aligns with the *CMAP ProTM* device.

The *Axio Recovery* device and software verification and validation testing follow similar requirements to the *CMAP ProTM* and *Axio Recovery* devices, specifically IEC 60601-1-11 (medical electrical equipment) and ISO 80601-2-78 (wearable physiological monitoring device). Priority testing (as outlined in K113074) includes mechanical strength/resistance, surface temperature limits, operational reliability, and hazard prevention. Substantive validation evidence will be provided through a Comparative Effectiveness Research (CER) study through the Cornell IRB Advisory Board to compare the functionality of the *Axio Recovery* device to the typical gold standard of motion capture. The study aims to recruit experienced baseball players and compare estimated valgus elbow torque from the *Axio Recovery* device against inverse kinematics estimations for valgus elbow torque in a professional motion capture studio. This characterization will act as our breakthrough study to directly compare the effectiveness and usability of integrated Hill-Musculoskeletal modeling with on-market products such as Driveline's *Pulse* product.

VIII. Reimbursement

The *Axio Recovery* device and workflow are billable under Remote Therapeutic Monitoring (RTM), which is covered by Medicare for specific patients. The Centers for Medicare and Medicaid Services (CMS) categorizes wearable devices for musculoskeletal conditions under RTM, especially for rehabilitation in post-operative ligament rehabilitation (Department of Health and Human Services). This guideline establishes the billing procedure for software and medical devices, specifically under the American Medical Association's CPT codes 98975-98985. This includes RTM device education (98975), device supply (98977), short-term monitoring (98985), and long-term remote treatment (98980 & 98981). *Axio Recovery* meets the specific device threshold as a medical device transmitting physiological information for clinical usage (Medbridge).

Axio Recovery is not reimbursable for the athletic users through Medicare or Medicaid; however, it is reimbursable for eligible participants through Medicare Part B and some state Medicaid programs. While athletes are not covered due to ineligibility in the Medicaid and Medicare services, eligible individuals are covered through specific monitoring criteria through both services. This includes limitations on building, requirements for patients to be afflicted with a diagnosed acute/chronic condition, and FDA compliance (Telehealth.HHS.gov). Under the Medicare Physician Fee Schedule (MPFS) in Medicare Part B, RTM for managing elderly patients' musculoskeletal health is covered through a fixed-cost program. Additionally, Medicare is likely to cover an assistive joint diagnostic to improve long-term patient outcomes and reduce joint regression, with proper rehabilitation service consultation. 42 States are currently enrolled in Medicaid reimbursement programs for remote patient monitoring devices, ranging from full coverage to reduced billing (Tashnek).

IX. Manufacturing Costs

The *Axio Recovery* device is expected to be retailed at $549.99, providing one set of sensor bands (3), one datalogger, and access to one user profile on the *Axio Recovery* online analysis software. The cost of goods (COGS) for one on-market product is about $353.73, incorporating equipment costs ($254.78), assembly/packaging costs ($66.79), and quality assurance ($32.16) for producing a single unit. Stock components are ~$132.06 of the equipment cost and are supplied by standard wholesale distributors such as DigiKey and MacMaster-Carr. Injection-molding and electronics fabrication are ~$122.72 of the equipment cost, and will be fulfilled by Protolabs (EUR) and PCBWay (CHN), respectively. All manufactured and stock components will be shipped domestically (USA) for assembly by a third-party medical fulfillment center such as Aretex. Quality assurance per unit is estimated at 10% of the equipment and assembly costs and accounts for Class II inspections, functional testing, firmware validation, documentation, FDA-compliant labelling, and compliant services.

While production services (injection-molding tooling, software management system, etc.) account for ~$40,000 in upfront administrative costs, a standard 510(k) submission for 21 CFR 890.1375 requires extensive initial investment (>$300,000) (HTF Market Intelligence). Additional administrative costs are expected and accounted for in a 3 YR financial proposal for managing shipping, middle-management logistics, and software access for each unit.

Our team expects ~35.69% in average revenue per unit (ARPU), as the pricing of one *Axio Recovery* device set is priced with the average cost for 1 hr of motion-capture studio time in a regional studio (MoCap, The Throwing Club). Considering our customer base regularly accesses these services during recovery, this positions our product to directly compete with the current gold-standard system. With a single purchase, players access a recovery tool for the entirety of their recovery process with more freedom, more accuracy, and unlimited data collection to discuss with physical therapists.

Estimated Pre-Revenue Device CPU	$353.73
Equipment	$254.78
Quality	$32.16
Packaging	$66.79
Estimated Post-Revenue Device CPU (35.69%)	$549.99
Initial Fees and Administrative Costs (3 YR)	$338,221.94
Tooling Costs	*$35,960.00*
Subscriptions	*$2,261.94*
Regulatory and QA (18-Month Timeline)	*$300,000.00*

Figure 8: Estimated CPU Breakdown for a single *Axio Recovery* device, including stock unit components, quality, packaging, and administrative fees.

X. Market Impact

Our purchasing customers are physicians in the orthopedic and sports medicine space, specialized in joint rehabilitation. Our targeted end users include UCL-R recovery patients and joint rehabilitation in the upper arm, including the elderly with joint instability and patients with generalized elbow pain. The major use case involves clinical staff members prescribing the *Axio Recovery* device for high-intensity professional throwing athletes in UCL-R rehabilitation. Similar to prescription orthopedic braces, a physical therapist provides a consultation post-operatively from UCL-R after players begin returning to interval training (150-200 days into recovery). With approval, the clinical specialist will prescribe the *Axio Recovery* device for use during non-competitive scrimmages and training to record practice data for analysis.

Axio Recovery is primarily distributed through institutional channels of athletic professional and collegiate programs with valid clinical staff, in addition to direct B2B wholesale to physical therapy clinics. Similar to motion-capture installation, devices are directly sold to athletic programs (such as the MLB, MiLB, NCAA, etc.) and administered by physicians on staff. Additionally, physical therapy clinics procure devices in 50 units wholesale from on-staff sales representatives, which are prescribed for patients with either ligament reconstruction (ex. UCL-R), joint recovery, or a considerable fall risk.

With this, our team anticipates piloting with 700 units (~$385,000 in inventory) based on a single quarter of demand through a standard Bass Forecast Model. The estimate is based on our initial market evaluation of the rehabilitation technology market. The United States Wearable Monitoring Device and Software segment in Sports Athletics serves as the serviceable available market (SAM), evaluated at ~$144.375 MN for overhand throwing athletes. With an estimated adoption rate of 5%, our serviceable obtainable market (SOM) is valued at ~$7.22 MN annually HTF Market Intelligence). The pilot program primarily accounts for the extreme demand for UCL-R assistive technology in professional baseball and aims to scale based on success in the sports therapy market. In the MLB and all MiLB (AAA, AA, High A, Low A, High Rookie, Low Rookie), approximately 13% of all players (~600 active players) require either UCL-R or elbow-based physical therapy to continue playing (Solomito et al.). Across the US, ~40,000 cases of UCL-related injuries immediately benefit from a management system that streamlines with physical therapists' regimens (Carr et al.).

Figure 9: The Total Accessible Market (TAM), Serviceable Available Market, (SAM), and Serviceable Obtainable Market (SOM) for the *Axio Recovery* product.

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