Team Results Document

Munich Bioneers

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1. Abstract: Summary for the SensUs website

Acute Kidney Injury (AKI) presents a daunting global health challenge, with early detection and continuous monitoring being critical for improving patient health outcomes. As Team Munich Bioneers from the Technical University of Munich, we tackled this issue by designing an innovative biosensor system for real-time creatinine monitoring. Guided by our mission to make kidney disease monitoring more accessible and user-friendly especially in underserved and remote areas, we developed a two-part solution that includes a electrochemical biosensor for continuous creatinine detection using a three-enzyme system with an amperometric readout alongside an intuitive wearable that utilizes microneedle technology for minimally invasive interstitial fluid solution diagnostics. This approach not only empowers patients to reassert control over their own health status but also enables earlier intervention in low healthcare equity regions. With a focus on accessibility, comfort and reliability, our biosensor aims to impact patient lives and reshape the future of kidney disease management.

2. AP award: Biosensor developed for the Eindhoven Testing Event

2.1. Molecular recognition

2.1.1 Detection

Hydrogen peroxide (H_2O_2) is widely used as a detection molecule in electrochemical biosensor applications such as glucose monitors due to its well-characterized electrochemical properties.[1] Since H_2O_2 allows for sensitive and direct amperometric measurements, our biosensor development is accordingly based on the amperometric detection of H_2O_2 via an enzymatic system that converts creatinine into H_2O_2.

This system consists of three enzymes, which work sequentially in the chain conversion of creatinine to H_2O_2 (**Figure 1**). The first enzyme, creatininase, oxidizes creatinine to creatine. The resulting creatine is subsequently transformed into sarcosine by creatinase, which is catalyzed into detectable H_2O_2 by sarcosine oxidase.[2]

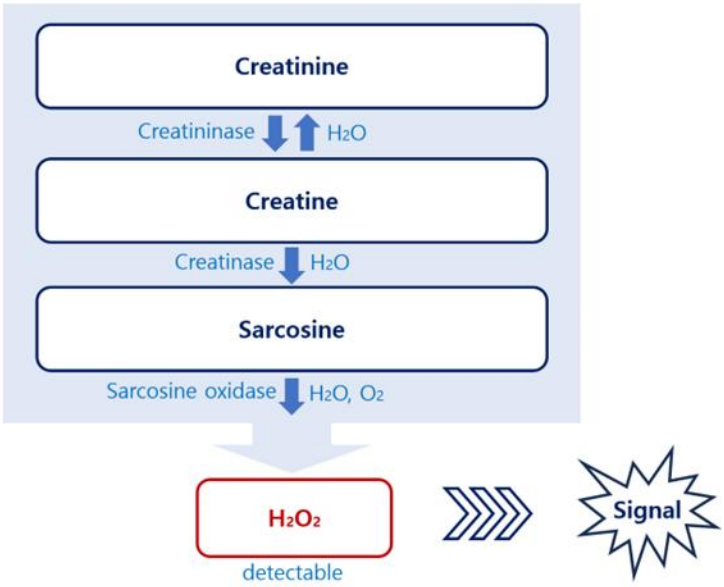

Figure 2.1 Schematic representation of the enzymatic cascade for creatinine detection. *Creatinine is sequentially converted by creatininase, creatinase and sarcosine oxidase into hydrogen peroxide (H_2O_2), enabling sensitive amperometric measurement.*

2.1.2 Immobilization

For immobilization, a combination of glutaraldehyde and bovine serum albumin (BSA) were chosen. Glutaraldehyde is a commonly used crosslinking agent and with its two reactive aldehyde groups, it can bind to both enzymes and BSA, bridging them together. This makes it a good choice for enzyme immobilization, minimizing enzyme loss during sensing and improving the overall robustness of the sensor itself.

As a stabilizing and spacing protein, BSA ensures that the enzymes preserve their natural structure and do not lose activity. It also contributes to the overall stability of the electrode by providing an additional mechanically stable layer on the electrode surface. Furthermore, it helps to prevent unwanted, non-specific binding of other interfering molecules.[3][4] Combining them provides following advantages: improvement of enzyme immobilization, producing stable films and consistent enzyme activity compared to other methods.[5]

2.2. Physical transduction

2.2.1 Method of measurement

To quantify the concentration of H_2O_2 and thereby creatinine, amperometry measurement was chosen due to its fast response time and reliable current measurement in steady state.[6] In amperometry, the steady state current resulting from the oxidation or reduction of molecules at a fixed potential is measured, which is proportional to the concentration of the target analyte. In our biosensor, H_2O_2 is oxidized at the working electrode and provides a sensitive yet rapid signal, enabling real-time monitoring of creatinine levels. In addition, amperometry offers advantages in terms of electronic system design: a digital-to-analog converter (DAC) is not required, which simplifies the overall implementation.

In contrast, cyclic voltammetry (CV) requires a voltage sweep to determine the peak voltage and its corresponding current. This typically involves the use of a DAC to apply the sweep to the electrode, which increases both the cost and complexity of the system. Therefore, we experimentally determined the peak voltage in advance and built an electronic system that applies this fixed potential to the electrodes for chronoamperometric measurements. By applying this potential, we obtained a steady-state current with a response time of 100–120 s.

2.2.2 Electrodes

A commercial screen-printed electrode (SPE) was used for the electrochemical measurements (Metrohm Deutschland, Product Code: DRP-710-U75). This SPE is composed of a single working electrode (WE) composed of Prussian blue/carbon, a carbon counter electrode (CE), and a silver reference electrode (RE). The electrical contacts are silver, and the substrate is made of ceramic.

Carbon is commonplace in biosensor applications due to its stability, excellent electrical conductivity and broad potential window, all of which enable efficient electron transfer.[7] At the working electrode, H_2O_2 undergoes a two-electron oxidation.

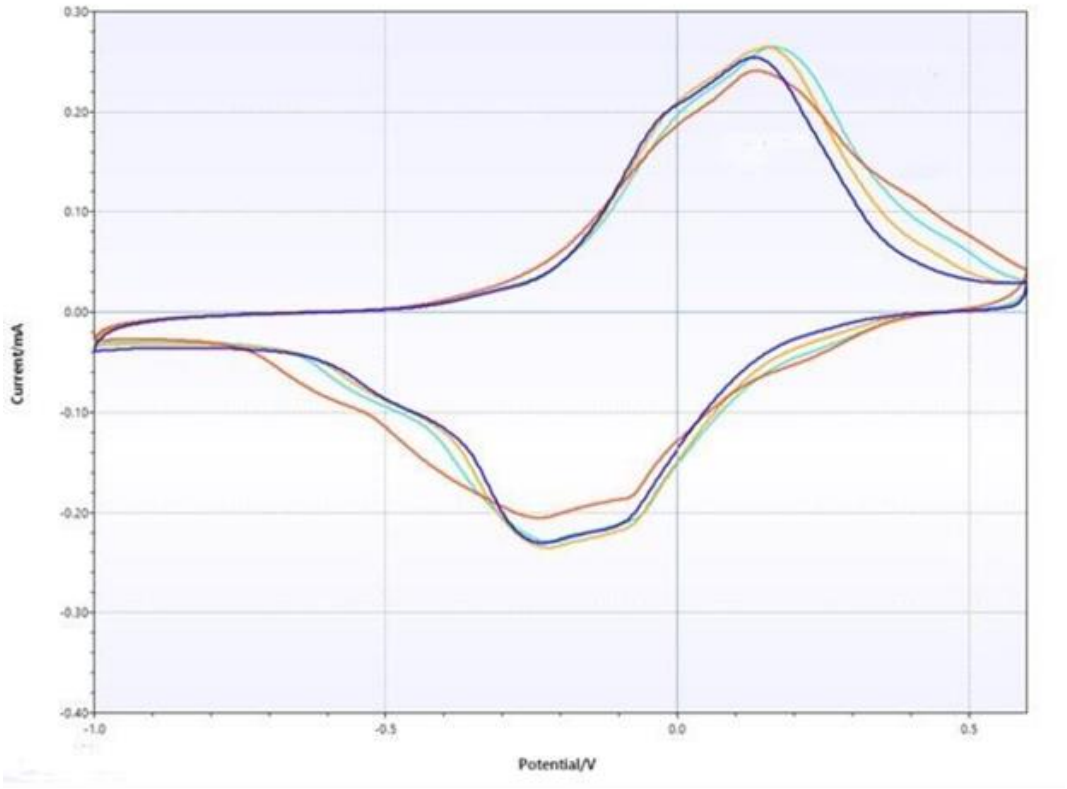

Figure 2.2 Cyclic voltammograms **of the Prussian Blue-modified carbon electrode showing current response to increasing H_2O_2 concentrations in PBS.** *CVs of the prussian=blue modified carbon electrode recorded over a potential range from −1.0 V to +0.6 V in phosphate-buffered saline (PBS, red) and in the presence of different hydrogen peroxide (H_2O_2) concentrations: 125 µmol (light blue), 250 µmol (orange), and 500 µmol (dark blue). The carbon-based working electrode facilitates the two-electron oxidation of H_2O_2, producing a current proportional to its concentration.*

The cyclic voltammogram in Figure 2.2 presents the CV curves for PBS and various concentrations of H_2O_2 diluted in PBS, showing only a slight decrease in current response with rising H_2O_2 concentration.

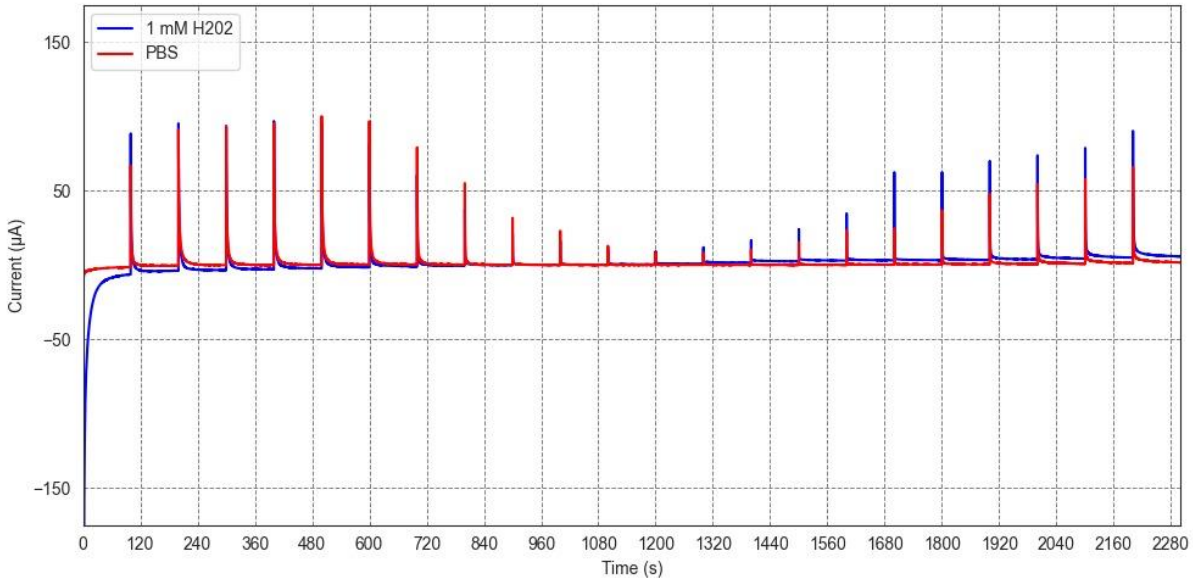

Figure 2.3. Chronoamperometric Measurements from −0.2 V to +0.9 V (0.05 V steps) for PBS and 1 mM H_2O_2

The chronoamperometry plot (Figure 2.3) shows the biosensor's response in PBS (red) and 1 mM H_2O_2 (blue) with applied potentials stepped from −0.2 V to +0.9 V in 0.05 V increments. PBS exhibits higher current than 1 mM H_2O_2 at potentials up to approximately +0.1 V, after which the trend reverses and H_2O_2 yields higher currents, consistent with its oxidation at more positive potentials.

2.3. Cartridge technology

The biosensor cartridge consists of a three-layer modular assembly, which comprises a solid PMMA bottom block, a PMMA top block with integrated inlet and outlet ports and a gasket layer in between. The gasket contains an iCell-style i.e., eye-shaped microfluidic channel featuring an impinging jet inlet and overlaid channel flow to ensure uniform exposure across the SPE surface [10]. A simplified CAD render can be found in **Appendix 1**.

Sample introduction is performed via pipetting at the inlet. The outlet is connected to a syringe pump, enabling precise displacement of the existing fluid with a new sample. This method maintains a stable measurement environment without introducing air bubbles or requiring wash steps. Our system supports continuous sensing by maintaining a constant flow and periodic replacement of sample fluid. The sensor responds in real-time to creatinine concentrations, with stable flow conditions allowing time-resolved signal acquisition for longitudinal measurements.

2.4. Reader instrument and user interaction

Our 5cm x 8cm printed circuit board (PCB) consists of the following electrical elements:

- Transimpedance amplifier (TIA)
- Analog-to-digital converter (ADC)
- Microcontroller unit (MCU)
- OLED Display

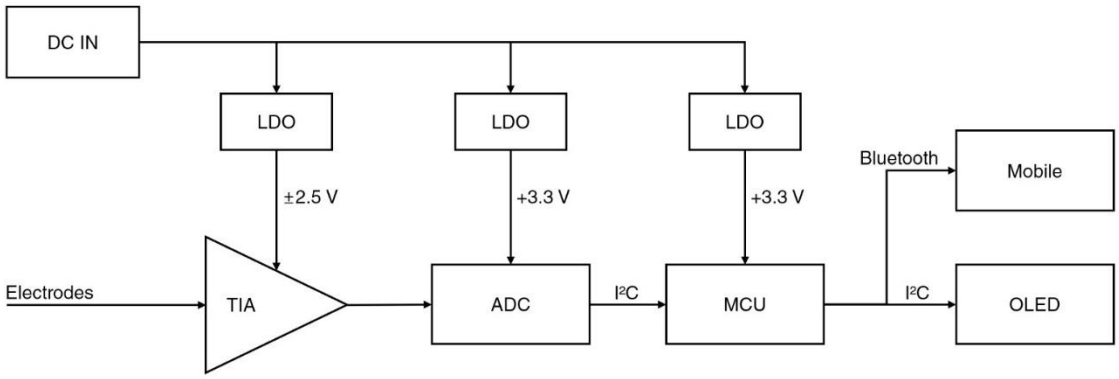

Figure 3. Block diagram of the biosensor reader system. *The PCB reader showing the signal pathway from the electrodes through the transimpedance amplifier (TIA), analog-to-digital converter (ADC) and microcontroller unit (MCU), with power regulation via low-dropout regulators (LDOs), and data/output interfaces including Bluetooth to mobile devices and an OLED display.*

The TIA is implemented as a current-to-voltage amplifier using an operational amplifier. Its main purpose is to convert the microampere range current into voltage, which enables generally easier signal processing. Due to sensitivity of raw signal against noise generated by the electrodes, it was crucial to select an operational amplifier with near ideal parameters e.g., very low input bias current (Analog Devices ADA4530-1). The output voltage is then fed into an ADC, which converts the value-continuous voltage into a discrete value output that can be read by the MCU. Again, to increase sensitivity, it was necessary to select an ADC with a high sampling rate and resolution. The output is then transmitted to the microcontroller via the I2C serial protocol. The MCU is programmed to read the serial output from the ADC, processes the signal values and finally, either displays the results on the OLED screen or transmits them to a user device via luetooth.

For the power supply of the system, we used a Li-Ion battery with a battery management system (BMS). We converted 3.7V of the battery into 6V and –4V with a DC-DC Converter. For the different operational voltage levels of TIA, the ADC and MCU, a low-dropout regulator (LDO) was introduced to ensure voltage stability and to prevent signal distortions. In the event that the manufacturing phase proves unsuccessful, an alternative approach involves utilizing the PalmSens 4 potentiostat, programmed via Python, to

acquire concentration data.

The implemented program on the Teensy 4.1 MCU acquires an analog signal from a sensor connected to pin A0, converts it into a corresponding voltage, applies a calibration step to determine a concentration value and transmits the processed data to a host computer via serial communication for monitoring and analysis. The built-in ADC of the MCU samples the input, producing integer counts in the range 0-255, which are proportionally mapped to voltages between 0V and the reference voltage of 3.3V. This measured voltage is then passed to a calibration function, where the equation for concentration will be determined and implemented once experimental results are obtained.

The proposed app presents creatinine levels in an intuitive way, helping patients and healthcare providers easily view and interpret results. Users can either log in or use the app with a guest account for one-time measurements. Features include an educational page on AKI and creatinine ranges (normal, high, very high), alerts for abnormal values, history of past readings, daily measurement reminders and kidney-friendly diet and exercise tips. Future updates may add PDF expot support, dark/light mode, an FAQ section, interactive quizzes and user surveys to improve experience and support research.

3. IN award: Biosensor innovation

Continuous monitoring of creatinine levels in the skin is critical for early detection and management of kidney failure and we propose a microneedle-based wearable biosensor capable of long-term, real-time measurement.

3.1. Wearable sensor

3.1.1. Technological novelty of wearable sensor

Our wearable biosensor utilizes a gold-coated hollow microneedle array for continuous, minimally invasive monitoring of creatinine concentrations in interstitial fluid (ISF). Hollow microneedles penetrate the stratum corneum and epidermis to reach the dermis, where ISF transport occurs primarily through convective flow (Samant & Prausnitz, 2018). The minimally invasive nature of microneedles offers significant potential for improving the standard of care for AKI and other conditions associated with abnormal creatinine levels. As a future prospect, the microneedle platform can also be adapted for drug delivery, forming a theranostic system that integrates both diagnosis and treatment for personalized health monitoring (Qin et al., 2025).

The main technological novelty behind our biosensor is its microneedle design. On each electrode site, silver pillars are created through a drop-on-demand (DOD) inkjet printing process, during which controlled voltage pulses drive a piezoelectric actuator, generating

pressure variations that propel droplets of silver nanoparticle ink from the printhead onto the substrate surface. By repeatedly depositing and accurately aligning these droplets at predefined coordinates, a vertically stacked, pillar-like structure is formed (Kopic et al., 2024). The DOD printed needles were then passivated with Parylene-C, opened with a UV-laser (**Figure 4**) and finally electroplated with gold. For smaller pillar openings in the micrometer range, one can use a Focused Ion Beam to expose the conductive core (**Figure 5**).

The provided microneedle images have a length of approximately 450µm, however the dimensions of the pillar can be adjusted by changing the number of droplets, ink properties and initial drop-to-surface interaction. The manufacturing of high aspect-ratio pillars was possible with an average opening diameter of approximately 23µm and lengths reaching up to approximately 1mm (Kopic et al., 2024).

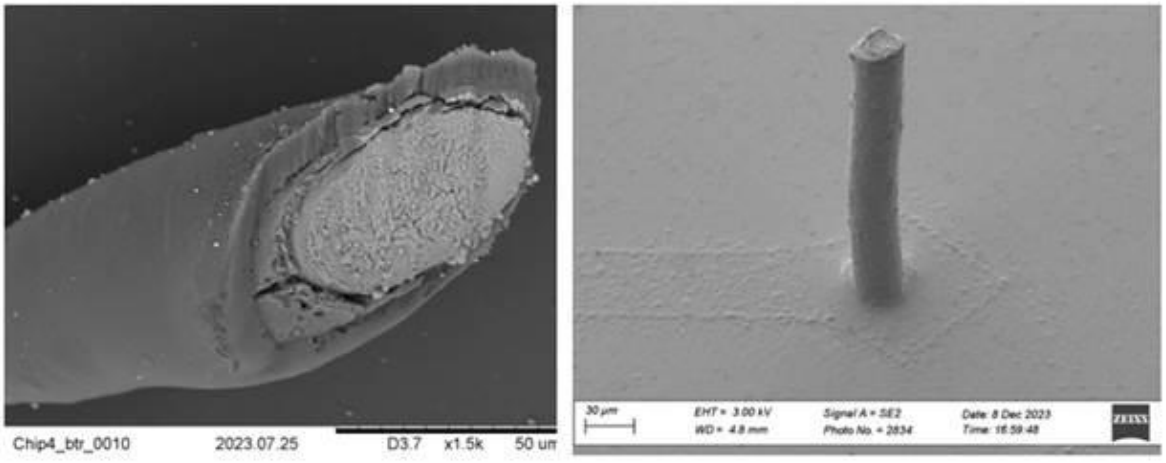

Figure 4. ***Scanning electron microscope images of a microneedle opened via UV-laser.***

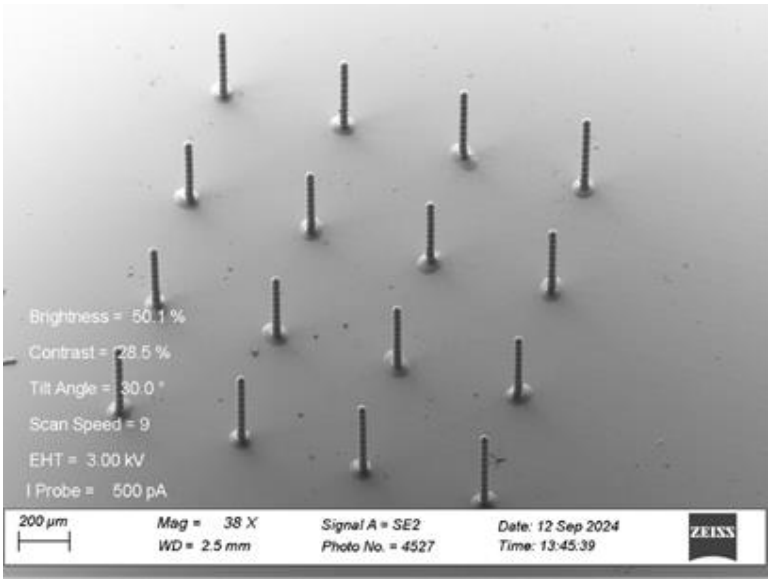

Figure 5. ***Scanning electron microscope image of a microneedle array opened via FIB***

The two-stage sensing pathway consists of a microneedle and a downstream microchamber, working in tandem to enable selective creatinine detection. In the upstream enzyme zone, the gold microneedle surface is functionalized with a thiol-based self-assembled monolayer (SAM) such as 11-mercaptoundecanoic acid (MUA). Following EDC/NHS activation, a three-enzyme cascade system (creatininase, creatinase and sarcosine oxidase) is covalently immobilized to convert creatinine into H_2O_2 through intermediate reaction steps. The lumen then directs the ISF into a downstream microchamber containing a secondary gold electrode region for amperometric detection of H_2O_2, where the chamber design ensures controlled flow, stable diffusion profiles and reduced interference from electroactive components in the ISF.

3.1.2. Technical feasibility of wearable sensor

The integrated patch houses the microneedle array, enzyme zone and the microchamber within a compact fluidic circuit. ISF enters the microneedle lumen via dermis-driven passive flow, passes over the enzyme zone for biochemical conversion and reaches the microchamber for amperometric measurement. Hollow microneedles have been shown to yield higher ISF volumes compared to porous or hydrogel-based microneedles, particularly when suction is applied (Samant & Prausnitz, 2018). The upstream enzyme zone minimizes dead volume for faster reaction kinetics, while the downstream gold electrode detects H_2O_2 amperometrically with interference mitigation strategies. Gold–SAM chemistry provides robust enzyme immobilization and Parylene-C passivation with FIB reduces non-specific adsorption. The concept's feasibility is supported by demonstrated high-aspect-ratio microneedle fabrication with lumen patency suitable for convective ISF flow and established multi-enzyme immobilization strategies on gold (Kopic et al., 2024).

3.1. Reliability of sensor output

3.2.1. Technological novelty of reliability concept

The proposed reliability strategy for our wearable sensor is based on anticipated challenges in ISF sampling and electrochemical stability, with solutions currently in the design phase. We envision incorporating hydromechanical self-validation by integrating miniature pressure and flow sensors at the microneedle base to monitor micropore patency and detect lumen blockage in real time. To address electrochemical drift, our design includes a dual-channel differential measurement approach, where one channel is functionalized with the three-enzyme cascade for creatinine conversion and the second, enzyme-free reference channel is used to quantify and subtract background noise, non-specific currents and environmental interference. Additionally, we propose spatial decoupling of the sensing stages: the upstream microneedle enzyme zone and the downstream gold electrode detection chamber would be physically separated to maintain separate stability profiles

and reduce fouling interactions between the stages. If implemented as designed, these elements should provide robust self-validation of sampling mechanics, preserve calibration integrity and enable long-term measurement accuracy in wearable form.

3.2.2. Technical feasibility of reliability concept

At this stage, the technical feasibility is assessed conceptually based on expected dominant variability sources and mitigation strategies drawn from literature. We anticipate that hydrodynamics at the skin interface will be a critical factor as the dermis is known to limit ISF transport and small changes in pore patency or skin compliance can substantially alter flow rates (Samant & Prausnitz, 2018). Variability in insertion depth and lumen condition is also expected to impact sampling performance, since minor differences in tip geometry or partial lumen blockage by fibrin or keratin could reduce the collected ISF volume (Samant & Prausnitz, 2018). Enzymatic drift, due to gradual activity decay or oxygen dependency is another potential source of error. Furthermore, electrode fouling from protein adsorption or biofilm formation on the gold surface may degrade signal quality over time (Brožková et al., 2022).

Our design proposes specific strategies to counter these issues. Continuous monitoring of flow and pressure at the microneedle inlet could provide immediate feedback on sampling stability, allowing for real-time detection of flow disruptions. The two channel-design is expected to minimize the influence of non-specific currents and environmental drift. Anti-fouling measures such as Parylene-C lumen passivation with selective FIB openings are planned to reduce non-specific adsorption. We also envision integrating thermistors and pH sensors into the patch to allow real-time correction for environmental variations affecting enzyme kinetics.

Mechanical robustness will also be addressed at the design stage through planned testing. The microneedles should be designed to surpass the skin penetration threshold (0.1-0.5N per needle) without need for excessive force, while maintaining a fracture force at least three times higher to prevent tip breakage during application. Adequate bending resistance will be considered to prevent buckling under lateral loads and lumen patency will be evaluated under simulated ISF conditions containing proteins and cellular components to ensure stable flow over extended use (Alrimawi et al., 2024; Ando et al., 2024).

By combining hydromechanical validation, drift-compensated electrochemistry, enzyme immobilization on gold and mechanical robustness testing our concept ensures consistent and clinically reliable creatinine monitoring. Their integration into a single wearable

platform remains the next step in development, with the aim of achieving clinically reliable creatinine monitoring over long-term use.

3.3. Original contributions

By Munich Bioneers,

The concept of developing a microneedle-based approach for continuous creatinine monitoring was conceived by Prof. Dr. Bernhard Wolfrum and Prof. Dr. Can Dincer, and the integration and recognition of the selected novel ideas for the wearable sensor were carried out collectively by the Munich Bioneers team. Inola Kopic manufactured and tested the 3D electrode arrays, which were originally intended for recording signals from cortical organoids, and the Munich Bioneers team subsequently adapted and adjusted these arrays for a three-enzyme creatinine sensing approach, replacing the cortical organoid recording functionality.

Prof. Dr. Bernhard Wolfrum Prof. Dr. Can Dincer Nihan Ozcan Helin Erbilir

4. TP award: Translation potential

We identified a critical gap in kidney disease monitoring for rural populations in developing countries by interviewing key stakeholders and conducting market research. Building on these insights, we developed a concept for a continuous microneedle-based creatinine biosensor and designed a validation study using existing glucose monitors to simulate the user experience and assess its potential impact and viability.

4.1. Customer interviews

To explore the need for an accessible, accurate creatinine monitoring solution, we conducted four targeted interviews: two with advanced kidney disease patients, one with a nephrologist and one with a senior health policy official from the Mongolian Ministry of Health. These stakeholders were purposefully selected to capture perspectives from direct end-users, healthcare providers and policy-level decision makers. Interviews followed a structured format to obtain both factual details and open-ended insights into real-world disease management (see **Appendix 2**).

Patient perspective

Patient 1 (elderly, nephrectomy due to an adjacent tumor 7 months ago) and Patient 2 (middle-aged, kidney transplant >1 year ago) both live in Central Anatolia, a region in Turkey notable for significant health equity issues alongside low income and education levels. Both require regular creatinine monitoring via blood tests at local health centers. Even though they comply with testing schedules, they reported several barriers: long wait times (often hours) especially during flu season and heightened risk of infection for immunocompromised individuals, physical strain from travel and mobility limitations and delayed access to results (several days).

Clinical perspective

The nephrologist, also practicing in Central Anatolia, confirmed that creatinine is closely tied to urine output and rises rapidly in acute kidney failure. Monitoring relies on regular blood plasma measurements, which often come too late as many patients seek care only after complications from surgery, infection or chemotherapy - a sentiment rooted in a broader mistrust of healthcare providers in the region alongside self-sufficient, insular attitudes. They noted a case where late diagnosis of vasculitis progressed to severe glomerulonephritis, which could have been prevented with earlier visits and detection. Distinguishing acute from chronic kidney failure without direct access to invasive diagnostic methods (biopsy) is a key challenge and current lab-based monitoring remains episodic and reactive. The nephrologist stressed that a continuous, real-time monitoring system, similar to glucose monitors in diabetes, could enable earlier intervention, improve public health reporting and help involve patients more actively in their own health matters. [8]

Policy perspective

The health policy official provided a systems-level view of Mongolia, where rural and nomadic populations (30% of the population) have minimal access to diagnostics and advanced care. Most specialized facilities are located in the capital city, with regional hospitals and rural health centers lacking sufficient dialysis and lab infrastructure. As a result, patients often present at late stages when complications are present. They emphasized that wearable, mobile-compatible monitoring tools could decentralize care, support earlier detection and improve health outcomes, particularly as chronic disease incidence rises. [9] They also noted that Mongolia’s robust public health insurance system, struggles with access equity in underserved areas - Turkey faces the same challenge. Despite different healthcare landscapes and demographics, both developing countries

face similar challenges in ensuring timely monitoring and care for (kidney) disease in remote populations.

Conclusion

These interviews helped us identify three main problem areas:

1. Physical and logistical barriers to testing
2. Delayed clinical feedback limiting early intervention
3. Systemic diagnostic inaccessibility in rural and low-income areas

These findings directly shaped our proposed solution: a microneedle-based wearable biosensor with networking capabilities for minimally invasive, mobile, real-time creatinine monitoring. Designed for low-resource settings and minimal user training, it addresses patient convenience and supports clinical decision making and system-level efficiency. Grounding the concept on input from multiple involved parties and stakeholders ensures not only relevance and usability but also potential for real-world impact. We also identified Mongolia and Turkey as ideal pilot study locations, owing to their large target market and challenge landscapes as well as our team's familiarity with both.

4.2. Design of validation study

Product definition

Based on interviews with stakeholders as well as current trends, we identified a significant challenge in kidney disease management: patients in underserved regions often have limited access to creatinine testing, leading to worse outcomes. This is particularly true for our initial target populations: nomads in Mongolia and rural inhabitants of central and eastern Turkey where regular hospital visits are impractical. Our hypothesis is that a wearable microneedle-based biosensor that measures both creatinine and estimates glomerular filtration rate (eGFR), paired with a simple display and networking (Bluetooth) would allow earlier detection of kidney dysfunction while reducing the need for in-person testing. The device would require no health literacy, cause minimal discomfort and integrate readily with telehealth services so doctors can reach patients and intervene sooner.

The proposed device consists of (for visual mock-up, see **Appendix 3**):

- Disposable microneedle patch for ISF sampling
- Reusable module equipped with a sensing element, a basic display, Bluetooth connectivity and vibration alerts
- Mobile app that records creatinine values, calculates eGFR using standard formulas and securely transmits data to healthcare providers

- Web-based telehealth dashboard for clinicians to review longitudinal patient data and advise patients remotely

Use case: An elderly kidney patient in a remote area applies the patch and wears it for 4-5 days. The display provides simple to digest information while the app alerts both the patient and their healthcare providers to any significant changes e.g. >20% increase in creatinine or declining eGFR. The clinicians can review current trends and contact the patient for further action, avoiding unnecessary travel and enabling earlier intervention.

It is important to consider the following points as well to increase device viability:

- Ease of use in limited health and tech literacy settings (ergonomic)
- Comfort and safety of microneedle wear and patch lifespan
- Data transmission in low infrastructure settings (mobile networks instead)
- User acceptance and adoption among patients and healthcare providers

Study design

Since the biosensor design has not been finalized, we will conduct an early-stage validation study using commercially available microneedle-based continuous glucose monitors (Dexcom G Series, Medtronic Guardian etc.) to simulate the user experience. We aim to include diabetics, ideally with concomitant kidney disease (diabetic nephropathy) in our study as this provides not only a realistic proxy for wearing, applying and interacting with our proposed device but also has a positive health impact on the study participants as well. [11]

We will recruit 45-50 participants with Type-2 diabetes (optional: diabetic nephropathy) from rural Central Anatolia and Mongolia with no prior experience with wearable continuous sensing devices. In addition, we will consult with 10-15 local clinicians familiar with kidney disease management.

Participants will wear a commercial glucose patch for 4-5 days paired with a basic display mock-up and a prototype app with an interface for creatinine readings. Before, during and after use, participants will be surveyed about comfort, ease of use, clarity of information and their willingness to use such a device for kidney monitoring. Clinicians will review the collected data and comment on usability, potential synergies, how it could impact patient management and how they would respond to abnormal readings. We will also document any technical and communication issues that might arise in our use case. Network

connectivity will be deliberately limited for a subset of participants to simulate low infrastructure conditions.

The following metrics will be vital for real-world value assessment and will be compared to predefined targets:

- % of patients finding the device easy to use without assistance (target >80%)
- % of patients reporting physical and mental discomfort (target <20%)
- Clinician rating of usefulness for early intervention (target >4 out of 5)
- % of patients and clinicians willing to replace lab tests with the device (target >70%)

Conclusion

By using continuous glucose monitors as a stand-in, we can gather early feedback on the comfort, usability and perceived value of our proposed creatinine biosensor. This will guide early design, support user needs and provide initial real-world evidence for its impact on patients and clinicians in underserved regions before full-scale development. In addition, we conducted in-depth market research and developed a working business plan and 5-year roadmap (**Appendices 4** and **5**)

5. Team and support

5.1. Contributions of the team members

- **Helin Erbilir** was responsible for developing customer interview questions and conducting market research. She also collected expert feedback on the design and business plan.
- **Nihan Ozcan** was responsible for team coordination and logistics. She managed budget planning, funding applications and organized accommodation and transportation for the team's trip to the competition venue.
- **Tayis Arslan** was responsible for leading the wet lab group. She conducted literature research on creatinine detection methods and enzyme crosslinking strategies. She carried out experimental work to implement these approaches and integrated the microneedle-based approach.
- **Melisa Karatas** was responsible for leading the electronics team. She contibuted to design of PCB schematics and layout, managed task distribution among team members and integrated the various hardware circuitries into the system. She also designed power system, managed tests and integrated the pump into the flow cell.

- **Jaehee Choi** was responsible for design of electronic system and analysing it via simulation programs such as Altium Designer and LTspice, particularly for TIA. She also supported the general research for wet lab team.
- **Elif Neva Yildirim** played an important role in the wet lab group. She conducted comprehensive literature research to identify the optimal detection molecule and the most suitable detection method. She contributed to the development of the biosensor through experimental comparison of different options as part of the wet lab team.
- **Tuguldur Tumurbaatar** contributed to the development of the business plan and performed in-depth market research to define the target segments and commercialization strategy also worked on flow cell.
- **Eyed Fetni** was tasked with the communication between the electrode system and the microcontroller system, developing the ADC needed to analyse the signal with the MCU.
- **Jeongjoo Lim** was responsible for microcontroller prototyping and programming to develop, test and implement signal processing mechanisms. In addition, he contributed to circuit designs for the user interface and the microcontroller.
- **Max Schultz** assisted with wet lab work, supporting experimental workflows and protocol execution.
- **Senyao Wang** and **Sebastian Freko** supported the team as coaches. They provided guidance on experimental setup, lab access and technical feasibility as well as valuable feedback on design ideas and practical implementation.
- **Prof. Dr. Bernhard Wolfrum** and **Prof. Dr. Can Dincer** co-supervised the team. They led the formation of the team, provided strategic and scientific feedback and supported the development of the project throughout the competition journey.

5.2. People who have given support

- **Merve Emir**, an entrepreneurship expert at UnternehmerTUM, provided critical feedback on the business plan and pitch strategy. Her input helped refine the overall structure and strengthen the investor-facing narrative.
- **Toon Stilma**, CEO of XS Innovations, shared valuable insights on the technical feasibility of the product. He also offered general feedback on the business pitch, drawing from his experience in medtech innovation.
- **Inola Kopic** designed and built the microneedle arrays for the innovation component of the project.

- **Julia Schiemainski** taught laboratory safety protocols and managed the entire orders and ordering process.
- **Josef Hintermair** gave instructions on lab usage and performed the safety onboarding.
- **George Al Boustani** served as the data official for a distributed testing event.
- **Defne Tuzun** assisted with the flow cell design.

5.3. Sponsors and partners

- The **TUM School of Computation, Information and Technology (CIT)** and **TranslaTUM** supported our project financially and provided access to research facilities.

Participating in the SensUs 2024 competition has been a transformative experience for the Munich Bioneers, offering us the opportunity to optimize biosensor innovation while addressing a real-world global health challenge. This project not only enhanced our technical and interdisciplinary skills but also deepened our understanding of healthcare problems and the urgent need for accessible diagnostic tools for the people.

We firstly want to thank to our main supervisors, Prof. Dr. Bernhard Wolfrum and Prof. Dr. Can Dincer, as well as our coaches, Senyao Wang and Sebastian Freko, for their invaluable guidance throughout the project. We would also like to thank Merve Emir, Toon Stilma, and our partners at UnternehmerTUM and Merck Sigma-Aldrich for their critical feedback and support. Special thanks go to the patients, clinicians, and health officials who shared their insights and helped ground our work in real-world needs.

Looking ahead, we aim to advance our wearable biosensor by integrating cutting-edge microneedle technology with user-centered design. Our goal is to make proactive kidney monitoring accessible to those who need it, anytime and anywhere in the world

6. References

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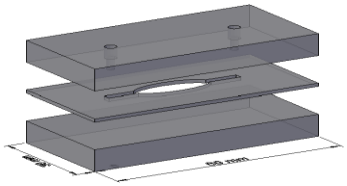
7. Appendix

Appendix 1: *Render of the modular assembly (made in AutoCAD)*



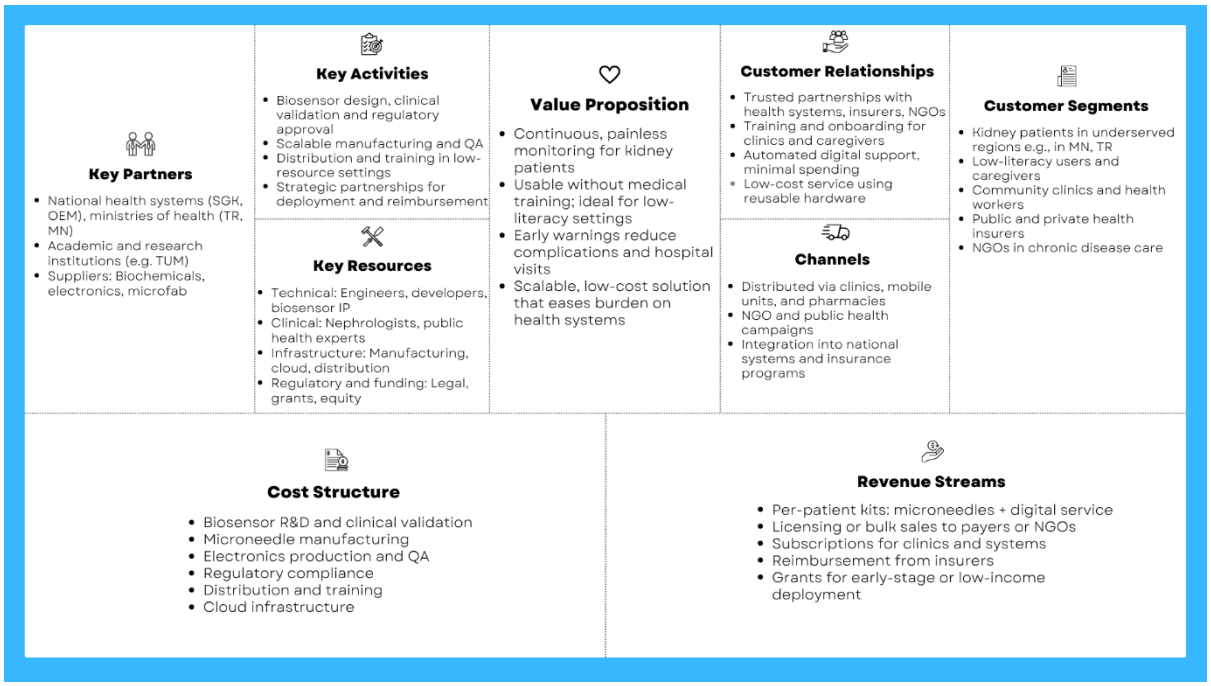
Appendix 2: *Interview questions*

Patient	***Healthcare professional***
Can you tell me about the last time you had to monitor your kidney function?	Can you walk me through how you currently monitor creatinine levels in patients with kidney disease?
What is the hardest part about managing your kidney disease?	What are the most common challenges you face when monitoring kidney function in patients?
How do you currently track changes in your creatinine levels, and how often do you get tested?	Can you share an example of when a patient's kidney disease worsened due to delayed detection?

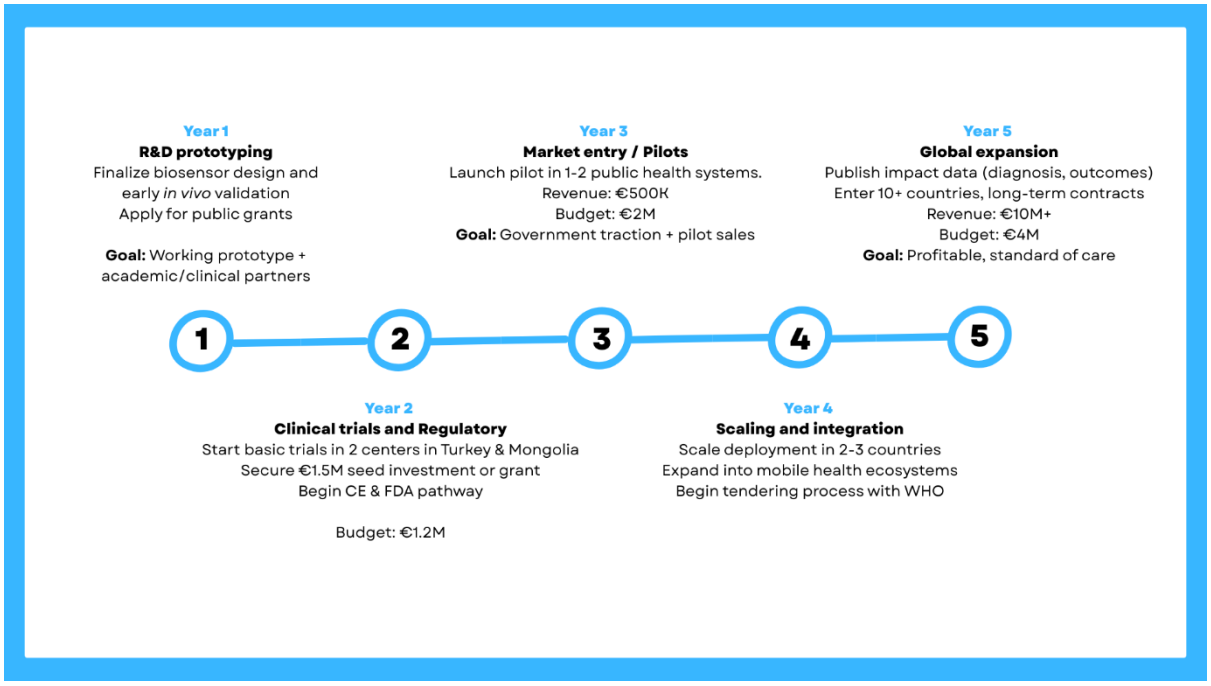
Have you ever missed a test or delayed getting your creatinine levels checked? What happened?	How do you currently interpret trends in creatinine levels, and what would make that process easier or more effective?

Appendix 3: *Mock-up of the final device (made in Adobe Photoshop)*

Appendix 4: *Our business model*



Appendix 5: *Our 5-year roadmap*


Year 1
R&D prototyping
Finalize biosensor design and early in vivo validation
Apply for public grants
Goal: Working prototype + academic/clinical partners
Year 2
Clinical trials and Regulatory
Start basic trials in 2 centers in Turkey & Mongolia
Secure €1.5M seed investment or grant
Begin CE & FDA pathway
Budget: €1.2M
Year 3
Market entry / Pilots
Launch pilot in 1-2 public health systems.
Revenue: €500K
Budget: €2M
Goal: Government traction + pilot sales
Year 4
Scaling and integration
Scale deployment in 2-3 countries
Expand into mobile health ecosystems
Begin tendering process with WHO
Year 5
Global expansion
Publish impact data (diagnosis, outcomes)
Enter 10+ countries, long-term contracts
Revenue: €10M+
Budget: €4M
Goal: Profitable, standard of care
1
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