Team Results Document

AixSense

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SensUs

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1. Abstract: Summary for the SensUs website

Chronic Kidney Disease (CKD) and the need for ongoing renal function monitoring are a major worldwide health issue. Current diagnosis techniques are founded on rare, intrusive blood sampling, leading to delayed detection of disease progress and non-adherence.

Our device, a new, wearable creatinine monitoring patch using minimally irritating microneedles, transforms kidney health tracking. By accessing the interstitial fluid (ISF) directly beneath the skin, our technology combines patient comfort, real-time data flow, and utilization of today's highest-quality glucose monitors with the robust clinical utility of creatinine as a measure of kidney function. This approach circumvents barriers of traditional blood testing, providing convenient and accurate kidney health feedback directly into daily life.

Our patch enables patients and healthcare workers: it offers real-time tracking of kidney function trends, early detection and pre-emptive disease management, and a new level of personal involvement in chronic care—remotely. We unlock a new era of precision nephrology and preventive care with this technology, maximizing patient outcomes while minimizing the strain on health systems.

By harnessing the potential of minimally invasive ISF-sampling and smart, wearable technology, our team stands poised to lead the revolution in kidney disease management—providing early detection, close monitoring, and customized treatment to millions at risk.

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

For the Eindhoven Testing Event, we developed and validated a novel biosensor platform for continuous creatinine detection. Our sensor, based on a copper–hexahydroxytriphenylene (HHTP) MOF [1] functionalized electrode and integrated into a custom cartridge with biomimetic Polydimethylsiloxane (PDMS), was designed for reliable and rapid electrochemical measurements using cyclic voltammetry and impedance spectroscopy. All testing was carried out in our institute, confirming the platform's reproducibility, sensitivity, and suitability for integration into wearable kidney health monitoring solutions.

2.1. Molecular recognition

Metal–organic frameworks (MOF) are constructed from periodically arranged organic ligands and inorganic nodes [2]. MOF possess adjustable pore sizes, high surface to volume ratios, and abundant active sites; these unique structural and chemical features make them particularly well suited for electrochemical biosensing applications. Creatinine, the product of human creatine metabolism, is known to form a specific complex with copper ions. [3] Herein, we exploit these two properties to devise a molecular-capture strategy based on copper–creatinine complexation using a Copper-2,3,6,7,10,11-hexahydroxytriphenylene metal-organic framework (Cu–HHTP MOF) , coated sensor chip. In our experiments, silica substrates were first coated with a thin gold film via sputtering, and the MOF layer was subsequently grown through a developed dipcoater machine, as seen in Fig. 2, by sequentially dipping in Cu/Ethanol/HHTP respectively to yield the functionalized sensor chip]. The chemical and physical parameters including the thickness of the MOF to be deposited can be adjusted with this dip coater.

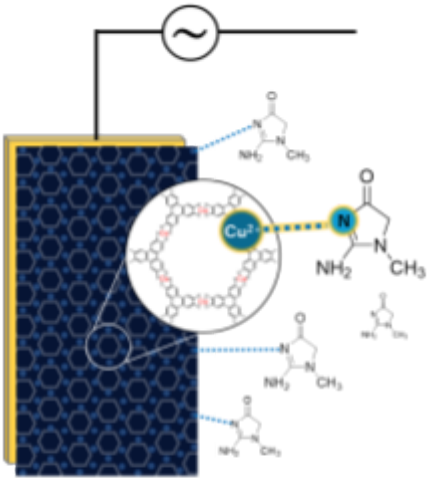

Fig. 1: Schematic illustration of creatinine sensor with the MOF film.

2.2. Physical transduction

We use cyclic voltammetry (CV), an electrochemical technique, to investigate redox behavior and calibrate each MOF-coated working electrode (WE). This ensures consistent sensor performance and a reliable baseline. During CV, we define scan parameters and measure the current response from redox events, which is associated with electron transfer in the vicinity of the WE [4]. This gives us the information about the stability of WE at different voltage levels during the potential scan.

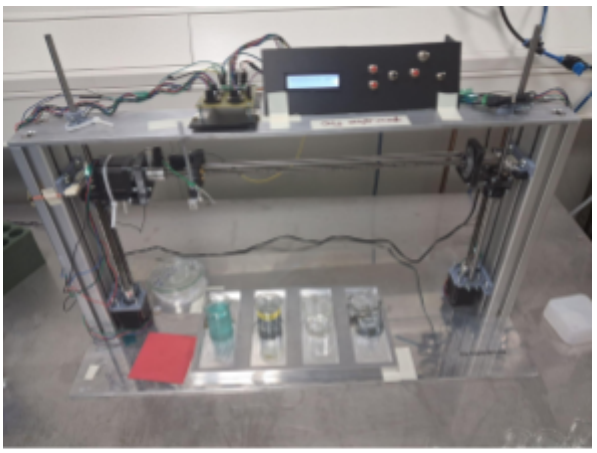

Fig. 2: Self developed dip coating device

The reference electrode (RE) provides a well-defined, stable equilibrium potential; in this case, an Ag/AgCl electrode is employed. The counter electrode (CE) consists of a platinum wire, selected for its high chemical stability and inertness in electrochemical measurements. In multi-electrode configurations, the platinum wire is arranged to maintain equal spacing from each WE. The peaks in CV give the information about the characteristic redox peaks of the Cu-HHTP-coated electrode.

After the stable region is determined from the CV, electrochemical impedance spectroscopy (EIS) is utilized for the final measurement of creatinine concentration. By examining impedance changes before and after analyte exposure, we are able to quantify both the presence of creatinine and its concentration in solution with high sensitivity. Using known concentrations of creatinine, the WE is calibrated and then is used to determine the unknown concentration of creatinine during the testing phase.

2.3. Cartridge technology

The cartridge enclosure for the testing event was developed through iterative prototyping, tailored to practical sample constraints and real-world needs. The final design features a compact, modular chamber optimized for a small testing volume of less than 100 µL, ensuring efficient use of sample material and allowing easy insertion of various sensor chip configurations for flexible testing, including both single and multiple working electrodes.

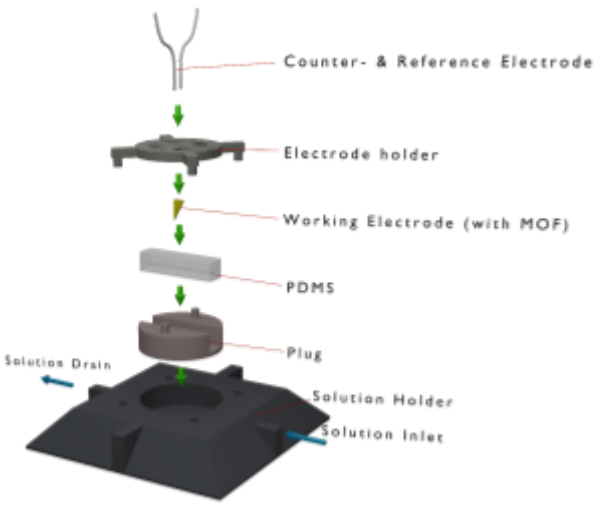

Fig. 3: Test setup showing the layers of the sensor prototype

As illustrated in Figure 3, a PDMS layer inside the cartridge facilitates measurement conditions comparable to the mechanical characteristics of skin, inclusive of biocompatible hydrogels that can eventually allow porosity to mimic the human skin. This provides a realistic platform to evaluate the structural integrity and stability of the microneedles during insertion. The sensor chips are oriented relative to the PDMS to precisely reproduce the insertion geometry. Furthermore, the enclosure allows for controlled adjustment of penetration depth, enabling a systematic investigation of how physical stress impacts sensor performance.

This modular cartridge platform accelerates wearable development while enabling comprehensive in vitro evaluation of sensor reliability and robustness under conditions closely matching those found clinically.

2.4. Reader instrument and user interaction

The measurement and user interface platform centers on the ADuCM350 development board, serving as the control and data acquisition hub for all EIS experiments. A custom GUI enables intuitive interaction, allowing users to connect the cartridge, reset the board, configure parameters, and initiate EIS measurements.

During data acquisition, the GUI shows live plots of real and imaginary impedance and generates magnitude and phase diagrams after each experiment. The software supports saving and loading sessions, curve fitting with calibration data, and provides advanced analysis. For improved quantification, a backpropagation neural network (BPNN) automates estimation of creatinine concentration from impedance features. The BPNN module is currently a separate script under development, pending full validation.

This integrated hardware–software system guarantees reproducible and user-friendly lab testing, while laying the foundation for a future miniaturized, app-based wearable interface.

3. IN award: Biosensor innovation

The core innovation is a wearable biosensor patch featuring a dense array of microneedles where each needle is engineered to function as a working, reference, or counter electrode, enabling continuous creatinine monitoring in interstitial fluid via a selective MOF coating. The sensor operates using electrochemical impedance spectroscopy, relying on a "self-flushing" principle where the MOF layer passively equilibrates with surrounding creatinine levels, ensuring real-time measurement without saturation [5]. While feasibility has been confirmed with a larger prototype and component level validation of the electronics, current work focuses on full system miniaturization and overcoming key challenges like biofouling and long-term stability. Our team's contributions established the foundational proof-of-concept by optimizing the electrode system, developing the measurement firmware and software, and creating the designs that pave the way for a fully integrated wearable device.

3.1. Wearable sensor

The final wearable form is envisioned as a patch containing an array of hundreds of minimally invasive microneedles for continuous creatinine monitoring, enabling real-time biochemical tracking through the skin. Central to the design is a dense array of miniaturized triangular gold electrodes, each configured as a microneedle, that partially penetrate the skin to access the interstitial fluid (ISF)—which closely reflects blood creatinine levels [6]. Employing an array of microneedles ensures consistent, reliable ISF sampling and robust sensor performance by increasing the effective detection area, enhancing both sensitivity and redundancy in measurement. This approach also maintains minimal pain levels and safe operation while supporting continuous, real-world monitoring in a wearable device [7].
In addition to the implemented microneedle array, we also considered an alternative design in which all electrode functions (working, reference, and counter) would be integrated onto a small, triangular electrode. Although this electrode would still be much smaller than classical electrodes, it would not achieve the minimal penetration depth and dermal integration of our microneedle array approach. Ultimately, we prioritized the microneedle configuration due to its superior minimally invasive properties, skin conformity, and continuous ISF access.

3.1.1. Technological novelty of wearable sensor

The core technological innovation of the wearable patch is the integration of all three essential electrodes for electrochemical impedance spectroscopy (EIS)—working (WE), reference (RE), and counter (CE)—directly within the microneedle array itself. Instead of a single monolithic electrode, the patch consists of many miniaturized microneedles, each precisely engineered to function as either a working, reference, or counter electrode.

This patterned array ensures that each working electrode microneedle is closely flanked by reference and counter electrode microneedles, guaranteeing reliable electrochemical measurement conditions across the contact area [8]. The tips of the working electrode microneedles, which penetrate into the interstitial fluid (ISF), are coated with a

metal-organic framework (MOF) selective for creatinine detection. Furthermore, the intrinsic microporosity of the MOF provides an additional layer of selectivity, as its precisely engineered pore dimensions act as a molecular sieve to sterically hinder larger, interfering species while allowing smaller creatinine molecules to freely access the active sites [37]. Reference and counter electrode microneedles are strategically positioned within the same array, facilitating local and spatially resolved measurements while eliminating the need for any external electrode placement.

By spatially distributing the electrode types within the microneedle array, this design achieves enhanced measurement stability, reduces interference, and ensures signal integrity—while dramatically simplifying device architecture and enhancing wearability for continuous monitoring [9].

Moreover, the MOF coating on the working electrode does not covalently bond to creatinine, enabling the sensor to operate in a self-flushing mode [10]. This design ensures that the local creatinine concentration within the MOF layer rapidly equilibrates with that of the interstitial fluid, allowing for continuous, real-time monitoring without sensor saturation.

During development, EIS measurements were performed using a prototype working electrode measuring 7×4 mm, demonstrating feasibility. This design is intended to be miniaturized to the microscale in the final wearable form, allowing safe, painless insertion and long-term compatibility with skin mounted patches.

3.1.2. Technical feasibility of wearable sensor

The feasibility of the wearable sensor is supported by successful EIS measurements using the fabricated 7 × 4 mm MOF coated gold electrode. These tests validated the integration of the working, reference, and counter electrodes on a single substrate and confirmed stable signal behavior when interfaced with mimicked interstitial fluid (ISF).

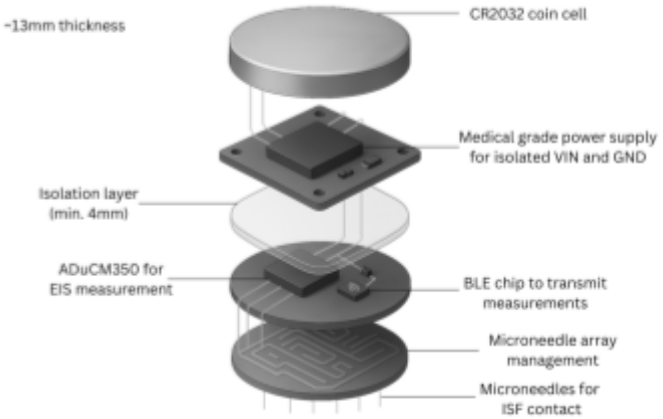

Fig. 4: Conceptual model of the envisioned AixSense wearable sensor.

In the envisioned wearable system, the microneedle array connects directly to a highly integrated and low-power ADuCM350 IC, which includes an on-chip potentiostat for performing electrochemical impedance spectroscopy (EIS), which is measures the impedance of the system [11] [12]. This compact chip is specifically designed for space- and energy-constrained biosensing applications (see Appendix 8.1.1 for IC integration details).

The entire patch, including sensing, data processing, and wireless communication, is powered via a medical grade isolated supply, ensuring patient safety for skin mounted use according to IEC 60601-1 standards [13]. Measurement and calibration cycles are optimized for ultra-low power operation, and all data is transmitted in real time via Bluetooth Low Energy (BLE) to a mobile device or base station. Through this wireless interface, users can monitor creatinine levels live, and automatic alerts can be triggered in case of critical changes or technical anomalies.

While full system integration into a final patch form is ongoing, the core sensing unit, electronics architecture, and data pipeline have already been validated at the component level. This supports the feasibility of fully autonomous,

continuous, skin-mounted creatinine monitoring, with all results accessible and interpretable via a mobile application derived from our current GUI and data processing workflow.

3.2. Reliability of sensor output

Ensuring the reliability of continuous creatinine sensing presents several significant challenges:

Miniaturization of electrodes: Further reduction in electrode size may affect signal stability and reproducibility, due to increased surface effects, susceptibility to noise, and manufacturing tolerances.

Validation of the continuous measurement principle: It remains critical to demonstrate that the sensor can track dynamic changes in creatinine concentration in real time, under conditions mimicking physiological fluctuations.

Biofouling: Prolonged skin or ISF contact may lead to protein and cellular adhesion or deposition (biofouling) on the microneedle surfaces—especially on the MOF layer—potentially attenuating signal response or altering selectivity. Strategies such as surface passivation, anti-fouling coatings, or integration of periodic electrochemical cleaning steps may be necessary to ensure long-term performance.

Potential toxicity of the MOF: The copper-based MOF (e.g., Cu-HHTP) utilized in our biosensor was selected due to its proven biocompatibility, cost-effectiveness, and favorable electrochemical properties. Current research demonstrates that, when synthesized and incorporated properly, these MOFs are generally considered biocompatible and suitable for integration in wearable sensor platforms [14]. Although all sensor materials must undergo thorough safety and stability evaluation, the porous structure and surface chemistry of MOFs can be engineered to limit any undesirable effects, and acute in vitro and in vivo testing has so far shown minimal adverse impact under conditions relevant for wearable skin contact. Ongoing research indicates that any remaining limitations can often be addressed by careful composite design and by using robust encapsulation strategies, further mitigating potential risks for the end user.

Mechanical and material durability: Repeated insertion/retraction of microneedles, as well as prolonged wear on mobile skin, may cause mechanical stress, delamination, or wear of the MOF and electrode coatings. The physical robustness of the entire microneedle array needs to be verified for routine use.

Sensor calibration drift and referencing: Small differences between chips, as observed in initial experiments (likely due to inhomogeneous MOF growth or setup variation), must be addressed by robust referencing and normalization routines. Periodic recalibration and reference measurements, as well as built-in diagnostic protocols, help maintain long-term accuracy and comparability across sensors [15].

Our work focuses on systematically addressing these challenges through a combination of electrochemical modelling, detailed experimental data, and iterative design improvements. All strategies are intended to ensure consistent, reliable, and safe sensor output—even as the system becomes increasingly miniaturized and integrated for real-world operation.

3.2.1. Technological novelty of reliability concept

The interface of our WE can be modelled as a Randles circuit, consisting of the electrolyte resistance (R_s) in series with the double-layer capacitance (C_{dl}) which is parallel connected to charge transfer resistance (R_{ct}) and constant phase element (Z_W) [16]. A more detailed description can be found in Appendix 8.1.4.

The circuit's charge transfer resistance (R_{ct}) and double-layer capacitance (C_{dl}) are designed to be sensitive to changes in creatinine concentration at the working electrode. Monitoring shifts in these impedance features across a frequency sweep allows for selective and stable inference of creatinine levels [17].

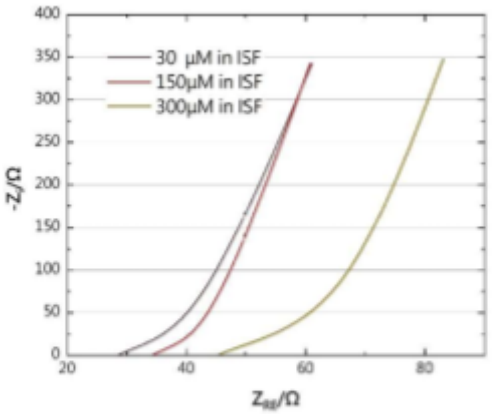

Fig. 5: Nyquist plot for various concentrations of creatinine in ISF.

Initial electrochemical impedance spectroscopy (EIS) measurements with the prototype showed a clear concentration-dependent response. Nyquist plots consistently shifted to the right on the real axis with increasing creatinine, suggesting that interactions with the MOF surface reduce charge transfer, which supports the sensing mechanism as shown in Fig. 5. This is because the real part of the impedance at low frequencies reflects the sum of charge transfer resistance (R_{ct}) and electrolyte resistance (R_s) (Appendix 8.1.4).

To ensure high precision and reproducibility, detailed measurements with closely spaced concentration steps were performed. Referencing and normalization routines were implemented to compensate for minor sensor chip variations, ensuring consistent performance across batches and long-term accuracy [18].

However, the current data has limitations. Some measurements lacked clear trends, likely due to non-uniform MOF coatings or other experimental inconsistencies. The small signal changes caused by varying creatinine concentrations can be easily masked if experimental factors are not tightly controlled. These issues are currently under investigation.

3.2.2. Technical feasibility of reliability concept

The continuous monitoring of creatinine depends on two key technical elements: the stable metal-organic framework (MOF) coating and the function of the microneedle array.

The MOF-coated working electrode operates based on reversible, non-covalent interactions with creatinine. As the concentration of creatinine in the interstitial fluid (ISF) changes, its distribution within the porous MOF layer shifts through passive diffusion, eliminating the need for active electrochemical regeneration [19]. This passive, self-renewing mechanism enables continuous, real-time sensing.

By relying on diffusion rather than external stimulation, the system reduces power consumption and minimizes local environmental disturbance, ensuring long-term signal stability. The MOF must remain unsaturated across the physiological creatinine range (45–110 µM) to maintain sensor reliability. This requires the MOF to have sufficient adsorption capacity, rapid molecular exchange, and resistance to irreversible binding or fouling [20].

The design uses a microneedle array where each needle acts as a working, reference, or counter electrode. Spatially distributing the electrodes this way ensures local electrochemical functionality, minimizing variability and enhancing signal reproducibility. This modular design is compatible with wearable patches, enabling minimally invasive, continuous operation [21].

Together, the diffusion-driven sensing and modular microneedle array design provide a robust foundation for continuous creatinine monitoring [22]. Experimental validation of long-term stability is ongoing, with current data suggesting feasibility in buffered solutions.

3.3. Original contributions

3.3.1. Team contributions

We began by exploring various electrode geometries for integration with the Cu-HHTP-based MOF sensor platform, including rectangular and triangular working electrodes. A microneedle-based configuration was also considered to enable minimally invasive sampling, though it remained at the conceptual stage due to time constraints. To ensure the stability of the MOF layer, we investigated appropriate voltage ranges using techniques such as cyclic voltammetry.

Efforts were made to obtain consistent and reliable impedance spectra, aiming to establish a clear correlation between measured impedance and creatinine concentration. The firmware for the ADuCM350 microcontroller was optimized to support efficient EIS measurement routines.

To analyze the measurement results, we evaluated various data fitting methods, including linear, logarithmic, and quadratic models. In parallel, we improved the graphical user interface to simplify measurement setup and data interpretation.

In addition to sensor optimization, we developed conceptual designs for a low-power, BLE measurement system, operating from a coin cell battery. A wearable patch integration was also outlined as a long-term goal. While these concepts were not physically realized, they lay the groundwork for future development toward a fully autonomous, wearable biosensor.

The supervisors provided excellent guidance throughout the process, especially during early planning and feedback phases.

3.3.2. Supervisor’s comments

Biologically sensitive electrical devices based on AC and DC readout principles have been widely reported in literature for the detection of creatinine. Many of such electrical platforms rely on enzymatic reactions and use miniaturization to increase the sensitivity and tenability in sensor operation. High technological readiness (high TRL) and commercial exploitation of such sensor platforms for creatinine monitoring from biological samples, however, remains elusive due to unreliability of biofunctional interfaces made of enzymatic complexes. Towards addressing the challenge of real-time monitoring of creatinine, use of high throughput fabrication technologies, high-level integration of a hybrid electrochemical surface plasmon resonance (EC-SPR) sensor platform for reliable wearable operation, and evaluation of a non-enzymatic approach formed the main criteria for the AixSense 2025 team. For the above-mentioned reasons, and for the healthcare challenges that can be addressed by monitoring creatinine in case of CKD amongst patients from different demographics, age-groups, professions and lifestyles, AixSense 2025 also held consultations from stakeholders and in accordance, adjusted their wearable biosensor development plans.

Considering factors related to the technological readiness and cost-related issues determining the market-readiness of the product, securing freedom of operation towards a successful business undertaking during such consultations, the team decided to use plasmon active gold electrodes as dual-mode biosensor platform. Gold is a widely available material and has been adopted in cleanroom technology for a variety of optical and optoelectronic applications. Interaction of small molecules such as creatinine at such gold electrodes can potentially be transduced via use of electrochemical impedance spectroscopy (EIS) approaches and plasmonic phenomena. The team decided to further advance the use of a Cu-HTTP based metal-organic frameworks (MOFs) to realize an efficient electrochemical

interface that offers complexation of creatinine with Cu clusters. For this, the team upscaled the synthesis of MOF thin films over gold electrodes to carry out statistical analyses of the sensing operation. While the realization of MOF-coated electrodes is already scaled up to 4-inch wafer, the team also constructed a lab-based prototype to mimic the configuration of a wearable device, to carry out design optimizations of the sensor platforms.

The team was successful in the realization of a sensor design that mimics a wearable-patch with creatinine-sensitive electrodes, which were tested in a cartridge mechanism imitating mechanistic characteristics of the skin. The AixSense team made use of various interdisciplinary approaches (involving simulations work, additive manufacturing, micromachining, microfluidics, packaging, data-acquisition and programming tasks) to finally demonstrate a working biosensor platform for creatinine monitoring. In addition, the platform allows further innovation opportunities to test creatinine-sensitive micro-needle arrays, various skin-models integrating array-based EIS monitoring and upgrade the platform for multiplexed monitoring of a panel of biomarkers in near future. In view of all these aspects, I consider the biosensor development plan well thought out and highly original and give my full recommendation.

Dr. Vivek Pachauri | Akhil Das | Louis Otter

Vivek Pachauri
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4. TP award: Translation potential

4.1. Customer interviews

During our customer discovery process, we interviewed Dr. Ingo Heschel, former CEO of a leading biotech company. He provided valuable insight into the patenting process, emphasizing that to be patentable, a product must demonstrate novelty, an inventive step, and industrial applicability. While the technological foundation of our sensor—its unique MOF chemistry and microneedle design—addresses the criteria for novelty and an inventive step, our research into the German healthcare landscape strongly supports its industrial applicability.

In parallel, we consulted Dr. Susa Koichiro (Dept. of Nephrology) and Prof. Sohara Eisei (Head of Nephrology Department) at the Institute of Science Tokyo Hospital [23], who offered a clinician's perspective on unmet needs in creatinine monitoring. They noted that CKD is typically detected through periodic outpatient blood tests—3–4 times per year for stage G3, with higher frequency in advanced stages—whereas AKI is often diagnosed in hospital after delays of up to 24 hours. They emphasized that continuous monitoring could provide the most benefit in the early AKI phase (first 6–12 hours), when timely intervention could alter outcomes. They identified priority patient groups—including high-risk AKI cases (e.g., cisplatin or NSAID treatment, post-transplant), dialysis patients for early validation, and elderly CKD patients prone to dehydration—as well as critical adoption criteria: ≥14-day wear time, painless microneedle insertion, smartphone integration, water resistance, and ±5% accuracy compared to serum

tests. While assay costs are low, they stressed that the true burden lies in hospital visits, consultation fees, and blood draws—making a home-based, minimally invasive device both clinically and economically attractive. The absence of any commercial continuous creatinine sensor was seen as a clear market opportunity, provided these usability and accuracy benchmarks are met.

For maximal clinical impact and efficient market introduction, the core target group is refined to those with severely impaired kidney function or established kidney failure, for whom precise, real-time creatinine monitoring can directly improve dialysis scheduling and overall care. In Germany alone, over 100,000 people currently undergo dialysis due to end-stage renal disease [24], and more than 1.5 million adults live with significantly impaired kidney function (eGFR <60 mL/min/1.73m²) [25]. A further key segment includes people living with diabetes—over 8.9 million nationwide [26]—who are at elevated risk for kidney disease; for these patients, integration of real-time creatinine sensing into existing glucose monitoring platforms represents a major opportunity for preventive digital health. Additionally, thousands of patients each year are exposed to nephrotoxic agents during imaging procedures or receive drugs known to potentially harm renal function, with hospital-based incidence rates for contrast-induced AKI ranging from 4% to 16% [27][28].

By focusing on these high-need groups—dialysis patients, at-risk diabetics, and those exposed to nephrotoxic medication—the device addresses a substantial and urgent clinical gap. This targeted approach strengthens the case for industrial applicability in Germany and aligns with global trends in digital and personalized medicine, thereby supporting the overall patentability and market relevance of the technology.

The economic evaluation of creatinine monitoring extends beyond the direct price of a single test. A comprehensive analysis must include systemic and labor-associated costs, which often constitute the largest portion of the total cost of diagnostics [29]. Current testing paradigms, whether performed at a central laboratory or at the point-of-care (POC), are built on a labor-intensive, per-test model.

Central laboratory testing involves significant costs associated with sample collection (phlebotomy), transport, and processing by trained technicians. Furthermore, the turnaround time, which can be several hours, introduces indirect clinical and economic costs due to delayed therapeutic decisions [29, 30]. While POC testing reduces the turnaround time to minutes, it shifts the labor burden from the lab to clinical staff, such as nurses, who must perform each manual test, conduct quality control, and manage the devices. Studies show that these POC-associated labor costs are a primary driver of their overall expense [31].

The AixSense continuous monitoring system proposes a fundamental shift away from this model. By replacing intermittent, manual measurements with an autonomous, wearable sensor, the primary cost driver of staff labor is virtually eliminated. The economic value of AixSense is therefore not merely in the cost of the consumable sensor itself, but in its potential to radically improve workflow efficiency. The transition from a reactive, labor-intensive testing model to a proactive, data-driven monitoring paradigm offers the potential for significant cost savings for the healthcare system, primarily through reduced labor and the clinical benefits of early intervention enabled by continuous data [30, 31].

4.2. Design of validation study

Potential solution (sensor + use case)

Based on in-depth interviews with nephrologists from the Institute of Science Tokyo Hospital and Uludağ University, we propose a minimally invasive, microneedle-based continuous creatinine monitoring device designed for both acute and chronic kidney care settings.

Core technical features:

- Analyte: Creatinine in interstitial fluid (ISF), converted automatically to estimated GFR (eGFR) using the CKD-EPI 2021 equation (sex- and age-adjusted). [32]
- Wear time: ≥14 days continuous operation (≥336 hours) without cartridge replacement. [33]
- Accuracy target: ±5% agreement with IDMS-traceable serum creatinine measurements across the clinical range (0.5–10 mg/dL). [34], [35]
- Form factor: Single-use adhesive patch with integrated painless microneedle array (<1 mm insertion depth, ISO 10993 biocompatible materials).
- Connectivity: Bluetooth Low Energy (BLE) to smartphone app, refresh rate every 5–15 minutes.
- Environmental durability: Minimum IPX4 water resistance to allow showering and light activity.
- User interface: Displays real-time eGFR trends, KDIGO AKI stage thresholds, and configurable alerts for rapid rises (≥0.3 mg/dL in 48 h or ≥1.5× baseline in 7 days). [36]

Primary use cases:

1. Stable haemodialysis patients — used as a positive control group to benchmark device accuracy against frequent, reliable blood measurements via dialyser inlet/outlet sampling.
2. High-risk AKI patients — ICU, oncology (cisplatin), and post-transplant (first 7 days) cases, where sub-daily creatinine trends can drive earlier intervention.
3. Elderly CKD outpatients — prone to dehydration and transport difficulties, benefiting from reduced hospital visits and remote monitoring.

The intended added value is to:

- Enable early detection of AKI within the first 6–12 hours.
- Reduce the logistical and physical burden of repeated hospital visits.
- Provide actionable, clinically contextualised information to patients and care teams.
- Support preventive care by integrating into existing digital health platforms.

Key aspects to test in first validation

The first validation study will focus on simulating the core experience of using the device before a working prototype is available. The study will test:

1. Clinical interpretability
    - Can patients and clinicians understand eGFR-adjusted readings and trend alerts?
    - Do clinicians recognise KDIGO-defined AKI alerts and consider them actionable?
2. Perceived clinical impact
    - Do clinicians believe that receiving creatinine/eGFR trends in near real time would change their management decisions?
    - For patients, does the device provide a sense of increased safety and control?
3. Usability and workflow fit
    - Can patients or caregivers apply the patch correctly with minimal training?
    - Is the app interface intuitive for non-specialists?
    - How easily can clinicians integrate the data into current documentation and decision-making processes?
4. Feature prioritisation
    - Is there demand for expanded renal panel parameters (potassium, sodium, phosphorus)?
    - What alert formats (numerical vs. colour-coded severity) are most useful?

Design of the first validation study

Since the functional sensor is not yet available, the first validation will use mock-ups to replicate the user experience and simulate the device's data output.

Participants:

- Patients:
    - 8–10 stable haemodialysis patients.
    - 5–8 high-risk AKI patients currently hospitalised (oncology, post-transplant).
- Clinicians:
    - 6–8 renal care professionals (nephrologists, ICU physicians, nurses, general practitioners).

Study materials:

- Mock-up patch: A realistic, non-functional wearable device matching expected size, weight, and adhesion.
- Simulated app: Displays pre-recorded or synthetic creatinine/eGFR data, including stable trends, gradual rises, and abrupt AKI events. Alerts are triggered using KDIGO criteria.

Procedure:

1. Patient simulation:
    - Participants wear the mock-up patch for a brief period and interact with the app.
    - They are shown scenarios including normal stability, dehydration-induced creatinine rise, and acute AKI alert.
    - Researchers observe whether participants interpret the data correctly and note what actions they would take (e.g., call clinic, hydrate, visit ER).
2. Clinician simulation:
    - Clinicians review mock case files with parallel sets of standard lab data and simulated device output.
    - They indicate whether earlier trends would have prompted different interventions.
    - Structured interviews probe their trust in the device, perceived accuracy threshold for adoption, and integration into workflow.

Data collection:

- Quantitative:
    - Task success rate (correct interpretation and appropriate action).
    - System Usability Scale (SUS) score (target ≥75).
    - Clinician likelihood-to-use rating on a 5-point Likert scale (target ≥4).
- Qualitative:
    - Thematic analysis of perceived benefits, concerns, feature requests, and workflow barriers.

Expected outcome

If conducted, this validation is expected to:

- Quantify perceived clinical and practical value among both patient and clinician groups.
- Identify usability challenges in patch application, app navigation, and data interpretation.
- Assess clinician trust and minimum accuracy requirements for adoption.
- Provide evidence for prioritising additional analytes or interface features.

The results will inform prototype development and the design of a Phase 2 functional validation study, beginning with accuracy testing in haemodialysis patients against serum creatinine, then expanding to AKI-risk populations to measure detection lead-time and intervention impact.

Fig. 6; The proposed user journey for the AixSense continuous monitoring system, from initial patch application to proactive clinical intervention

5. Team and support

5.1. Contributions of the team members

Akhil Das and Louis Otter served as team leaders throughout the project. Louis was responsible for the 3D printing and prototyping of the sensor's structural components, actively participated in sensor testing, and took charge of filming and editing the team's vlog. Akhil made significant progress in chip fabrication and testing and provided effective leadership and coordination for the team.

Leping Kang, Leyao Wang, Jing Zhu, and Quynh Thao Nguyen contributed to the implementation of impedance measurements on the microcontroller and participated in the development of the graphical user interface (GUI) as members of the Microcontroller Team.

Jacklyn Emmanuel-Wilcox supported the business team and was responsible for comprehensive project documentation.

Nursina Sentürk contributed to the conceptual development of the hardware design for the end device, assisted with impedance measurements on the microcontroller, and introduced enhancements to the GUI.

Shun Sato contributed to sensor testing and the preparation and writing of the Technical Report Document (TRD).

Johannes Bruker was responsible for designing and 3D printing the sensor's components and played an active role in device testing.

Quang Duc Hoang oversaw the business team, interviewed with doctors, designed the validation study for Translation Potential, and provided support wherever it was needed.

5.2. People who have given support

Our supervisors, Dr. Vivek Pachauri, Dibyendu Khan, and Aidin Nikookhesal, have all played a pivotal role in guiding and supporting our team throughout this project. Each has generously shared their expertise, provided valuable feedback across all technical and organizational aspects, and offered unwavering encouragement during every phase. Their collective mentorship, dedication, and effective coordination between institute, team, and competition organizers have been instrumental in our progress and success. We are deeply grateful for their time, commitment, and constant support.

Dr. Chishu Homma, from IWE1, extended his invaluable support throughout our work, generously sharing his technical expertise and offering laboratory assistance whenever needed.

Johanna Werz from WZL provided us with significant support during the 3D printing process, enabling efficient prototyping and iteration.

In addition, Younes Sayegh Ruiz from the Gemeinschaftswerkstatt Walter-Schottky-Haus (GWSH) of RWTH Aachen University assisted us greatly with expertise and hands-on help throughout this crucial project step.

5.3. Sponsors and partners

We would like to extend our heartfelt gratitude to the IWE1 Institute at RWTH Aachen for supporting us with their facilities, funding the project and providing us with mentorship during the development process. We would also like to thank Dr. Ingo Heschel for sharing his insights on the patenting process, which greatly supported the work of our business team. We would also like to acknowledge Dr. Susa and Prof. Sohara at the Institute of Science Tokyo Hospital, Department of Nephrology, for offering invaluable clinical perspectives on target patient groups, device usability requirements, and unmet needs in creatinine monitoring, which informed our translation potential strategy. In addition, we thank the staff at the WZL and the GWSH from RWTH Aachen, who played a crucial role in our prototyping and 3D printing process for the test environment.

6. Final remarks

To conclude, the AixSense team would like to sincerely thank our sponsors, professors and everyone who has supported us professionally, emotionally and otherwise. The encouragement we received during this journey has been instrumental to how far we have come. We would also like to express our heartfelt gratitude to the organizers of the Sensus competition, who have provided us with this amazing opportunity and to the esteemed judges for their time and meaningful feedback. This project has been an invaluable learning experience and we are very excited to see what comes next for us.

Our work on the AixSense biosensor has laid a foundational proof-of-concept for a wearable device that could revolutionize kidney health monitoring. The core innovation lies in the use of a Metal-Organic Framework (MOF) coated microneedle array for continuous, minimally invasive creatinine detection in interstitial fluid (ISF). This approach addresses a critical gap in current diagnostics, which often rely on infrequent and invasive blood draws. The development of our sensor, based on a copper-HHTP MOF and integrated into a custom cartridge, successfully validated its reproducibility, sensitivity, and suitability for wearable solutions during the Eindhoven Testing Event.

While our current work has established the technical feasibility of the core sensing unit and its electronics architecture, challenges such as miniaturization, biofouling, and long-term stability still need to be systematically addressed. We've developed a modular cartridge platform that closely simulates ISF sampling to evaluate sensor performance and a GUI for a user-friendly lab testing experience. Ultimately, our goal is to create a fully autonomous, continuous, and skin-mounted monitoring system with all results accessible via a mobile application. The translation potential for this device is significant, targeting high-need groups like dialysis patients and people with diabetes, and addressing a substantial clinical need in Germany. We believe our work represents a significant step towards a new era of precision nephrology and preventive healthcare.

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8. Appendix

8.1 Biosensor System

8.1.1 Wearable patch IC design

The wearable patch integrates the Analog Devices ADuCM350, a highly compact and low-power system-on-chip specifically designed for electrochemical measurements. It features an on-chip potentiostat, ADC, DAC, and a Cortex-M3 microcontroller, enabling precise electrochemical impedance spectroscopy (EIS) within a minimal footprint.

The microneedle array connects directly to the ADuCM350's analog front end, allowing accurate impedance acquisition across a configurable frequency range. All signal generation and measurement processes are handled internally, with onboard calibration routines ensuring consistent performance under varying environmental conditions.

The IC interfaces with a Bluetooth Low Energy (BLE) module via SPI, supporting real-time wireless data transmission to a mobile device or base station. Power is supplied through a medical-grade isolated source, ensuring compliance with IEC 60601-1 standards for patient safety. Measurement and communication cycles are optimized for ultra-low power operation, allowing continuous wearable use without compromising data fidelity.

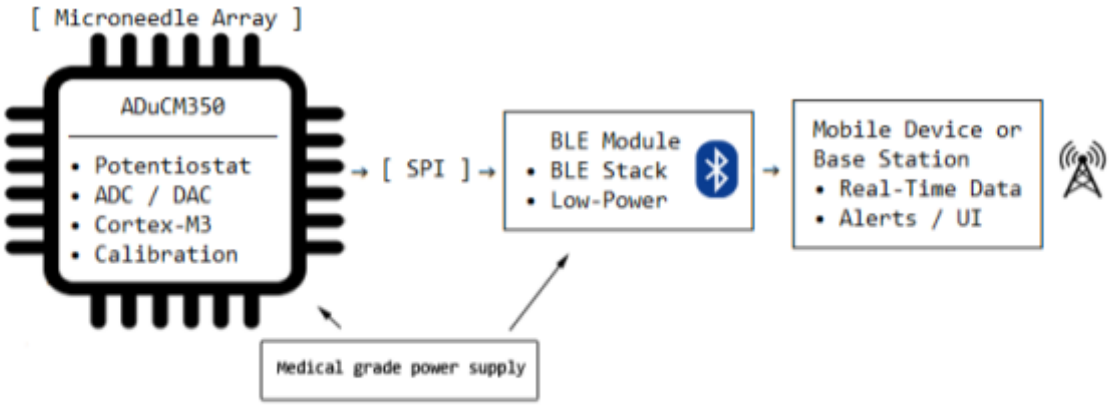

Fig 7: The flow diagram showing the working, data transfer and communication of the microneedle prototype.

8.1.2 Randles Circuit

The Randles model, introduced by Randles in 1947, describes the impedance behavior of an electrochemical system with an electrical double layer. The total impedance Z_{total} is given by:

$$Z_{total} = R_s + \frac{1}{j\omega C_{dl} + \frac{1}{\left(R_{ct} + \frac{A}{(j\omega)^{\alpha}}\right)}}$$

Here,

- ω is the angular frequency,
- R_s is the solution (electrolyte) resistance,
- C_{dl} is the double-layer capacitance,
- R_{ct} is the charge transfer resistance,
- A and α are constants characterizing diffusion processes.

At low frequencies, the impedance contribution of the capacitive and diffusion elements becomes negligible, and the real part of Z_{total} approaches R_s+R_{ct}. If R_s is assumed constant across different creatinine concentrations, variations in Z_{total} primarily reflect changes in R_{ct}. Therefore, creatinine concentration can be estimated from the impedance spectrum, particularly from the intercept of the EIS signal with the real axis.

8.1.3 Rules and Regulations

MDR (Medical Device Regulation) Classification:

- Short-term Use: Normally intended for continuous use for between 60 minutes and 30 days.
- Invasive Device: Any device which, in whole or in part, penetrates inside the body.
- Active Device Intended for Monitoring: Detecting, diagnosing, monitoring, or treating physiological conditions.

MDR Rules:

- Rule 5 Class II-A: Intended for short-term use.
- Rule 9 Class II-B: All active devices intended to control or monitor the performance of active therapeutic class IIb devices, or intended directly to influence the performance of such devices, are classified as class IIb.
- Rule 11 Software Class II-A: Intended to provide information used to make decisions with diagnostic or therapeutic purposes.

International Standards (First identified – Approvals will be taken based on market expansion plan):

- **ISO 13485**: Quality management system (QMS) for medical devices.

- **ISO 14971**: Risk management for medical devices. Processes for identifying, evaluating, and controlling risks associated with medical devices throughout their lifecycle.
  ISO 10993: Biological evaluation of medical devices, ensuring biocompatibility.

IEC Standards:

- **IEC 60601**: Standards for the safety and performance of electrical medical equipment. Relevant parts of this standard ensure the electrical safety of biosensors.
- **IEC 62304**: Establishes requirements for the life cycle processes for medical device software, including biosensor software.
- **ISO 9241**: Ensures ergonomics and human-centered design processes.

8.1.4 GUI

AixScan is a desktop GUI application developed for performing Electrochemical Impedance Spectroscopy (EIS) measurements. It provides a streamlined interface for configuring test parameters such as voltage, frequency range, and spacing; connecting to a measurement device via a serial COM port; starting, monitoring, and stopping live impedance measurements; visualizing data in real time through Nyquist, magnitude, and phase plots; loading and analyzing saved measurement files; and performing calibration routines.

Fig. 8: Developed Graphical User Interface showing the Nyquist plot.

To start a measurement, first choose the correct port to connect with the microcontroller. Then, enter the required parameters in the corresponding input fields and click ‘Configure’ to apply them. Next, click ‘Start Measurement’. Finally, the impedance will be plotted live. The magnitude and phase plots will be updated at the end of measurement.

8.2. Kidney Patient Care Timeline

Patient Group	Stage	Timeframe	Key Steps
AKI	Initial Stage	0-7 days	Diagnosis: Serum creatinine, urine output; Immediate Treatment: Fluid management, stop nephrotoxic drugs, dialysis if necessary; Monitoring: Daily renal function; Hospitalization: Likely required
AKI	Early Recovery	1-4 weeks	Ongoing Monitoring: Every 2-3 days; Treatment Adjustment: Gradual change in medications
AKI	Long-term Recovery	1-3 months	Regular Follow-up: Weekly to bi-weekly; Rehabilitation: Nutritional support, physical therapy; Preventive Measures: Lifestyle modifications
AKI	Stable Phase	3-6 months	Periodic Monitoring: Monthly; Management of Comorbidities: Control hypertension, diabetes
CKD	Early Stage	0-1 year	Diagnosis: GFR, albuminuria; Initial Treatment: Lifestyle changes, BP and glucose control; Monitoring: Every 3-6 months
CKD	Moderate Stage	1-5 years	Ongoing Treatment: Medication adjustments, dietary restrictions; Monitoring: Every 1-3 months; Patient Education: Adherence to treatment
CKD	Advanced Stage	5+ years	Intensive Management: Preparing for dialysis/transplant; Frequent Monitoring: Monthly or bi-monthly; Supportive Care: Psychosocial support
After Kidney Transplant	Immediate post-surgery	0-1 month	Hospitalization: 5-10 days; Intensive Monitoring: Daily blood tests
After Kidney Transplant	Early Recovery	1-3 months	Frequent Follow-up: Weekly visits; Patient Education: Medication adherence, signs of complications
After Kidney Transplant	Mid-term Recovery	3-12 months	Regular Monitoring: Bi-weekly to monthly; Lifestyle Management: Diet, exercise, infection prevention
After Kidney Transplant	Long-term Care	1+ year	Stable Phase: Quarterly to bi-annual check-ups; Chronic Care: Management of comorbidities, continuous medication adjustment
On Medications Affecting Kidney Function	Initial Stage	0-1 month	Risk Assessment: Identify high-risk patients, baseline tests; Patient Education: Inform about side effects
On Medications Affecting Kidney Function	Ongoing Monitoring	1-12 months	Regular Follow-up: Bi-weekly to monthly tests; Adjustments: Modify dosages, switch medications if needed
On Medications Affecting Kidney Function	Long-term	1+ year	Periodic Monitoring: Every 3-6 months; Preventive Measures

Frequency of monitoring glomerular filtration rate (GFR) and albuminuria in people with chronic

kidney disease (CKD).