

McGill University

Team members:

Anders Schwarz
Tanjin Sultana
Syphax Ramdani
Gwen Sammon
Osandi Hewage
Tesnim Obey
Clara Mickail
Cris Izzi
Carolyn Denton
Claire Levasseur
Martin Nakouzi

Mathilde Wagner

Sasha Tan

Supervisor:

Prof. Wachsmann-Hogiu

Coaches:

Xinyue Hu (MSc.)



1. Abstract

Acute Kidney Injury (AKI) is a common condition seen in emergency medicine settings and is projected to grow in prevalence in the coming decade. Due to the urgent nature of this disease, traditional diagnostic methods involving medical labs fail to provide timely data, leading to worsening patient outcomes. Additionally, remote communities such as those in the Canadian territories often do not have sufficient access to lab infrastructure, preventing many individuals from receiving care.

Thus, our team proposes an alternative solution: a modular enzyme-based sensor that can be integrated as either a wearable patch or point of care (POC) system. This sensor relies on creatinine deiminase which catalyzes creatinine, the target molecule for AKI diagnosis, into ammonium. Ammonium is a charged molecule and can therefore be detected and quantified by an electrode. This reading is then sent wirelessly to a user interface, thereby providing a rapid diagnosis which can both improve patient outcomes and better inform a physician's treatment plan.







Table of Contents

2. AP award: Biosensor developed for the Eindhoven Testing Event	4
2.1. Molecular recognition	4
2.2. Physical transduction	4
2.3. Cartridge technology	5
2.4. Reader instrument and user interaction	5
3. IN award: Biosensor innovation	6
3.1. Wearable sensor	6
3.2 Reliability of sensor output	8
3.3. Original contributions	9
4. TP award: Translation potential	11
4.1. Customer interviews	11
4.2. Design of validation study	12
5. Team and support	15
5.1. Contributions of the team members	15
5.2. People who have given support	15
5.3. Sponsors and partners	15
7. References	17
8 Appendix	21





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

2.1. Molecular recognition

Our biosensor detects creatinine through enzymatic catalysis coupled with electrochemical transduction on a screen-printed electrode (SPE). Creatinine deiminase converts creatinine to N-methylhydantoin and ammonia (Fig 1) (Pundir et. al., 2013). At physiological pH, ammonia rapidly protonates to ammonium, which diffuses through the gelatin layer onto the ammonium-selective carbon electrode (Pundir et. al., 2013). These ions produce a quantifiable electrochemical signal, which is proportional to the creatinine concentration.

Creatinine deiminase
$$NH_3$$
 NH_4
 NH_4

Figure 1: Enzymatic conversion of creatinine by enzyme creatinine deiminase.

The enzymatic sensing method was chosen due to substrate specificity and rapid turnover rate, enabling timely and accurate detection (Mohabbati et. Al., 2012). The enzyme was immobilized in a gelatin matrix to retain enzyme functionality over time and reduce both non-specific adsorption and electrode fouling (Betancor et. al., 2005).

2.2. Physical transduction

Ammonium is quantified using an ammonium-selective carbon SPE via open-circuit potentiometry. The working electrode is coated with an ammonium-selective proprietary ionophore and supported by a solid-contact layer for ion-to-electron transduction. Selective binding of ammonium ions at the membrane induces a localized positive charge accumulation, which attracts electrons to the electrode surface, leading to an increase in electrical potential (Lyu et al., 2020). A silver chloride reference electrode provides a stable baseline potential (Metrohm). The resulting potential difference between the working and reference electrodes, measured under zero-current conditions, is related to ammonium concentration through the Nernst equation shown below (Lyu et. Al., 2020).

$$E = K + \frac{RT}{F}\log(C) \tag{1}$$

E is the measured potential difference, K is a constant, R is the ideal gas constant, T is the temperature, F is Faraday's constant, and C is the concentration of ammonium.

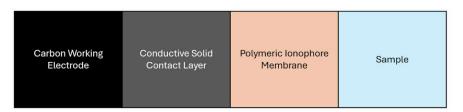


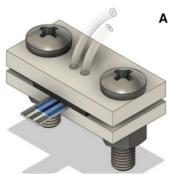
Figure 2: Representation of layers present in the sample-electrode sensing interface





2.3. Cartridge technology

The flow cell consists of a bottom mount that houses the screen-printed electrode and a top mount containing the fluidic interface, including the inlet, outlet, and sample chamber positioned above the electrode. Tubing connections are secured with adhesive, and the electrode chamber is sealed using an adhesive-backed gasket to prevent leakage. Samples are injected consecutively into a custom 3D-printed enclave containing a rubber septum fixed to the tubing with adhesive. Upon needle withdrawal between injections, the septum reseals to maintain a closed system, preventing air ingress and subsequent bubble formation within the sample flow path. Additional details on the septum inlet, flow cell materials and specifications are provided in Table 1 in the Appendix section.



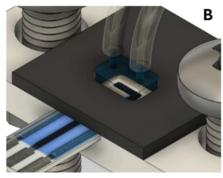




Figure 3: (A) Flow cell containing ammonium sensitive electrode (B) Close-up of electrode chamber of the flow cell (C) Visual of entire sensor setup

2.4. Reader instrument and user interaction

The electrode is first placed in the bottom mount of the cartridge, and the top mount is secured by hand-tightened bolts. The SPE is connected to a Zimmer and Peacock Anapot potentiostat which is plugged into a laptop via USB. The potentiostat measures the potential difference between the working and reference electrodes via open source potentiometry. Using the PSTrace software, a reading is taken after sample insertion, and the resulting pssession files are stored in a dedicated folder and used in our own software.

The developed software used to extract and analyze the data from the collected .pssession files is a lightweight, terminal-based processing system. Upon startup, the user is prompted to enter a mode: 'monitor' or 'summary'. In 'monitor' mode, the software continuously watches the data/ subfolder, automatically processing any newly added .pssession files. It extracts time and voltage readings, filters out invalid data points (where status is specified to be unstable when data collected), and converts the voltages to creatinine concentrations using a calibration curve based on Equation 1. For each file, it generates and displays a concentration-time graph and appends the average concentration and standard deviation to a 'summary.csv' file. At any point during operation, the user may enter the command 'summary' into the terminal to generate a bar chart displaying the mean concentrations and standard deviations across all processed datasets. he interface is designed for minimal user input; newly added files in the data/ directory are automatically parsed without manual intervention. Thus, only basic commands require to be typed in based on the user's needs. The current interface is currently purely command-line-based, which may limit usability for non-technical users.





3. IN award: Biosensor innovation

3.1. Wearable sensor

Our biosensor employs a single-enzyme approach for creatinine detection, in which ammonium, both naturally present in interstitial fluid and produced by the enzyme, serves as the target analyte. To mitigate signal interference from baseline ammonium levels, the system incorporates two spatially separated electrodes to independently quantify endogenous and enzyme-derived ammonium.

Wearable biosensors can access ISF via many ways, however, microneedle arrays were selected for their ease of self-administration, painless insertion, and user comfort (Saifullah & Rad, 2023). Silicon was chosen as the microneedle substrate due to its conductivity, biocompatibility, low cost, and established use in other wearable sensors (Zhang et. al., 2024). To enable differential measurement, one electrode array is coated with a hydrogel-entrapped layer of creatinine deiminase, while the other remains uncoated to measure baseline ammonium levels. This configuration draws on existing enzyme-coated microneedle technologies used in continuous glucose monitors (CGMs) (Windmiller et. al., 2011) and is highly relevant to our use case (section 4) by minimizing direct electrode exposure to ISF, allowing the electrodes to be reused. Generated signals are transmitted through the conductive microneedles and a biocompatible adhesive interface, which connects to microelectronic wiring embedded within the wearable patch. These wires route to a miniaturized potentiostat capable of simultaneous dual-analyte detection. The potentiostat could transmit data wirelessly via Bluetooth to a medical database or mobile application accessible to the patient.

Given the point-of-care, single-use nature of the intended applications (see Section 4), the wearable sensor is designed to be modular to reduce implementation costs. The microneedle array, which comes into direct contact with the patient, is intended to be disposable, while the electrodes and potentiostat components are detachable. An example of a detachable potentiostat is shown below in Figure 3.



Figure 4: Palmsens' Sensit Wearable, an example of a modular potentiostat that can be attached and removed to a disposable microneedle patch (Palmsens)

3.1.1. Technological novelty of wearable sensor

The main technological novelties for this biosensor design include a two-electrode system and modular design. In the literature, the interference of endogenous ammonium in single enzyme systems is treated as an inherent disadvantage, and there is little mention of methods to obtain baseline ammonium readings (Jayasekhar-Babu et. al., 2022), (Pundir et. al., 2013), (Mohabbati et. al., 2012). Note that we do not assert that such a suggestion does not exist in literature, merely that it is not commonly discussed and remains underexplored.

The modular design is also unconventional within the biotechnology sector. For example, diabetic patients using CGMs must repurchase the entire electrical interface for





every new sensor used, even though the only truly disposable component is the enzyme-containing component whose output accuracy degrades after 14 days (Forlenza et. al., 2019). While modularity is more of a concern for our target use case in point of care applications, it helps reduce medical waste and cost of care, two highly critical considerations regardless of the specific application at hand.

3.1.2. Technical feasibility of wearable sensor

The critical elements of the sensor include the spacing of the enzyme coated and non-enzyme coated sensing regions and integrity of the enzymes. If the enzyme- and non-enzyme- containing microneedles are positioned too closely, interference from the diffusion of enzymatically generated ammonium may result in an overestimation of baseline ammonium. Conversely, excessive separation complicates sensor placement and raises the risk of accidental detachment during basic movements. Both the structural and functional stability of the enzymes are significant concerns, as physical damage from storage or poor handling would compromise their efficacy.

Due to encountering logistical difficulties (discussed in section 6), the following results are obtained from literature, rather than our team's own experiments. The ammonium calibration curve which would be obtained by applying solutions of known concentration to the electrode repeatedly to get a range of voltages. This calibration curve is expected to resemble the one shown in Figure 4 below.

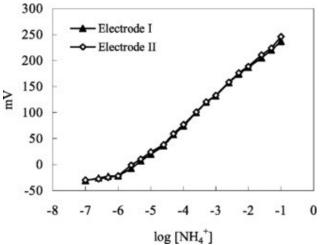


Figure 5: Literature calibration curve for ammonium measured using potentiometry on an ammonium-sensitive carbon electrode (Karakus et. al., 2009)

Using this calibration curve, conversion of the enzyme reaction could be determined. Solutions with known concentrations of creatinine would be applied to an enzyme-coated electrode, and the corresponding voltage would indicate how effectively the enzyme is converting creatinine to ammonium. Then, the enzyme electrode could be tested by first measuring the baseline ammonium in a biological sample with a non-coated electrode, then exposed to the enzyme electrode. This reading would be compared to an existing reliable creatinine quantification method carried out in a medical lab. These readings would be repeated until enough data has been gathered to determine whether the difference between the biosensor and traditional method are statistically significant.





3.2 Reliability of sensor output

An important source of error for any continuous sensor is the degradation of the sensing elements. In our case, the three main aspects to consider are enzyme stability, leaching, and biofouling. The use of a gelatin membrane for enzyme immobilization mitigates these challenges (Betancor et. al., 2005), making our sensor reliable for continuous measurement, especially considering the relatively short time span necessary for our use case.

Additionally, since the biosensor quantifies ammonium, it is critical to account for endogenous ammonium variability both between patients and over time within the same patient. Therefore, accurate and reliable measurement of baseline ammonium is essential for ensuring sensor precision.

3.2.1. Technological novelty of reliability concept

Our method of enzyme immobilization, covalent crosslinking within a gelatin hydrogel, is a simple and cost-effective way to increase sensor stability by dealing with all three aspects mentioned above. The gelatin gel creates a protective microenvironment against outside factors such as temperature, pH, or enzymatic degradation (Betancor et. al., 2005). This allows the enzyme to function in a broader range of conditions and reduces enzyme damage. Immobilization within a gel also increases storage stability, as it limits the degree of conformational movement the enzymes can undergo, limiting denaturation.

Permanent, covalent cross-linking with glutaraldehyde not only prevents enzyme leaching, but also mechanically reinforces the gelatin structure, increasing stability (Esimbekova et. al., 2023). Finally, gelatin provides a biocompatible hydrogel which can help prevent biofouling. Hydrogels in general provide a barrier to the deposition of biomolecules, not only physically but also through the strong hydration force of bound water molecules (Jarosińska et al., 2024).

To account for endogenous ammonium, our team plans to have a second ion-selective SPE devoid of enzymes. Combining multiple measurements allows us to account for and remove sources of error, delivering a more precise result.

3.2.2. Technical feasibility of reliability concept

The sensor is composed of a gelatin layer containing creatinine deiminase enzymes cross-linked with glutaraldehyde located over an ammonium-selective SPE. This enzyme converts creatinine to ammonium, which is detected using open circuit potentiometry. A second electrode devoid of enzymes detects the endogenous ammonium present in the patient sample. Finally, a thermocouple is included in the chamber to measure sample temperature. The resulting signal of both the SPEs and the thermocouple is a voltage difference, read by our own Bluetooth-enabled potentiostat.

Though the gelatin layer reduces loss in enzyme activity over time (Betancor et. al., 2005), it also can create a barrier to diffusion (Esimbekova et. al., 2023). However, as creatinine is a small molecule, it is unlikely that the collagen network would hinder the diffusion process. As an example, fluorescein, a molecule around three times larger than creatinine, has a similar diffusion coefficient in collagen gels as in solution (Hettiaratchi, 2018). Considering our gel is very thin, at 0.5 mm thickness, and using a diffusion coefficient of around 10^{-3} mm²/s, we can estimate the diffusion time as L²/D, where L is the gel thickness and D is the diffusion coefficient (Tomsa et al., 2025). Thus, diffusion takes around 4 minutes to complete, which is a reasonable time for our use case.





Our design lends itself well to the inclusion of a second SPE. To include it, all that would be required is an additional chamber for the electrode. In addition, our electrochemical technique, open circuit potentiometry, is relatively easy to multiplex. We plan on making our own device to replace the potentiostat, using an analog-to-digital converter (ADC) and a microcontroller. Including this second SPE would only require an additional ADC.

As our sensor is meant to be used in a medical clinic, precise measurements are preferred compared to ease of use. For this purpose, the devices will have to be calibrated using known creatinine and ammonium concentrations.

3.3. Original contributions

3.3.1 Statement from the Team

Several transduction and biorecognition pathways were explored by the team, including the use of molecularly imprinted polymers, Raman spectroscopy, nanomaterial composites, and anti-creatinine aptamers. Numerous detailed proposals were internally drafted and evaluated, and following consultation with our supervisor as well as assessment of our available resources and limited timeframe, the team decided on an enzymatic recognition approach coupled with electrochemical transduction.

Enzymatic approaches for creatinine recognition typically employ a multienzymatic cascade reaction producing redox-active hydrogen peroxide as a byproduct. Our biosensor instead offers a robust monoenzymatic approach generating ammonium in a simple, single-step reaction. While ammonium is not classically redox-active, our biosensor selectively quantifies it using an ionophore membrane wrapped over the surface of a working electrode operating in open circuit potentiometry. From similar approaches in literature (Nguyen et. al., 1991), our team devised and executed a standard operating procedure for replicable enzyme immobilization on the surface of a screen-printed electrode via a glutaraldehyde cross-linked hydrogel. Our team subsequently designed and optimized a microfluidic system centered around screen-printed electrodes, offering both easy replenishment of the sensing elements and potential for future modular systems that can sense multiple analytes in series using SPEs.

The development of our technology has been hindered by faulty equipment, including a large order of ammonium-detecting screen-printed electrodes that could not perform in basic conditions. This has significantly inhibited and prolonged the quantitative assessment of the biosensor performance.





3.3.2 Statement from our Supervisor

Creactive is McGill University's team competing in the SensUs competition with a novel design for continuous creatinine measurements.

While most solutions involve electrochemical readouts, the team has focused on designing a reliable bioreceptor and an optimized electrochemical flow cell. They used glutaraldehyde to initiate crosslinking on screen printed electrodes for the monoenzymatic detection of ammonium. This bioreceptor construct is further complemented by the design of a flow cell that allows for continuous and reliable flow of the creatinine-containing solution. The designs presented by the team have been developed independently and were not available to the students from other sources. This solution could provide a simple, inexpensive, and reliable way of detecting creatinine in a continuous flow, if unwanted artifacts can be adequately controlled.

Prof. Sebastian Wachsmann-Hogiu Team Supervisor Anders Schwarz Team Captain

Surves

Tanjin Sultana Team Captain





4. TP award: Translation potential

4.1. Customer interviews

Scope & Methodology

Over four months, 13 virtual interviews were conducted with physicians and patients across the Canadian kidney care ecosystem to understand clinical needs and constraints that would shape our device development. This included patients, nephrologists, ER physicians, radiologists, and a medical director. Kidney care is inherently collaborative: ER physicians typically handle acute presentations upon arrival, nephrologists manage both acute and chronic cases, radiologists provide imaging that informs diagnosis and treatment, and medical directors influence the adoption of new technologies and programs. Engaging with these stakeholders enabled us to develop a holistic understanding of real-world challenges and opportunities.

Interviews were conducted in pairs and trios to ensure ethical oversight, facilitate note-taking and support the formulation of clarifying questions. Consent forms were made available to patients and practitioners alike. Interview guides were tailored to each stakeholder group and evolved with our use case. We ensured consistency by including some core questions which were recurrent across all interviews. Discussions were semi-structured, ensuring we received consistent, reproducible insights while leaving space for respondents to share their ideas freely.

Stakeholder Insights

Across nearly all interviews, clinicians emphasized the need for faster creatinine results at the point-of-care. ER physicians described lab turnaround times of 30 minutes to two hours, even for STAT requests. This delay frequently forces important treatment decisions, such as the ordering of dialysis or scans employing nephrotoxic contrast, to be made without lab results. This can have lasting impacts on patient disposition. As one ER physician noted, "If a point-of-care creatinine test was available, we would always use it".

This urgent need for rapid testing directly challenged our initial assumption that there would be strong demand for continuous creatinine monitoring. Furthermore, most clinicians felt that continuous monitoring would be unnecessary for most CKD patients. Unlike glucose, which fluctuates rapidly and warrants continuous tracking, creatinine levels are relatively stable over short timeframes, except in cases of acute kidney injury (AKI). As such, clinicians viewed continuous monitoring as an ineffective use of hospital resources, with periodic testing seen as sufficient in nearly all CKD contexts.

Nephrologists strongly supported the use of a rapid test and suggested it be used in inpatient settings beyond initial triage. Currently, they rely on serial creatinine testing during the first 12 to 24 hours of intervention, but it can take multiple hours to get results and the volume of such requests can place undue strain on lab resources. Several clinicians also highlighted the value of rapid, accurate, point-of-care testing in remote or underserved settings, especially those where a full on-site lab is not available. One nephrologist expressed that in their region, healthcare resources were scarce and that patients requiring dialysis were frequently airlifted due to deteriorating health that could have been sooner identified. In contrast, another nephrologist noted that larger hospitals sometimes initiate dialysis prematurely due to missing labs, suggesting that faster testing could prevent both under-treatment and over-treatment.

Across interviews, the consensus was that our device must integrate seamlessly into existing ER and ICU workflows. Clinicians emphasized the importance of avoiding the need for specialized training. In subsequent interviews, ER physicians appreciated the compact





and portable design of our sensor, noting its suitability for placement on crash carts or bedside trays without disrupting standard care practices.

Barriers to Adoption

When asked about their concerns with the technology and its use in clinical practice, the nephrologists, ER physicians, and radiologists all pointed to measurement accuracy as a critical factor. While some noted that error margins of a couple eGFR percent would be acceptable for initial screening in emergency care, almost all of the clinicians affirmed that any device which informs clinical decision-making ultimately requires a high level of precision.

Some clinicians also noted that creatinine alone can be insufficient to guide urgent treatment decisions unless the values measured were extreme. Particularly, it was stressed that while creatinine is indicative of whether kidney function is impaired, it does not help elucidate which complications have emerged from that impairment. Nephrologists and ER doctors alike independently highlighted that a potassium concentration is critically indicative of life-threatening complications arising AKI like cardiac arrhythmia which may necessitate immediate dialysis. A multiplex test, particularly one which includes essential electrolytes like potassium, was accordingly described as being significantly more useful in acute care.

Patients generally weren't enthusiastic about receiving additional needles. However, they generally deferred to clinicians' judgement and expressed their willingness to undergo testing if recommended. No other patient concerns were raised about the device or its intended use.

Design Direction & Limitations

Through in-depth interviews with a diverse group of stakeholders, we have identified an urgent, recurring problem in kidney care. Delays in creatinine testing at the point of care are leading to diagnostic uncertainty and delays which are directly impacting patient disposition. Our secondary research also supported these findings, leading us to shift our focus away from developing a continuous monitoring system, and instead focused on a point-of-care solution capable of delivering accurate results within five minutes. We are also exploring the possibility of incorporating the detection of additional analytes, particularly potassium, to align with clinician needs in acute care settings.

While we engaged stakeholders across multiple regions and roles, we were unable to reach nurses or lab technicians, both of whom would be impacted directly by our device. Their perspectives would be valuable in informing our future work.

4.2. Design of validation study

Problem Identification

Access to creatinine levels, as well as those of other electrolytes, is key to guiding clinical intervention for AKI. Yet, our interviews revealed that when making crucial kidney care decisions in emergency settings, clinicians can't obtain the data they need on time. This has a direct impact on patient outcomes and overall costs.

AKI affects roughly 20% of hospitalized patients (Lee, Hsu, 2018), and is projected to grow up to 10% per year (Mihai et. al., 2021). The condition can progress rapidly; however, current diagnostic tools can only detect AKI after substantial injury, and are typically processed in centralized labs, delaying results. In the ER, CT scans are used in a quarter of all cases, yet the highly prevalent iodinated contrast agents are nephrotoxic and estimated to cause 11% of all AKI cases (Faucon et. al., 2019). Speed matters most in high-risk settings





- dialysis patients, those undergoing contrast-enhanced imaging, and critically ill individuals in the ICU. Rural communities face an even sharper challenge: blood samples often require transport to distant facilities, adding hours to turnaround time, which has caused consistently higher AKI-related mortalities (Xu et. al., 2024), underscoring the deadly consequences of diagnostic delay and ensuing disposition.

From a financial perspective, delayed AKI detection fuels a chain reaction of costs: longer ICU stays, increased dialysis initiation, higher readmission rates, and the transition of patients into chronic kidney disease management, an ongoing expense for healthcare systems in Canada, costing 125M EUR annually (Collister et. al., 2017). Rapid diagnostics can break this cycle by enabling earlier intervention. Our biosensor is projected to save hospitals $\sim \in 7,200- \in 10,200$ per patient annually by cutting imaging delays, staff burden, and readmissions, as broken down in Appendix Table 3. Our biosensor addresses these gaps with a turnaround time of under five minutes, is highly portable, and is designed for multiple reusable tests per device. With a cost per test approximately being between $\in 4$ and $\in 7$, it offers an affordable, scalable alternative to standard lab tests ($\in 5$ –10 per test with long delays) or commercial systems like i-STAT ($\in 12.56$ per single-use test) summarized in Appendix Table 4.

Conceptual Design

To address this unmet clinical need, we propose the integration of the Creactive biosensor into a portable, multi-electrolyte biosensor built on our modular microfluidic platform. The system would provide rapid (\leq 5 min), multiplexed detection of creatinine and four key electrolytes, including potassium, from a single blood sample of 300 μ L.

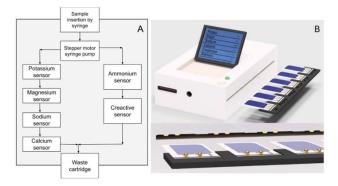


Figure 6: (A) Process flow diagram (PFD) outlining the conceptual prototype, (B) Conceptual prototype

As shown in Figure 5, the design features two parallel flow paths with discrete sensor modules built around SPEs from our current supplier Metro Ohm at no additional cost (Metrohm.com). These SPEs use the gold standard electrochemical potentiometric method to measure electrolyte concentrations across the full clinical range for both healthy and impaired renal function (Chen et. al., 2021). They remain operational for up to 4 hours before degradation, which would necessitate replacement. This operation is easily achieved by a mechanical locking mechanism first releasing the SPEs from their housing units, before they can be individually removed and replaced from a rail consisting of springloaded pogo pins connecting to the working and counter electrodes. While the IoT component is still in development, the device can be battery-powered for several hours of operation. Our existing microfluidic platform is built around syringe administration of samples, and in this integrated prototype, a heparinized syringe containing the patient





sample is inserted into the sample port and introduces a volume sufficient to internally displace the previous sample from the flow cell into a waste cartridge. A barcode on the syringe is scanned to locate the patient's hospital ID and produce a file with outcomes from the test, while a screen interface displays the real-time results.

Our proposed biosensor narrows its focus to analytes most relevant for AKI, thereby improving reliability and reducing false readings. The device also supports continuous use in the same patient, allowing for ongoing monitoring during vulnerable periods without requiring repeated cartridge replacement.

Study Design

To support the clinical viability and diagnostic utility of our proposed point-of-care creatinine sensor, we will conduct a comprehensive validation study evaluating real-world use, stakeholder needs, device performance, and clinical impact in time-sensitive and resource-limited environments.

The sensor's diagnostic performance will be assessed in a stratified cohort study of 300 participants across inpatient and outpatient settings, accounting for age, sex, ethnicity, and diagnosis type (e.g., AKI, CKD, transplant monitoring). Interference from endogenous ammonium will be specifically addressed by measuring both initial ammonium levels with an enzymatic and a non-enzymatic sensor. Reproducibility will be tested using 20 samples spanning the dynamic range, analyzed across five independent laboratories with standardized protocols (Das B., 2011). Each sample will be run in triplicate per site to confirm accuracy and precision (targeting <10% CV). Analytical parameters (LOD, LOQ, linear range) will be evaluated per CLSI EP17/EP6 guidelines, as these are widely used in literature to validate study design and efficacy (NIH.gov, 2025). Time-to-result, device failure rate, and user error incidence will also be measured to assess performance in clinical settings. The prototype will be deployed in several medium-sized Canadian hospitals and clinics without laboratory infrastructure, following a B2G model. Integration into hospital digital workflows will precede structured training for clinicians, nurses, and lab technicians on device operation and data interpretation.

The study aims to establish the biosensor as a reliable, practical alternative to standard laboratory-based creatinine testing. By accelerating time from triage to interventions such as dialysis, the device supports timely, informed clinical decisions to be made for diagnosing and treating renal dysfunction. Its integrated electrolyte panel (testing for potassium, magnesium, calcium, and sodium) provides early insight into imbalances indicative of kidney failure and facilitates the detection of cardiac arrhythmias (Thu Kyaw & Maung, 2022). Moreover, the sensor enables real-time serial monitoring of renal status post-transplant or dialysis, advancing personalized patient management. Positive results will support scale-up, post-market surveillance, and broader clinical adoption.





5. Team and support

5.1. Contributions of the team members

Anders Schwarz: Team Captain who oversaw managerial work including funding and R&D. Organized and participated in several meetings with physicians for translation potential.

Tanjin Sultana: Team Captain who oversaw the team's logistics, R&D & finances, translation potential (entrepreneur insights & patient), financial feasibility and recruiting of external help

Syphax Ramdani: Research lead who contributed to in-person lab sessions, lead flow cell design and assisted with overall troubleshooting.

Gwen Sammon: Research lead who contributed primarily during in-person lab sessions, assisting with flow cell design and overall troubleshooting.

Osandi Hewage: Conducted preliminary literature review, prepared SOP and assisted during in-person lab sessions with biosensor fabrication and testing.

Alex Butler: Summer research member heavily involved in exploring translation potential. **Clara Mickail:** Research members who assisted with preliminary literature review and biosensor design concepts, focusing on electrical connectivity of components.

Claire Levassuer: Research member who contributed both to literature review and by purchasing materials, contacting suppliers, and relaying funding to suppliers from various sources.

Carolyn Mae Denton: Summer research member who contributed during in person lab sessions.

Tesnim Obey: Summer research member who contributed during in person lab sessions. **Martin Nakouzi, Sasha Tan, Mathilde Wagner:** Research members who assisted with preliminary literature review and biosensor design concepts, as well as sourcing potential suppliers during the academic year.

5.2. People who have given support

Professor Sebastian Wachsmann-Hogiu provided invaluable support by guiding our literature review towards a feasible plan, providing us with lab space access.

Xinyue Hu supported our literature review and attended many meetings at unorthodox hours in our support.

Sara Fraser and **Emma Wong** were Co-Presidents of McGill BioDesign who secured the collaboration with the team's supervisor, prepared the application to join SensUs, and recruited the Team Captains.

The many **doctors** who provided valuable insight into existing medical technology and hospital operations. These individuals did not wish for their names to be published, but a list of their name and specialty will be provided separately to the jury.

Anonymous patients shared their experiences with the current medical technology and improved our understanding of how said technology can be improved.

5.3. Sponsors and partners

McGill Biodesign, McGill Engineering Undergraduate Society (EUS), and McGill Alumni donors provided invaluable funding that allowed the purchase of high-quality reagents and assisted with travel fees.

McGill Department of Bioengineering provided supplementary funding allowing for the purchase of reagents.





6. Final remarks

Our team is representing McGill at SensUs for the first time, and we are entering a competition where most other teams have been refining their designs from the previous competition in 2024 that featured the same theme.

Our original electrodes did not function as was advertised which was recognized fairly late. Our second order of electrodes from a different company (Metrohm) will arrive in early August, so at time of writing we have few relevant results. In the next couple weeks, our ammonium calibration curve will be built as the flow cell design, optimization of our enzyme immobilization method, and our patient and physician interviews have been completed.

Nevertheless, we wanted to express gratitude towards Prof. Wachsmann-Hogiu and Xinyue Hu for their mentorship, the many doctors and patients who lent us their limited free time, and our sponsors who allowed us to build a biosensor prototype and represent our school internationally. For many team members, this was our first long-term engineering project, and all involved can attest that it was a valuable learning experience.





7. References

Betancor, L., López-Gallego, F., Hidalgo, A., Fuentes, M., Podrasky, O., Kuncova, G., Guisán, J. M., & Fernández-Lafuente, R. (2005). Advantages of the Pre-Immobilization of Enzymes on Porous Supports for Their Entrapment in Sol-Gels. *Biomacromolecules*, 6(2), 1027–1030. https://doi.org/10.1021/bm0493077

Chen, L.-D., Wang, W.-J., & Wang, G.-J. (2021). Electrochemical Detection of Electrolytes Using a Solid-State Ion-Selective Electrode of Single-Piece Type Membrane. *Biosensors*, 11(4), 109. https://doi.org/10.3390/bios11040109

Collister, D., Pannu, N., Ye, F., James, M., Hemmelgarn, B., Chui, B., Manns, B., & Klarenbach, S. (2017). Health Care Costs Associated with AKI. *Clinical Journal of the American Society of Nephrology*, 12(11), 1733–1743. https://doi.org/10.2215/cjn.00950117

Creative Enzymes - creatinine deaminase(EC 3.5.4.21). (2025). Creative-Enzymes.com. https://www.creative-enzymes.com/product/creatinine-deaminase_14717.html

Das, B. (2011). Validation Protocol: First Step of a Lean-Total Quality Management Principle in a New Laboratory Set-up in a Tertiary Care Hospital in India. *Indian Journal of Clinical Biochemistry*, 26(3), 235–243. https://doi.org/10.1007/s12291-011-0110-x

Elżbieta Jarosińska, Zuzanna Zambrowska, & Emilia Witkowska Nery. (2024). Methods of Protection of Electrochemical Sensors against Biofouling in Cell Culture Applications. *ACS Omega*, 9(4), 4572–4580. https://doi.org/10.1021/acsomega.3c07660

Esimbekova, E. N., Torgashina, I. G., Nemtseva, E. V., & Kratasyuk, V. A. (2023). Enzymes Immobilized into Starch- and Gelatin-Based Hydrogels: Properties and Application in Inhibition Assay. *Micromachines*, 14(12), 2217. https://doi.org/10.3390/mi14122217

Faucon, A.-L., Bobrie, G., & Clément, O. (2019). Nephrotoxicity of iodinated contrast media: From pathophysiology to prevention strategies. *European Journal of Radiology*, 116, 231–241. https://doi.org/10.1016/j.ejrad.2019.03.008

Forlenza, G. P., Kushner, T., Messer, L. H., Wadwa, R. P., & Sankaranarayanan, S. (2019). Factory-Calibrated Continuous Glucose Monitoring: How and Why It Works, and the Dangers of Reuse Beyond Approved Duration of Wear. *Diabetes Technology & Therapeutics*, 21(4), 222–229. https://doi.org/10.1089/dia.2018.0401

Gelatin - Sigma Aldrich. (2025). Blue-White Screening & Protocols for Colony Selection. Merck, 7(1). https://www.sigmaaldrich.com/MX/en/technical-documents/technical-article/genomics/cloning-and-expression/blue-white-screening

Gil Rosa, B., Akingbade, O. E., Guo, X., Gonzalez-Macia, L., Crone, M. A., Cameron, L. P., Freemont, P., Choy, K.-L., Güder, F., Yeatman, E., Sharp, D. J., & Li, B. (2022). Multiplexed immunosensors for point-of-care diagnostic applications. *Biosensors and Bioelectronics*, 203, 114050. https://doi.org/10.1016/j.bios.2022.114050

Hettiaratchi, M. H., Schudel, A., Rouse, T., García, A. J., Thomas, S. N., Guldberg, R. E., & McDevitt, T. C. (2018). A rapid method for determining protein diffusion through hydrogels





for regenerative medicine applications. *APL Bioengineering*, 2(2), 026110. https://doi.org/10.1063/1.4999925

Jayasekhar Babu, P., Tirkey, A., Mohan Rao, T. J., Chanu, N. B., Lalchhandama, K., & Singh, Y. D. (2022). Conventional and nanotechnology based sensors for creatinine (A kidney biomarker) detection: A consolidated review. *Analytical Biochemistry*, 114622. https://doi.org/10.1016/j.ab.2022.114622

Karakuş, E., Pekyardımcı, Ş., & Kılıç, E. (2006). A New Potentiometric Ammonium Electrode for Biosensor Construction. *Artificial Cells, Blood Substitutes, and Biotechnology,* 34(5), 523–534. https://doi.org/10.1080/10731190600862910

Lee, B. J., & Hsu, C. (2017). Acute Kidney Injury Is Important in the Hospital and Afterward. *Journal of Hospital Medicine*, 12(2), 126–127. https://doi.org/10.12788/jhm.2691

Lyu, Y., Gan, S., Bao, Y., Zhong, L., Xu, J., Wang, W., Liu, Z., Ma, Y., Yang, G., & Niu, L. (2020). Solid-Contact Ion-Selective Electrodes: Response Mechanisms, Transducer Materials and Wearable Sensors. *Membranes*, 10(6), 128. https://doi.org/10.3390/membranes10060128

Mihai, D. A., Stefan, D. S., Stegaru, D., Bernea, G. E., Vacaroiu, I. A., Papacocea, T., Lupușoru, M. O. D., Nica, A. E., Stiru, O., Dragos, D., & Olaru, O. G. (2022). Continuous glucose monitoring devices: A brief presentation (Review). *Experimental and Therapeutic Medicine*, 23(2), 174. https://doi.org/10.3892/etm.2021.11097

Mohabbati-Kalejahi, E., Azimirad, V., Bahrami, M., & Ganbari, A. (2012). A review on creatinine measurement techniques. *Talanta*, 97, 1–8. https://doi.org/10.1016/i.talanta.2012.04.005

National Institute of Health (NIH). (2025). *CLSI Standards: Guidelines for Health Care Excellence*. Nih.gov; Clinical and Laboratory Standards Institute. https://www.ncbi.nlm.nih.gov/books/NBK544376/toc/?report=printable

Nguyen, V. K., Wolff, C. Michel., Seris, J. Louis., & Schwing, J. Paul. (1991). Immobilized enzyme electrode for creatinine determination in serum. *Analytical Chemistry*, 63(6), 611–614. https://doi.org/10.1021/ac00006a011

Metrohm - Potentiometric sensor for ammonium detection. (2025, July 16). Metrohm. https://metrohm-dropsens.com/products/electrodes/modified-screen-printed-electrodes/potentiometric-sensor-for-ammonium-detection/

Pololu - A4988 Stepper Motor Driver Carrier. (n.d.). Www.pololu.com. https://www.pololu.com/product/1182

Potentiometric sensor for ammonium detection - Metrohm. (2025, July 16). Metrohm. https://metrohm-dropsens.com/products/electrodes/modified-screen-printed-electrodes/potentiometric-sensor-for-ammonium-detection/





Potentiometric sensor for calcium detection - Metrohm. (2025, July 16). Metrohm. https://metrohm-dropsens.com/products/electrodes/modified-screen-printed-electrodes/potentiometric-sensor-for-calcium-detection/

Potentiometric sensor for potassium detection - Metrohm. (2025, July 16). Metrohm. https://metrohm-dropsens.com/products/electrodes/modified-screen-printed-electrodes/potentiometric-sensor-for-potassium-detection/

Pundir, C. S., Yadav, S., & Kumar, A. (2013). Creatinine sensors. *TrAC Trends in Analytical Chemistry*, 50, 42–52. https://doi.org/10.1016/j.trac.2013.04.013

Rahman, M., Shad, F., & Smith, M. C. (2012). Acute Kidney Injury: A Guide to Diagnosis and Management. *American Family Physician*, 86(7), 631–639. https://www.aafp.org/pubs/afp/issues/2012/1001/p631.html

Saifullah, K. M., & Faraji Rad, Z. (2023). Sampling Dermal Interstitial Fluid Using Microneedles: A Review of Recent Developments in Sampling Methods and Microneedle-Based Biosensors. *Advanced Materials Interfaces*, 2201763. https://doi.org/10.1002/admi.202201763

Sen, D., & Lazenby, R. A. (2023). Electrochemical Biosensor Arrays for Multiple Analyte Detection. *Analysis & Sensing*. https://doi.org/10.1002/anse.202300047

Sensit Wearable - PalmSens. (2024, November 29). PalmSens. https://www.palmsens.com/product/sensit-wearable/

Singh, G., Savage, N. M., Gunsolus, B., & Foss, K. A. (2019). Requiem for the STAT Test: Automation and Point of Care Testing. *Laboratory Medicine*. https://doi.org/10.1093/labmed/lmz080

Stepper Motor NEMA 17 (1.8°, 12V, 0.33A, Bipolar). (2019). Canada Robotix. https://www.canadarobotix.com/products/451?srsltid=AfmBOop5VFDRxX-WjKOvuCrvXKK4U_3J9ZXPJRHjs-ABYxePCm58PKSS

Thu Kyaw, M., & Maung, Z. M. (2022). Hypokalemia-Induced Arrhythmia: A Case Series and Literature Review. *Cureus*, 14(3). https://doi.org/10.7759/cureus.22940

Tomsa, D., Liu, Y., Stefanson, A., Ren, X., Sokoro, A. A. H., Komenda, P., Tangri, N., Zahedi, R. P., Rigatto, C., & Lin, F. (2025). A passive flow microreactor for urine creatinine test. *Microsystems & Nanoengineering*, *11*(1). https://doi.org/10.1038/s41378-025-00880-z

Uline - Dri-Shield® Heavy Duty Moisture Barrier Bags - 10 x 12". (2025). Uline.ca. https://www.uline.ca/Product/Detail/S-15503/Static-Shielding-Bags/Dri-Shield-Heavy-Duty-Moisture-Barrier-Bags-10-x-12

Windmiller, J. R., Valdés-Ramírez, G., Zhou, N., Zhou, M., Miller, P. R., Jin, C., Brozik, S. M., Polsky, R., Katz, E., Narayan, R., & Wang, J. (2011). Bicomponent Microneedle Array Biosensor for Minimally-Invasive Glutamate Monitoring. *Electroanalysis*, 23(10), 2302–2309. https://doi.org/10.1002/elan.201100361





Xu, F., Miyamoto, Y., Zaganjor, I., Onufrak, S., Saelee, R., Koyama, A. K., & Pavkov, M. E. (2024). Urban-Rural Differences in Acute Kidney Injury Mortality in the United States. *American Journal of Preventive Medicine*. https://doi.org/10.1016/j.amepre.2024.08.009

Zhang, X., Wang, Y., He, X., Yang, Y., Chen, X., & Li, J. (2024). Advances in microneedle technology for biomedical detection. *Biomaterials Science*, *12*(20), 5134–5149. https://doi.org/10.1039/d4bm00794h





8. Appendix

Table 1: Materials and specifications of flow cell and septum holder

	Material	Printing Method	Specifications
Flow Cell	Elegoo Standard Translucent Photopolymer Resin	masked stereolithography, Elegoo MARS Resin	Volume of electrode chamber: 75uL
		Printer	Fitted to tubing with 3/32" outer diameter, 1/32" inner diameter
Rubber Septum Holder	PLA Filament	Prusa Filament 3D Printer	-

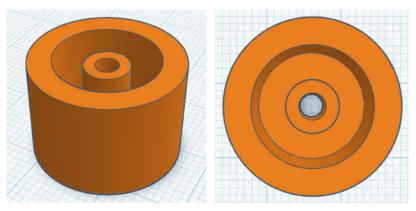


Figure 7: Visual of rubber septum holder

Table 2: Cost breakdown of Creactive biosensor

Item	Supplier	Unit Cost (€)*
Ammonium Sensor	Metro ohm	5.97
Creatinine Deiminase	Creative Enzymes	0.96
Gelatin (Powder)	Sigma Aldrich	0.18
Stepper Motor Syringe Pump	Canada Robotix	
NEMA 17 Stepper Motor	Canada Robotix	23.16
A4988 Stepper Motor Driver	Polulu	7.43
Carrier		
Magnesium Sensor	Metro Ohm	5.97
Calcium Sensor	Metro Ohm	5.97
Potassium Sensor	Metro Ohm	5.97
Sodium Sensor	Metro Ohm	5.97
Fluidics (Tubing, reservoir,	Various	5
connectors)		
Electronics (Control board,	Various	25
ADC, connectors)		
Chemicals (Crosslinker,	Various	10
buffer, calibration standard)		





Packaging and Shipping	Uline	1.54
(ESD bags)		
Labour	N/A	12.56
Total		115.68

^{*}All products are linked in the references under the same product name and supplier as is listed in this table

Table 3: Estimated Hospital Savings Per AKI Patient**

Catagory	Current Cost	Creactive	Estimated	Notes
Category	Current Cost with Standard			Notes
	with Standard Testing (€)	Device Related Cost (€)	Savings (€)	
Imaging Delays / Repeats	~€340–€680	Mostly avoided	~€340–€680	Faster biomarker tracking reduces need for contrast CT and repeated imaging.
AKI-Related Readmission	~€4,104–€5,823	Reduced via early detection	~€4,100–€5,800	Early intervention reduces risk of readmission and complications.
Material / Test Costs(30–50 tests)	€150–€500	€120-€335	~€30–€165	Based on €4– €6.70 per test (from €200 device amortized over 30–50 uses).
Hospitalization from Undetected AKI	~€2,570–€4,080	Reduced by preventing escalation	~€2,700–€3,400	Timely intervention prevents progression to costly stages.
Total Estimated Savings / Patient	-	-	~€7,200–€10,000	Based on settings with high AKI risk and limited lab access (e.g., rural, emergency care).

^{**} All costs and clinical discussions were based on literature values obtained from Collister et. al. (2017).





Table 4: Comparison of Creactive Biosensor vs. Standard Lab and POC Testing Methods

Test Method	Cost per Test (€)	Replacement	Turnaround Time (min)	Analyte Technology	Staffing Required
Standard Blood Test (Urgent)	5-10	N/A	40-60 (Singh et. al., 2020)	Serum creatinine and electrolyte panels processed in central analyzers; delayed sensivity for AKI detection	Lab technician
Existing POC Device (e.g. i-STAT Chem 8+ Test – Abbott Laboratories)	13	Single use cartridge	<5	Multi-analyte cartridge (Na, K, Cl, iCa, Glu, BUN, Creatinine, Hct, HCO ₃ -, AG, Hb); prone to signal interference (Gil Rosa et. al., 2022)	Nurse/Technician
Creactive Device	4-6.7	Reusable up to 30-50 tests (200 EUR device cost amortized)	<5	Modular electrochemical sensors for Na, K, Ca, Creatinine; reduced cross-reactivity and improved specificity (Sen & Lazenby, 2023)	Nurse/Technician

