Team Results Document

BiosensUM



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SensUs

1. Abstract

Parkinson's disease affects a growing number of people worldwide, creating an urgent need for more personalized and effective care. Levodopa, the main treatment for Parkinson's can significantly relieve motor symptoms, but its effects vary between patients and throughout the day, making treatments adjustments challenging.

To address this problem, the BiosensUM team developed a proof-of-concept electrochemical biosensor designed to continuously monitor levodopa. The device converts a negligible amount of the medication into a measurable electrical signal, providing a convenient approach to tracking changes in levodopa levels over time.

Interviews with patients' healthcare professionals, patient organizations, researchers, and entrepreneurs revealed that measuring levodopa alone would not provide the full picture. These insights inspired the development of *DopaSync*, our conceptual multimodal platform, which combines continuous levodopa monitoring with the assessment of motor symptoms. Through a four-step "Measure-Correlate-Interpret-Personalize" cycle, DopaSync aims to identify how each patient's medication levels relate to their symptoms and provide healthcare professionals with meaningful information to support personalized treatment decisions.

Together, our functional proof-of-concept and stakeholder-informer platform demonstrate how biosensing innovation could contribute to a more objective continuous, and patient-centred Parkinson's care.

2. AP award: Biosensor

2.1. Molecular recognition

Our biosensor uses copper oxidase (MCO), an engineered multicopper oxidase (MCO) with high selectivity toward L-DOPA. The original thermostable enzyme, McoP is derived from the hyperthermophilic archaeon *Pyrobaculum aerophilum.* During the reductive half-reaction, McoP oxidizes L-DOPA to dopaquinone and accepts the released electrons at its type 1 copper centre (T1) (1). These electrons are normally transferred to the trinuclear type 2/type 3 copper centre (T2/T3), where the oxidative half-reaction reduces molecular oxygen to water. Since oxygen acts as the terminal electron accept, direct electron transfer (DET) between the enzyme and an electrode is normally negligible.

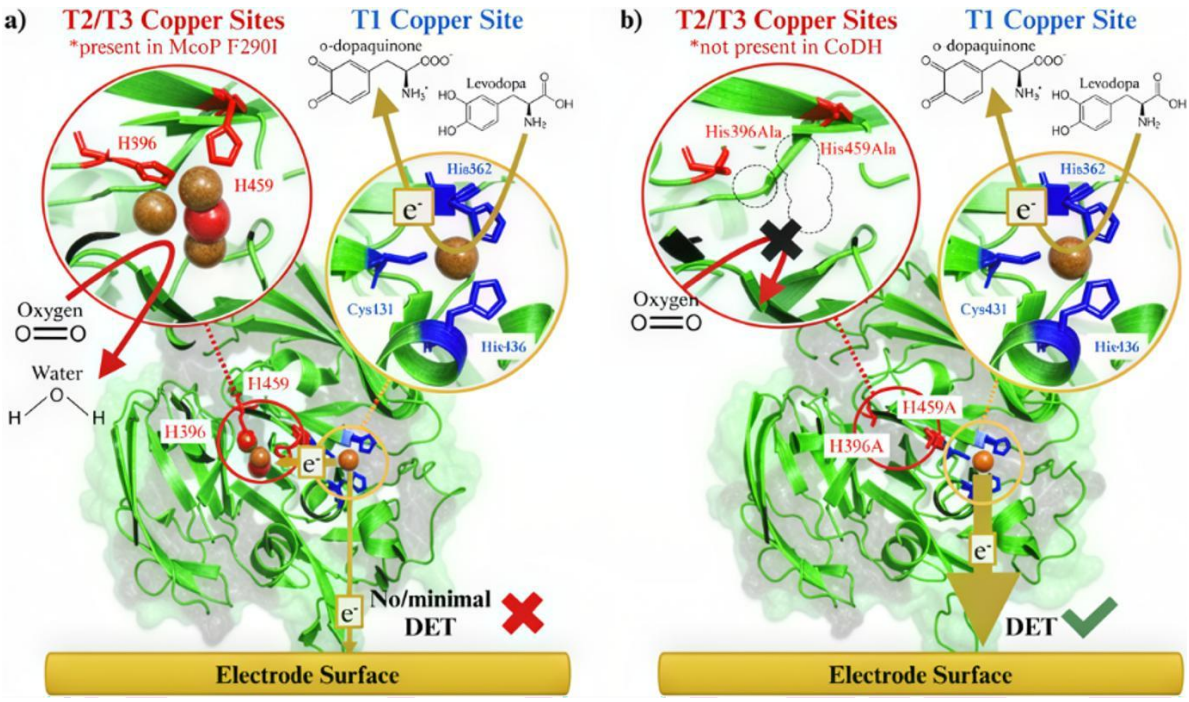


Figure 1. Engineering of McoP into a CoDH capable of direct electron transfer. (a) In the original McoP, electrons obtained from L-DOPA oxidation are transferred from T1 to the T2/T3 centres, where oxygen is reduced to water, making DET to the electrode negligible. (b) Mutating the histidine residues coordinating the T2/T3 centres prevents oxygen reduction while preserving L-DOPA oxidation at T1, allowing the electrons to be transferred directly to the gold electrode (1).

To enable electrochemical detection, the enzyme was engineered by replacing the histidine residues coordinating the T2/T3 copper centres by alanine ones (H396A and H459A), while preserving the catalytically active T1 centre. Moreover, the phenylalanine resitdue at the position 290 has also been replaced by an isoleucine residue, which improves the initial oxidation process. The resulting F2901/H396A/H459A mutant, termed copper dehydrogenase, CoDH, can therefore oxidize L-DOPA without efficiently transferring the resulting electrons to oxygen. When CoDH is immobilized on a gold electrode and an appropriate potential is applied, the electrode acts as the primary

electrons' acceptor. This DET generates a measurable current proportional to the L-DOPA concentration, enabling mediator-free electrochemical detection (1).

2.2. Physical transduction

L-DOPA concentration is measured through chronoamperometry. CoDH is immobilized on the surface of gold-wire working electrode using a self-assembling monolayer (SAM) of dithiobis(succinimidyl hexanoate) (DSH). The disulfide group of DSH binds to the gold surface, while its reactive succinimidyl ester groups form covalent bonds with primary amines on the enzyme. Figure 2 illustrates a comparable protein-immobilization mechanism using dithiobis(succinimidyl propionate) (DSP); the same sequence applies to the immobilization of CoDH using DSH.

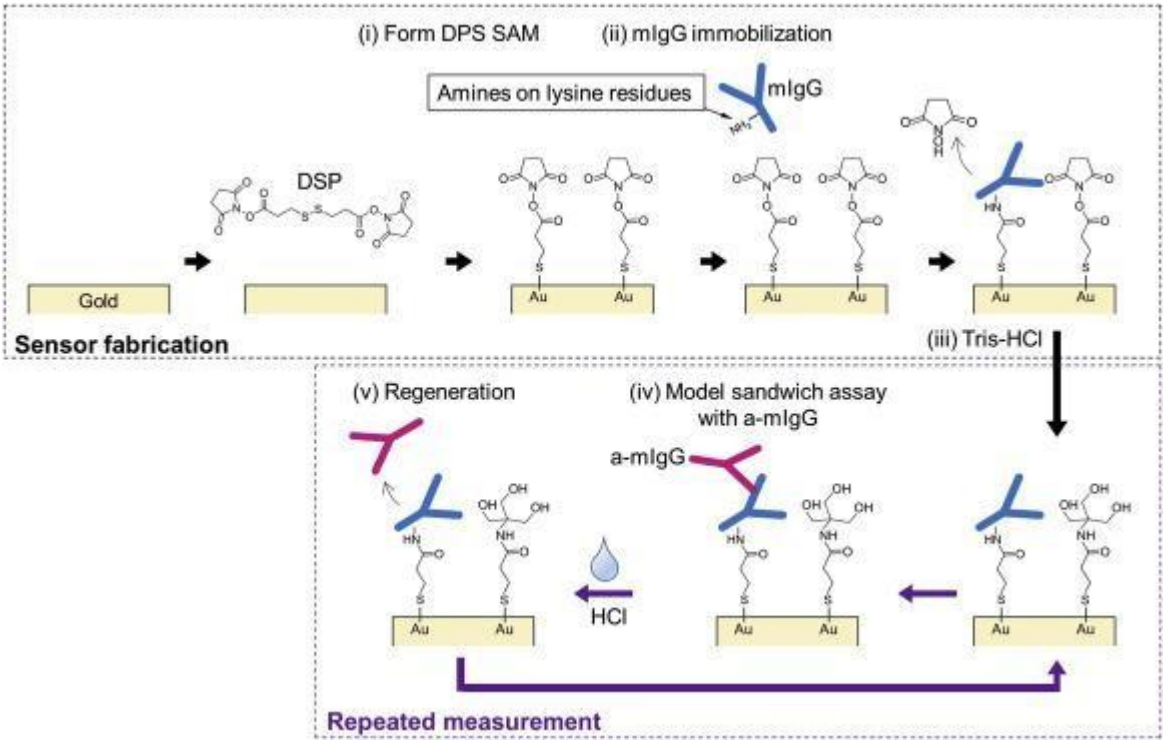


Figure 2. Immobilization of proteins on gold surface using dithiobis(succinimidyl proprionate) (DSP). The diagram illustrates the sequential immobilization of antibodies on gold through DSP self-assembled monolayer. CoDH follows the same mechanism but uses dithiobis(succinimidyl hexanoate) (DSH) as the crosslinker (2).

A potential of +0.3V is applied to the gold working electrode relative to the Ag/AgCl pseudoreference electrode, while a platinum counter electrode completes the electrochemical circuit. A potentiostat assembled from the open-source FreiStat (3) maintains the applied potential and records the resulting oxidation current for three (3) minutes. As CoDH oxidizes L-DOPA, the electrons transferred directly from its T1 copper centre to the gold electrode generate a measurable current. The average current recorded during the final 30 seconds is then translated to a L-DOPA concentration using a previously established calibration curve.

2.3. Cartridge technology

To perform continuous flow monitoring, a microneedle is designed to contain the electrodes and will constitute our flow cell. For the competition, the prototype will be tested on a silicone skin model, as human skin requires further technical validation and ethical approval. Its design is provided in appendix 8 but is standard in microfluidics. The needles' material is currently a standard commercial acrylate-based photocurable resin, as proof-of-concept. If clinical trials were planned, more appropriate material would be used. For example, proper medical-grade polyimide or polyetheretherketone or even surface-treated titanium would be more suited for this application. The samples will be inserted in the silicone channel using a syringe and connected tubing. A few designs were conceived for the microneedle. First, the idea was to make a needle for each of the electrodes that would then be pricked into a patient's skin. The electrodes used would be as described in the previous section. One issue from this configuration would be possible discrepancies in the concentrations/chemical environment between the needles.

2.4. Reader instrument and user interaction

To measure the low currents expected from the enzymatic electrodes, the reader was built around the AD5941 analog front end. This choice was made because the measurement range and resolution are compatible with the estimated sensor output (Appendix X). Rather than developing a new PCB around this component, BiosensUM assembled and adapted the open-source FreiStat hardware and software platform (3). The firmware controls the three-electrode system and performs chronoamperometric measurement. A Python GUI allows the operator to configure the parameters, start the experiment, visualize the response in real time and export the data.

A new GUI inspired by FreiStat software was developed to facilitate users' operation of the software by only allowing chronoamperometric measurement and limiting the number of settings, while making the visuals more colourful. The new GUI also offers the ability to change the preferred language and offers a dark mode for reducing eye strain and improvement of visibility.

The cartridge is connected to the potentiostat through the working, reference and counter electrodes. After introducing the sample as described in Section 2.3, the user starts the measurement from the interface. Pictures, dimensions, schematics, the bill of materials and software details are provided in Appendix 8.

3. IN award: Biosensor innovation

3.1. Wearable sensor

The envisioned device is a compact wearable system. A microneedle interface accesses interstitial fluid and transfers it to a disposable sensing cartridge. The cartridge connects to a reusable wireless reader. Measurements are performed automatically at regular intervals. Results are transmitted to an external display or connected device. Patient-specific L-DOPA trends can then be viewed alongside medication intake and reported symptoms.

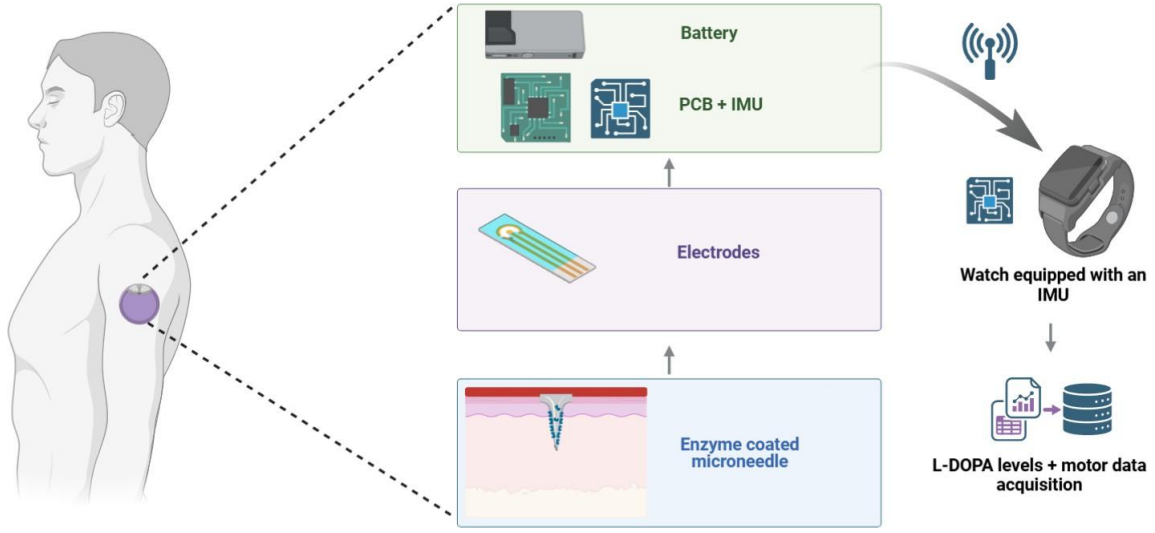


Figure 3. Schematic representation of the wearable biosensor.

3.1.1. Technological novelty of wearable sensor

The central novelty is the use of an engineered CoDH that does not rely on oxygen as the terminal electron acceptor. This reduces sensitivity to local oxygen fluctuations, while its higher specificity limits interference from related compounds. Direct electron transfer to the electrode simplifies the readout. The reported shelf life and thermostability support its potential for long-term monitoring. The microneedle array part provides passive capillary access to interstitial fluid, avoiding active pumps and complex microfluidics. The electronics were selected for integration into a compact wireless reader.

3.1.2. Technical feasibility of wearable sensor

The reader was tested in two stages. Firstly, resistive and RC dummy cells were used to evaluate the hardware, firmware and low-current acquisition independently of electrochemical variability. With the external 10 MΩ transimpedance configuration, the response was linear between approximately −43 and +38 nA (R^2= 0.999996). With the RC dummy cell, the measured time constant was 66.9±0.91ms, compared with a theoretical value of 67.73 ms. These results confirm that the reader can measure both stable and time-

varying nanoampere signals. The complete setup, parameters and results are provided in Appendix 8 : Electrical Bench Validation Using Dummy Cells

Secondly, the reader was tested in a three-electrode electrochemical cell containing ferricyanide in KCl, and its performance was compared with a commercial BioLogic potentiostat controlled using EC-Lab software. Chronoamperometric measurements from 5 to 100 µM showed a linear relationship between current and concentration for both our reader (R^2 = 0.9943) and the commercial instrument (R^2 = 0.9947). Although the calibration slopes differed, both instruments reproduced the expected concentration-dependent responses. Together, these results demonstrate that the reader can perform chronoamperometric measurements in solution. The complete protocol and comparison are presented in Appendix 8: Wet electrochemical validation.

The current reader measures 54 × 23 × 25 mm, while its thickness mainly results from the development board and pin headers. A dedicated PCB could integrate the electronics, microcontroller, wireless communication and power management into a lower-profile format. The electrical and wet electrochemical tests support the feasibility of the reader and its operation in solution. However, the CoDH-functionalized electrodes have not yet been tested with our built reader. This complete biosensor validation, together with cartridge integration and microneedle sampling, is planned before the competition demonstration. Wireless operation and battery autonomy also remain to be evaluated for the wearable concept.

Some tests were performed using the silicone channel to make sure sample injection was feasible. During the optimization process, a few adjustments were made to prevent leaks and to provide a clean environment. Using a dual syringe system, we were able to introduce samples in the channel and, by diffusion, in the needles. We could not produce chronoamperometric measurements in time using the channel in this document, though this is to be done before leaving and will hopefully be included in the presentation.

3.2. Reliability of sensor output

Using a molecular recognition system, such as an enzyme, can be challenging. These proteins are often very sensitive to fluctuation in temperature, pH, substrate availability, and, in the case of electrochemical detection devices, the presence of mediators to measure the produced electrons (1).

3.2.1. Technological novelty of reliability concept

Our CoDH enzyme alleviates some of the issues associated with the use of enzymes in biosensors. Since it originates from a thermoresistant organism, the enzyme itself is thermoresistant. It can maintain its structural integrity at temperatures reaching 80 degrees Celsius. This implies that the enzyme is perfectly stable at body temperature. This has been tested by Kartheek Batchu et al. whereby the CoDH is able to give reliable and consistent DET measurements at room and body temperature (1).

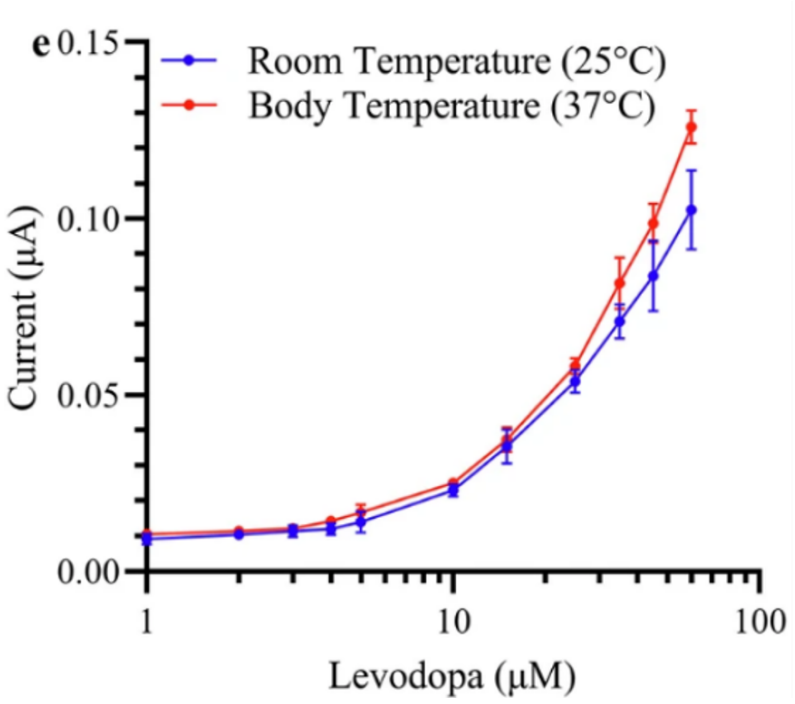


Figure 4. Stability of the CoDH enzyme at room and body temperature. DET tests performed by Kartheek Batchu et al. demonstrate the stability of the signal produced by the CoDH enzyme at room and body temperature. (1)

Moreover, the CoDH being oxygen-insensitive, fluctuations in blood oxygen concentration should not affect the sensor. This means that the sensor should function as expected regardless of the physical activities undergone by the user. In addition, this enzyme shows remarkable specificity towards L-DOPA. Kartheek Batchu et al. showed that common interfering molecules present in ISF as well as the metabolites of L-DOPA barely affect the signal. (1)

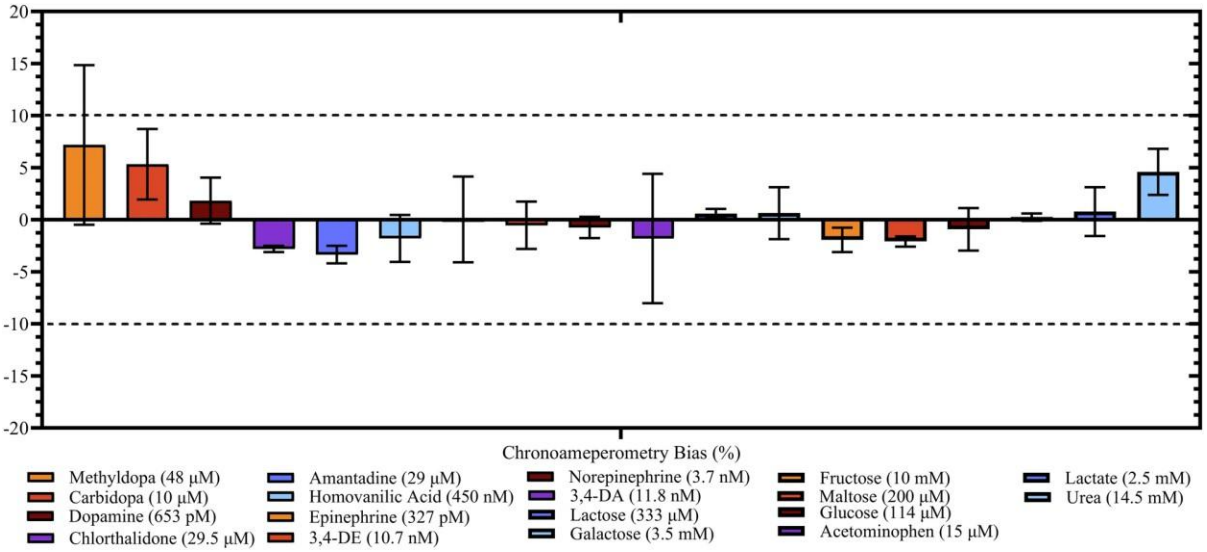


Figure 5. Chronoamperometric fluctuations caused by endogenous and exogenous interferents. Kartheek Batchu et al showed that these common interferents have marginal effects on chronoamperometric measurements. Only methyldopa showed a bias of slightly more than 10%. All the metabolites were tested at concentrations several times higher than what is usually found in vivo. (1)

Furthermore, the DET aspect of our sensor nullifies the need for a mediator in the electron detection process. This removes a vital variable in most wearable biosensors. Immobilization on the working electrode surface prevents the loss of enzyme. The short and constant distance from the gold surface allows for efficient and reliable measurements, as per Marcus's theory on the exponential decay of current with distance during electron transfer.

3.2.2. Technical feasibility of reliability concept

Using our functionalized electrode, we provide here the results of our preliminary tests of chronoamperometric measurements. Using an ISF control, a 3µM and a 10µM L-Dopa solutions, we show here how the 3-electrodes set-up is applicable to correlate chronoamperometric data to L-Dopa concentration.

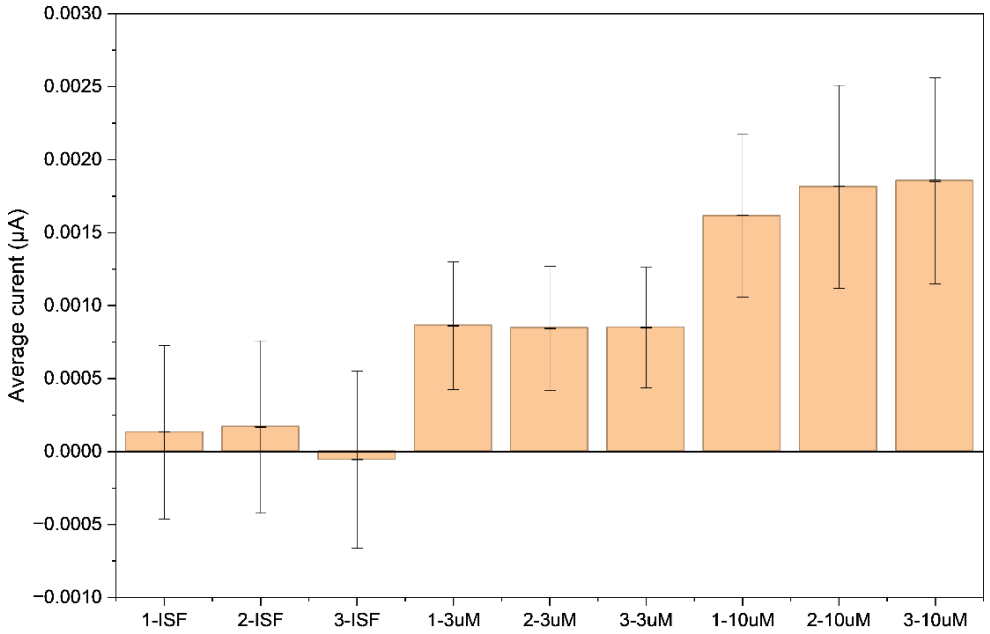


Figure 6. Average quasi steady state current measured by chronoamperometry of L-Dopa in ISF solutions. Each measurement is performed in triplicates over 180 s, at a rate of a measurement every 10 ms and cycled thrice. Largest error band is standard deviation, and smallest is standard error of mean. N = 16488 for every solution. Raw data are provided in appendix 8.10.

A few things to discuss on these results; First, the potential applied for this experiment is +300 mV against an Ag/AgCl pseudo-reference (1). This means that L-Dopa is partially oxidized in dopaquinone by this applied potential. No enzymatic activity is proven by this assay, though it can still be concluded that our chronoamperometric methodology is reliable. If enzymatic activity were to be presented here, a more insightful approach would have been to apply a negative potential excessing its reduction potential. Then, a loop of oxidation by the enzyme and reduction by the electrode is made possible on the electrode surface. A second issue emerges when observing the raw data in appendix 8.10. Because the surface area of the functionalized working electrode is too important, saturation is observed at the beginning of the curve. This causes significant issues when plotting current against the negative inverse square root of time. As shown in the next figure, the response is not linear as expected.

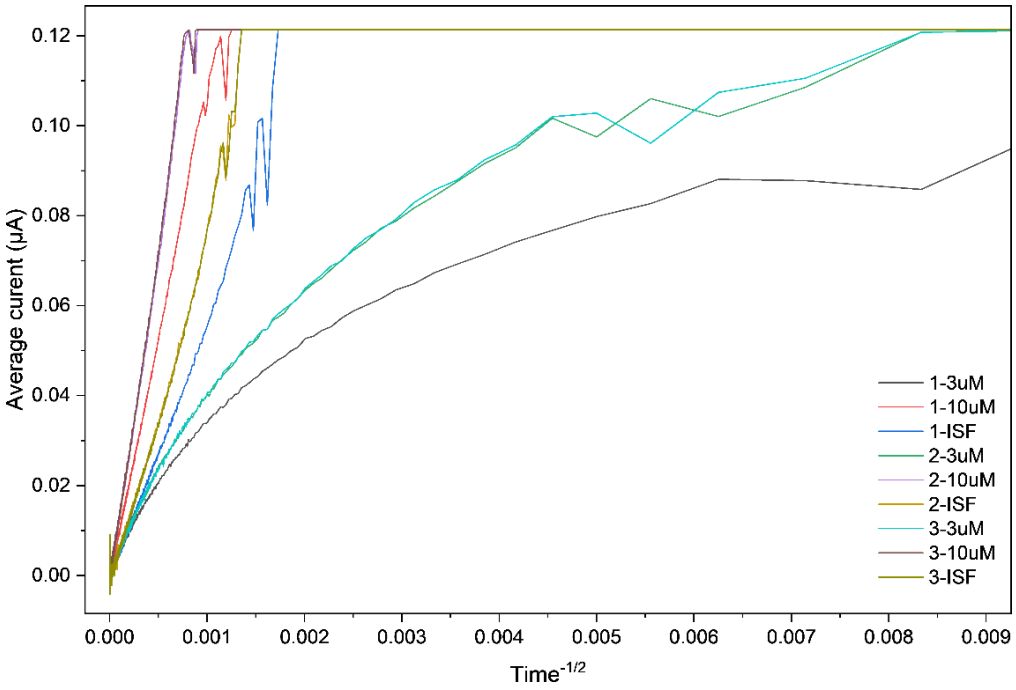


Figure 7. Average steady-state current measured by chronoamperometry of L-Dopa in ISF solutions against negative inverse square root of time. Correlation between 3µM and ISF control solutions seems to disappear. We hypothesized that this is produced by saturation of the current value. We observe great replicability between cycles 2 and 3.

It also highlights the need to verify that Cottrell's equation model is undisturbed by enzymatic activity, which remains unsupported in this newly conceived system. This can be circumvented though by focusing on the linear domain at the beginning of the curve. This corresponds to the plateau observed in the raw data and represents a state where the ionic double layer on the surface is mostly organized by the potential; no more influences from capacitive current. It is labelled quasi steady state because it is assumed that enzymatic activity contributes actively to the movement of the chemical species forming those layers; although it might be mislabeled because of the impact of diffusion. This correlation is also hypothesized to be a result of the degradation of the SAM allowing for more available surface area on the gold wire. More experiments are necessary to prove this concept is reliable, but the promising data presented here suggests we are heading there.

For further investigation, we intend on diminishing the working electrode area to prevent saturation. Measurements over a larger range of concentrations and with more data point is also necessary to obtain reliable calibration curve. These results were also produced in another electrochemical cell than presented in section 2.2; therefore, this needs to be changed too. Data processing also needs to be improved to reduce the impact of noise and to be automated to keep up with the continuous monitoring.

3.3. Original contributions

Team's part: The team was responsible for the conceptualization, design and development of the microfluidic device, the potentiostat, and the overall integration of the technology and biochemical components. The enzyme sequence was selected based on published literature and synthesized by *Twist Bioscience*. The downstream experiment was carried by the team using protocols adapted from literature, including recombinant enzyme expression, purification, functionalization and immobilization on gold electrode surface.

Professor Masson's part:

The team was fully independent in their project. They benefitted from some guidance at the beginning of the project and assistance on the logistical aspects of their participation to the competition. However, they did not receive any assistance during the conception and development phase of the project. As such, I testify that all the items described by the team was done independently.



Dylan Ngoya
Co-captain



Axelle Drouard
Co-captain



Pr. Jean-François Masson
Supervisor

3.4. Bonus criteria Innovation

Most wearable biosensors report biomarker concentrations without determining whether the measured exposure produces the intended therapeutic response. This limitation is particularly important in Parkinson's disease, as similar L-DOPA concentrations may produce different motor responses between patients. Zhou et al. likewise concluded that levodopa concentration alone does not fully reflect treatment effectiveness and proposed combining biochemical measurements with objective motor assessment (4).

We therefore propose extending the BiosensUM sensor into a multimodal monitoring platform. A miniature inertial measurement unit (IMU), integrated directly into the custom reader PCB (Figure 3), would allow record movement simultaneously with electrochemical L-DOPA measurements. Its small size and low power consumption would remain compatible with the proposed upper-arm wearable.

Our proposed solution would combine three complementary sources of information: electrochemical L-DOPA trends, movement data from the integrated IMU or a compatible smartwatch, and patient-reported outcomes. Previous work combining wearable levodopa sensing with objective movement monitoring supports the relevance of this multimodal approach for evaluating treatment response in Parkinson's disease (4).

Patient-reported outcomes would complement these measurements through short, structured check-ins on a mobile conversational interface. Medication intake, wearing-off, episodes, dyskinesia, adverse effects and perceived well-being could thus be synchronized with L-DOPA exposure and movement features.

Once sufficient longitudinal data are collected, these synchronized measurements could support the development of personalized models linking L-DOPA exposure to motor response and patient experience. These models could eventually highlight periods of insufficient symptom control or possible adverse effects and generate interpretable summaries for clinicians. Treatment decisions would remain under clinical supervision.

Although not experimentally validated within the current project, the proposed architecture is technically feasible based on commercially available low-power IMUs and previously demonstrated wearable levodopa and movement monitoring. It provides a concrete pathway for transforming the sensor from an isolated concentration reader into a patient-centred platform connecting drug exposure with real-world therapeutic response.

4. TP award: Translation potential

4.1. Customer interviews

4.1.1. Identification of potential stakeholders

To ensure our biosensor successfully addresses a clinically relevant need in Parkinson's disease management, we identified stakeholders representing different perspectives across the care, treatment, and device-use journey. Parkinson Québec supported this process through its knowledge of the community and connections with patients and healthcare professionals.

Patients were identified as our primary end users because they would directly experience the benefits and burdens of wearing the biosensor. Their perspectives were essential for assessing its acceptability, affordability, and compatibility with daily life. **Movement disorder specialists (Neurologists)** were selected because they prescribe levodopa and manage motor complications such as dyskinesia and tremor. Their input helped identify clinically meaningful measurements and potential uses of sensor data in treatment decisions.

Pharmacists contributed expertise in medication management, including complex dosing schedules and factors influencing levodopa response. **Rehabilitation professionals** were included because they assess motor function and could evaluate the device's practicality for patients experiencing tremor, rigidity or reduced dexterity.

MedTech entrepreneurs and **innovation specialists** provided complementary perspectives on commercialization, market access and clinical implementation. **Caregivers and Parkinson's nurses** were also identified as highly relevant stakeholders due to their involvement in daily symptom monitoring and care coordination. Although they could not be interviewed within the project timeline.

4.1.2. Interview approach and execution

The interviews aimed to understand the patient journey, stakeholder experiences and unmet needs in Parkinson disease management. A **semi-structured** methodology was used across stakeholder groups, covering recurring themes such as current challenges, uncertainties, unmet needs, and desired improvements. This approach ensured consistency while allowing follow-up questions based on each participant's responses.

Patients' recruitment followed a research protocol approved by the **Université de Montréal's Research Ethics Committee in Health and Sciences (CERSES)**. The study compromised three (3) planned phases. First, participants were recruited for individual interviews conducted in person or remotely after verbal consent was obtained generating **qualitative data** on their experience and needs. Second, a survey was distributed to collect **quantitative data** and characterize patient profiles. Combining both approaches allowed the team to compare individual experiences with larger response patterns. A planned third

phase involving targeted interviews with patient subgroups identified during the first two phases could not be completed within the project timeline. Ethics approval, recruitment materials, consent documentation and patient questions are available in Appendix 8.11.

Interviews with **physicians, pharmacists, rehabilitation specialists, and MedTech entrepreneurs** followed the same semi-structured principles and lasted approximately **30-60 minutes**. A three-member team conducted each interview: one interviewer, one note-taker, and one timekeeper. All stakeholders answered common questions about the need for continuous L-DOPA monitoring, while additional questions were adapted to their expertise. For example, pharmacists addressed L-DOPA pharmacology, whereas rehabilitation specialists discussed motor function and physical activity.

Following each interview, the team prepared a structured summary and classified the findings into core problems, primary needs and expectations. Each finding was linked to the stakeholder group that raised it to enable comparison and traceability across interviews. Interviews guides, ethics and recruitment documents, stakeholder specific questions and the complete traceability table are provided in Appendix 8.11.

4.1.3. Interview results and conclusions

The **main problem** identified was the difficulty of adjusting levodopa treatment because drug responses and motor fluctuations vary between patients throughout the day. Stakeholders also indicated that brief clinical consultations provide only a limited view of these fluctuations, while manually recording medication intake and symptoms creates an additional burden for patients.

The **primary needs** were continuous monitoring, wearability and personalized interpretation. Stakeholders emphasized the importance of correlating levodopa concentrations with motor and functional outcomes while ensuring that the device remains comfortable, removable, and affordable for long-term use. Sensor data should be interpreted according to relevant clinical and physiological factors and presented as clear summaries rather than raw measurements.

Stakeholders **expected** the biosensor to improve understanding of dose-effect relationships, support treatment adjustments between consultations, and reduce the burden of symptom tracking. Rehabilitation professionals also identified potential value in adapting physical activity to patient's functional responses. However, clinicians warned that unrestricted access to raw data or excessive alerts could cause anxiety or misinterpretation. Finally, implementation specialists emphasized that manufacturability, commercialization, and clinical integration should be considered early in development. The correspondence between these findings and the contributing stakeholder groups is provided

4.2 Design of validation study

4.2.1 Selection of the problem

Stakeholders interviews identified the lack of objective, continuous information linking L-DOPA levels to motor symptom fluctuations in patients' daily lives. Current assessments rely mainly on brief consultations, patient recollection, and manual symptom diaries, providing an incomplete view of each patient's individualized response to treatment. This limits healthcare professionals' ability to characterize dose-response relationships and adjust medication, rehabilitation and follow-up between consultations.

This problem is suitable for a sensor-based solution because L-DOPA levels and motor manifestations can both be measured repeatedly, synchronized and correlated over time. Our proposed sensor, ***DopaSync*** would combine electrochemical L-DOPA monitoring with motor symptom tracking to generate individualized profiles of treatment response and ON/OFF fluctuations. These longitudinal summaries could support clinical and rehabilitation decisions while reducing the burden of manual tracking. Its wearable, removable, and low-burden design also responds directly to stakeholder priorities concerning long-term usability, affordability and professional oversight.

4.1.4. Conceptual design and use case.

DopaSync is a wearable multimodal continuous biosensor designed to address the lack of objective and continuous information linking L-DOPA exposure to motor fluctuations in people with Parkinson's disease. It combines biochemical and motor symptoms measurement to generate individualized profiles supporting clinical and rehabilitation decisions (Figure 8).

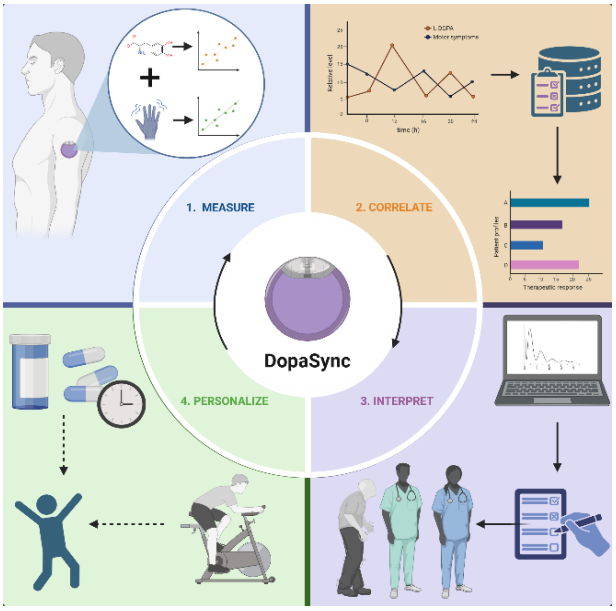


Figure 8. Conceptual design of DopaSync.

Its intended use follows a four-phase **Measure-Correlate-Interpret-Personalize cycle.** First, **Measure**: an electrochemical microneedle sensor monitors L-DOPA trends in the interstitial fluid, while an integrated inertial measurement unit records movement patterns associated with motor fluctuations, including tremors and dyskinesia. Second, **Correlate:** both data streams are synchronized to characterize response delay, fluctuation intensity and response duration. Medication timing, physical activity and relevant patient characteristics could be incorporated following appropriate algorithm training and validation. Third, **Interpret:** clinically relevant trends are

converted into clear summaries for healthcare professionals and discussed with the patient limiting the risks associated with uninterpreted raw data. Fourth, **Personalize**: healthcare professionals may use these insights to inform medication timing or dosage, rehabilitation activities and follow-up planning. Continued monitoring would then evaluate these adjustments and progressively refine the patient's profile.

DopaSync would reduce reliance on memory and handwritten symptom diaries while capturing fluctuations between consultations. It would provide clinicians with objective longitudinal trends and help patients better understand their treatment response without encouraging autonomous medication changes.

The concept is supported by previous demonstrations of wearable electrochemical L-DOPA detection and inertial motor monitoring (5). Its innovation lies in integrating. Its innovation lies in integrating and correlating both measurements to produce clinically interpretable, individualized profiles. This directly reflects stakeholder priorities for continuous, wearable and low-burden monitoring, personalized interpretation and maintained professional oversight.

4.2.2 Validation study design

Phase	Evaluation and quantitative outcomes	Applicable requirements
I. Preclinical, analytical validation (12-18 months)	This phase will consist in testing the calibration range, sensitivity, detection limit, response time, drift and repeatability in buffer and interstitial fluid (ISF). Assess interference from dopamine, ascorbic acid and carbidopa; compare results with a reference method; verify IMU synchronization and signal stability.	ISO 13485 design controls (6); ISO 14971 risk management (7); IEC 60601-1/61010-1 electrical safety (8,9)
II. Clinical Validation (18-24 months) n= 150**	This phase will consist in recruiting patients across disease stages and treatments regiments through the Quebec Parkinson Network*. Compare sensor and reference measurements after L-DOPA administration; quantify agreement, bias, data completeness and between-patient variability. Correlate synchronized L-DOPA levels and IMU data with clinically annotated ON/OFF periods.	Health Canada authorization, if required; SOR/98-282, Part3: Investigational Testing Authorization (ITA) (10) ISO 14155 (11) TCPS 2 and REB approval (12) Informed consent forms (13,14)
Phase III : Usability & Duration: 12-24 months n= 300**	This phase will assess application, removal and operation by patients with motor impairments. Measure task completion, use errors, comfort, adherence, device failures and data completeness. Evaluate clinicians' interpretation time, understanding and use of summaries, alongside symptom burden and treatment satisfaction.	IEC 62366-1 usability (15); IEC 62304 software lifecycle (16,17); ISO 14971 Use-FMEA; continued ethics, privacy and safely monitoring (18,19)

Quebec Parkinson Network (QPN) letter of support is provided on the Appendix 8.11. To be confirmed.*

4.3 Bonus criteria Translation Potential

Following a consultation with the Université de Montréal commercialization specialist ("Bureau recherche-développement valorisation, BRDV") we established a preliminary intellectual property and market-transfer strategy. Commercially valuable details (e.g. algorithm code) remain confidential until an invention disclosure and patentability assessment are completed. If the technology qualifies as a ***University Product***, the University could provide patent counsel and finance a provisional patent application (Appendix 8.11), establishing **a 12-month priority** period to refine the technology and secure funding. Depending on the assessment, the device-integrated algorithm could be patented or maintained confidential know-how. Commercialization could then proceed through an exclusive license to a team-created start-up or an established MedTech company.

Precision medicine is central to this strategy. Integrating continuous L-DOPA sensing with genotyping and motor monitoring could reduce trial-and-error treatments that fail to capture Parkinson's disease (PD) variability. Approximately **15%** of cases are inherited through mutations in genes such **as LRRK2, PARK2, PARK7, PINK1, and SNCA** (20, 21). PINK1 variants are associated with slower progression and strong levodopa (L-DOPA) responses (22), whereas GBA1 variants found in **3% to 20%** of Indian cohorts (23) and prevalent in African and African-admixed populations (24), are associated with faster motor and non-motor symptom progression (25). Three sisters with an SNCA duplication also experienced severe motor fluctuations despite tailored therapies (26).

Selecting genetically and clinically diverse participants could strengthen biosensor validation and support research on disease-modifying therapies (27). Combining biosensor measurements with patient characteristics could generate individualized profiles and support treatment optimization across diverse markets, including admixed populations such as in Mexico (28).

This approach could also reduce PD's economic burden. Genotyping targeted genes before interventions such as deep brain stimulation may improve outcome prediction and reduce unsuccessful expenditures (29). In Canada, long-term care patients face average out-of-pocket expenses of **CAD$65,032** for medication, doctors, and medical devices. Dopa-derivative reimbursements reached **$67.5 million in 2022**, while PD's national economic burden was projected to hit **$3.3 billion in 2024**, rising to **$4.4 billion by 2034** (30).

5 Team and support

5.2 Contributions of the team members

The team's contributions were distributed across three sub-teams: Entrepreneurship, Science, and Technology.

Sub-team	Name	Contribution
Science Sub-team	Axelle Drouard	Co-captain & Science Sub-team leader; Protocols, Enzyme extraction; Sensus team meetings; Funding;
	Sai Ittoo	Protocols; Enzyme extraction; Functionalization; Electrochemical measurements;
	Sophie-Rose Boulanger	Lab work preparation; Protocols; Functionalization; Electrochemical measurements;
	Mathilde Lafontaine	Lab work preparation; Functionalization; Electrochemical measurements; Funding; Project presentation;
Technology Sub-team	Thomas Bourgois	AFE design, conception & fabrication; Potentiostat calibration; Software & Firmware
	Mohamad Kanj	Software & Firmware; Functionalization; Electrochemical measurements; Potentiostat calibration; Project presentation;
	Zackary Tardif	Microneedle optimization; Functionalization; Electrochemical measurements; Potentiostat calibration;
	Xavier Simard	Software & Firmware; Project presentation;
Entrepreneurship Sub-team	Dylan Ngoya	Co-captain & Entrepreneurship Sub-team leader; Stakeholder's interviews; Funding; Grant applications; Ethics Counsel approval process;
	Ninon Croze	Funding; Fundraising; Grant applications; Budget; Social media; Stakeholders' interviews;
	Magalie Durand	Funding; Fundraising; Grant applications; Social media; Project presentation;

5.3 People who have given support

We thank our teaching lab's staff, Medgine and Kevin for the provided equipment and for their knowledgeable inputs.

We also recognised the suggestions of a few of graduate students in Pr. J.-F. Masson's, D. Rochefort's, J. N. Pelletier's and R. Trouillon's lab; Therefore, we thank Caroline, Louis and Samy for their answers to our questions.

5.4 Sponsors and partners

Sponsors and partners	Contribution
Forces AVENIR	Provided financial support for the development of our project.
ÉduCOOP	Provided funding to support our team's activities and project development.
Parkinson Québec	Supported patient recruitment and helped us conduct customer interviews. The organization also assisted us in identifying key stakeholders within the Parkinson's disease community.
Réseau Parkinson Québec	Provided guidance on the design of a future validation study involving people living with Parkinson's disease. The organization also issued a letter of support for future patient testing.
Twist Bioscience	Provided a discount that reduced the cost of the enzyme required for our biosensor development.

6 Final remarks

This edition of SensUs challenged us to work at the intersection of neuroscience, engineering, healthcare and entrepreneurship. The brain remains one of the most complex organs in the human body and much remains to be understood about neurological conditions such as Parkinson's disease. Developing a continuous biosensor for levodopa therefore required us to navigate numerous scientific, technological and human-centred questions from detecting the molecule and designing a comfortable wearable device to identifying the stakeholders whose perspectives should guide its development.

Despite these challenges, our team developed *DopaSync*, a technology that we believe could one day contribute to a more personalized Parkinson's disease management. This experience demonstrated the strength of interdisciplinary collaboration: by bringing together students with different expertise and perspectives, we transformed uncertainty into creativity and ambitious ideas into a concrete concept.

We sincerely thank the graduate students, researchers, mentors, compagnies and organizations whose support made this journey possible. Above all, we are deeply grateful top the people living with Parkinson's disease and the healthcare professionals whose shared their experiences, needs and insights with us. Their contributions continuously reminded us that meaning innovation must begin with and remain centred on the people it aims to serve.

As Canadian actor and Parkinson's advocate Michael J. Fox once said: "To me, hope is informed optimism." It is with this combination of hope, knowledge and determination that we look toward DopaSync's future.

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Figures 3 and 7 have been generated with the Biorender software.

8 Appendix

8.1 Reader instrument

The electrochemical reader used in this project was assembled and adapted from the open-source FreiStat platform developed by IMTEK. The system combines a FreiStat electrochemical front-end PCB with an Adafruit Feather M0 WiFi microcontroller and a Python-based computer interface. The reader was configured for chronoamperometric measurements of low-current electrochemical signals expected from the enzymatic sensor.

8.2 Hardware architecture

The main electronic component of the reader is the AD5941 analog front end, which controls the electrochemical measurement and acquires the current response from the three-electrode system. The reader interfaces with the working, reference and counter electrodes of the cartridge through dedicated connectors. To improve sensitivity for low-current measurements, an external 10 MΩ transimpedance resistance was implemented. The main components used for the assembled system are summarized in Table A1, while Figure 8.1 presents the functional architecture of the reader.

Component	Function	Example part
Analog front end	Electrochemical measurement control and signal acquisition	AD5941BCPZ-RL7
Microcontroller	Device control and communication	Adafruit Feather M0 WiFi
Low-bias op-amp	Current measurement support	LMP7721MA/NOPB
External RTIA	Low-current transimpedance measurement	10 MΩ resistor
RTIA compensation capacitor	Stabilization of external transimpedance path	220 pF capacitor
Electrode connector	Connection to WE/RE/CE	2×8 headers

Table 1: Main components of the electrochemical reader

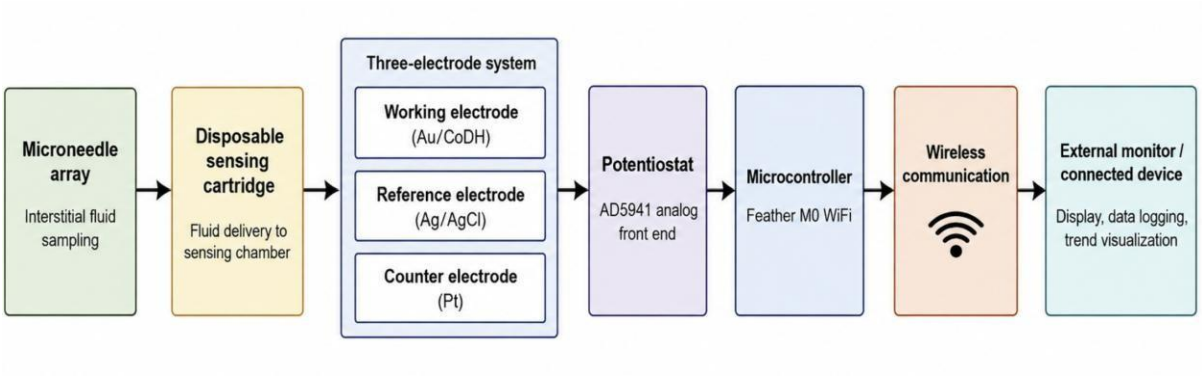


Figure 8.1 : functionnal architecture of the electrochemical reader

8.3 Software and graphical user interface

The embedded firmware controls the chronoamperometric sequence and manages communication between the analog front end and the computer. A Python graphical user interface was used to configure the measurement parameters, start the experiment, visualize the current response in real time and export the recorded data.

To simplify operation, a new GUI inspired by the original FreiStat software was developed. This interface provides a more intuitive visual design with possible update to be user friendly.

8.4 User interaction

The cartridge is connected to the reader through the working, reference and counter-electrode terminals. After introducing the sample into the cartridge, the user starts the measurement from the graphical interface. The current response is then displayed in real time and can be exported for further analysis. The final concentration calculation will be based on the calibrated electrochemical response.

8.5 Dimensions and current prototype

The current reader PCB measures approximately 54 × 23 × 25 mm. Its thickness is mainly determined by the development board and pin-header assembly. In a future dedicated version, the analog front end, microcontroller, communication and power-management elements could be integrated on a single compact PCB to reduce the overall size and improve suitability for wearable use. Figure 8.2 shows a photograph of the assembled bench prototype reader with dimensions annotation.

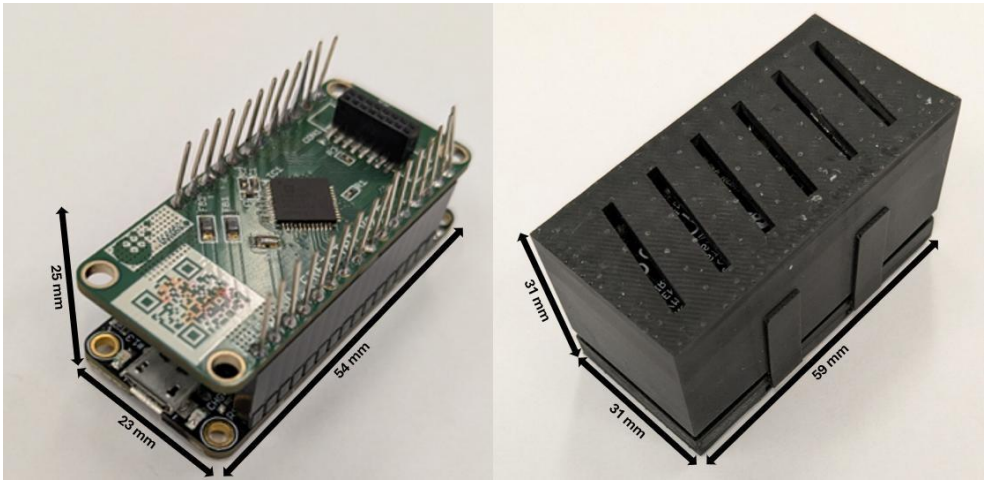


Figure 8.2 : Dimensions of our sensor with and without the casing

8.6 Bill of material

Category	Reference / component	Function	Package or specification
Analog electronics	AD5941BCPZ-RL7	Analog front end for potentiostatic control and electrochemical current acquisition	QFN-48
Analog electronics	LMP7721MA/NOPB	Ultra-low-input-bias operational amplifier	SOIC-8
Microcontroller	Adafruit Feather M0 WiFi	Firmware execution, data acquisition and communication with the computer	Feather development board
Connector	1.27 mm-pitch SMD header, 2 × 8, female	Connection to the electrode interface, CON1	SMD 2 × 8
Connector	1.27 mm-pitch SMD header, 2 × 8, male	Connection to the electrode interface, CON1	SMD 2 × 8
Connector	Feather stacking headers	Connection between the FreiStat PCB and the microcontroller board	12-pin and 16-pin female headers
Resistor	R1, 200 Ω	PCB resistor	0402, 0.1%
Resistor	R2, 10 MΩ	External transimpedance resistor for nanoampere-range measurements	0402, 1%
Resistor	R3, 2 kΩ	PCB resistor	0402, 0.1%
Resistor	R4–R7, 100 Ω	PCB resistors	0402, 0.1%
Capacitor	C1, 220 pF	Compensation capacitor for the external transimpedance path	0402, 5%
Capacitor	C2, 220 nF	Filtering and decoupling	0402, 10%

Capacitor	C3, C4, C6–C9, 470 nF	Filtering and decoupling	0402, 10%
Capacitor	C5, 4.7 µF	Filtering and decoupling	0402, 20%
Capacitor	C10, C11, C13 and C15, 10 µF	Power-supply filtering and decoupling	0402, 20%
Capacitor	C12, C14 and C16, 100 nF	Local decoupling	0402, 10%
Capacitor	C17, 1 µF	Filtering and decoupling	0402, 10%
Ferrite bead	BLM21PG121SN1D	Power-supply noise filtering	Surface-mounted ferrite bead
Electrode	Gold working electrode	CoDH immobilization and measurement of the current generated by L-DOPA oxidation	Final geometry to be confirmed
Electrode	Platinum counter electrode	Completes the electrochemical circuit and carries the balancing current	Final geometry to be confirmed
Electrode	Ag/AgCl reference electrode	Provides a stable reference potential for control of the working-electrode potential	Final format to be confirmed

Table 2 : Bill of materials for the electrochemical reader

8.7 Validation of the electrochemical reader

Electrical bench validation

Before testing the reader with functionalized electrodes, its electrical performance was evaluated using dummy cells with known resistive and capacitive properties. This approach isolated the potentiostat hardware, firmware and signal-processing chain from electrode and solution variability.

After assembly and soldering of the Freistat-based reader, it was connected to either a resistive dummy cell or a series RC dummy cell using breadboard. The reference and counter-electrode terminals were short circuited. The dummy cell was placed between these terminals and the working-electrode input. The resistive cell contained a nominal 100 kΩ resistor, independently measured as 99.6±1.0 kΩ. The RC cell contained the same resistance in series with a nominal 0.68 µF capacitor, giving a theoretical time constant of :

Chronoamperometric measurements were performed with a sampling interval of 10 ms. An internal 20 kΩ transimpedance resistance was used for microampere-range validation, while the low-current configuration used an external 10 MΩ transimpedance resistance

with a 220 pF parallel capacitor. The 50/60 Hz notch rejection filter was enabled for nanoampere measurements.

8.8 Resistive validation:

The internal transimpedance configuration was first tested at currents close to ±1µA. Three repeated measurements produced coefficients of variation of approximately 0.05% for positive currents and 0.07% for negative currents. A potential sequence from −100 to +100 mV produced a linear current response with R^2=0.999993.

The external 10 MΩ configuration was then evaluated over the low-current range relevant to the expected enzymatic signal. Potential steps generated currents from approximately −43.4 to +38.2 nA. The current–potential response was highly linear, with R^2=0.9999996, as shown in Figure A.1. The apparent resistance calculated from the regression slope was 99.15 kΩ, compared with the independently measured value of 99.6±1.0 kΩ. The nominal difference of 0.45% was therefore smaller than the uncertainty of the reference measurement.

The positive and negative regression slopes differed by approximately 0.021%, and the maximum hysteresis between increasing and decreasing potential steps was 0.047 nA. Activating the mains-frequency filter reduced the measured noise by approximately 75%. The noise in the final external configuration was approximately 0.7–0.9 nA RMS.

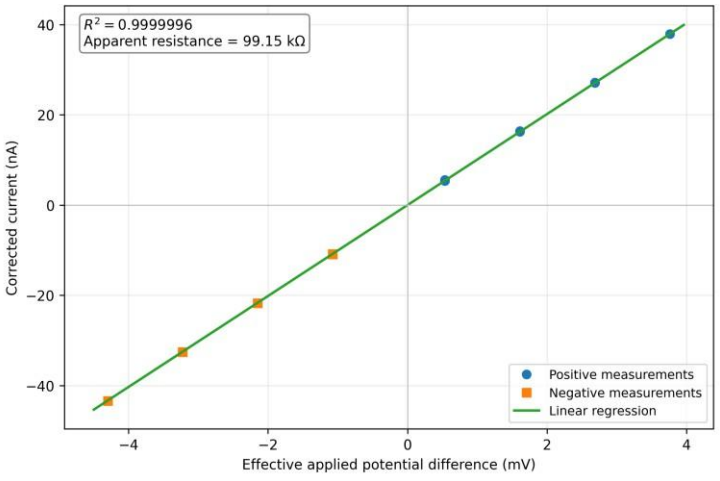


Figure 8.3 : External-mode linearity. Steady-state current measured with the 99.6 kΩ resistive dummy cell using the external 10 MΩ transimpedance resistor.

8.9 Dynamic RC validation:

The RC dummy cell was used to determine whether the reader could reproduce time-dependent signals of the order of nanoamperes. In the external 10 MΩ configuration, potential steps of approximately ±2 mV generated transient currents of approximately 12–18 nA.

Exponential fitting of four successive charge and discharge transients produced a mean time constant of:

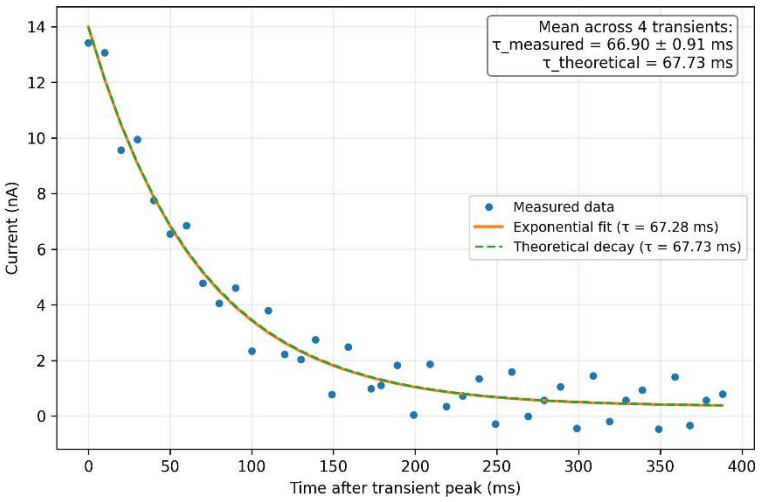


Figure 8.4 : RC transient response. Representative current transient measured with the 99.6 kΩ–0.68 µF series dummy cell. The measured time constant was 66.90±0.91 ms, close to the theoretical value of 67.73 ms.

This differed by approximately 1.2% from the theoretical value of 67.73 ms. The corresponding apparent capacitance was 0.687±0.008 µF, compared with the nominal value of 0.68 µF. The stabilized noise during this experiment was approximately 0.72 nA RMS. A representative transient and exponential fit are presented in Figure A.2. Similar agreement was obtained using the internal transimpedance configuration, for which the measured time constant was 68.11±0.51 ms.

Conclusion: The dummy-cell experiments validated the potential-generation, current-conversion, timing, polarity and data-acquisition functions of the reader under controlled electrical conditions. They also demonstrated that the external 10 MΩ configuration can acquire stable and time-varying signals in the nanoampere range expected for the biosensor. These experiments do not determine the analytical detection limit of the complete L-DOPA sensor, which will additionally depend on the functionalized electrodes, sample matrix and biological variability.

8.10 Wet electrochemical validation

To know more about the potentiostat accuracy in a real solution, where mass transport and faradic processes take place. To test that, different solutions with varying concentration of ferricyanide in 1 M KCl were used to determine whether the potentiostat was comparable to a commercial one, which was the BioLogic SP-150. Chronoamperometric measurements were taken with the same three electrodes, which consisted of a glassy carbon working electrode, a platine counter-electrode and an Ag/AgCl reference electrode. A potential of 100 mV was applied from 5 to 10s, with no potential from 0 to 5s and 10 to 15s. A sampling rate of 10 ms was used and 3 cycles were taken. The internal 20 kΩ transimpedance resistance was used. When changing from one potentiostat to the other, the electrodes weren't placed in the same position, which brought some uncertainty in the measurements. However, this didn't seem to affect the results obtained as much, as can be seen in the figure A.3 below.

The measured concentrations went from 5 to 100 µM. The current near the end of the measurement was plotted against the concentration to see a linear trend. To ensure a more stable current value for each concentration, the current was averaged between 9.9 and 10s.

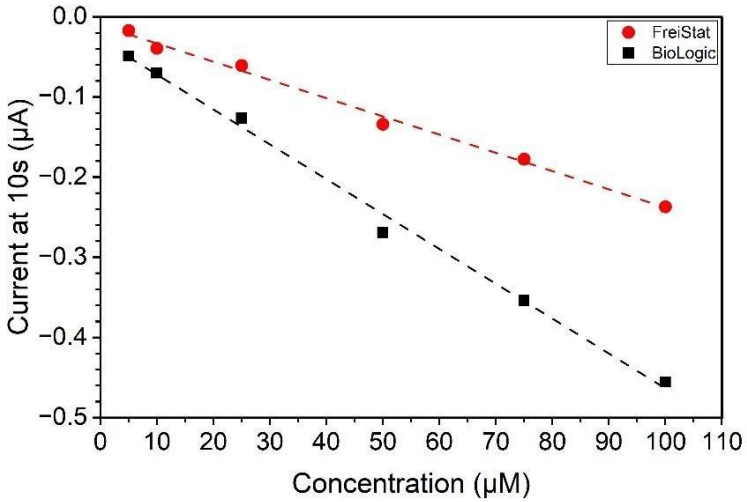


Figure 8.5 : Comparaison of our potentiostat and a commercial potentiostat. Linear trends show a correlation between the concentration of $KFe(CN)_6$ and current. (red: y = -0.0023x – 0.0105, R^2 = 0.9943; black: y = -0.0043x -0.0287, R^2 = 0.9947)

The slope obtained can be understood through Cottrell equation as a constant resulting from the characteristics of $KFe(CN)_6$ and our working electrode, so both results should've shown the same slope. However, as can be seen, our slope is two times less greater than the one obtained from the commercial potentiostat. Since all the data seem to have been affected, it means that our potentiostat acts as intended, but that the slope is divided by a constant of ≈ 2. Therefore, our device is able to determine a trend between current and concentration through internal calibration. If we wanted to determine any experimental parameters, such as the area of the electrode, that constant factor should be taken into account. Further testing should be done to determine if the deviation is replicable or if it changes from system to system or from time to time.

Chronoamperometric measurements

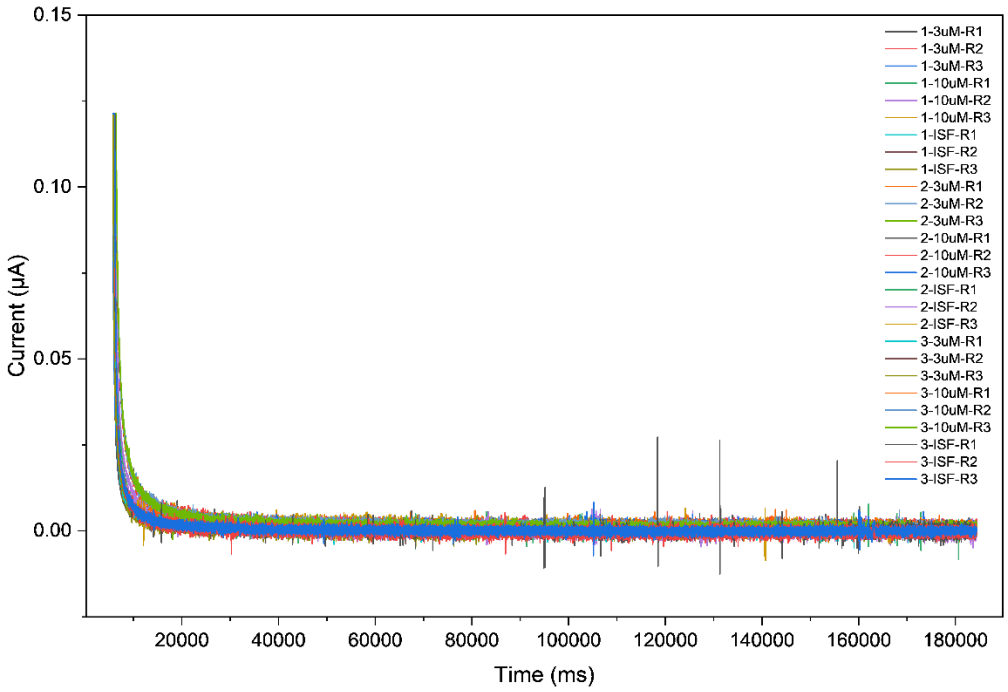


Figure 8.6 : Raw data for average current measured by chronoamperometry of L-Dopa in ISF solutions

Silicone channel

Another electrode configuration was evaluated, one in which a single needle would be required. In this needle would be an oxidized, chloride covered silver wire acting as pseudo-reference electrode on which a polyimide film would be partially applied. This film would then be coated with gold using physical vapor deposition, providing surface to perform functionalization (type 2). Unfortunately, due to the lack of availability and training, this configuration has been dropped.

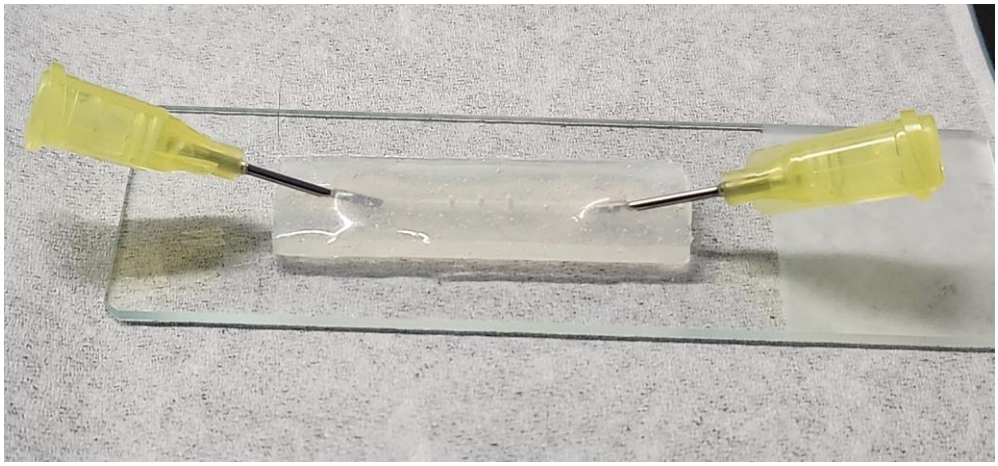


Figure 8.7 : Silicone channel (older version)

8.11 Translation potential section

8.11a Research protocol approval by the Université de Montréal's Research Ethics Committee in Health and Sciences (CERSES) (*French only*).

Comité d'éthique de la recherche en sciences et en santé (CERSES)

Bureau de la conduite responsable en recherche

Université de Montréal

01 juillet 2026

Jean-François Masson, professeur titulaire
Département de chimie
Faculté des arts et des sciences
Université de Montréal

Dylan Ngoya, étudiant

OBJET :	Projet # 2026-8298 - Approbation éthique finale Titre : Étude exploratoire mixte des besoins et perceptions de patients atteints de la maladie de Parkinson en lien avec le développement de technologies pour le suivi thérapeutique. Financement : Non financé

Bonjour,

Le Comité d'éthique de la recherche en sciences et en santé (CERSES) de l'Université de Montréal a évalué votre projet de recherche jugé à risque minimal et une approbation conditionnelle vous a été émise en date du 22 juin 2026.

Nous accusons réception des précisions et corrections demandées via le formulaire de conditions F20 ainsi que des documents en vue de l'approbation finale du projet mentionné en rubrique. Suite à la révision de ces documents, le tout ayant été jugé satisfaisant, j'ai le plaisir de vous informer que votre projet de recherche a été approuvé à l'unanimité par le CERSES.

Les documents que le CERSES a approuvés et que vous pouvez utiliser pour la réalisation de votre projet sont les suivants :

- Protocole de recherche - PJ (Protocole_2026_05_01.pdf)
- Collecte - PJ (Questionnaire_BiosensUM du 01-06-2020_version1.docx)
- Collecte - PJ (Guide_entrevue_BiosensUM_01-06-2026_version1.docx)
- Recrutement - PJ (Affiche_BiosensUM_2026_06_22.png)
- Consentement - PJ (FIC_majeur apte_entrevue_2026-06-23.docx)
- Consentement - PJ (Révisé_FIC_majeur apte_questionnaire_2026-07-01.docx)

Les documents que le CERSES a approuvés et que vous pouvez utiliser pour la réalisation de votre projet sont disponibles dans la section Fichiers avec couleur, située sous l'onglet "Fichiers" de votre projet.

NAGANO Approbation finale par le comité d'éthique 1 / 2

Cette approbation éthique est valide pour un an, à compter du 01 juillet 2026 jusqu'au 01 juillet 2027. Il est de votre responsabilité de compléter le formulaire de renouvellement (formulaire F9) que nous vous ferons parvenir annuellement via Nagano 1 mois avant l'échéance de votre approbation, à défaut de quoi l'approbation éthique délivrée par le CERSES sera suspendue.

Dans le cadre du suivi éthique continu, le Comité vous demande de vous conformer aux exigences suivantes en utilisant les formulaires Nagano prévus à cet effet :

- Soumettre, pour approbation préalable, toute demande de **modification** au projet de recherche ou à tout autre document approuvé par le Comité pour la réalisation du projet (formulaire F1).
- Soumettre, dès que cela est porté à votre connaissance, toutes **informations supplémentaires, nouveau renseignement et/ou correspondances diverses** (formulaire F2).
- Soumettre, dès que cela est porté à votre connaissance, tout **incident ou accident** lié à la réalisation du projet de recherche (formulaire F5).
- Soumettre, dès que cela est porté à votre connaissance, l'**interruption prématurée** du projet de recherche, qu'elle soit temporaire ou permanente (formulaire F6).
- Soumettre, dès que cela est porté à votre connaissance, toute **déviation** au projet de recherche susceptible de remettre en cause le caractère éthique du projet (formulaire F8).
- Soumettre une demande de **renouvellement** un mois avant l'échéance de la date d'approbation afin de renouveler l'approbation éthique (formulaire F9).
- Soumettre le rapport de la **fin du projet de recherche** (formulaire F10).

Nous vous rappelons que la présente décision vaut pour une année et peut être suspendue ou révoquée en cas de non-respect de ces exigences.

Le CERSES de l'Université de Montréal est désigné par le ministre de la Santé et des Services Sociaux aux fins de l'application de l'article 21 du Code civil du Québec. Il exerce ses activités en conformité avec la *Politique sur la recherche avec des êtres humains* (60.1) de l'Université de Montréal ainsi que l'*Énoncé de politique des trois conseils* (EPTC). Il suit également les normes et règlements applicables au Québec et au Canada.

Cordialement,

Pour la présidente du CERSES,

Marie-Alexia Masella
Conseillère en éthique de la recherche
Bureau de la conduite responsable en recherche
Université de Montréal
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cerses@umontreal.ca

Envoyé par :

Marie-Alexia Masella

Signé le 2026-07-01 à 03:03

8.11b Research protocol

BiosensUM – 2026

1. Project Title

Exploratory mixed-methods study of the needs and perceptions of patients with Parkinson's disease in relation to the development of technologies for therapeutic monitoring.

2. Context and Problem Statement

Parkinson's disease is a major health issue, being the second most common neurodegenerative disease and its prevalence is increasing. The primary treatment is based on L-DOPA, the response to which varies considerably from one patient to another, thus complicating dose adjustments. Currently, treatment monitoring relies mainly on symptom assessment and clinical consultations, which can limit the accuracy of care, particularly in a context of increased pressure on health systems. In this context, it seems relevant to better understand patients' needs and perceptions regarding the monitoring of their treatment. This project is part of this approach and aims to collect, through interviews and/or questionnaires, information on the experience of patients with Parkinson's disease related to the management of their treatment. The data collected will help identify the challenges encountered and guide the future development of monitoring tools better suited to the realities of patients.

3. Goals

The overall project of the BiosensUM team aims to contribute to the development of tools enabling more personalized monitoring of Parkinson's disease treatment. Within the specific context of this request to the ethics committee, the main objective is to collect qualitative and quantitative data from patients with Parkinson's disease in order to better understand their needs, experiences and perceptions in relation to the monitoring of their treatment, particularly with a key drug, namely L-DOPA.

More specifically, this study aims to:

- Document current practices for monitoring treatment in patients;
- Identify the perceived challenges and limitations in treatment management;
- Explore the acceptability and expectations of potential personalized tracking tools;

The results obtained will help guide the future design of solutions adapted to the realities and needs of patients.

4. Methodology

a. Research quote

This study adopts a mixed-methods sequential exploratory design, combining qualitative and quantitative approaches. This methodology allows for an in-depth exploration of patients' experiences, followed by the validation and quantification of themes in a larger sample.

b. Participants

Participants will be adults with Parkinson's disease, recruited mainly in Quebec through community organizations such as Parkinson Québec (and possibly Parkinson Canada).

Inclusion criteria

- Confirmed diagnosis of Parkinson's disease by a healthcare professional
- Current or recent L-DOPA treatment
- Age ≥ 18 years
- Ability to provide free and informed consent
- Ability to participate in an interview or complete a questionnaire. Expected characteristics.
- Approximate age: 50 to 80 years old
- Gender diversity (men, women and other identities, if applicable)
- Participants followed in a clinical setting or at home. Sample size.
- Qualitative phase: approximately 10 to 15 participants
- Quantitative phase: approximately 50 to 150 participantsThe total number of participants remains flexible due to the exploratory nature of the study and the method of disseminating the questionnaire.

c. Recruitment

Participants will be recruited through communications disseminated by Parkinson Québec (e.g., emails, newsletters, community networks). Participation will be voluntary.

d. Data collection

Data collection will take place in three (3) phases:

Phase 1: Exploratory qualitative interviews

Semi-structured individual interviews will be conducted to explore:

- the patient's experience with the disease;
- their management of L-DOPA treatment;
- their daily challenges and monitoring needs;

The interviews will last approximately 30 to 60 minutes and will be conducted in person or remotely, depending on the preferences and availability of the participants.

Phase 2: Quantitative Questionnaire

An online questionnaire will be developed based on the results of phase 1. It will be distributed to a larger number of participants via Parkinson Québec's communication channels.

This questionnaire will aim to:

- validate the identified themes;
- to measure their importance;
- Assess their variability within the population;

Phase 3: Targeted qualitative interviews

A second series of semi-structured interviews will be conducted with a subgroup of participants selected based on their answers to the questionnaire. This phase will allow us to delve deeper into certain specific issues, particularly for patients facing particular challenges in managing their treatment. The interviews will also last between 30 and 60 minutes.

Collection managers

Data collection will be carried out by student members of the research team (BiosensUM), trained in interview methods and ethical principles.

Data analysis

The qualitative data will be analyzed using thematic selection to identify recurring patterns and issues. Quantitative data will be analyzed using descriptive statistics, in order to quantify and compare the identified themes.

Study duration

- Planned start of the collection: around July 1, 2026

- Expected completion date: August 22, 2026
- Total duration: approximately 4 months

Partners and data access

Community partners (e.g., Parkinson Québec, possibly Parkinson Canada) will contribute to recruitment and distribution of the questionnaire. They will not have access to the raw data. Only aggregated results will be shared.

5. Risks and mitigation measures

Within the framework of this project, the anticipated risks are minimal and primarily psychological and social in nature.

- Psychological risks
    - Participation in interviews or questionnaires about the experience of Parkinson's disease and treatment management may cause mild emotional discomfort, particularly when discussing personal difficulties or challenges related to the disease.
- Social risks (confidentiality)
    - There is a limited risk of loss of confidentiality that could lead to feelings of exposure or discomfort if personal information were disclosed.

No significant physical, economic, legal or other risks are anticipated in this study. Several prevention and mitigation measures have been put in place: Psychological protection

- The questions will be formulated respectfully, non-intrusively, and adapted to the participants' context;
- Participants may refuse to answer any question without justification;
- Participants may discontinue their participation at any time, without consequence;
- A supportive and collaborative atmosphere will be fostered during the interviews; confidentiality will be protected (social risks).
- The data will be anonymized either at the time of collection or during processing;
- No information that could directly identify a participant will be disclosed;

- The results will be presented in aggregate form;

The data will be stored securely and accessible only to the research team;

6. Potential benefits for participants

This research does not provide direct clinical benefits for the participants.

However, their participation could offer them the opportunity to reflect on their personal experience in relation to managing their treatment, which may be perceived as positive by some.

In addition, participants may feel a sense of contributing to the advancement of knowledge, particularly by participating in a project aimed at better understanding the needs of people with Parkinson's disease and guiding the future development of more suitable monitoring tools.

7. Privacy and data management

a. Nature of the data

As part of the project, two types of data will be collected:

- The data from the interviews will not be anonymous at the time of collection, but will be de-identified (coded) before analysis.
- The data from the online questionnaire will be collected anonymously without the possibility of directly or indirectly identifying the participants.

b. Data depersonalization

For interviews:

- Each participant will be assigned an alphanumeric code;
- Any identifying information (name, location, specific details) will be removed or altered during transcription;

For the questionnaire:

- No personally identifiable information will be collected;

c. Right of withdrawal

- For the interviews, participants will be able to withdraw until the time of data anonymization;
- For the anonymous questionnaire, no withdrawal will be possible after submission, since the data cannot be traced;

d. Data storage and security

- The data will be stored on secure computers (password protected access);
- The files will be stored in digital formats (e.g., Word, Excel);

Only authorized members of the BiosensUM team will have access to the results.

e. Shelf life

The data will be kept until the end of the project (August 2026), then can be deleted or securely archived in accordance with institutional requirements.

f. Data controllers and access

- Data collection and management will be handled by student members of the BiosensUM team;
- No external partner will have access to the raw data;
- Only aggregated results can be shared;

g. Data sharing

No deposit in a public database is planned.

8. Consent

Verbal consent will be obtained for interviews in this study, and checkbox consent will be used for the questionnaire.

9. Project timeline

Recruitment: May-June

- Collection: June-July
- Analysis: July-August

8.11c Questionnaire and Statistical analysis (*French only*)

Quantitative Questionnaire – L-DOPA Monitoring

(BiosensUM Project – Portable biosensor for monitoring L-DOPA in patients with Parkinson's disease)

Section 1 – Interest in biosensors

1) How interested would you be in a device that can measure your L-DOPA concentrations in real time?
   - ☐ Not interested at all
   - ☐ Not very interested
   - ☐ Moderately interested
   - ☐ Interested
   - ☐ Very interested
   - ☐ I prefer not to answer

2) Which device format did you prefer?
   - ☐ Skin patch (e.g., to be applied to the arm)
   - ☐ Smartwatch
   - ☐ Implantable device (e.g., in the arm)
   - ☐ External portable device
   - ☐ No preference
   - ☐ I prefer not to answer

3) Would you be comfortable using a mobile application linked to the biosensor?
   - ☐ Not at all comfortable
   - ☐ Uncomfortable
   - ☐ Moderately comfortable
   - ☐ At ease
   - ☐ Very comfortable
   - ☐ I prefer not to answer

4) How often would you be willing to use such a device?
   - ☐ Once a week
   - ☐ Once a day
   - ☐ Several times a day
   - ☐ Continuously
   - ☐ I would not wish to use it
   - ☐ I prefer not to answer

5) In your opinion, would a portable biosensor improve your quality of life?
   - ☐ No way
   - ☐ Little
   - ☐ Moderately
   - ☐ A lot
   - ☐ Enormously

- I prefer not to answer

Section 2 - Dosage and Symptom Management

6) How many doses of L-DOPA do you take per day?
   - 1
   - 2
   - 3
   - 4
   - 5 or more
   - I prefer not to answer

7) How long do the effects of a dose typically last?
   - Less than 1 hour
   - 1-2 hours
   - 2-4 hours
   - 4-6 hours
   - More than 6 hours
   - I prefer not to answer

8) How often do you experience fluctuations in the effects of the treatment throughout the day?
   - Never
   - Rarely
   - Sometimes
   - Often
   - Very often
   - I prefer not to answer

9) Have you ever experienced dyskinesia or involuntary movements related to the treatment?
   - Never
   - Rarely
   - Sometimes
   - Often
   - Very often
   - I prefer not to answer

10) Which method of monitoring your L-DOPA concentration did you prefer?
   - Follow-up only at the end of dose efficacy
   - Monitoring at certain key times of the day
   - Continuous monitoring throughout the day
   - I don't know
   - I prefer not to answer

11) Have you ever had to change your medication schedule because of an incorrect dosage adjustment?
   - Never
   - Rarely
   - Sometimes
   - Often

- Very often
- I prefer not to answer

12) When the intervals between doses are properly adjusted, do you observe a reduction in side effects?
    - No way
    - Little
    - Moderately
    - A lot
    - Enormously
    - I prefer not to answer

Section 3 – Hospital Experience

13) How would you rate the waiting time for your follow-ups or analyses related to the treatment?
    - Very short
    - Short
    - Moderate
    - Long
    - Very long
    - I prefer not to answer

14) Do you think a wearable device could reduce your visits or the time spent in the hospital?
    - No way
    - Little
    - Moderately
    - A lot
    - Enormously
    - I prefer not to answer

15) Have you ever observed delays in care related to a lack of hospital staff?
    - Never
    - Rarely
    - Sometimes
    - Often
    - Very often
    - I prefer not to answer

Section 4 – Demographic Data

16) How long ago did you receive your Parkinson's diagnosis?
    - Less than a year
    - 1-3 years
    - 3-5 years
    - 5-10 years old
    - More than 10 years
    - I prefer not to answer

17) What is your age group?
- Under 40 years old
- 40-50 years old
- 51-60 years old
- 61-70 years old
- 71 years and older
- I prefer not to answer

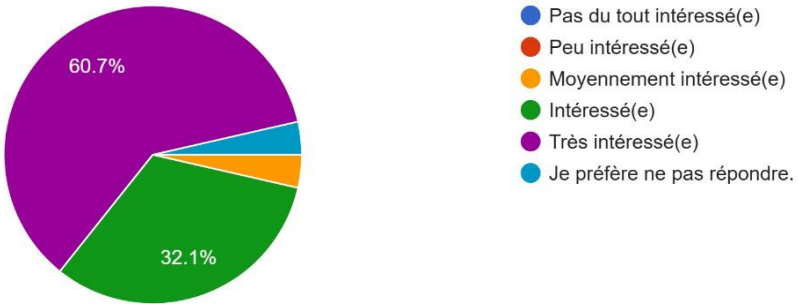
18) How often do you use a smartphone?
- Never
- Rarely
- Sometimes
- Often
- Every day
- I prefer not to answer

19) What is your gender?
- Women
- Man
- Non-binary
- I prefer not to answer
- Other : _____

20) Do you identify with one of the following ethnocultural groups?
- Caucasian
- Black
- Asian
- Arab/Middle East
- Latin American
- First Nations
- Mixed/multiracial
- I prefer not to answer
- Other : _____

À quel point seriez-vous intéressé(e) par un appareil permettant de mesurer vos concentrations de L-DOPA en temps réel ?

28 responses



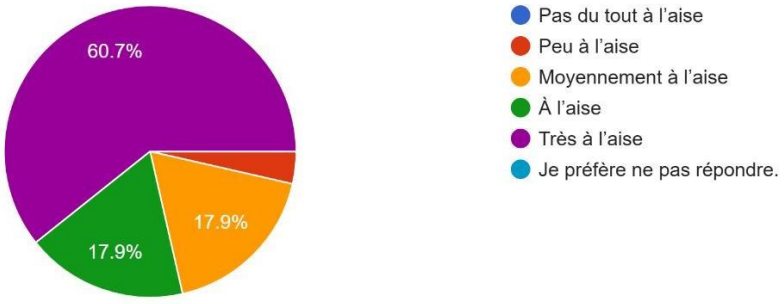
Quel format de dispositif préfériez-vous ?

28 responses



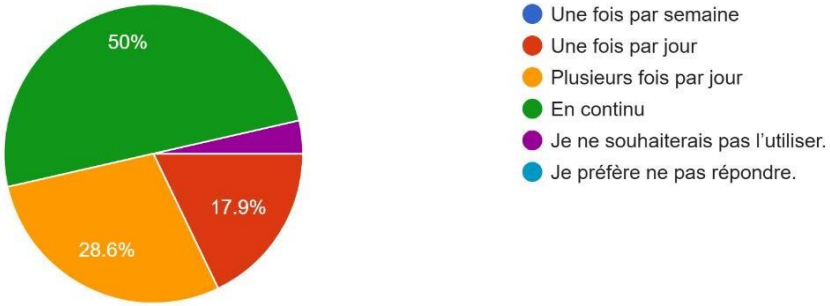
Seriez-vous à l'aise d'utiliser une application mobile liée au biosenseur ?

28 responses



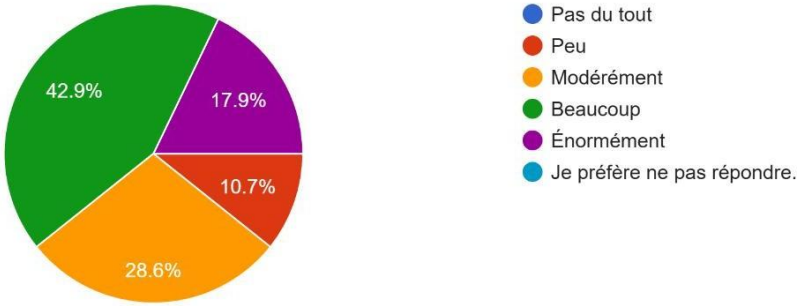
À quelle fréquence seriez-vous prêt(e) à utiliser un tel dispositif ?

28 responses



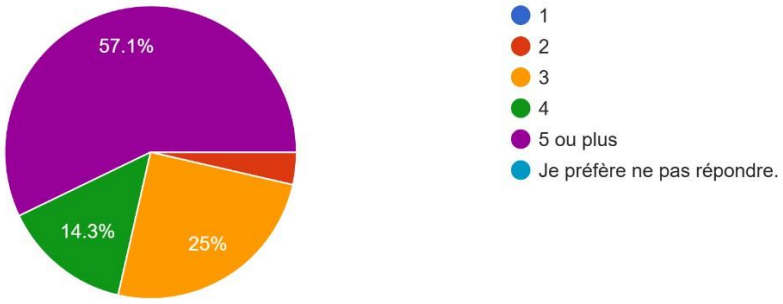
Selon vous, un biosenseur portable améliorerait-il votre qualité de vie ?

28 responses



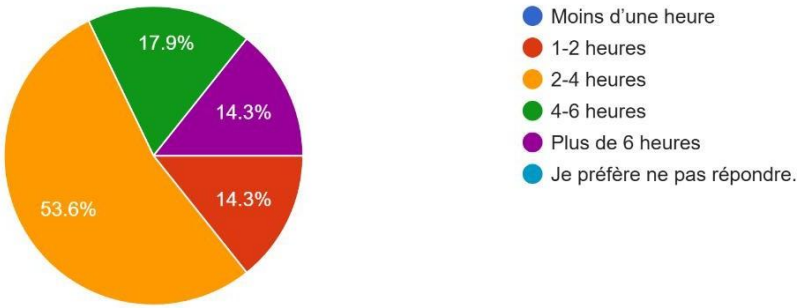
Combien de doses de L-DOPA prenez-vous par jour ?

28 responses



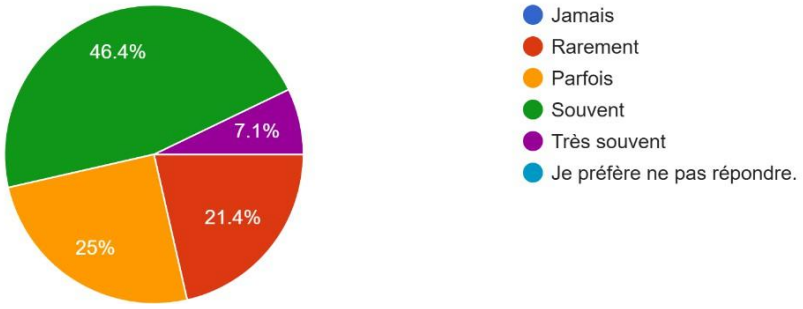
Pendant combien de temps les effets d'une dose sont-ils généralement efficaces ?

28 responses



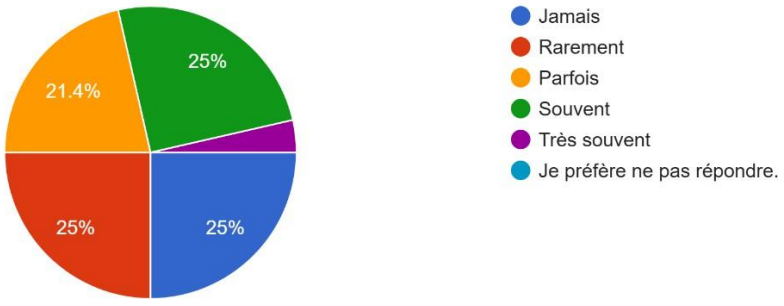
À quelle fréquence ressentez-vous des fluctuations des effets du traitement dans la journée ?

28 responses



Avez-vous déjà eu des dyskinésies ou mouvement involontaires liés au traitement ?

28 responses



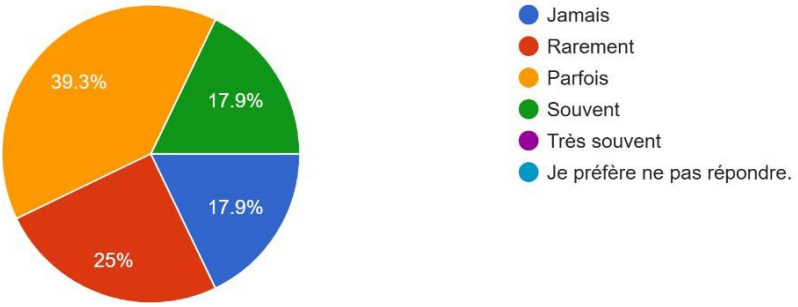
Quel mode de suivi de votre concentration de L-DOPA préfériez-vous ?

28 responses



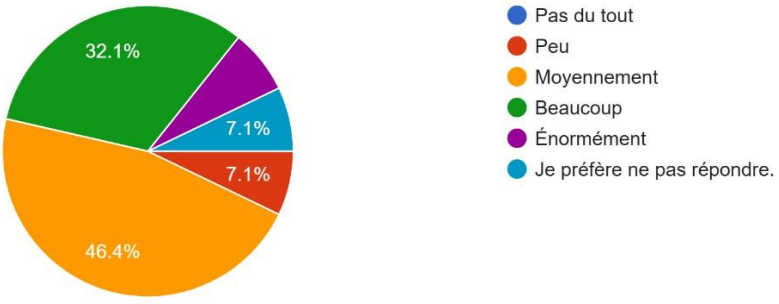
Avez-vous déjà dû modifier vos horaires de prise de médicament à cause d'un mauvais ajustement des doses ?

28 responses



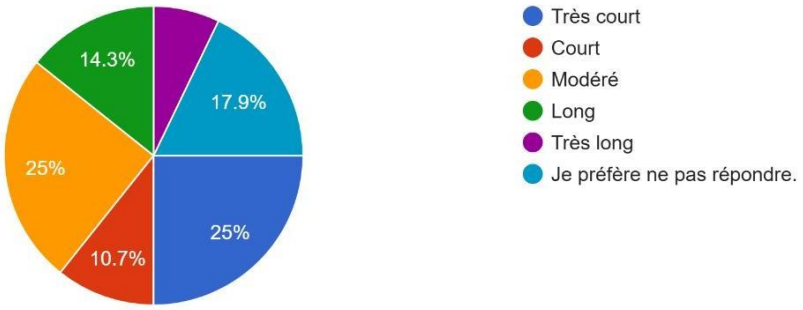
Lorsque les intervalles entre les doses sont bien ajustés, observez-vous une réduction des effets secondaires ?

28 responses



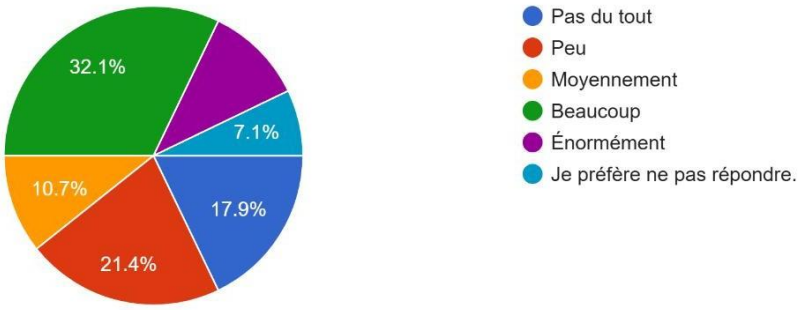
Comment évalueriez-vous le temps d'attente pour vos suivis ou analyses liés au traitement ?

28 responses



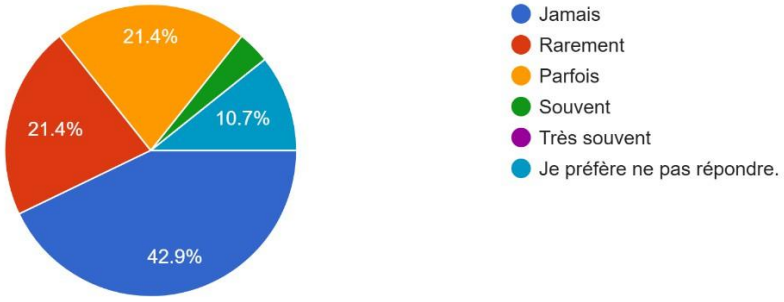
Pensez-vous qu'un dispositif portable pourrait réduire vos visites ou le temps passé à l'hôpital ?

28 responses



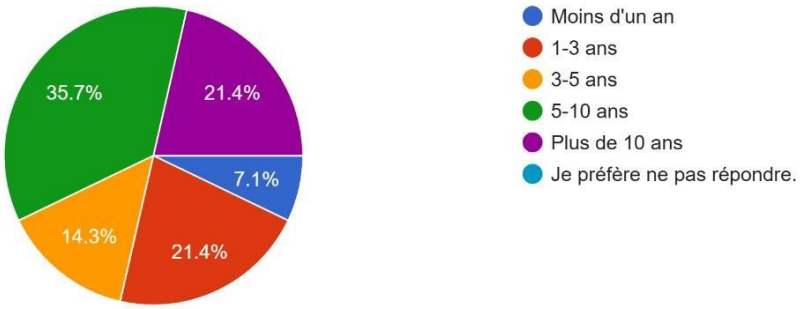
Avez-vous déjà observé des retards de soins liés à un manque de personnel hospitalier ?

28 responses



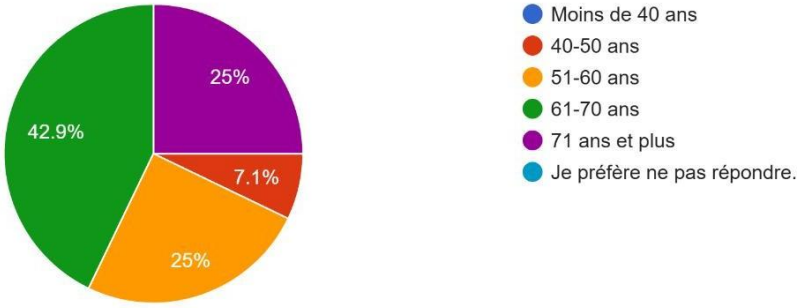
Depuis combien de temps avez-vous reçu votre diagnostic de Parkinson ?

28 responses



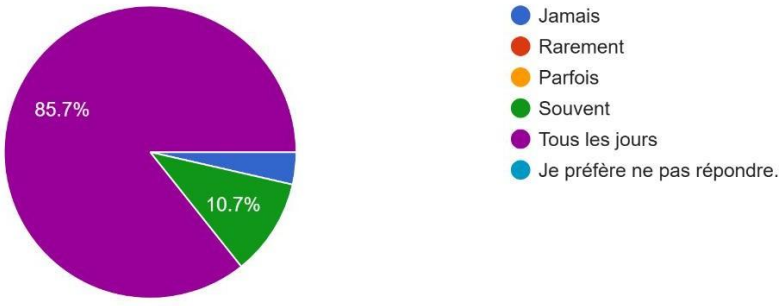
Quel est votre groupe d'âge ?

28 responses



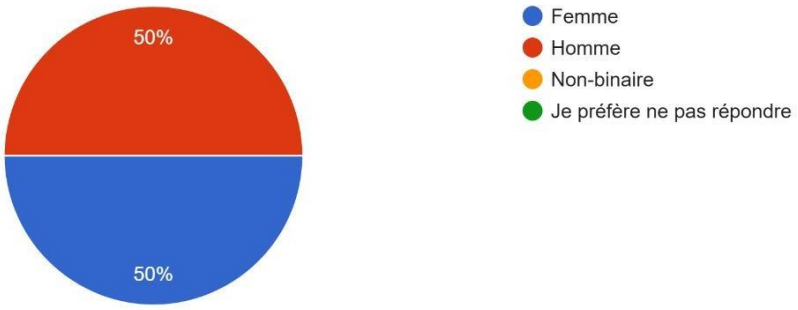
À quelle fréquence utilisez-vous un téléphone intelligent ?

28 responses



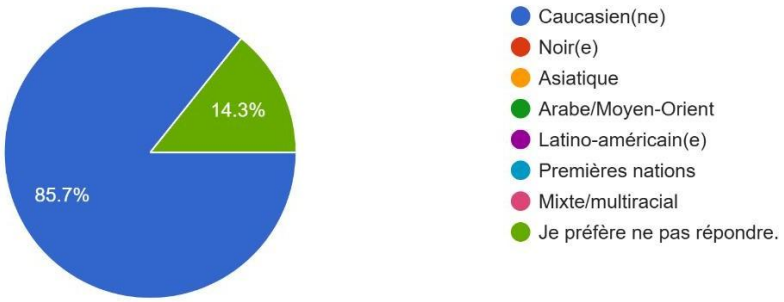
Quel est votre genre ?

28 responses



Vous identifiez-vous à l'un des groupes ethnoculturels suivants ?

28 responses



8.11d Guide for semi-structured interviews

Guide to a semi-structured interview

BiosensUM Project – Development of a portable biosensor for monitoring L-DOPA in patients with Parkinson's disease

1- Introduction

Hello Mr. X or Mrs. X,

Thank you for participating in this interview as part of the BiosensUM project. Our team is developing a biosensor, a device designed to measure L-DOPA concentrations in order to better understand variations in treatment throughout the day.

The aim of this interview is to better understand:

- Your experience with the treatment;
- Challenges related to dose monitoring;
- Opinion regarding a potential portable tracking device

There are no right or wrong answers. You are free to not answer certain questions or to end the interview at any time.

The approximate duration is 30 to 60 minutes.

2- General Information

a) How long have you been living with Parkinson's disease?

b) Can you briefly describe your overall experience with your current treatment?

Possible follow-up actions:

- Daily difficulties?
- What are the most disturbing symptoms?
- Variability of symptoms?

3- Experience with L-DOPA

a) How would you describe the effects of L-DOPA on your symptoms?

Possible follow-up actions:

- Tremors?
- Fluidity of movement
- Speed of movements
- Rigidity

b) How long do you usually feel the effects of a dose of L-DOPA?

Possible follow-up actions:

- Are the effects constant?
- Do the effects diminish rapidly?
- Are there times of day when the medication is less effective?

c) How many doses of L-DOPA do you usually take per day?

Possible follow-up actions:

- Are the hours fixed?
- Do the doses change from day to day?

d) Have you ever noticed significant fluctuations in your symptoms throughout the day despite taking the medication?

Possible follow-up actions:

- Nausea
- Fatigue
- Loss of effectiveness before the next dose
- Dyskinesias

e) Have you ever had to adjust:

- When to administer the doses?
- Interval between doses?
- Concentration of doses?

Possible follow-up actions:

- For what ?
- Side effects?
- Lack of efficiency?
- Difficulty knowing when to take another dose?

4- Perception of a portable biosensor

f) What do you think of the idea of a biosensor that can monitor L-DOPA concentrations in real time?

Possible follow-up actions:

- Perceived advantages?
- Concerns?
- Is it useful in everyday life?

g) In what format would such a device seem most comfortable or acceptable to you?

Possible follow-up actions:

- Skin patch;
- Smart watch;
- Small portable device;
- Implantable;
- Other ?

h) Would a portable version linked to a mobile application seem feasible to you?

Possible follow-up actions:

- Comfort with smartphones
- Ease of use
- Notifications
- Data visualization

i) What would you think of an option that would:

- To contact a relative;
- Healthcare professional, in case of a concerning situation detected by the device?

Possible follow-up actions:

- Reassuring?
- Intrusive?
- Useful in an emergency?
- Concerns related to confidentiality?

j) In your opinion, would it be more useful:

- to monitor L-DOPA concentration at certain key times?
- to follow continuously (throughout the day?)

Possible follow-up actions:

- Variability of symptoms
- Difficult moments during the day
- Night vs. Day

5- Potential impact on quality of life

a) Do you think such a device could have an impact on your quality of life?

Possible follow-up actions:

- Stress reduction
- Better symptom control
- Sense of security
- Autonomy

b) Do you think a portable biosensor could reduce:

- Time spent in the hospital;
- Medical travel;
- Improve your daily life with your loved ones;

Possible follow-up actions:

- Waiting time
- Travel
- Accessibility of care
- Peace of mind

6- Conclusion

a) Is there anything else you would like to add regarding:

- Your treatment?
- What are your needs?
- What is your opinion on this type of technology?

8.11e Recruitment poster

Participer à une étude sur la maladie de Parkinson et le traitement de lévodopa

Pourquoi participer?

Ce projet est mené par l'équipe étudiante BiosensUM de l'Université de Montréal dans le cadre de l'édition 2026 de la compétition internationale SensUS. Vos réponses contribueront au développement d'un appareil de détection portable visant à améliorer le suivi du traitement de la maladie de Parkinson.

Qui peut participer?

Toute personne agée de 18 ans ou plus résident au Québec, Canada qui a un diagnostic confirmé de la maladie de Parkinson par un professionnel de la santé.

Toute personne qui a la capacité de comprendre et signer un consentement éclairé, qui est en mesure de participer à une entrevue ou répondre à un questionnaire clairement.

Il est nécessaire de prendre un traitement actuel ou récent à la L-DOPA pour participer à cette étude.

Cliquer ici:

https://docs.google.com/forms/d/e/1FAIpQLSctPGpwFNx8-TGeLSw_zrbX8igi6Dr2IgwUH8D3JdtzRMym1w/viewform

ou scanner:

Comment participer?

Pour participer, deux options s'offrent à vous:

Option 1:

Répondre à un questionnaire anonyme d'une durée d'environ 15 minutes (juste ici). ⟶

Option 2:

Participer à une entrevue (virtuelle ou en personne) d'une durée d'envion 30 à 60 minutes.

Approbation éthique et confidentialité

Cette étude est réalisée sur une base volontaire, les réponses sont confidentielles et il y a possibilité de se retirer à tout moment sans conséquence pour le participant ou la participante. Ce projet est approuvé par le comité d'éthique de l'Université de Montréal.

Pour obtenir plus d'information

Équipe BiosensUM: ✉ biosensumumontreal@gmail.com

Université de Montréal

8.11f Core problems, primary needs and expectations of key stakeholders

Core problems	
Result	**Stakeholders**
Difficulty determining and adjusting the appropriate L-DOPA dosage	Neurologist, patient, pharmacist
Limited information on fluctuations occurring outside clinical consultations	Neurologist, patient
Burden of manually recording medication intake and symptoms	Patient
Variability in motor function and physical capacity	Patient, kinesiologists
Risk of anxiety or misinterpretation when patient access raw data	Neurologist, kinesiologists

Primary needs	
Result	**Stakeholders**
Continuous monitoring of L-DOPA levels and motor fluctuations	Neurologist, patient
Correlation of L-DOPA levels with motor and functional outcomes	Neurologist, kinesiologists, patient
Comfortable and appropriate positioning for continuous wear	Patient, Parkinson Québec, MedTech specialist
Durable and removable format that minimize replacement costs	Patient
Personalized interpretation based on relevant clinical physiological factors	Neurologist, pharmacist
Clear and clinically interpretable summaries rather than raw data	Neurologist, kinesiologists

Expectations	
Result	**Stakeholders**
Better understanding of dose-effect relationships	Neurologist, patient
Improved treatment adjustment using data collected between consultations	Neurologist, patient
Automated symptom and medication tracking to reduce patient burden	Patient
Support for planning and adapting physical activity	Kinesiologist
Improved communication between patients and healthcare professionals	Neurologist, patient
Progress monitoring without generating excessive alerts or anxiety	Neurologist, kinesiologist
Feasible manufacturing, commercialization, and clinical implementation	MedTech specialist

8.11g Letter of support from the Quebec Parkinson Network (QPN)

Clotilde Degroot, MSc
Managing Director - Neuro Genomics Partnership
Manager – Quebec Parkinson Network
The Neuro
McGill University

July 29, 2026

Subject: Letter of Support from the Quebec Parkinson Network (QPN) for the BiosensUM 2026 Team

To Whom It May Concern,

The **Quebec Parkinson Network (QPN)** is pleased to express its full support for the **BiosensUM 2026** team, which will represent Canada at the **SensUs 2026** international competition taking place at the end of August.

QPN recognizes the significance of this initiative, which aims to develop an innovative technology for monitoring levodopa (L-DOPA) treatment in people living with Parkinson's disease. Such a device has the potential to improve treatment monitoring, support more personalized clinical care, and ultimately enhance the quality of life of individuals living with Parkinson's disease.

To support the development and validation of this technology, QPN is committed to providing the BiosensUM team with access to its network of research participants living with Parkinson's disease. Specifically, QPN will leverage its research infrastructure to identify and recruit eligible participants interested in taking part in the evaluation and validation of the device developed by the team.

QPN represents a unique research resource in Quebec. Its registry includes more than **1,500 individuals** living with Parkinson's disease who have expressed their willingness to participate in research studies. In addition, QPN maintains a comprehensive research database containing clinical, demographic, epidemiological, and genetic information, enabling the efficient identification of participants meeting specific study criteria and supporting the successful execution of high-quality research projects.

We are confident that this collaboration will provide the BiosensUM team with an exceptional opportunity to evaluate their technology under real-world conditions while contributing to the development of a promising innovation addressing an important unmet clinical need in Parkinson's disease.

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Managing Director - Neuro Genomics Partnership
Manager – Quebec Parkinson Network
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The Quebec Parkinson Network is proud to support this initiative and looks forward to working with the BiosensUM team to facilitate the validation of this innovative technology within the Parkinson's community.

Thank you for considering this funding application. We sincerely hope that this project will receive the support needed to bring this promising innovation to fruition.

Sincerely,



Clotilde Degroot, MSc
Managing Director - Neuro Genomics Partnership
Manager – Quebec Parkinson Network
The Neuro
McGill University

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8.11h Inventor declaration form Université de Montréal (french only, page 1)

Université de Montréal

Date : 02-10-2024
Dernière mise à jour : 09-09-2021

DÉCLARATION D'INVENTION

Ce document strictement confidentiel est à l'usage **exclusif** des chercheurs de l'Université de Montréal

Le formulaire peut être complété en partie ou en totalité en français ou anglais (si nécessaire).

Préambule et indications pour remplir la Déclaration d'Invention :

La présente divulgation est faite en vertu de la *Politique de l'Université de Montréal sur les brevets d'invention : Principes, Règlements et procédure* et de la *Politique de l'Université de Montréal sur la propriété intellectuelle*. Elle est obligatoire pour tout professeur de l'Université qui a l'intention de valoriser par voie de commercialisation une invention ou tout autre produit universitaire.

Le Bureau Recherche-Développement-Valorisation (BRDV) a pour mission de fournir des services relatifs à la valorisation et à la commercialisation des résultats de la recherche provenant des chercheurs de l'Université de Montréal. Le BRDV identifiera des entreprises existantes pouvant bénéficier des transferts technologiques, négociera des ententes de transfert technologique et, le cas échéant, participera à la mise sur pied d'entreprises dérivées.

Si vous préférez que la valorisation se fasse dans un cadre autre que celui privilégié par l'Université, vous devrez le préciser à la section 5.5 du présent formulaire et fournir les justifications de votre préférence. L'Université évaluera alors votre proposition et ne pourra la rejeter sans motif raisonnable. Le professeur est prié d'informer le BRDV de son projet de présenter une proposition et de s'enquérir, à cette occasion, des critères pouvant s'appliquer au type de dossier qu'il compte présenter avant d'entreprendre des démarches coûteuses et laborieuses.

Si vous avez des restrictions à la commercialisation liées à la liberté académique ou aux valeurs éthiques en recherche, tenant par exemple à des considérations sociales, politiques ou écologiques ou encore pour préserver certains droits affectant vos recherches futures, vous pourrez les indiquer à la section 5.6.

Si l'Université décide de s'engager dans la valorisation par voie de commercialisation, un contrat par lequel vous ferez cession de vos droits de propriété intellectuelle devra être signé entre vous les inventeurs et l'Université. Ce contrat prévoira une clause de partage des revenus découlant de la commercialisation.

Espace réservé à la DGR
Numéro de dossier : _____

Date : _____

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1. L'invention

1.1 Titre de l'invention
