

医療機器

急性腎障害の
早期発見が可能になる

新規リアルタイム モニタリングシステム

Competitive Advantage

Criterion	Serum creatinine	Urine output	NGAL / L-FABP	Continuous UPO ₂
Signal	Glomerular filtration	Urine volume	Tubular stress or injury	Medullary oxygenation proxy
Timing	Intermittent and delayed	Usually assessed hourly	Intermittent	Continuous, minute-scale
Workflow	Blood sampling	Standard urinary catheter	Urine or blood assay	Continuous bedside monitoring
Clinical role	Diagnosis and staging	Diagnosis and staging	Risk stratification	Early risk recognition and response monitoring



麻酔科学 井口 直也

Continuous Urinary Oxygen Tension Monitoring

Real-time renal oxygenation assessment for earlier AKI risk recognition

Kansai Medical University
Clinical Professor, Department of Anesthesiology
Naoya Iguchi, MD, PhD

Executive Summary

Clinical need:

AKI is often recognized after kidney function has already changed, leaving limited time for preventive intervention.

Intended use:

Continuous UPO₂ monitoring tracks changes in renal oxygen balance and prompts earlier clinical review.

Current status:

AMED approved the program for its Startup HealthTech initiative for FY2026–FY2027, with planned public funding totaling JPY 50 million. We have used the refined prototype in approximately 40 perioperative cases and are conducting a 55-patient prospective observational study.

Investment and partnership objective:

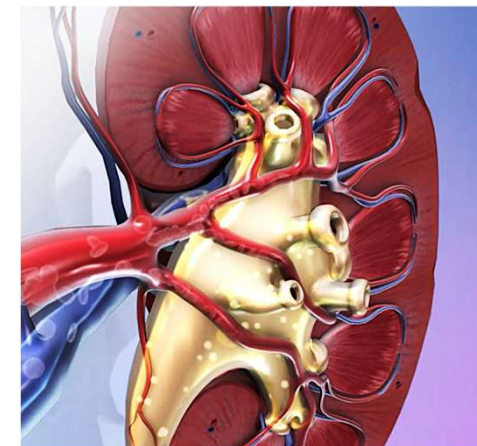
We seek VC investment to establish the startup and fund the work needed beyond the AMED program to reach commercialization.

Background and Clinical Goal

Renal medullary hypoxia may occur before conventional biochemical signs of AKI.

Serum creatinine and injury biomarkers provide intermittent assessments. Urine output also reflects nonrenal factors.

Bladder urinary oxygen tension (UPO_2) may enable continuous assessment of renal medullary oxygenation without placing an instrument in the kidney.



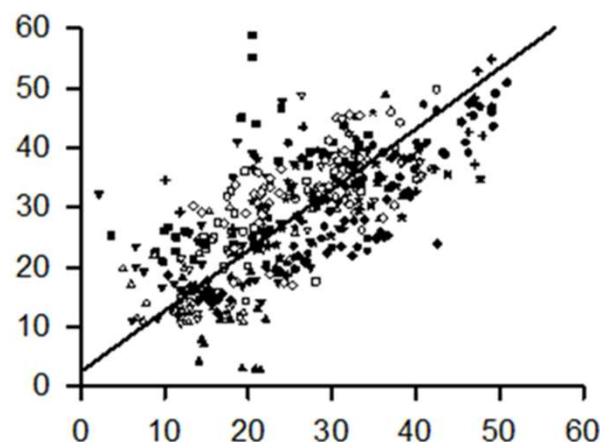
Clinical Goal

Visualize renal oxygenation during surgery and critical care so clinicians can respond while the underlying physiology may still be modifiable.

Initial settings: cardiac surgery and intensive care

Published Evidence of Biological Validity

Confirmed Biological Validity in a Rabbit Model



In anesthetized rabbits, changes in bladder urinary PO_2 correlated strongly with changes in renal medullary PO_2 (within-rabbit $r^2 = 0.87\text{--}0.90$).

Sgouralis I et al. Am J Physiol Regul Integr Comp Physiol. 2016;311:R532–R544. doi:10.1152/ajpregu.00195.2016

This slide presents published non-confidential evidence. We can share unpublished product-performance and patient-level data selectively after a Non-Disclosure Agreement (NDA).

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Continuous UPO₂ monitoring complements established diagnostic criteria for acute kidney injury (AKI) with the aim of enabling its early detection.

Evidence and Development Foundation

Scientific foundation

Peer-reviewed animal and human studies support the biological rationale and feasibility of continuous urinary oxygen monitoring.

Clinical development

Approximately 40 perioperative uses of the refined prototype, an ongoing 55-patient prospective observational study, and a 9-institution research network support the next stage of clinical evaluation.

Validation and diligence

We can share unpublished product-performance and patient-level data selectively after an NDA.

Disclosure Scope

Included in this deck

Clinical need and published evidence

Development status, anonymized partner roles, public patent information, and a high-level roadmap

Available after an NDA

Device structure and specifications, unpublished performance and patient-level data, detailed partner scope, regulatory strategy, and non-public IP / know-how

AMED-Aligned Development Roadmap

Workstream	FY2026	FY2027	FY2028–2029	2030 and beyond
Product and regulatory	Prototype refinement, nonclinical and performance evaluation, and regulatory consultation	Regulatory application preparation and manufacturing/quality-system setup	Approval follow-up and expanded clinical development	Launch readiness and further development
Clinical evidence	Ongoing 55-patient observational study	Completion, analysis, and next-study planning	Broader clinical validation	Additional evidence planning
Business and market access	Initial business development plan and VC dialogue	Startup formation and seed financing	Manufacturing and market-access partnerships	Commercial launch and reimbursement strategy

AMED supports the defined FY2026–FY2027 development plan. Timing beyond FY2027 remains provisional and depends on regulatory review, study results, and financing.

Team

Member or organization	Primary responsibility
Naoya Iguchi, MD, PhD Clinical Professor, Department of Anesthesiology Kansai Medical University	Project leadership, clinical strategy, UPO ₂ research program, and product concept
Tomomi Yamada Specially Appointed Professor, Data Coordinating Center The University of Osaka Hospital	Study design, data management, and biostatistics
Translational support Innovation and Venture Promotion Office, Kansai Medical University Medical Center for Translational Research, The University of Osaka Hospital	Intellectual property, startup formation, industry liaison, and translational support

Established Clinical Network:

Urinary Oxygen Tension Study Group across 9 institutions. International collaborators contribute scientific expertise in Australia and Europe.

VC Investment and Partnership Opportunity

AMED funding supports the defined FY2026–FY2027 development program. VC capital will build the company and fund the work needed to progress from the AMED development phase to commercialization.

Priority	VC's strategic support
Company formation and operating capability	Startup incorporation, core staffing, quality system development, and readiness to serve as the marketing authorization holder
Clinical and regulatory expansion	Work beyond the current AMED plan, including broader validation and regulatory execution
Manufacturing and market access	Design transfer, manufacturing scale-up, partner agreements, and launch preparation

We can share additional diligence materials selectively after an NDA, including technical, clinical, IP, and regulatory documentation.