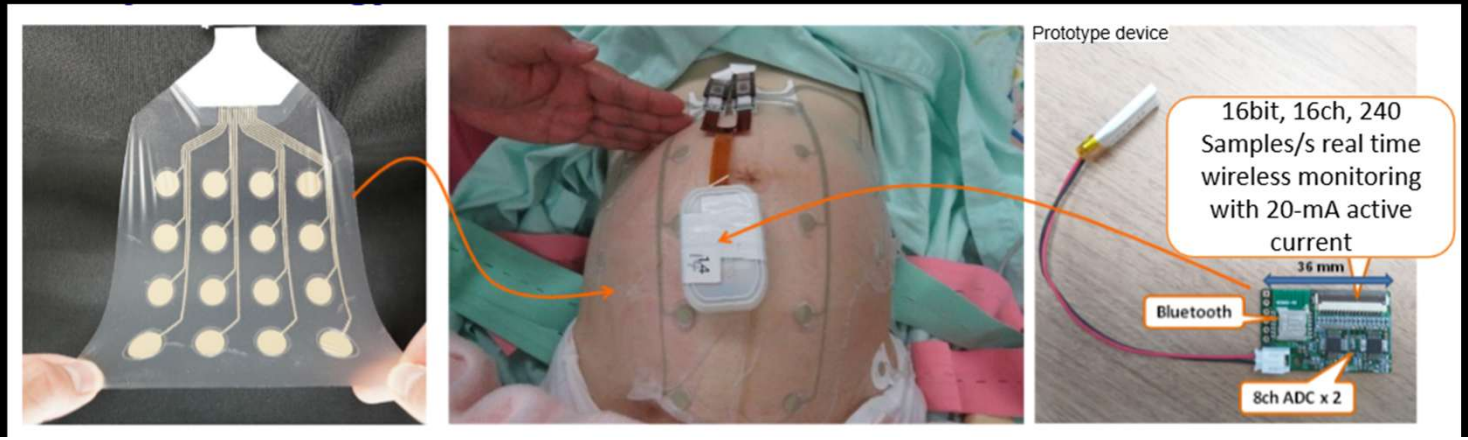
医療機器

株式会社HAKATTE

HAKATTE

母体と胎児状態を同時に把握
簡便・高精度な
分娩モニタリングシステム

Flexible Electrode Sheet & Wireless Device



工学研究科　和泉 慎太郎

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Flexible Sheet-Type Fetal Heart Rate and Uterine Contraction Monitor

フレキシブルシート型胎児心拍数陣痛図（CTG）

Kobe University

Professor, Shintaro IZUMI

神戸大学

教授・和泉慎太郎

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Executive Summary

Objective

Flexible wearable CTG for fetal and labor monitoring

Technology

Flexible electrodes + AI-based fetal signal extraction

Value Proposition

Comfortable, low-cost, telemedicine-ready monitoring for perinatal care

Collaboration Needs

Battery technology, product engineering, commercialization partners

Backgrounds

Current Challenges in Fetal Monitoring

Conventional CTG is uncomfortable, requires clinical infrastructure, and remains inaccessible in many healthcare settings.

Opportunity for Innovation

A wearable, low-cost, AI-enabled CTG platform could expand access to fetal monitoring from hospitals to homes and underserved regions.

Targeted Goal

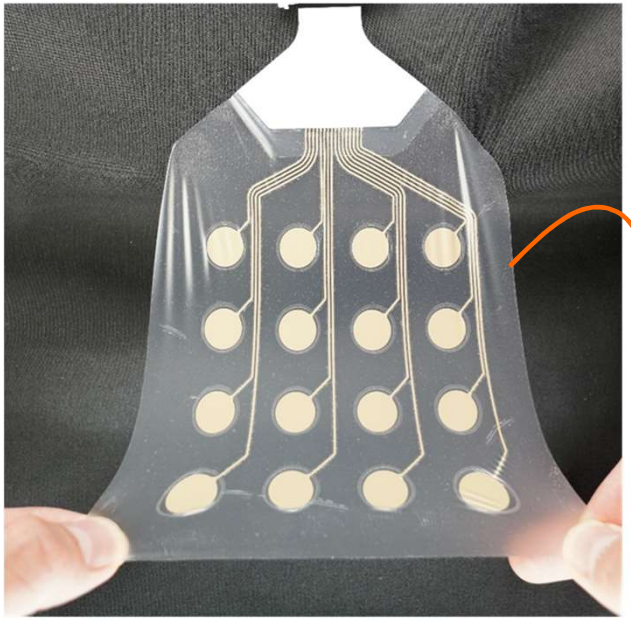
Research Goal

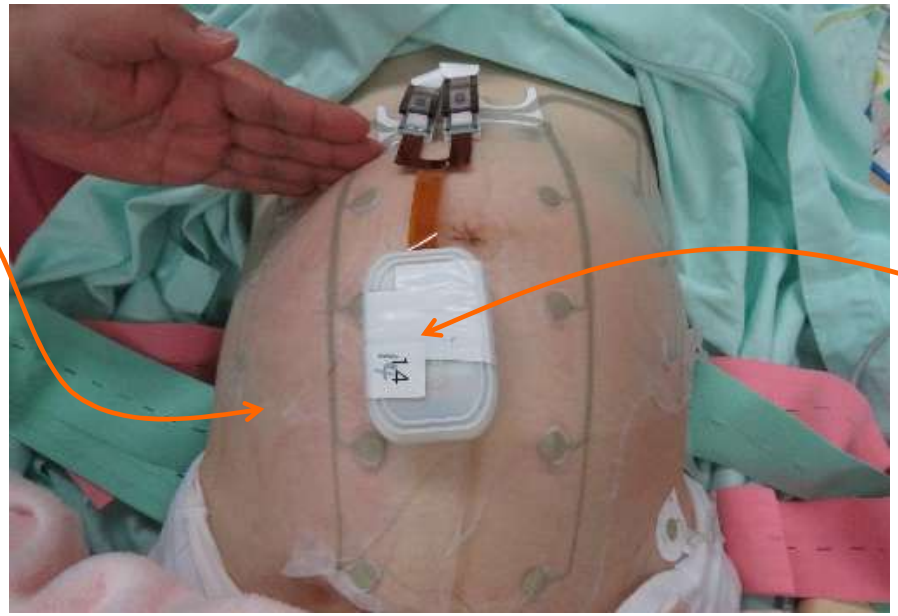
To develop a wearable CTG platform for early detection of fetal distress through continuous monitoring of fetal heart rate and uterine contractions.

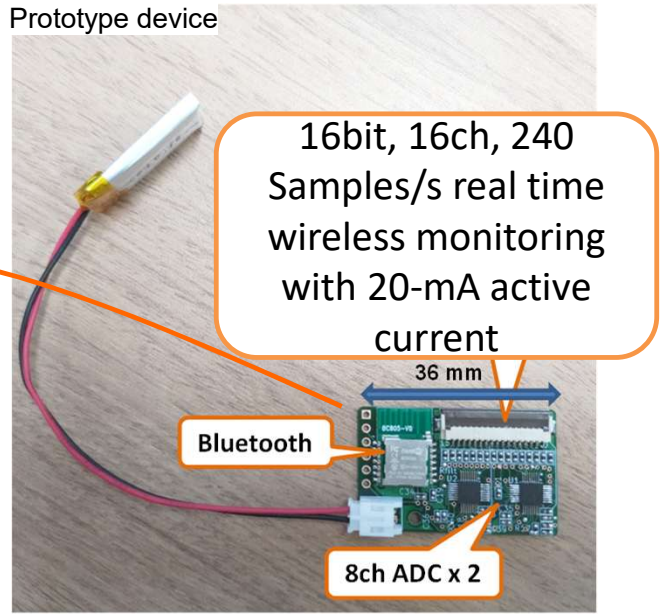
Intended Exit / Commercial Vision

To commercialize a low-cost, home- and hospital-use fetal monitoring device that expands access to perinatal care in both developed and resource-limited regions.

Key Technology 1







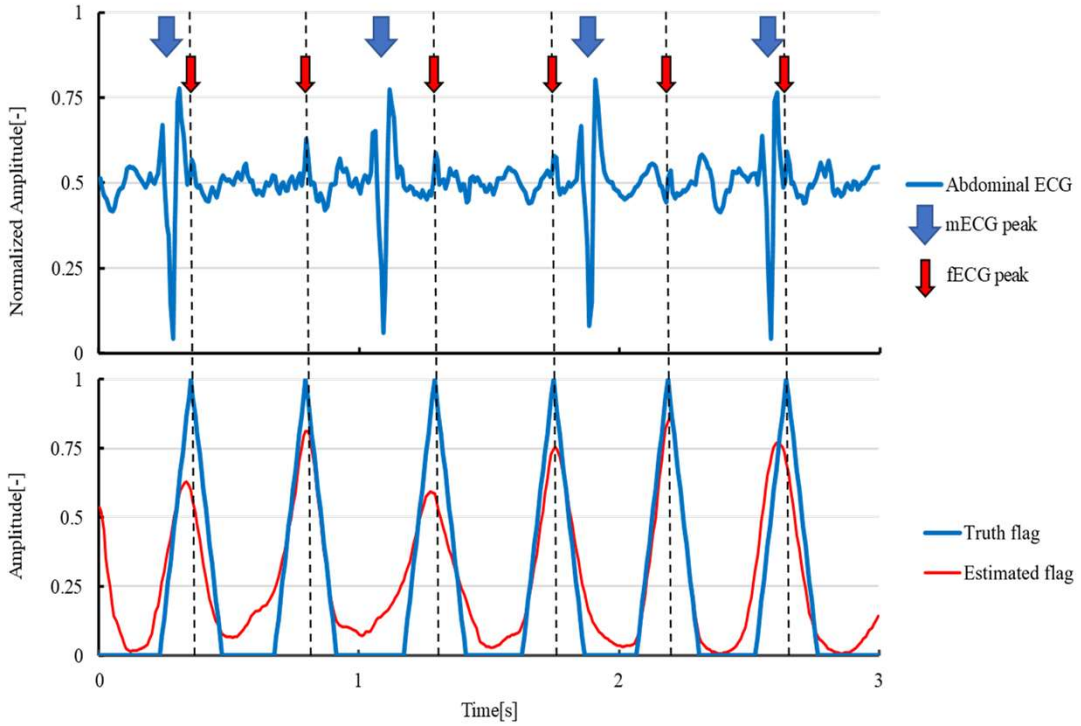
Flexible Electrode Sheet & Wireless Device

Developed a wearable prototype combining a stretchable high-density electrode sheet with a wireless monitoring device for continuous fetal monitoring.

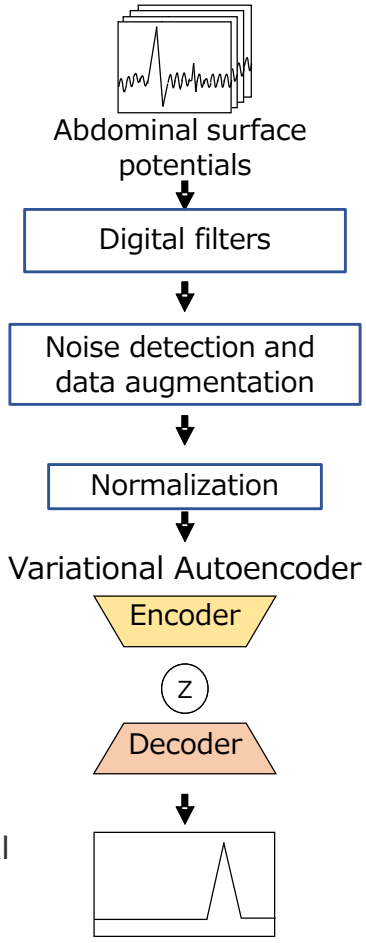
Key Technology 2

Fetal ECG Extraction

- Developed a **VAE-based method** for fetal ECG extraction from maternal abdominal recordings
- Achieved **state-of-the-art performance** on public benchmark datasets
- Currently refining the method using data collected from a **16-channel wearable prototype**



Method	Database	F1	Se	PPV
ICA	PCDB	91.16	84.45	99.71
PCA+DWT	NIFECGDB	98.77	98.01	99.54
R2W-Net	PCDB	98.03	98.23	97.74
	NIFECGDB	97.08	96.76	97.39
Prop.	PCDB	**98.69**	**98.72**	**98.66**
	NIFECGDB	**99.61**	**99.62**	**99.61**

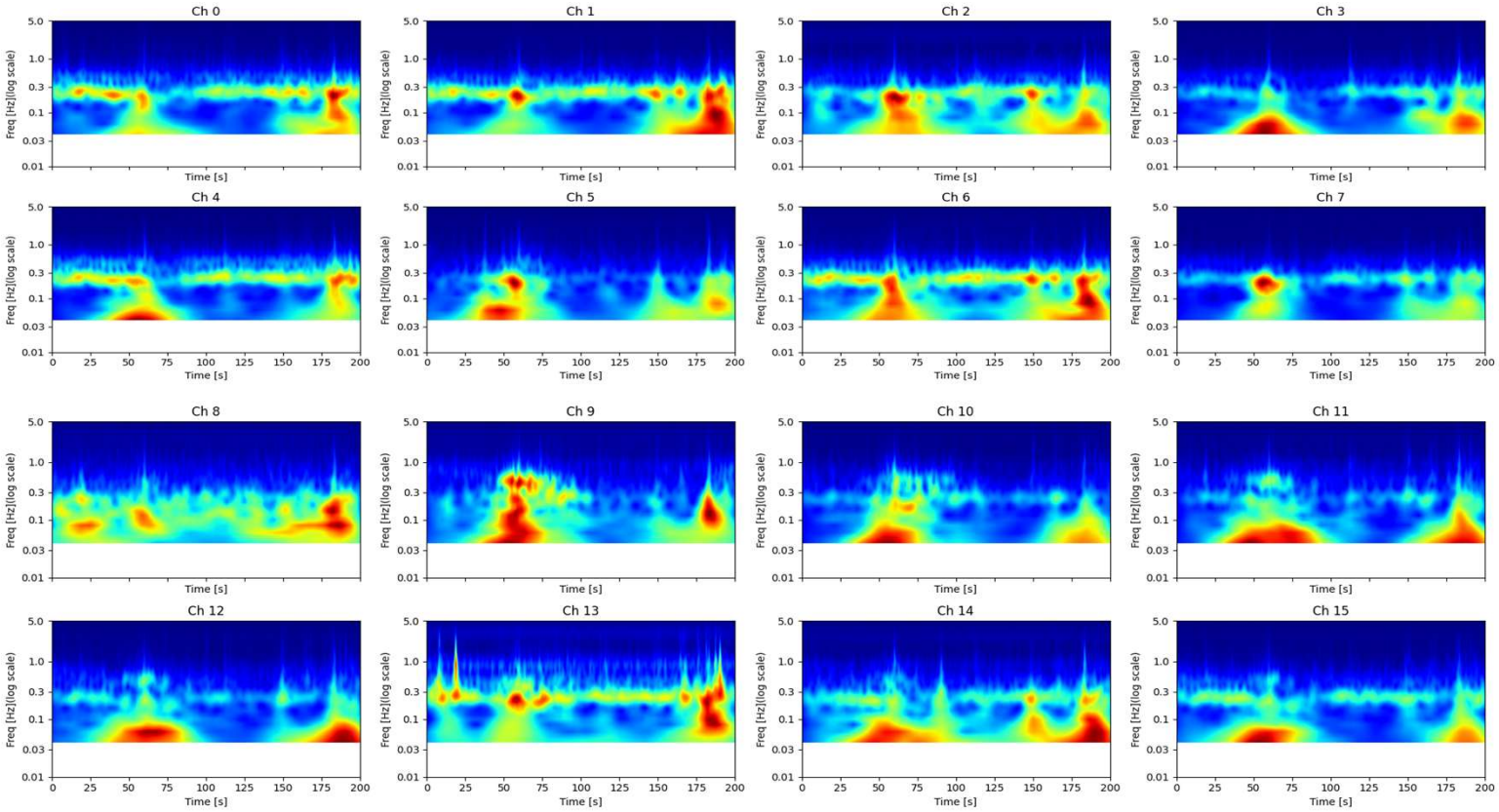


Y. Honda, H. Kawaguchi and S. Izumi, "Robust Fetal ECG Extraction From Abdominal Surface Potentials Using a Variational Autoencoder," in *IEEE Access*, vol. 13, pp. 151726-151735, 2025

Key Technology 3

Electrohysterography (EHG) Extraction

Developing algorithms for extracting electrohysterography (EHG) signals from maternal abdominal recordings to enable non-invasive uterine contraction monitoring.



Representative EHG signals acquired with the 16-channel prototype. The system accurately captures ultra-low-frequency electrical activity (<0.1 Hz), a key characteristic of uterine smooth muscle contractions.

Challenges & Development Plan for 2026

Clinical validation

Initiate pilot studies and international clinical evaluations to establish clinical evidence and demonstrate real-world performance.

Technology Maturation

Improve fetal ECG/EHG extraction algorithms, battery life, and system reliability using multi-channel datasets.

Regulatory & Quality Strategy

Develop regulatory pathways and quality management systems for future medical device approval.

Business Development

Establish partnerships for manufacturing, distribution, and market expansion.

Reference（Patents / Key Papers）

Patent: Filed on Mach 13, 2023 (WO/2024/190471)
Applicants; National University Corporation Kobe, The University of Osaka
"BIOLOGICAL-SIGNAL-PROCESSING SYSTEM, SIGNAL-PROCESSING DEVICE, COMPUTER PROGRAM, AND METHOD FOR GENERATING BIOLOGICAL SIGNAL"

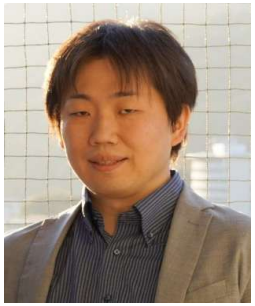
Key papers;

1. Y. Honda, H. Kawaguchi and S. Izumi, "Robust Fetal ECG Extraction From Abdominal Surface Potentials Using a Variational Autoencoder," in *IEEE Access*, vol. 13, pp. 151726-151735, Aug. 2025.
2. Y. Honda, H. Kawaguchi and S. Izumi, "Fetal ECG Extraction Using a Variational Autoencoder and a Flexible Abdominal Sensor," *2025 IEEE-EMBS International Conference on Wearable and Implantable Body Sensor Networks (BSN)*, May 2025.
3. 本田由羽, 川口博, 和泉慎太郎,「変分オートエンコーダを用いた非侵襲的胎児心電図の高精度抽出」, 生体医工学シンポジウム, 2025.

Our Team

Kobe University

Principal Investigator



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SANKEN

Co-Founder

Co-Founder

HAKATTE Inc*.（Commercialization of biosensing technologies）

*: HAKATTE Inc. is Osaka University-born that develops ultra-thin sheet sensors and advanced AI models for smart infrastructure monitoring.

Collaboration

Hospitals and healthcare institutions in Vietnam, Cambodia, and Zambia

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