

THE DECISION THE DEVICE NEVER RECORDED

A 360-Variable, 21-Layer Decision Manifold for Capturing Moment-of-Action Clinical Reasoning

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60th year with type 1 diabetes · 100,000+ insulin injections and millions of micro-decisions · the person adaptive AI is being built to manage

STUDY TYPE: N-of-1 proof of concept

THE CORE PROBLEM: Devices record what happened — not what the person knew, weighed and decided.

BACKGROUND & PROBLEM

Clinical data records outcomes, not the reasoning that produced them. A glucose value shows the endpoint — not what the person observed, expected or weighed. That missing execution-state context is the layer this work captures.

METHODS / IMPLEMENTATION

A novel decision-provenance dataset built from a single subject over one continuous 60-day window. Each treatment action was captured with its pre-decision state, context, uncertainty, timing and judgment, then aligned to device data on the same timescale.

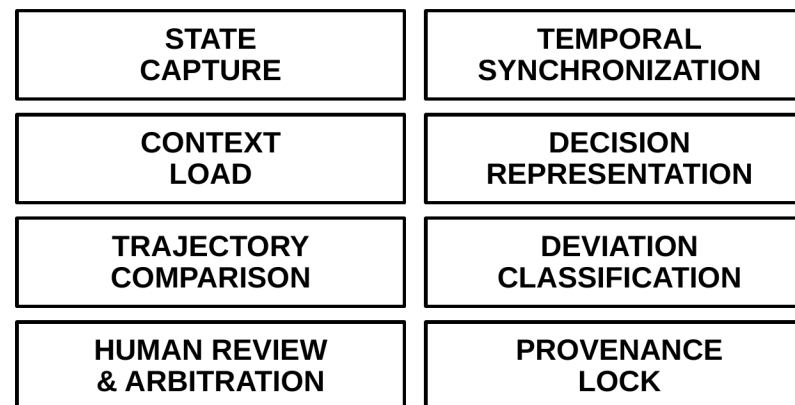
Decision Deviation Signal (DDS)

Divergence between expected and observed trajectories is classified before root-cause attribution: MISSED · DELAYED · RESISTANT · OVER-CORRECTIVE.

SELECTED REFERENCES

Sambasivan et al. Data cascades in AI. CHI 2021.
U.S. FDA. PCCP guidance, AI device software. 2024.

THE ARCHITECTURAL PIPELINE



CORE FINDING

Same endpoint. Different provenance.

Identical glucose outcomes, different decision pathways. All values mmol/L.

RECORD A · DAY 10

State 14.7, drifting
Judgment restraint
Action **2.0 U**
End **13.9 at +93 min**

RECORD B · DAY 23

State 14.4, post-meal
Judgment escalation
Action **4.0 U**
End **13.7 at +130 min**

N-OF-1 IMPLEMENTATION · 60 CONSECUTIVE DAYS

537 DECISION RECORDS · 340 VARIABLES
21 ANNOTATION LAYERS · 360 DECISION EVENTS

Single subject · one 60-day window · not a cohort.
Proof of concept, not validation.

WHAT THE MANIFOLD CAPTURES

- Pre-decision physiological and sensor state
- Context the device cannot observe
- Uncertainty held at the moment of action
- The judgment applied, as structured data

VERIFICATION & VALIDATION ROADMAP

DEMONSTRATED N-of-1 implementation · structured decision capture · auditable provenance

NOT YET ESTABLISHED design verification · formal risk analysis · intended-use validation · safety & efficacy

PLANNED NEXT inter-rater reliability · cross-user evaluation · prospective study design · regulatory pathway

KEY FINDING: Clinical reasoning can be represented as structured, computable data.