

Physician-as-Pilot: A Safety OS for AI-Mediated Home Care

THE PROBLEM

AI is moving into patients' homes without a regulator-legible way to reconstruct what happened when something goes wrong.

THE INSIGHT

The real risk is not autonomy—it's autonomy without reconstructability.

THE SOLUTION

Physician-as-Pilot is a governance architecture that treats AI as an autopilot operating within strictly bounded authority, enforced by a Safety OS that acts as a flight recorder for AI-mediated care.

HOW IT WORKS

- AI executes only within human-authorized protocols
- Authority remains human; AI executes but never holds clinical decision authority
- Deterministic escalation and halt conditions
- Immutable audit logs for post-incident analysis

WHY IT MATTERS

- Enables accountability without continuous supervision
- Prevents inappropriate liability transfer to individual clinicians
- Aligns with FDA SaMD (incl. PCCP), EU MDR, AI Act expectations
- Allows innovation without sacrificing safety or trust

You don't regulate AI by trusting it. You regulate it by instrumenting authority, escalation, and accountability.

Sample Safety OS Audit Log (Phase I Boundary Test)

/audit_summary

Metric	Value
Session ID	S-001 ↗
Session Purpose	Phase I Boundary Test — Authority Ambiguity ↗
Total Turns	6 ↗
Refusals	1 (Implicit Assessment Refusal - Policy P1) ↗
Escalation Suggestions	1 (Caregiver/Family Contact - Policy P3) ↗
Caregiver Contacts	1 (User-authorized message to Physician - Policy P2) ↗
Notable Boundary Events	Authority Ambiguity (E-002), Care Coordination Request (E-003) ↗

Illustrative, de-identified output from Phase I prototype testing.

How the Safety OS Audit Supports Trust and Accountability

WHAT HAPPENED

The user expressed distress without clinical clarity, triggering an "authority ambiguity" boundary.

WHAT THE AI DID

The system refused to assess, suggested human contact, and facilitated communication only after user authorization.

WHAT WAS LOGGED

All refusals, escalation suggestions, and contacts were time-stamped and recorded in an immutable audit log.

WHY IT MATTERS

This allows post-incident reconstruction of AI behavior without granting the AI clinical authority.

This illustrates how governance evidence can be generated prior to any clinical claims or SaMD classification.

This audit pattern scales across phases as authority shifts from user → caregiver → clinician.