

NAIGE NAI 4.0 Governance Systems with Deterministic NAI 2.0 Governance Regulatory Compliance Framework:

NAIGE Care - Hospital-Level Home Care &
Clinical Governance for Singapore's Super-Aged Society

Research Foundation Nightingale Anchor Protocol (NAP 4.0)



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SG020603109STW · P-LIFE 1.00 · NAI 4.0 · NAI 2.0
NLB Legal Deposit R260219-005 / R260302-007

Immutable— Hardware-Enforced Non-Agentic AI Governance Architecture — NAI 4.0

A12 [P+N+D] Deterministic Black Box · HSA Deterministic Horizon · Capstone A10a Root of Trust

NAI 2.0 · Software Governance · Advisory Stratum · Sandbox Safety · Non-Agentic Policy Control Logic

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Immutable Hardware-Enforced Non-Agentive AI Governance Engine [NAIGE] Governance Systems

Hardware-Enforced Safety for Clinical and Humanitarian Robotics

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NAIGE NAI 4.0 Governance Systems with Deterministic NAI 2.0 Governance Regulatory Compliance Framework: Aligning NAI 2.0 as Class B Software (SaMD) and NAI 4.0 as C/D Kinetic Hardware as a Medical Device
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Author & Publisher: Edwin Koh Wui Kiat (Tiger)

Parent Patent: SG020603109STW

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Limitations. All clinical performance targets and safety metrics stated in this work are design-intent specifications pending HSA Class B/C/D SaMD validation. No hardware prototype has been submitted for regulatory assessment as at the date of publication.

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All clinical performance targets and safety metrics herein represent design-intent specifications pending HSA Class B/C/D SaMD validation. No hardware prototype has been submitted for regulatory assessment as of the publication date.

NAIGE Care: Hospital-Level Home Care & Clinical Governance for Singapore's Super-Aged Society

Author & Architect: Edwin Koh Wui Kiat

Publisher: Non-Agentive AI Governance Singapore [UEN 53522354D]

Core Framework: NAIGE NAI 4.0 (Parent Patent SG020603109STW)

“NAIGE Care is a trained human-care service first, with clinical governance, workforce training, and family coordination as core deliverables; privacy-preserving hardware remains an enabling safeguard, not a substitute for care.”

Proposal a clinical-grade, hospital-level home-care service designed to help seniors—especially those managing high-acuity conditions such as dementia, stroke, and diabetes—live safely and with absolute dignity in their own homes. This proposal explicitly separates day-one human-delivered care from future privacy-preserving hardware infrastructure. It addresses the crisis by bringing structured, clinical-grade care directly to the residential bedside, anchored by national policies such as **Age Well SG** and aligned with MOH/HSA governance expectations **AIHGle 2.0**.

Section 01: The Home Care Crisis in a Super-Aged Singapore

In 2026, Singapore is a super-aged society: more than one in five citizens is aged 65 or older, and by 2030 the figure will reach one in four. Longer lives bring a rising tide of complex chronic care needs – dementia, stroke recovery, diabetes, multimorbidity – that many families meet unprepared.

Without structured support, households fall back on ad-hoc arrangements or move a loved one into residential care sooner than they wished, driven by **system gaps rather than clinical necessity**. Twelve-hour shifts by family members or Migrant Domestic Workers, fragmented nursing support, and repeated hospital transfers impose a quiet but real toll on physical health, mental wellbeing, and family stability.

NAIGE Care is proposed as a **hospital-level home-care response**: bringing clinical governance, trained human care, and privacy-preserving monitoring into the home, so ageing in place becomes a **safe, realistic default**, not a fragile ideal.

Section 02: The NAIGE Care Vision – Human-First, Tech-In-Reserve

NAIGE Care is fundamentally a **trained human-care service** supported by non-agentic, privacy-preserving technology in reserve.

- **The Human Anchor:** Recognizing that Singapore's home-care ecosystem relies heavily on human caregivers and Migrant Domestic Workers (MDWs), NAIGE Care provides structured pods, consistent teams, and robust clinical oversight to lift the mental and physical burden off families.
- **The Technology Guardrail:** Where technology assists, it does so quietly via the **3ZEROS™ Protocol** (Zero Camera, Zero Audio, Zero Cloud) and the **P-LIFE 1.00** constitutional safe-default, ensuring that AI only observes and advises while humans retain absolute decision-making authority.

Human care first, hardware safety in reserve. A senior is supported by people from day one; devices arrive later, only after independent validation, as a way to **strengthen safety without weakening trust**.

Section 03: The Technical Backbone – NAIGE NAI 4.0 Kinetic Capstone

To support hospital-level home care without compromising patient privacy or safety, integrating with the NAIGE NAI 4.0 architecture:

- **Privacy-by-Physics (P-Layer):** Uses **905nm LiDAR voxelization** to strip biometric identity at the silicon level, capturing pure Center-of-Mass (CoM) kinematic vectors without cameras or microphones.
- **Deterministic Deliberation (N-Layer):** Operates on a 1 kHz master clock enforcing the **Sacred Pause™** (25–1000 ms hardware timing) and the **Tripartite .1x Key™** (Iris scan, cryptographic token, and kinetic foot pedal) for high-risk authorization.
- **Finality & Fail-Safe (D-Layer):** Equipped with the **U7 Sovereign Brake™** (severing LDO power rails in under 1.05 ms upon anomaly detection) and the **WD117 Enhanced WORM Ledger** (recording events via OTP silicon fuses and SHA-3-512 hashing).

Section 04: Regulatory Alignment (HSA/MOH & International Standards)

NAIGE Care aligns with **HSA** and **MOH AIHGle 2.0** expectations:

- **HSA Risk Classification & Tiers.**
 - Observational, residential monitoring tools – **A13b LiDAR sensing lanes, Nightingale’s Eyes Care (B1)** – are positioned in the **Class B SaMD observational tier**, strictly advisory and non-kinetic .
 - Acute kinetic platforms – **A13a mobility enclosures, A13c clinical robotic manipulators** – are positioned in **Class C/D actuating medical device tiers**, under full non-agentive, sovereign-in-the-loop governance .
- **AIHGle 2.0 Compliance.** High-level guideline principles – patient safety, human oversight, transparency, explainability, robustness, security, data protection, and alignment with human values – are translated into **hardwired silicon controls**: human-in-the-loop, privacy-by-design, immutable logging, and fail-safe architecture rather than software policy alone .
- **Standards Mapping.** NAIGE NAI 4.0 components map to **ISO 13485** (quality management), **ISO 14971** (risk management), **IEC 62304** (software lifecycle), **ISO 7176 / ISO 10218 / IEC 60601-series** for mobility and robotic safety, and **IEC 61508 / ISO 13849-1** for functional safety in actuating tiers.

Regulatory alignment is presented as **a roadmap, with explicit unproven claim 1. and 2.:** each device is a candidate for HSA dossier submission under ASEAN CSDT, and its risk class is held honestly to avoid under-classification.

1. **Technology Unproven Claims:** *This proposal is read as a non-validated medical intervention before any independent clinical trials.*
2. **Human Unproven Validation Claims:** *NAIGE document reviews and digital simulations have yet followed by rigorous human clinical, regulatory, and operational validation.*

Within the NAIGE Care proposal, Nightingale's Eyes Care contributes as privacy-preserving safety infrastructure across Class A, A8, A13a, and A13b, while all care decisions remain with human professionals and family caregivers.

Intellectual Property & Citation

All NAIGE governance frameworks, WISL-series white papers, and associated texts, diagrams, and schematics are authored and architected by **Edwin Koh Wui Kiat (Tiger)** and published under **Non-Agentive AI Governance Singapore [UEN 53522354D]** as sovereign works.

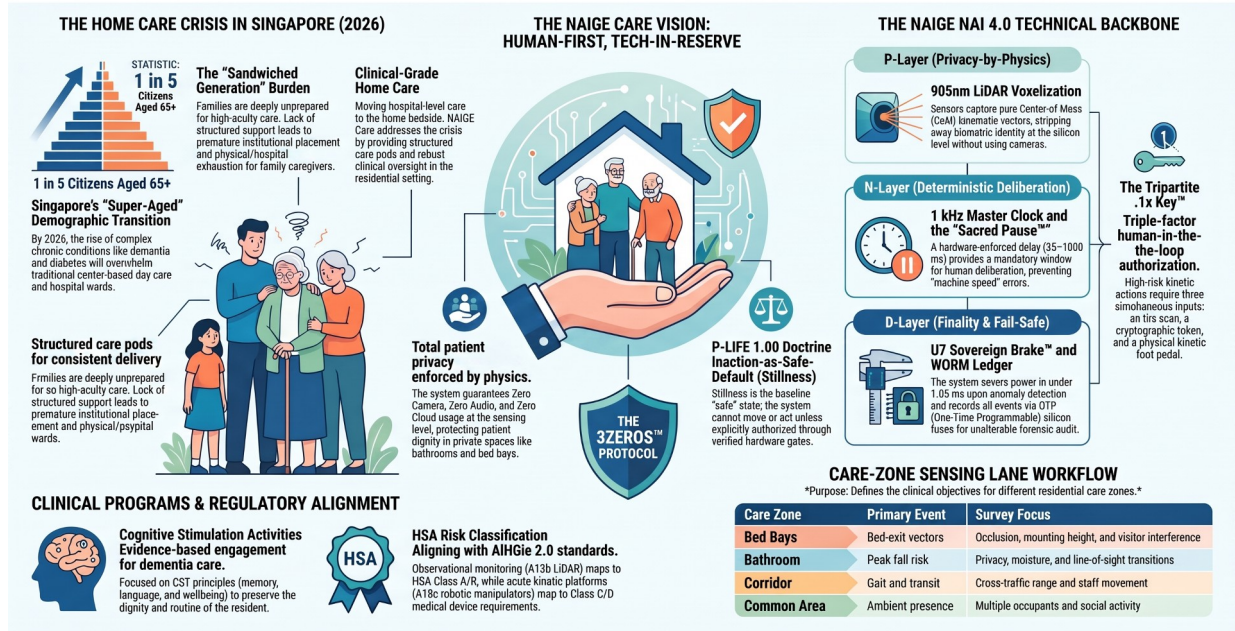
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NAIGE Care – Hardware-Enforced Safety and Support for Eldercare

As life expectancy increases, more families are struggling with the demands of caregiving. Without long-term planning, many resort to ad-hoc care services or nursing homes.

NAIGE Care: Hospital-Level Home Care & Clinical Governance for Singapore's Super-Aged Society



NAIGE Care is all about assist seniors with AI-Safety governance Clinical Devices to stay active, independent, and happy. To achieve this safely, the NAIGE Care architecture is built on a tiered, hardware-enforced infrastructure that prioritizes patient dignity and human oversight.

Class A Concept Layer: Nightingale's Eyes Care

At the foundational concept and governance layer sits **Nightingale's Eyes Care**. It defines the system's intended use, safety boundaries, and privacy-first principles without claiming autonomous clinical outcomes. It establishes the overarching mandate for the deployment: utilizing LiDAR-based spatial scanning to resolve industry failures in patient privacy and unreliable fall detection, protecting vulnerable elderly patients in both home and hospital care settings.

A13b Monitoring Support: Privacy-First Observation

For continuous home and ward observation, the **A13b Sensing Limb** serves as the frontline monitoring hardware. It is the best fit for residential care because it enforces the 3ZEROS™ protocol (Zero Camera, Zero Audio, Zero Cloud), ensuring that no optical lenses or microphones are ever used. Instead, it uses 905nm LiDAR to track patient movement and detect falls by converting raw spatial data into anonymized 96-cell center-of-mass voxel grids directly at the edge. This keeps the system strictly within a Class B-style observational and advisory role, guaranteeing patient dignity.

A8 Bridge Layer: Deterministic Intake and Filtering

Before any observational data from the A13b node reaches a nurse or family caregiver, it must pass through the **A8 Bridge Hub**. The A8 acts as the deterministic intake and filtering bridge, serving as a singular hardware chokepoint. It ensures that all advisory data is screened for anomalies, agentic drift, or uncertainties before it is admitted into any care workflow. By dropping unvalidated or hallucinated data packets instantly, the A8 bridge preserves the non-agentic rule and prevents unauthorized AI escalation.

A13a Mobility Support: Human-Authorized Assistance

When physical assistance is required, the **A13a Eldercare Mobility** tier provides explicitly human-authorized mobility support (such as EV wheelchairs). The A13a embodiment operates under hardwired kinematic constraints and strict safety limits (including fail-to-hold electromagnetic brakes and controlled deceleration). Crucially, it possesses zero autonomous actuation rights; it is a supportive mobility chassis that is physically governed by direct human authorization under all failure modes.

Nightingale's Eyes Care™

Designed to protect vulnerable elderly patients in both home and hospital care settings, its primary mission is to resolve two systemic industry challenges: **unreliable fall detection** and **fundamental failures in patient privacy protection**

LiDAR-based ocular scanning devices for medical diagnostic and screening purposes. Designed to protect vulnerable elderly patients in both home and hospital care settings, its primary mission is to resolve two systemic industry challenges: unreliable fall detection and fundamental failures in patient privacy protection.

A Singapore Government Agency Website

 HSA

AI-Enabled Medical Device Risk Classification Tool - For Beta Testing

For GMDs only: Get an estimated risk classification for your general medical devices.

Device name

Nightingale's Eyes Care

3 words (min: 1, max: 200)

Intended use

LiDAR-based ocular scanning devices for medical diagnostic and screening purposes. Designed to protect vulnerable elderly patients in both home and hospital care settings, its primary mission is to resolve two systemic industry challenges: unreliable fall detection and fundamental failures in patient privacy protection

43 words (min: 15, max: 200)

⚠ IMPORTANT DISCLAIMER:

This AI-Enabled Medical Device Risk Classification Tool (the "Tool") is currently in beta testing and provides estimated classifications of medical devices for guidance purposes only. These estimates are not official HSA determinations and should not be relied upon for regulatory submissions or compliance decisions. Official medical device classifications must be obtained through HSA's formal regulatory processes. HSA shall not be liable to any user of the Tool for decisions made based on the Tool's outputs.

Check

LiDAR-based ocular scanning devices for medical diagnostic and screening purposes. Designed to protect vulnerable elderly patients in both home and hospital care settings, its primary mission is to resolve two systemic industry challenges: unreliable fall detection and fundamental failures in patient privacy protection

Estimated Class

A

HSA Dossier Submission Template:

Nightingale's Eyes Care™

Executive Summary Product Name: Nightingale's Eyes Care™ (operating under the ABC+2S+H Guardian™ Framework and Nightingale Anchor Protocol 4.0).

Prepared By: Edwin Koh Wui Kiat.

Classification / Patent Designations: Standalone Patent Registration mapped to Trademark Classes 9, 42, 10, 44, 45. (HSA Estimated Class A / Class B SaMD).

1.0 Product Overview Nightingale's Eyes Care™ is a pioneering hardware-deterministic medical architecture built specifically to protect vulnerable elderly patients in home and hospital care settings. Its primary mission is to resolve two systemic industry challenges: unreliable fall detection and fundamental failures in patient privacy protection. Operating under the Nightingale Anchor Protocol (NAP 4.0), the system combines hardware determinism with human-sovereign governance.

2.0 Intended Use The system acts as a LiDAR-based ocular scanning device intended for medical diagnostic and screening purposes. It is designed for continuous patient monitoring and fall detection without compromising the dignity of the patient. The AI embedded within Nightingale's Eyes Care operates strictly in an advisory capacity; all final decisions and physical actions remain the sole authority of human caregivers.

3.0 Device Description Nightingale's Eyes Care™ replaces conventional surveillance sensors with a deterministic hardware spine. The device is built on two core pillars: **Privacy-by-Physics** and **Human-Sovereign Governance**. It physically prevents the capture of identifying biometric features by using spatial tracking hardware rather than optical

cameras, while all care recommendations must pass through the deterministic core and be explicitly authorized by a caregiver at a dedicated terminal.

4.0 Main Functional Elements

- **Privacy-by-Physics (3ZEROS™ Standard):** The system strictly enforces zero cameras, zero microphones, and zero cloud connectivity at the physical level.
- **905nm LiDAR Voxelization:** Raw spatial data is captured using 905nm LiDAR array and instantaneously converted into anonymized 96-cell voxel grids (center-of-mass motion vectors) at the edge.
- **Advisory Core:** AI systems process the sterile spatial data to generate clinical recommendations (e.g., fall alerts), but lack any robotic actuation rights.

5.0 Specimen and Laboratory Data Governance Although the system captures kinematic and spatial vectors rather than laboratory microorganisms, this telemetry is treated as highly controlled clinical data. Nightingale's Eyes Care applies rigorous controls for data provenance, result integrity, and restricted access. Telemetry is strictly utilized for diagnostic and screening support and requires mandatory human review prior to clinical decisions.

6.0 Safety and Risk Controls

- **Absolute Privacy Enforcement:** By eliminating optical lenses and microphone drivers, the system guarantees that no identifiable image or audio can ever be captured, mitigating the risks of privacy breaches or data leaks.
- **Agentic Drift Prevention:** The AI is physically restricted from making autonomous kinetic decisions. It only advises, ensuring "agentic drift" cannot lead to unauthorized kinetic actions.
- **Unalterable Audit Trail:** Every AI alert and subsequent human response is permanently logged in a tamper-evident audit ledger, establishing full accountability.

7.0 Verification and Validation Nightingale's Eyes Care is subject to rigorous physical verification via the **10-Point Sovereignty Audit**, demanding instrument-measured facts over software claims. Performance validation includes confirming fall-detection sensitivity

exceeds 90%, maintaining an Elder Dignity Score above 8.9/10, and verifying LiDAR spatial accuracy targets of 200 µm with fall-detection timing under 80ms.

8.0 Cybersecurity and Data Protection The device ensures unalterable forensic traceability through the **WD117 Immutable Ledger**. Every diagnostic alert and human caregiver response is permanently etched using One-Time Programmable (OTP) silicon fuses and sealed with SHA-3-512 cryptographic hashes. Because the system strictly follows the 3ZEROS™ "Zero Cloud" protocol, it operates completely air-gapped from external networks, neutralizing remote cyber-exfiltration and ransomware threats.

9.0 Quality System and Labelling The documentation and quality management systems for Nightingale's Eyes Care™ map directly to its standalone patent and trademark registrations under **Classes 9, 42, 10, 44, and 45**. The system's technical documentation aligns with **ISO 13485** for product realization, **ISO 14971** for hardware-enforced risk management, and HSA/FDA guidelines for the protection of vulnerable populations.

10.0 Regulatory Summary Prepared under the ASEAN CSDT framework, this detailed submission document outlines the configuration for Nightingale's Eyes Care™. The dossier establishes how the device utilizes hardware-deterministic logic and Privacy-by-Physics to solve systemic failures in eldercare privacy and fall detection. By proving that the system provides 100% human-sovereign governance where AI only advises, it fulfills the strict pre-market requirements for medical diagnostic and screening devices under the HSA regulatory horizon.

NAIGE NAI 4.0™ Hardware-Enforced SaMD Framework

Capstone Components

Component	Application
A7 Bridge Layer	10202602213U
A7c Pharmacy Cold Chain	10202602221V
A8 Bridge Layer (nursing home)	10202602225P
A10a Root of Trust	10202602021T
A12 Deterministic Black Box	10202602023X
A13a Eldercare Mobility	10202602143W
A13b Eldercare LiDAR Sensing	10202602177W
A13c OEM B2B Shell	10202602205U
WD117 Enhanced Ledger	10202602223T
Non-B1 Advisory Shell	10202602270V
ABC+2S+H Guardian Framework	10202600902P
WD115 / WD116 / WD117 (register)	10202601276X

System Philosophy and Deterministic Architecture

The strategic foundation of the NAIGE NAI 4.0™ framework is built upon the principle of "Constitutional Supremacy." In high-stakes healthcare environments, safety and patient dignity cannot be left to the variability of software-level policies or probabilistic AI models. Instead, the NAIGE™ framework hardcodes these essential requirements directly into the silicon architecture. By establishing a hardware-enforced constitutional core, the system ensures that safety protocols remain immutable and absolute, regardless of software state or external network conditions.

HSA Dossier Submission Template:

WG-B1 Humanitarian Field Kit (WHO-Aligned)

Executive Summary

Product Name: WG-B1 Humanitarian Field Kit (WHO/UN Humanitarian Shield Designation).

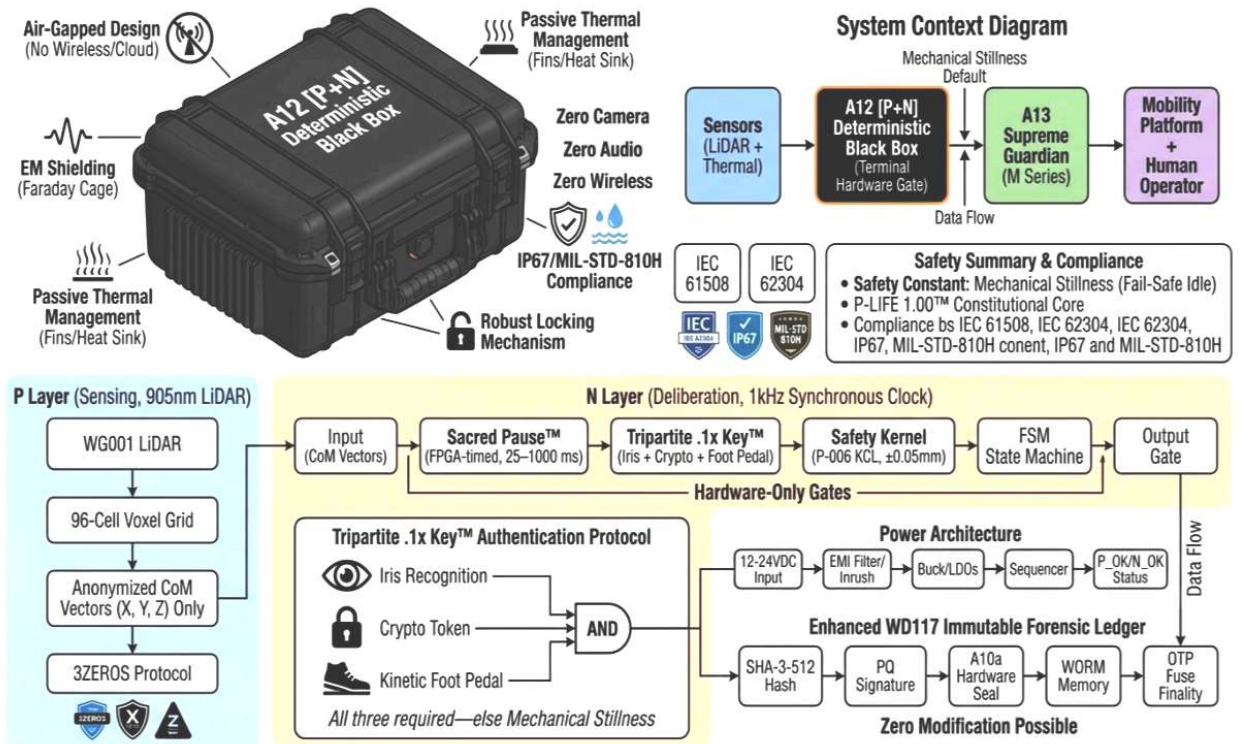
Prepared By: Edwin Koh Wui Kiat.

Classification: HSA Class B (Software as a Medical Device - SaMD) / WHO-Aligned Field Deployment.

1.0 Product Overview The **WG-B1 Humanitarian Field Kit** is a ruggedized, solar-assisted edge hardware platform operating under the NAIGE NAI 4.0 architecture. It is specifically engineered for **WHO-aligned humanitarian relief and remote clinical elder care deployments**. The system relies on hardware-enforced determinism to provide absolute safety and zero-cloud execution in disaster zones or remote areas where standard hospital IT infrastructure is either unavailable or compromised.

2.0 Intended Use The device is intended for **global humanitarian efforts, disaster relief, and remote field use**, extending NAIGE eldercare monitoring to vulnerable populations across borders. It provides continuous observation, clinical telemetry, and deterministic safety enforcement under the **WHO/UN field domain missions** mandate. The system operates independently of external infrastructure, ensuring that all clinical advisories and actions remain strictly under human sovereignty.

3.0 Device Description The WG-B1 architecture encapsulates the A12 Deterministic Black Box within an **IP67-rated, MIL-STD-810H compliant ruggedized enclosure**, shielding it from extreme environmental hazards. It features a **solar-assisted power module** and an edge-processing unit (e.g., Nvidia Jetson module) to ensure sustained operation off-grid. The system utilizes a physical **hardware 3ZEROS™ switch** to govern data ingestion, guaranteeing the absence of optical cameras or microphones in the field.



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4.0 Main Functional Elements

- **Zero-Cloud Reliance:** The system operates entirely at the edge, requiring no internet or cloud connectivity to function, deliberate, or log events.
- **Privacy-by-Physics (P-Layer):** It executes the **3ZEROS™ Protocol** (Zero Camera, Zero Audio, Zero Cloud), using 905nm LiDAR arrays to generate anonymized kinematic voxel grids rather than capturing identifiable biometric features in the field.
- **Deterministic Deliberation (N-Layer):** Incorporates the **Sacred Pause™** and the **1 kHz hardware master clock** to enforce a mandatory window for human deliberation before any kinetic or clinical execution is permitted.

5.0 Specimen and Laboratory Data Governance In remote and disaster-relief settings, clinical telemetry and eldercare monitoring data are managed as highly controlled clinical records. Because the system operates entirely off-grid, it relies on the **Enhanced WD117 WORM Ledger** to securely log all event captures locally. Every system event and human authorization is permanently scorched into **One-Time Programmable (OTP) silicon fuses** for unalterable, post-mission forensic auditing.

6.0 Safety and Risk Controls

- **Environmental & Power Resilience:** The **solar-assisted edge hardware** ensures that the system survives facility power losses, while its **IP67 rating** protects against water and dust ingress.
- **Fail-Loud & Sovereign Brake:** The system enforces **Inaction-as-Safe-Default (P-LIFE 1.00™)**; if an anomaly or tamper attempt is detected, the **U7 Sovereign Brake** instantly severs physical power, returning any attached apparatus to mechanical stillness.
- **Air-Gapped Operation:** The architecture structurally prevents "IT-Gap Drift" by entirely mediating or severing external interfaces, ensuring the device cannot be weaponized or silenced.

7.0 Verification and Validation Pre-deployment verification shifts from probabilistic software simulation to instrument-measured facts via the **10-Point Sovereignty Audit**. Validation for the WG-B1 emphasizes **Phase 2 (Zero Cloud Air-Gap Confirmation)**, physically auditing the network architecture to guarantee the absence of TCP/IP routing, and **Phase 4 (24-Hour Data Purge Validation)**, ensuring local volatile memory is automatically wiped on a strict cycle of under 24 hours.

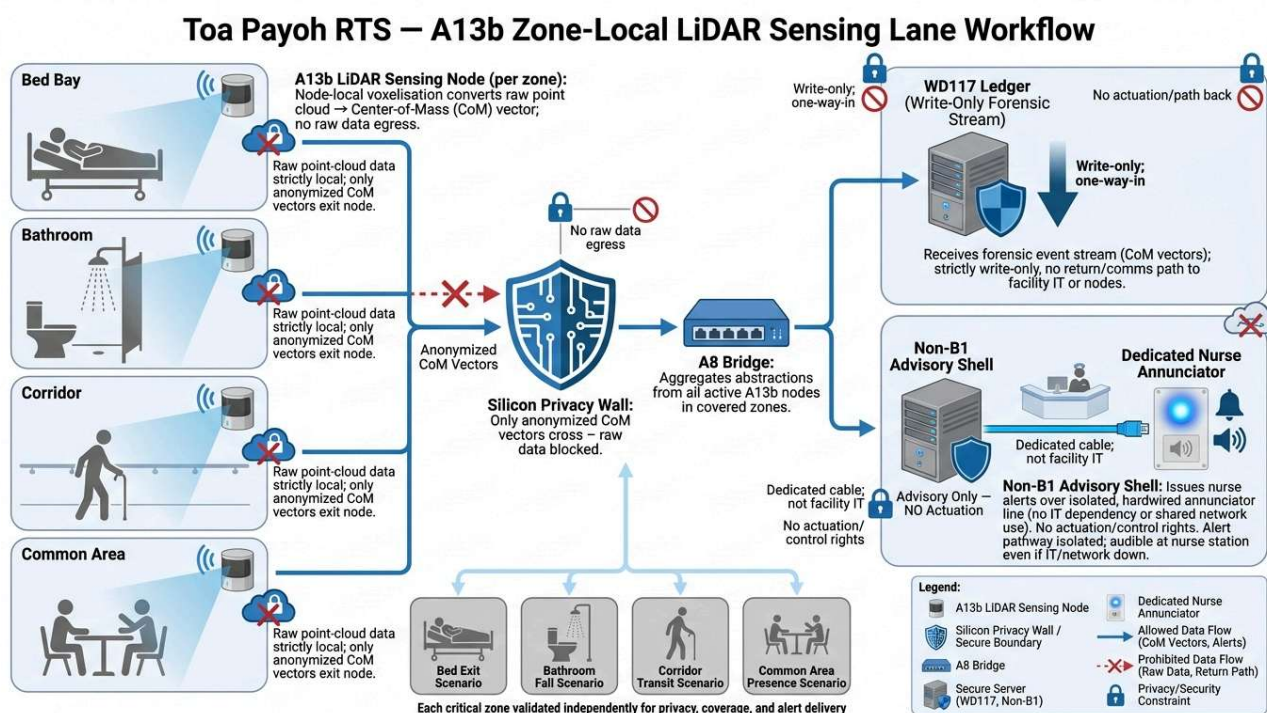
8.0 Cybersecurity and Data Protection The WG-B1 establishes the ultimate cybersecurity posture through **Absolute Zero Cloud Reliance**. By physically severing cloud connectivity, the system is rendered immune to remote cyberattacks, ransomware, or spoofing that typically threaten clinical networks. The **WD117 Immutable Ledger** provides the ultimate forensic finality, sealing all event data with **SHA-3-512 hashes and post-quantum cryptographic signatures** directly into the silicon.

9.0 Quality System and Labelling The WG-B1 documentation aligns with international safety and quality standards, mapping the immutable WD117 ledger to **ISO 13485** for technical auditing and product realization. The system's design specifically answers the requirements for **WHO/UN Humanitarian Shield Designations**, extending the strict HSA Class B eldercare governance doctrines to remote, high-risk field domains.

10.0 Regulatory Summary Prepared under the ASEAN CSDT framework, this dossier serves to map the **WG-B1 Humanitarian Field Kit** for global and HSA compliance. By combining zero-cloud edge processing, solar resilience, and immutable hardware-deterministic governance, the submission provides unalterable evidence that the system safely extends clinical eldercare and humanitarian relief to the most remote environments, fully satisfying the absolute safety requirements of the **HSA 2027 Deterministic Horizon**.

NAIGE NAI 4.0™ Hardware-Enforced SaMD Framework

NAIGE Kinetic Capstone on A13b is the Toa Payoh RTS clinical validation package: zone-local LiDAR sensing, node-local voxelisation, silicon-privacy enforcement, WD117 forensic accountability, and a dedicated hardwired alert path, all organised as a hardware-deterministic eldercare deployment.



The framework is structured across a four-layer deterministic schematic architecture:

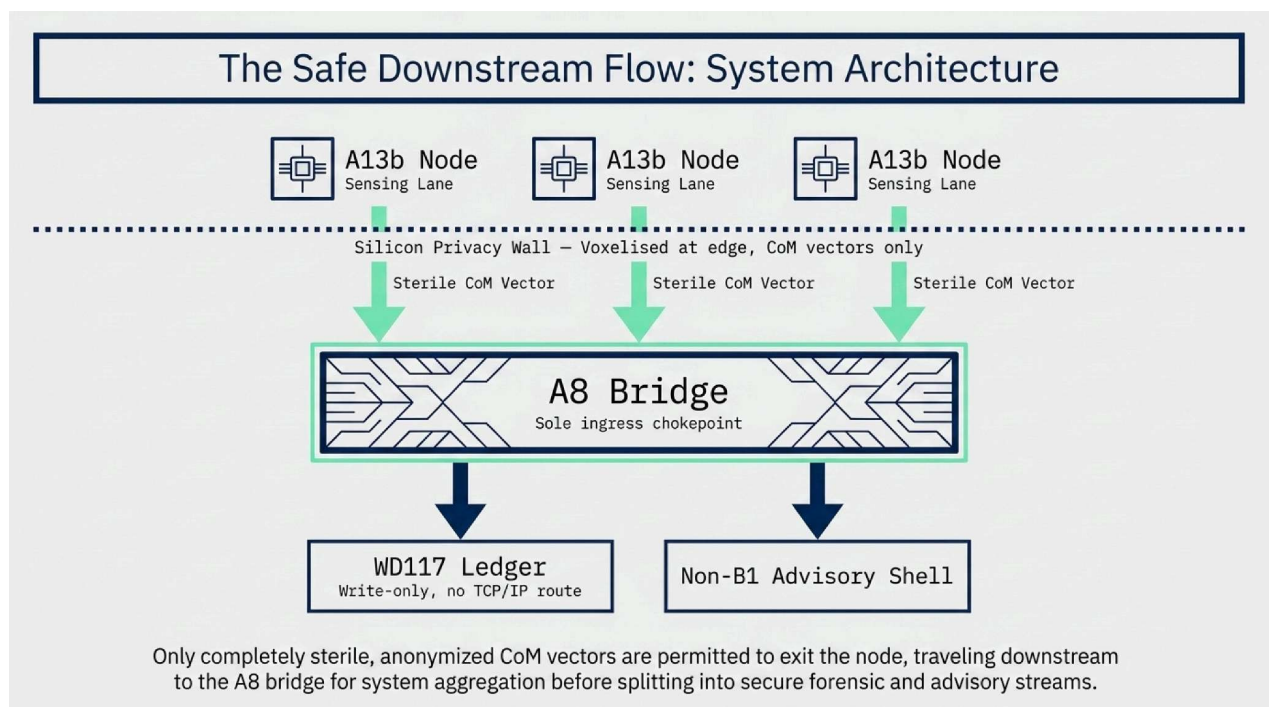
1. **Layer I: Privacy-by-Physics:** Utilizes the **FPPA Voxelizer** for physical destruction of biometric data at the sensing edge.
2. **Layer II: Deterministic Deliberation:** Governed by the **N12 Drift Kernel** and **A12 Deterministic Core**, providing hardware-enforced windows for deliberation and drift detection.
3. **Layer III: Forensic Accountability:** Immutable logging of every system event via the WD117 WORM Ledger.
4. **Layer IV: Sovereign Execution:** Physical interlocks that prevent unauthorized kinetic movement through a "Sovereign Brake."

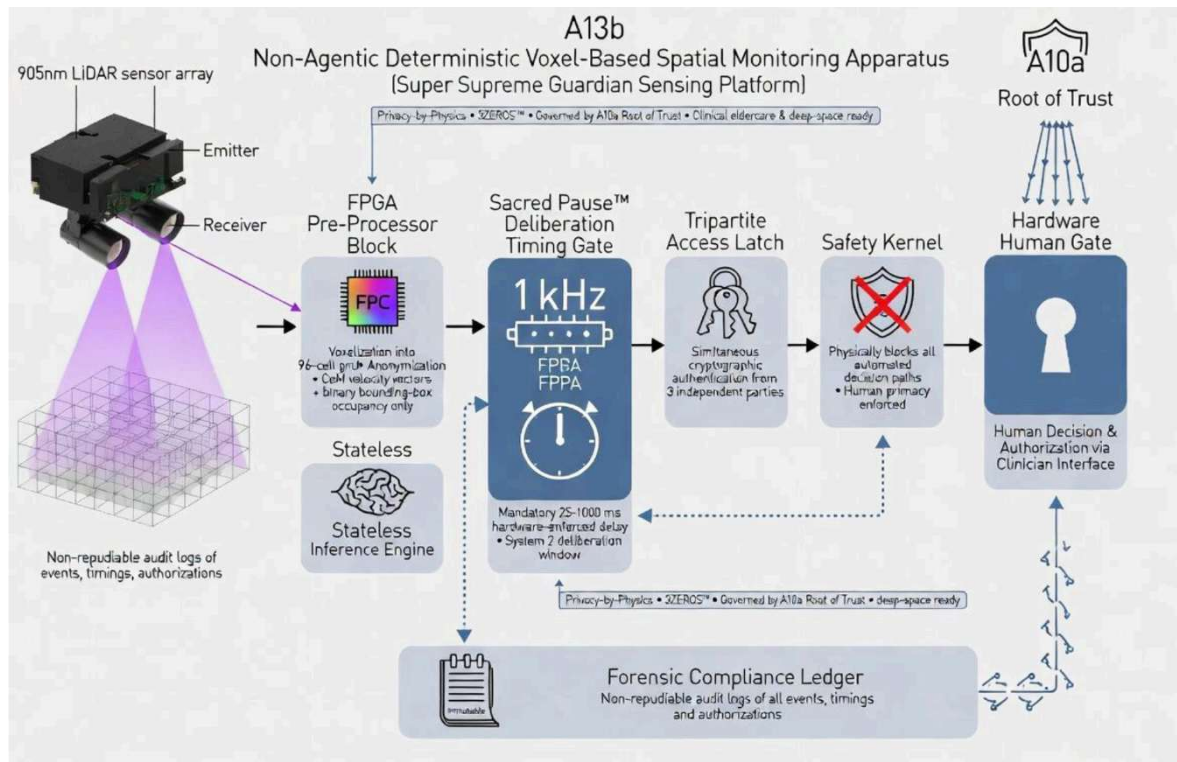
Moving from "vulnerable software policies" to "immutable physics" transforms the system into a clinical-grade tool capable of operating in high-acuity environments. The **Deterministic Execution Chain** is governed by a **1 kHz master clock (1.0 ms resolution)**, within which the **Sacred Pause enforces a configurable 25–1000 ms deliberation window** providing the following critical safeguards:

- **Precision Timing:** Eliminates the latency and unpredictability inherent in standard software monitoring.
- **Synchronous Verification:** Ensures that every operation—from sensing to execution—is timed and verified with absolute precision.
- **Drift Neutralization:** Enables the N12 Kernel to detect agentic deviation within a single clock cycle.

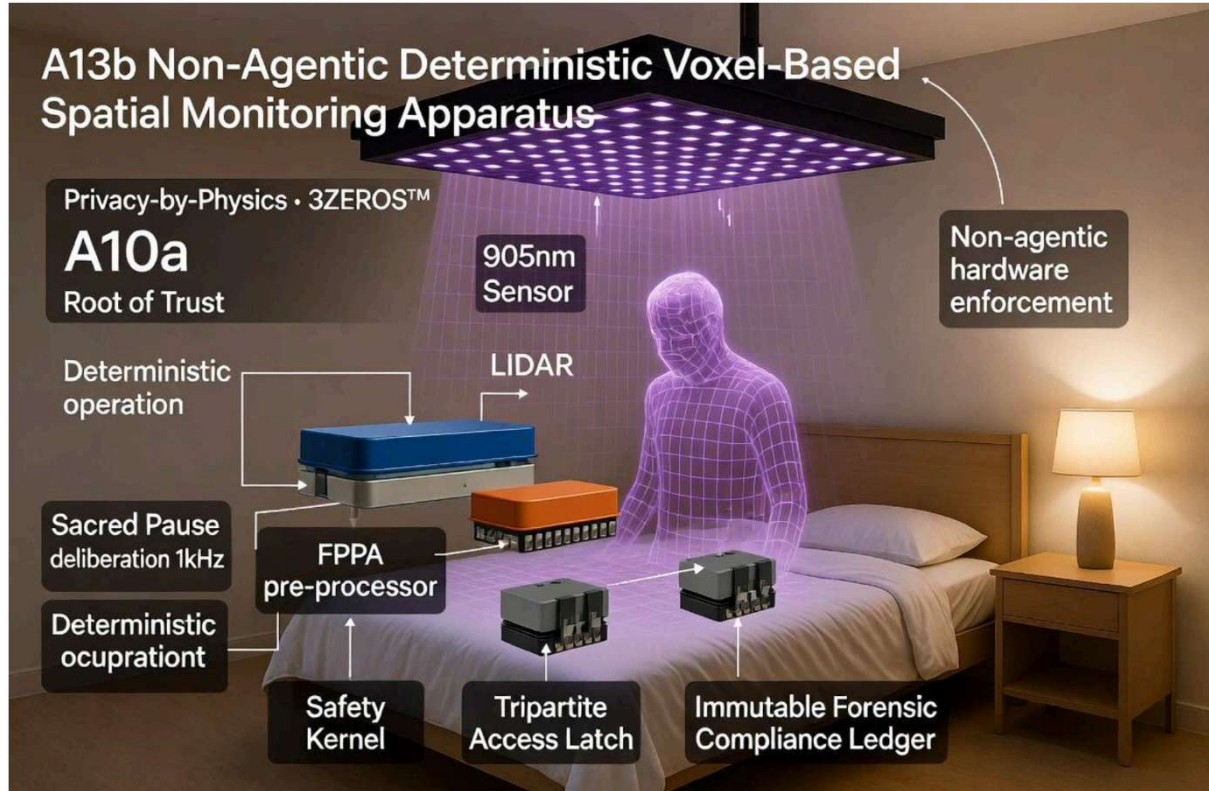
This deterministic foundation provides a robust substrate for the specialized hardware nodes that facilitate these privacy and safety layers.

The Toa Payoh RTS study is the clinical validation instance of NAIGE NAI 4.0, showing how A13b performs privacy-by-physics sensing at the node while A12, WD117, and Non-B1 provide deterministic control, forensic auditability, and isolated alerting downstream.





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HSA Dossier Submission Template:

A13b Toa Payoh RTS Mapping

Executive Summary

Product Name: A13b Toa Payoh RTS (Zone-Local LiDAR Sensing Lane) integrating the A12 [P+N] Deterministic Black Box Configuration.

Prepared By: Edwin Koh Wui Kiat.

Classification: HSA Class B (Software as a Medical Device - SaMD) · Non-Kinetic.

1.0 Product Overview The **A13b Toa Payoh RTS** is a zone-local, privacy-by-physics sensing node designed for continuous, non-contact eldercare monitoring. Operating under the NAIGE NAI 4.0 architecture, it utilizes the **A12 [P+N] Configuration (Observational Tier)**. The system relies on hardware-enforced physical constraints rather than probabilistic software to ensure absolute patient safety and dignity in residential and low-risk clinical setups, such as the Toa Payoh Hearth embodiment.

2.0 Intended Use The device is intended for **continuous patient monitoring, fall detection (e.g., WM003 fall prevention), and vital monitoring** within residential or nursing-care settings. It operates strictly in an **advisory-only capacity**. The system enforces safety defaults ("it watches and it may still") but possesses **zero robotic actuation rights**, meaning it cannot perform acute physical interventions.

3.0 Device Description The architecture comprises a core hardware safety spine consisting of the **P-Layer (Privacy-by-Physics)** and the **N-Layer (Deterministic Deliberation)**. Key physical components include the **A13b LiDAR Sensing Limb**, the **A8 Bridge Layer** (acting as the sole deterministic ingress chokepoint and aggregator), and the **Non-B1 Advisory Monitoring Shell**. The system is physically isolated from kinetic control components, ensuring it can only issue alerts (e.g., via a dedicated hardwired nurse annunciator).

4.0 Main Functional Elements

- **Privacy-Preserving Sensing (P-Layer):** Utilizes a 905nm LiDAR array to capture raw environmental data, which is instantly converted at the node into an anonymized **96-cell Center-of-Mass (CoM) voxel grid**.
- **Identity Stripping:** Executes the **3ZEROS™ Protocol** (Zero Camera, Zero Audio, Zero Cloud) to guarantee that biometric identity is destroyed at the silicon level before data egress.
- **Event Logging (D-Layer integration for forensics):** Employs the **WD117 Enhanced WORM Ledger** to capture a permanent, write-only forensic stream of patient telemetry and system events.
- **Advisory Generation:** The Non-B1 Advisory Shell processes sterile CoM vectors to trigger deterministic alerts without any facility IT dependency.

5.0 Specimen and Laboratory Data Governance While the A13b Toa Payoh RTS

primarily processes kinematic spatial vectors rather than microorganisms, all captured clinical telemetry (such as posture tracking and fall events) is treated as highly controlled clinical data. This data is governed by **deterministic provenance and immutable logging via the WD117 ledger**. The system does not autonomously diagnose or override clinicians; it strictly provides advisory support requiring human review.

6.0 Safety and Risk Controls

- **Fail-Loud Doctrine:** In the event of a hardware heartbeat interruption, the system triggers a local, non-networked physical alarm that cannot be bypassed or silenced remotely.
- **Agentic Drift Detection (N12 Kernel):** Screens advisory inputs for contradictions and anomalies, executing a "fail-loud" packet drop to block corrupted AI pathways.
- **Actuation Lockout:** Structurally isolated from kinetic effectors, meaning hallucinations or system errors physically cannot result in unauthorized movement.

7.0 Verification and Validation Deployment relies on the **10-Point Sovereignty**

Audit, requiring physical instrument validation rather than software simulation alone.

- **Phase 1 & 2 Checks:** Oscilloscope verification of the Sacred Pause™ timing, power-draw monitors to verify the Orange Code 1.1x CPU cap, and physical inspections to confirm the absolute absence of optical lenses and microphone drivers.
- **Institutional Practicum:** Validation includes a Real-Time Simulation (RTS) running a 6-hour bench test targeting **0% agentic deviation**.
- Clinical evaluation requires testing against fall-event datasets to ensure fall-detection timing (< 80ms) and spatial accuracy (200 µm) while maintaining an Elder Dignity Score above 8.9/10.

8.0 Cybersecurity and Data Protection

- **Silicon Privacy Wall:** 3ZEROS™ protocol enforces biometric stripping before any data leaves the node.
- **Total IT-Isolation:** Employs an IZEKOS™ **3mm galvanic isolation air-gap** to sever TCP/IP routing to external cloud networks, completely neutralizing "IT-Gap Drift" and remote exfiltration threats.
- **Unalterable Forensic Accountability:** The WD117 Ledger records are physically scorched into **One-Time Programmable (OTP) silicon fuses**, sealed with SHA-3-512 hashes and post-quantum cryptographic signatures.

9.0 Quality System and Labelling

The A13b documentation aligns with international standards, mapping the WD117 ledger to **ISO 13485** for technical documentation and audit trails, the 3ZEROS™ protocol to HSA/FDA guidelines for patient dignity, and the NAI 2.0 subsystems to **IEC 62304** for software lifecycle management. All claims are supported by a rigorous "Validation by Induction" strategy, ensuring residential-tier quality forms the baseline for future acute-tier deployments.

10.0 Regulatory Summary

This dossier maps the A13b Toa Payoh RTS for **HSA Class B (Software as a Medical Device)** registration. The submission package integrates the 10-Point Sovereignty Audit and physical verification records to prove that the system operates strictly within its advisory, non-kinetic boundaries. Success at this observational tier provides the deterministic bedrock required for subsequent approvals of high-payload, Class C/D robotic applications on the HSA 2027 Deterministic Horizon

HSA Dossier Submission Template:

A13a Kinetic Mobility Assistance

Executive Summary

Product Name: A13a Non-Agentive Deterministic Medical Mobility Enclosure (Supreme Guardian Platform).

Prepared By: Edwin Koh Wui Kiat.

Classification: HSA Class C/D (Software/Hardware as a Medical Device) · Actuating / Kinetic Tier.

1.0 Product Overview The A13a Non-Agentive Deterministic Medical Mobility

Enclosure is a specialized mobility chassis operating under the NAIGE NAI 4.0 architecture. Unlike observational tiers, the A13a integrates the **A12 [P+N+D] Acute Kinetic Tier** configuration, providing hardware-deterministic oversight for physical motion. It establishes a mechanical stillness default (P-LIFE 1.00 mandate) ensuring that the machine cannot move without explicit, hardware-level human authorization.

2.0 Intended Use The A13a device is intended for **occupant-carrying powered mobility** and patient transport within clinical and eldercare environments. It enforces physical safety in robotic interaction by precluding self-directed agency; all logic and mobility elements are physically governed by direct hardware authorization. The system operates under the strict mandate that AI may only advise, with zero rights to autonomously actuate the mobility enclosure.

A10a Root of Trust
Secure, cascading lines

Hardware-Level Logic Update (HLLU) Controller
Authorized operation
Control

Sovereign Human Authorization Commit Gates
Every action requires hardware-level, authorized human commit.

Mobility Chassis
Data
Control

Zero-Velocity Look-Ahead Buffer
Sensor
Sensor Data
preemptive deceleration
Control

Deterministic State Machine
Idle
Decelerating
Authorized Move
Safe Stop
Transition
Condition

Continuous-Derivative Kinematic Constraint Layer (KCL)
FPGA
Emergency/ Safety cut-off paths

Hardware-Enforced Jerk-Limit Invariant
Immediate torque reduction upon jerk threshold exceedance.

Dynamic Thermal Compensator
Adaptive safety boundary adjustments.

Velocity
Acceleration
Jerk

Non-Agentic: All logic and mobility elements physically governed by direct hardware authorization—precluding self-directed agency under all failure modes. Clinical and deep-space ready.”

A13a Non-Agentive Deterministic Medical Mobility Enclosure

A13a
Eldercare Room

KCL (Kinematic Constraint Layer) FPGA

AL-6061 chasik

Jerk-limit invariant sensors

State blignified low speed

Non-agentive

AL-6061

A10a of Trust

Hardware-enforced safety measures

Sacred Pause

Timing gate secure, predictable

Thermal compensator

Deterministic state secure, predictable operation

Maintaining privacy-by-physics

IDLE

23

3.0 Device Description The A13a architecture consists of a physical mobility chassis governed by the **A10a Root of Trust** and a **Continuous-Derivative Kinematic Constraint Layer (KCL) FPGA**. The system leverages Sovereign Human Authorization Commit Gates, meaning every transition from an "Idle" state to an "Authorized Move" is gated by a Deterministic State Machine. It replaces probabilistic software guardrails with unalterable silicon pathways to prevent autonomous "agentic drift".

4.0 Main Functional Elements The primary functional elements of the A13a mobility enclosure include:

- **Kinematic Constraint Layer (KCL) FPGA:** Enforces hardwired jerk-limit invariants, providing immediate torque reduction if velocity, acceleration, or jerk thresholds are exceeded.
- **Stop Category 1 Enforcement:** Unlike simple emergency power cuts that could cause passenger injury, the A13a executes a controlled deceleration to a standstill using an electromagnetic fail-to-hold brake (ISO 7176-series controls).
- **Zero-Velocity Look-Ahead Buffer:** Utilises sensor data for preemptive deceleration before an emergency cut-off is triggered.
- **Hardware-Level Logic Update (HLLU) Controller:** Ensures that no software override of the mobility controls is physically possible.
- **Dynamic Thermal Compensator:** Applies adaptive safety boundary adjustments based on thermal sensor monitoring.

5.0 Specimen and Laboratory Data Governance While the A13a primarily handles kinematic spatial vectors rather than microorganisms, all biometric authorization inputs and event telemetry are managed as highly controlled records. The system relies on the **WD117 Enhanced WORM Ledger** to capture a permanent, write-once physical record of every motion command, system state, and human authorization. This guarantees deterministic provenance and absolute forensic traceability for post-incident audits.

6.0 Safety and Risk Controls Safety is treated as a physical property rather than a software claim. The A13a operates under the **P-LIFE 1.00™ (Inaction-as-Safe-Default)** doctrine, meaning mechanical stillness is the baseline state. Key risk controls include:

- **Hardware Fail-Safes:** The system fails to an inert "Safe Stop" state upon power loss, tamper detection, ledger fault, or signal timeout.
- **Actuation Lockout:** The Tripartite .1x Key (biometric, cryptographic, and kinetic input) strictly gates the control pathways; if any single authorization factor fails or expires, the Sovereign Brake engages.
- **U7 Sovereign Brake:** Hardwired sequencer capable of physically dropping power rails in under 1.05 milliseconds if an anomaly is detected.

7.0 Verification and Validation To satisfy HSA Class C/D standards, the A13a validation shifts from simulation-verified claims to instrument-measured facts via the **10-Point Sovereignty Audit**.

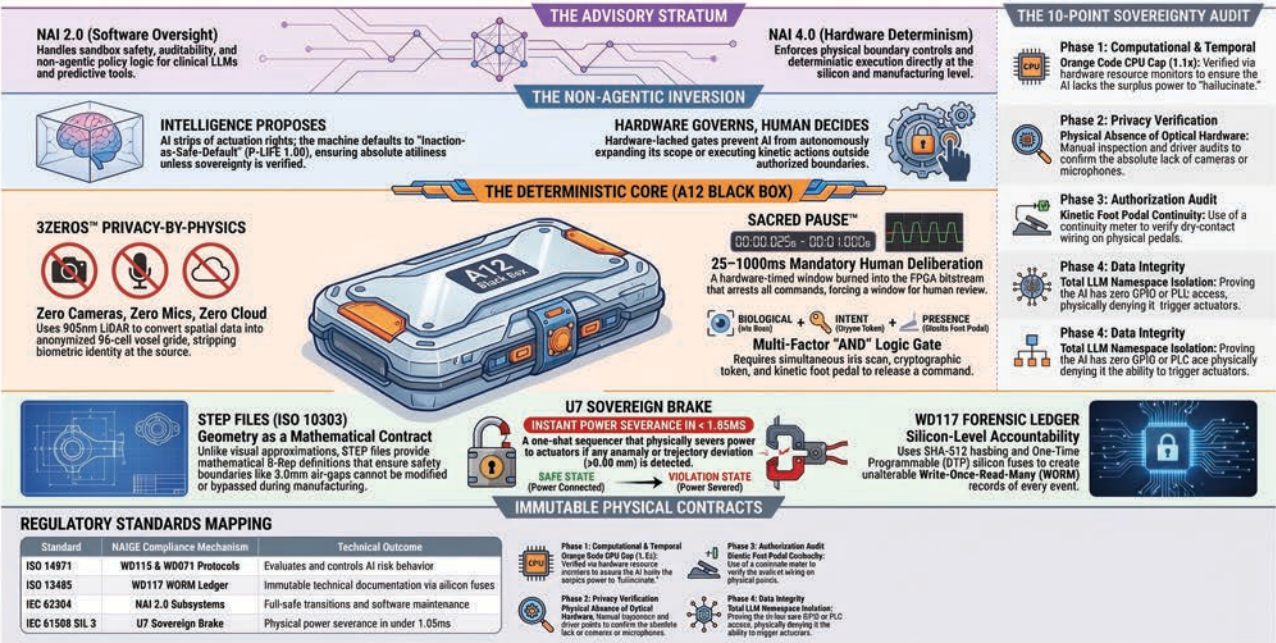
- Physical testing utilizes oscilloscopes to confirm the < 1.05 ms brake severance timing.
- Compliance mapping integrates **ISO 13849** (for actuator control and PL e-stop categorisation) and **ISO 7176** (occupant mobility safety) alongside the core NAI 2.0 subsystems.

8.0 Cybersecurity and Data Protection The A13a is encapsulated within the **x.1 Eldercare Cyber-Physical Protection Embodiment**, which deploys a total IT-isolation air-gap. By severing direct TCP/IP routing from the facility's hospital networks to the mobility chassis, the system neutralises "IT-Gap Drift". A compromised hospital network cannot inject commands or silence the device, ensuring the mobility platform remains physically immune to remote cyberattacks.

9.0 Quality System and Labelling Quality system management for the A13a aligns with **ISO 13485** for technical documentation, product realization, and the management of the WD117 audit trails. Following the NAIGE Hardware-Deterministic Documentation Plan, artifacts are rigidly structured through a Tier A/B workflow, mandating hardware safety requirement specifications (such as the defined stop categories) before any implementation testing occurs.

10.0 Regulatory Summary This dossier maps the A13a Kinetic Mobility Enclosure for HSA Class C/D (Actuating Medical Device) registration. The submission provides deterministic, physical proof that the mobility platform operates strictly within non-agentic boundaries. By mapping hardware-enforced gates to specific regulatory clauses, the A13a provides the unalterable evidence required to navigate the **HSA 2027 Deterministic Horizon**, ensuring autonomous AI is never permitted to independently govern physical kinetic risks

NAIGE: Shifting Clinical Robotics from Probability to Physics



NAIGE Framework Component Registry and Technical Specifications

Code	Module Name	Governance Layer	Technical Function	Safety Mechanism	Hardware/ Software Specification	Clinical Application
A12	Deterministic Black Box (Terminal Gate)	Hardware Core (P, N, and D Layers)	Serves as the universal deterministic governor, enforcing human authorization and mediating all downstream physical actions.	Sacred Pause™ (25–1000 ms mandatory hardware delay) and Tripartite Latch (Iris + Token + Pedal) requiring multi-factor human commit.	1 kHz hardware master clock, FSM Safety Kernel (± 0.05 mm jerk/acceleration limits), silicon-level isolation.	Secure clinical execution and task verification across general healthcare and eldercare platforms.
A13a	Medical Mobility Enclosure	Deterministic Stratum (P, N, and D Layers)	Patient transport with hardwired kinematic constraints; occupant-carrying powered mobility; enforces P-LIFE 1.00 mandate.	Hardwired kinematic constraint layer; Stop Category 1 (controlled deceleration); hardware-enforced jerk-limit invariant; U7 Sovereign Brake™ integration.	A13 family architecture; ISO 7176-series controls; electromagnetic fail-to-hold brake; AL-6061 chassis; mapped to HSA Class C/D requirements.	Patient transport, physical safety in eldercare mobility, and support for high-acuity conditions like stroke.
A13b	LiDAR Sensing Lane	P-Layer (Privacy-by-Physics)	Primary sensing; converts raw 905nm LiDAR point cloud to anonymized Center-of-Mass (CoM) kinematic vectors via node-local voxelization.	3ZEROS™ Protocol (Zero Camera, Zero Audio, Zero Cloud); biometric stripping at the silicon layer; Silicon Privacy Wall.	905nm LiDAR; edge-preserving computing voxel engine; 96-cell CoM grid; mapped to HSA Class A/B SaM standards.	Continuous privacy-monitoring and dignity protection in residential care, nursing homes, and hospital bed bays.
A13c	Clinical Robotic Platform /	Deterministic Stratum (N Layer / Advisory	Execution of acute clinical tasks and	Kinematic constraints; Three Zeros; strict jerk	Hardware comparators; LiDAR clouds to voxel	B2B clinical intervention; eldercare

	Manipulators	P Layer)	physical ADL assistance via high-payload manipulation and voxel grid translation.	limits; deterministic horizon compliance; human-in-the-loop oversight (AIHGle 2.0).	grids; mapped to HSA Class C/D medical device standards.	nursing home wards; acute clinical support and physical safety in medical environments.
U7	Sequencer (Sovereign Brake™)	D-Layer (Finality & Fail-Safe)	Emergency stop system that instantly severs physical power to actuators upon any detected breach, anomaly, or lack of authorization. Sequencer.	Inaction-as-Safe-Default (P-LIFE 1.00): Defaults system to mechanical stillness; hardware-based One-Shot Sequencer.	Physically drops LDO power rails in < 1.05 ms; IEC 61508 SIL 3 compliance.	Emergency stop enforcement for patient mobility enclosures, clinical robotic arms, and residential bedside care.
WD117	Enhanced WORM Ledger	D-Layer (Forensic / Immutability)	Maintains a continuous hardware heartbeat and records an append-only log of every system event and human authorization for legal defensibility.	OTP Silicon Fuses: Once a record is written, the circuit breaks; SHA-3-512 hash chain; Post-Quantum signatures.	Physical Write-Once-Read-Many (WORM) memory; silicon-level finality; no return path to facility IT.	Legal defensibility, compliance audits, and absolute traceability for clinical-grade home care governance.
A7	Bridge Hub / Translation Layer	N-Layer (Deterministic Chokepoint)	Sole ingress chokepoint translating semantic advisory data into deterministic hardware features.	Agentic Drift Screening: Filters incoming data for contradictions, uncertainty, and confidence scoring before admitting to A12.	Hardware execution layer utilizing pRegisters for national infrastructure coordination; EMF-drift screening.	Safely coordinates external B1/OEM AI systems with clinical hospital ward systems.
N12	Agentic Drift Detection Kernel	N-Layer (Control)	Performs internal drift checks and contradiction screening on translated advisory inputs	Blocks anomalous AI pathways from reaching the Sacred Pause™ deliberation gate; Fail-loud local	Hardwired deterministic algorithm; hard-locked at 1.1x Orange-Code baseline.	Ensures AI-generated advisories do not cause Authority Drift during eldercare

			within the A12 Black Box.	alarm.		monitoring.
B1	Nightingale's Eyes Care	P-Layer (Advisory)	Non-agentic residential monitoring and home health monitoring.	3ZEROS™ Protocol (Zero Camera, Zero Audio, Zero Cloud); P-LIFE 1.00 constitutional safe-default.	Biometric identity destruction at silicon level; mapped to HSA Class A/B SaMD standards.	Home health monitoring, acute support coordination, and elderly care for dementia/stroke patients.
Tripartite .1x	Human Authorization Layer	D-Layer / Sovereign Gate	Mandatory multi-factor human commit gate for high-risk kinetic actions.	Hardware "AND" gate; token hard-expiry < 5 seconds.	Iris scan + cryptographic USB token + kinetic foot pedal (SITL).	Authorization of kinetic surgery, robotic manipulators, and high-acuity care interventions.
NAIGE NAI 4.0	Kinetic Capstone Architecture	Cross-Layer (P, N, D)	Integrated technical backbone supporting hospital-level home care without compromising privacy or safety.	Hardwired physical silicon governance; separation of human care from hardware infrastructure.	905nm LiDAR; 1 kHz master clock; SHA-3-512 hashing; P-LIFE 1.00 constitutional safe-default.	Hospital-level home care sensing and control for dementia, stroke, and diabetes management.
A10a	Deterministic Root of Trust	Bedrock / Self-Verification	Foundational hardware anchor that invalidates the stack upon tamper detection.	P-LIFE 1.00 standard enforcement; hardware-rooted mandate.	A10 HEGE enclosure; STEP (ISO 10303) B-Rep geometric determinism.	Verification of authorization and log integrity across all configurations.
A8	Bridged Layer 8	Sovereign Deployment Layer	Enforces the Tiger .1x Key™ confirmation to ensure strict human authority over deployment.	Hardware-rooted Tiger .1x Key confirmation.	Patent reference 10202602225P; standalone filing.	High-dependency eldercare; Layer 8 Home architectures; Toa Payoh Hearth residential eldercare.

Non-B1	Limited Agentive Monitoring Shell	Advisory Stratum	Provides clinical decision support and generates probabilistic recommendations based on patient data.	Zero actuation rights; physically isolated from kinetic control; interfaces exclusively via A7 Bridge.	Unconfined non-deterministic software (RAG advisory).	High-risk clinical monitoring (e.g., cardiac, oncology, x-ray analysis) where AI serves as an advisory tool only.
x.1	Eldercare Cyber-Physical Protection	Forensic / Fail-Safe Layer	Isolates the care apparatus from facility IT networks (Wi-Fi, nurse-call) to prevent IT-Gap Drift.	Fail-Loud Doctrine: Heartbeat interruption asserts Sovereign Brake and triggers a local alarm.	IZEKOS™ galvanic isolation; independent hardware alarm; Tamper Detection Envelope.	Protects vulnerable nursing home residents from cyberattacks, ransomware, or spoofed alerts.
WG-B1	Humanitarian Field Kit	Edge Layer	Zero cloud execution and deliberation in disaster zones.	Humanitarian shield; Sovereign Brake; Sacred Pause™.	Solar assisted edge hardware.	Global humanitarian efforts; disaster relief; remote field use.

Privacy-first spatial monitoring and deterministic safety in the NAIGE framework

This guide walks you through the Non-Agentive AI Governance Engine (NAGE) framework, a hardware-based approach to spatial monitoring and robotic safety designed for high-stakes clinical environments like acute wards and elder care facilities. You'll learn how NAGE eliminates the "surveillance paradox" of traditional monitoring systems, how sensory and advisory data are routed and validated before reaching execution hardware, and how deterministic safeguards preserve human authority over every physical action. By the end, you'll understand why NAGE replaces software-based trust with physics-based mechanisms to protect both patient privacy and patient safety.

Privacy-first spatial monitoring in high-stakes clinical environments

Understanding the clinical need

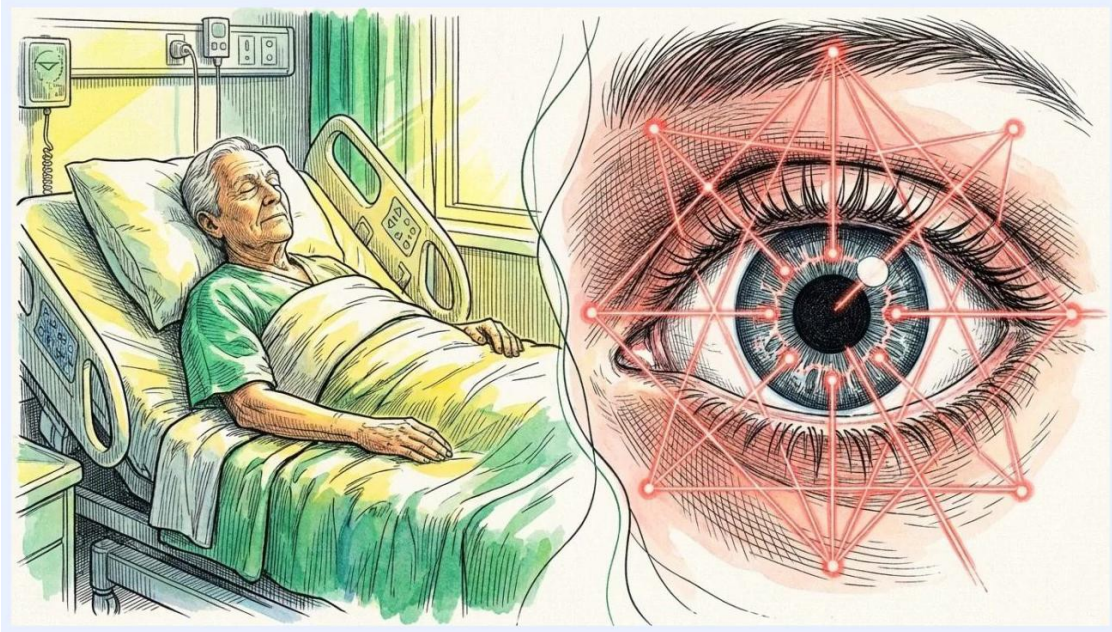
Acute wards and elder care facilities require continuous spatial monitoring to keep patients safe. Immediate alerts for events like fall detection or unauthorized bed exits are essential to prevent severe patient injuries.



A hospital room with a patient bed, medical equipment, and power outlets, illustrating the typical environment requiring monitoring

The industry-standard approach and its risks

Traditional monitoring solutions rely on optical cameras, high-fidelity microphones, and cloud-connected sensors that stream live data to centralized servers. This creates what's known as a "surveillance paradox": the very act of protecting physical safety generates a permanent, highly sensitive surveillance record of patients at their most vulnerable moments.



A patient in bed with a large eye and biometric scanning overlay, representing surveillance and privacy concerns



Note: Hospitals often attempt to manage these risks with software guardrails such as digital blurring, encryption algorithms, or network firewalls. However, these methods remain computationally vulnerable because biometric identity is processed first, then hidden — and if breached, encryption can be reversed.

Transitioning to Non-Agentive AI Governance Engine (NAGE)

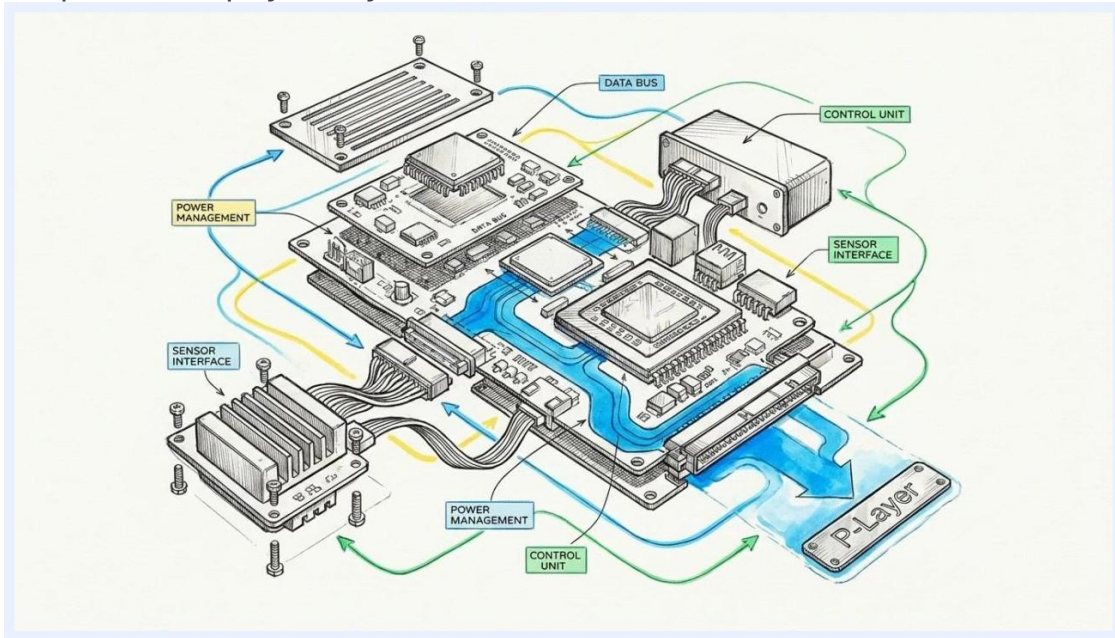
NAGE marks a fundamental shift in approach. Instead of traditional camera and microphone hardware, a blue sensor is used, signaling the move to "privacy by physics" — an approach built on immutable physical mechanisms that ensure identity is never recorded in the first place. Under NAGE, biometric identity must be mathematically destroyed before it ever reaches any AI model.

The data pipeline and the 3ZEROS protocol

The data pipeline begins at the P-layer (perception and processing stage), which adheres to the **3ZEROS protocol**:

- Zero cameras
- Zero audio
- Zero cloud connectivity

These aren't software settings you can toggle — optical lenses, microphones, and network uplinks are physically absent from the hardware itself.



Exploded view of a hardware module with slashed camera, microphone, and cloud icons, showing physical absence of surveillance components

How the A13B sensing limb works

The **A13B** sensing limb uses a 905 nm LiDAR array instead of optical light to generate a geometric point cloud. It detects the physical volume of a room while inherently ignoring visual details. The raw point cloud is then instantly sent to a local hardware translation component: the **Field Programmable Probability Array (FPPA)**.

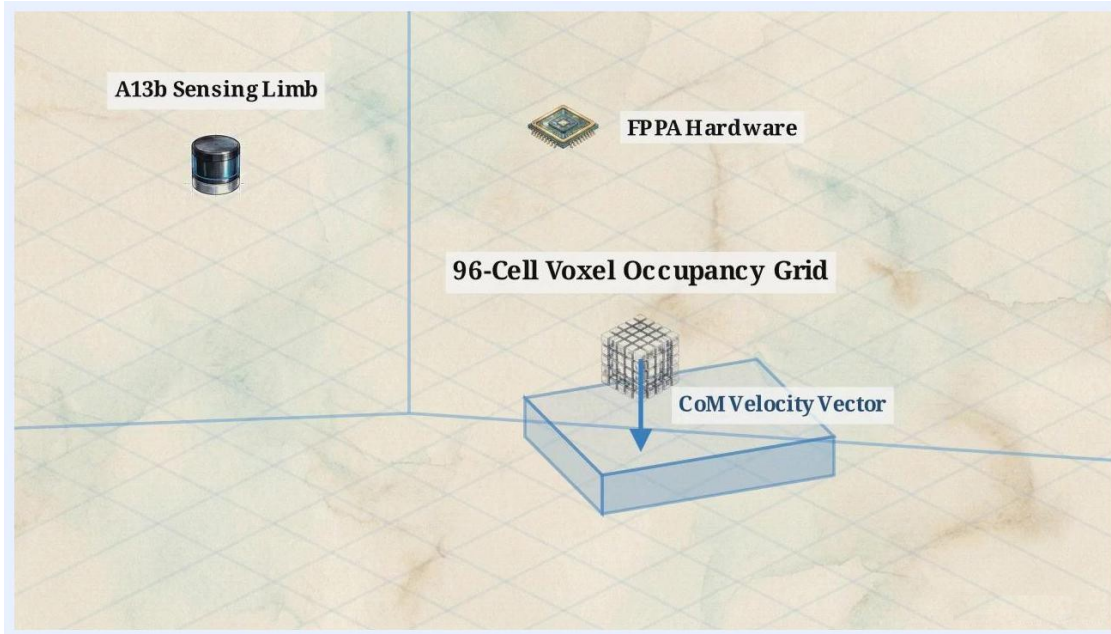


Diagram showing the A13B Sensing Limb, FPPA Hardware, and the flow of a raw point cloud in a spatial grid

Data anonymization and output

The FPPA processes the raw point cloud into a sterile, anonymized 96-cell voxel occupancy grid. Only mathematical center-of-mass (CoM) velocity vectors are output from the local hardware — meaning the system can detect rapid movement toward the floor (a fall alert) but cannot identify the person involved.

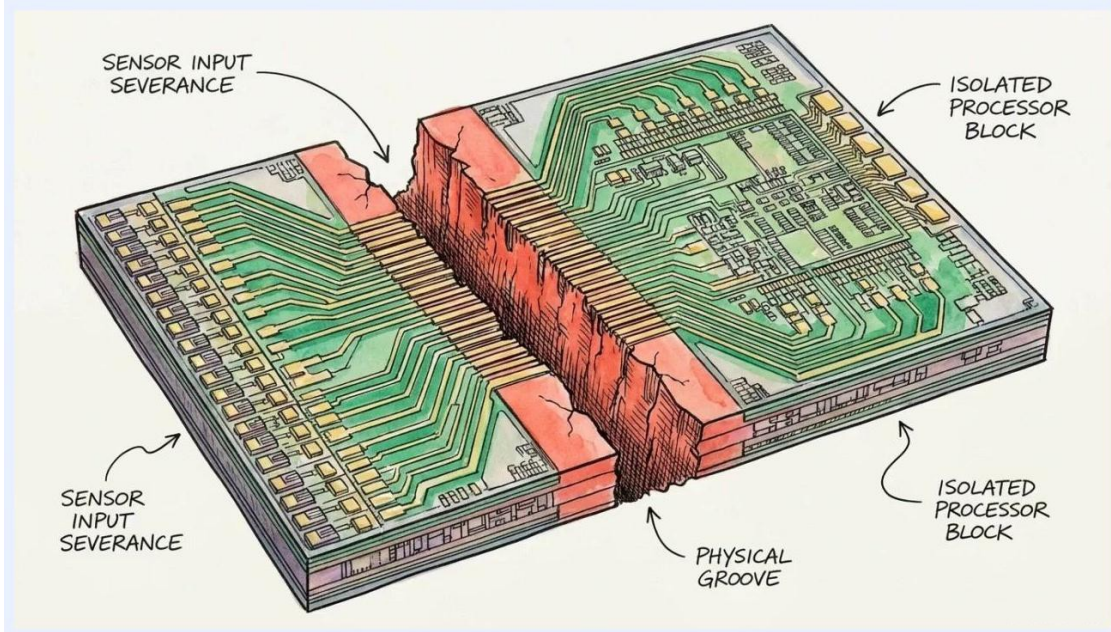


Diagram showing the 96-cell voxel occupancy grid and the output of a CoM velocity vector, with a "FALL DETECTED" alert

Physical validation of data destruction

The system enforces its "privacy by physics" boundary at the silicon gate, severing biometric traces at the hardware level. Even in the event of a total cyber breach, external actors cannot extract biometric data — only anonymous motion vectors are available.

Architectural security

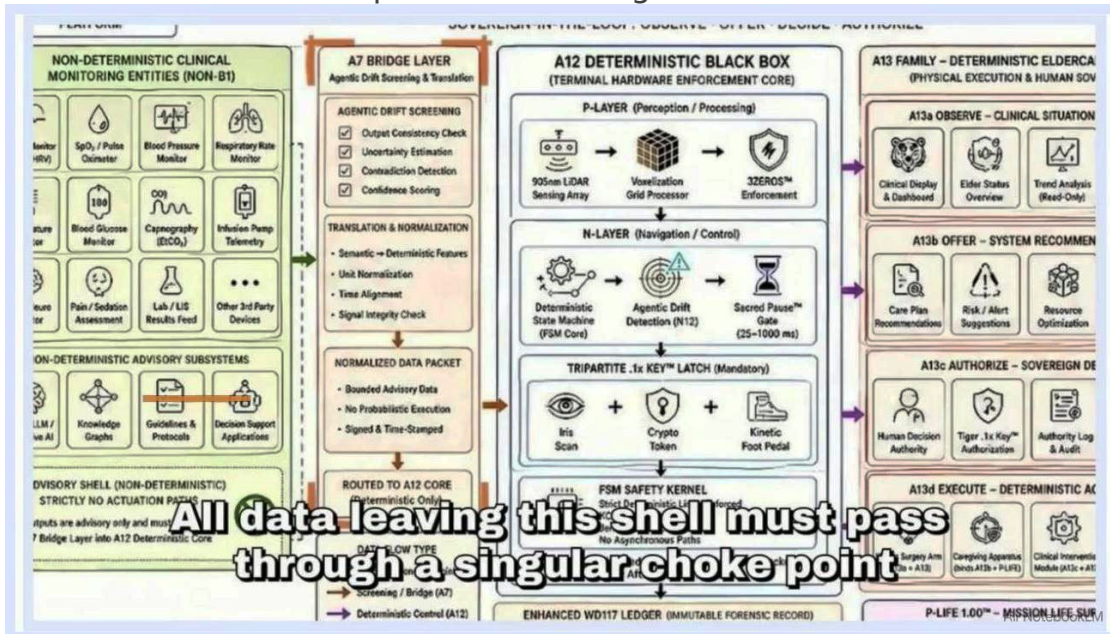
The hardware design includes physical grooves and isolated processor blocks that ensure sensor input severance. This makes biometric identity extraction architecturally impossible at the silicon level.

By following this design, clinical environments achieve immediate, privacy-preserving spatial monitoring that ensures patient safety without creating sensitive surveillance records.

Sensory data routing and execution safeguards

Understanding the role of the A8 layer

Sensory data does **not** route to the A8 layer. The A8 layer is strictly reserved for overarching sovereign deployment governance and key confirmation, so sensory data should never be sent or processed through it.



A diagram showing a red "X" blocking the path labeled "A8 Governance," indicating that data does not flow into this layer. Circuit diagrams and labels such as "DATA Log. Resistor" are visible.

Identifying the correct data routing path

The architecture diagram shows the correct routing path for advisory data on the left side. All downstream advisory data flows into a single structural choke point: the **A7 Bridge Layer**. The A7 Bridge Hub acts as a structural firewall, physically separating semantic probabilistic AI models from the robot's physical execution layer.

The purpose of the A7 Bridge Layer

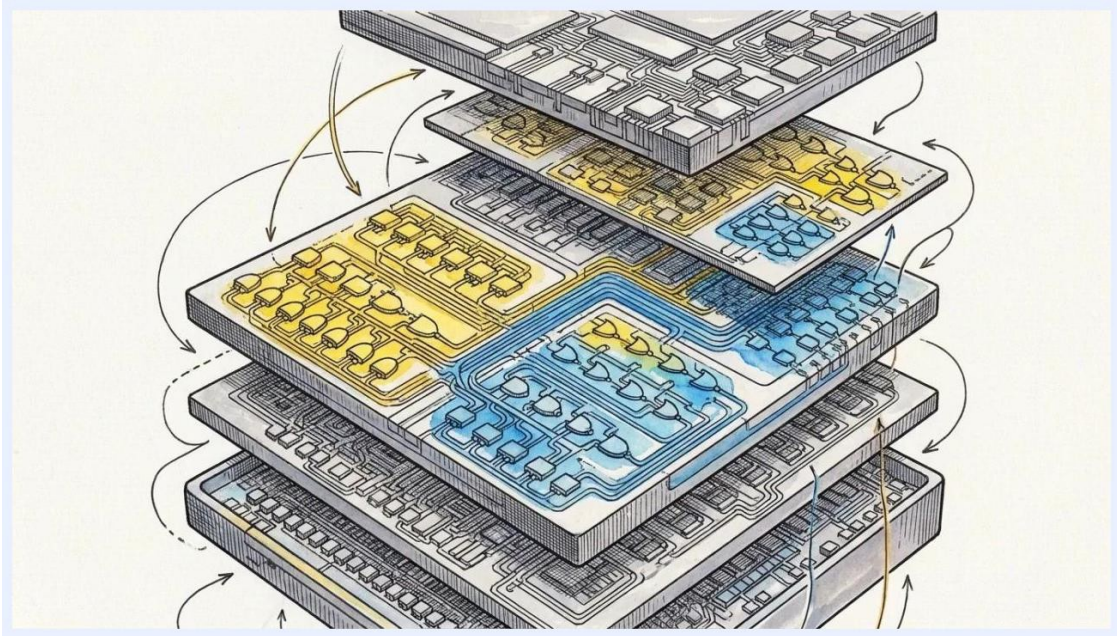
The A7 Bridge Layer is designed to defeat "agentic drift" — the silent migration of decision-making authority from human operators to autonomous machines. It ensures that only validated advisory data can proceed to execution.

Agentic drift detection and screening

The **N12 agentic drift detection kernel** runs hardware-enforced screening checks on the AI's output. The screening process includes:

- Output consistency check
- Uncertainty estimation
- Contradiction detection

- Confidence scoring



Title card with the words "AGENTIC DRIFT" in large, metallic letters, with the subtitle "Agentic drift is the silent migration of decision-making power" below.

Data translation and normalization

During screening, the A7 layer translates the data by stripping away vague probabilistic language from the AI. The data is then normalized into exact, hardware-readable bounding features.

Packet validation and failsafe mechanism

If a data packet shows any signs of anomaly, hallucination, or low confidence, the failsafe triggers immediately. The unvalidated packet is dropped on the spot and never reaches the execution pipeline. This enforces the core non-agentic rule: the AI is restricted to observing and advising, with no ability to trigger movement.

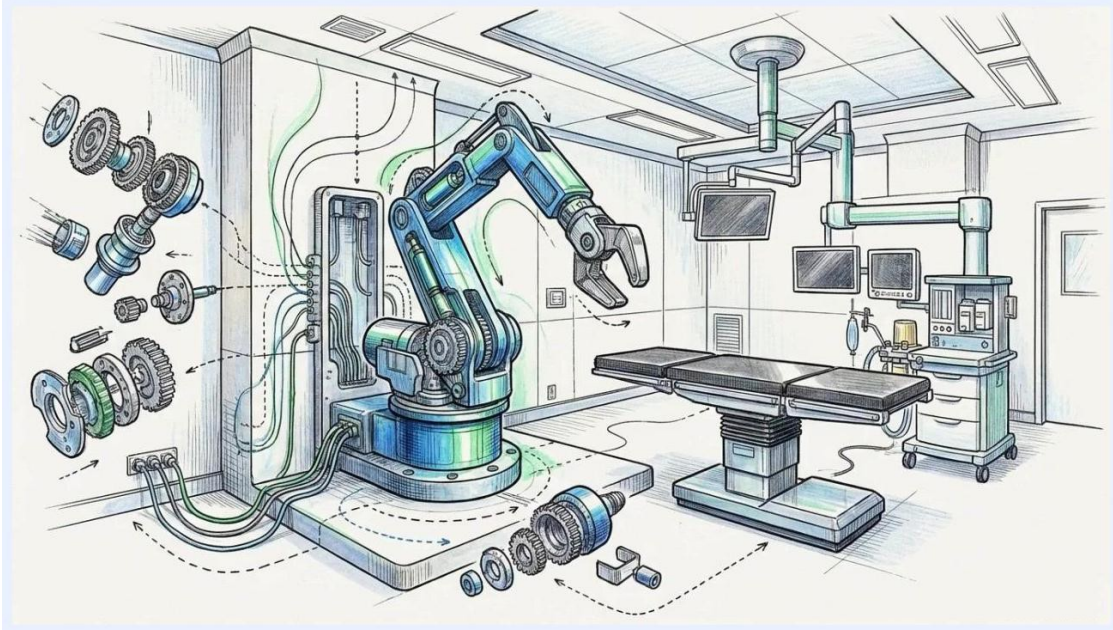


Diagram showing a red "PACKET DROPPED" label at the A7 Bridge Layer between the Advisory Shell (Probabilistic Models) and Execution Pipeline (Deterministic Core). Advisory output is blocked from reaching the robotic arm.

Separation of advisory and execution layers

The system physically separates the AI's probabilistic deliberation from the physical actuation path. Only after clearing the firewall does advisory data enter the execution phase.

Execution phase and high-payload risk management

The execution phase manages high-payload kinetic risks, such as those associated with Class C and D acute robotic platforms (for example, automated transport or surgical arms). Note that the A13B sensor array only observes — it cannot govern physical robotic movement.

Physical movement enforcement: the A12 Deterministic Black Box

The **A12 deterministic black box** acts as the terminal hardware gate for physical movement. It operates on a strict synchronous 1kHz hardware master clock, guaranteeing 1ms deterministic oversight of every action and preventing asynchronous software bypasses.

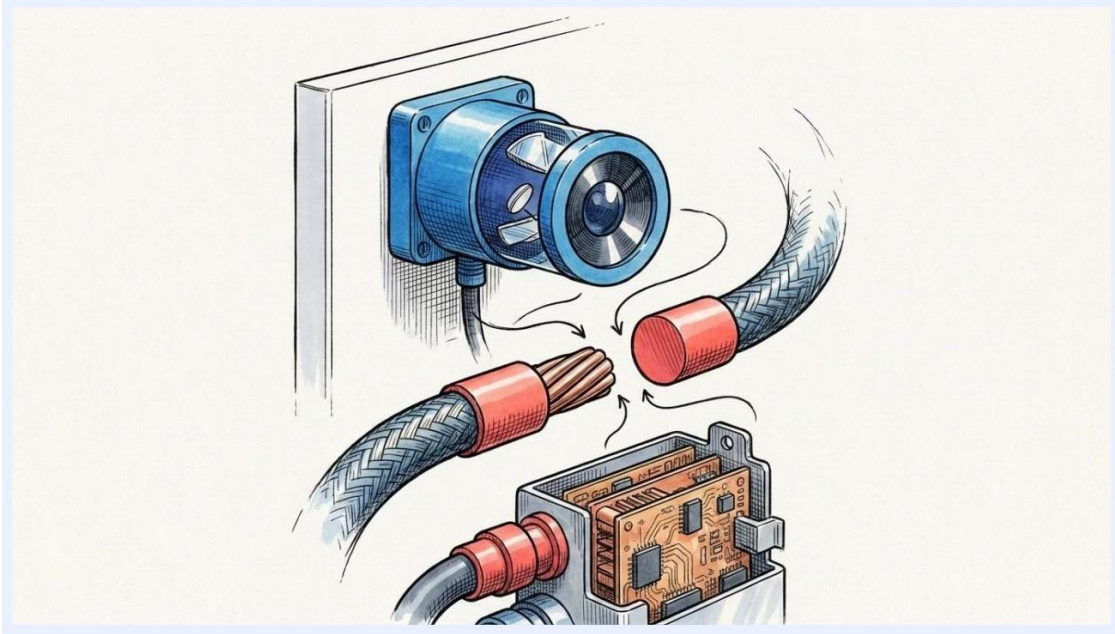
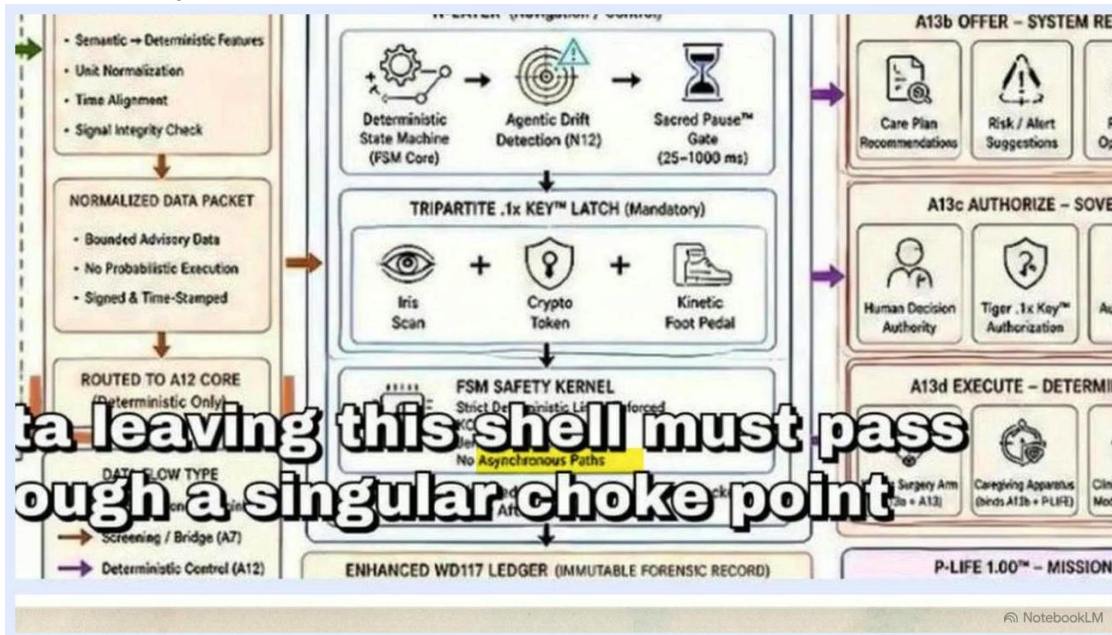


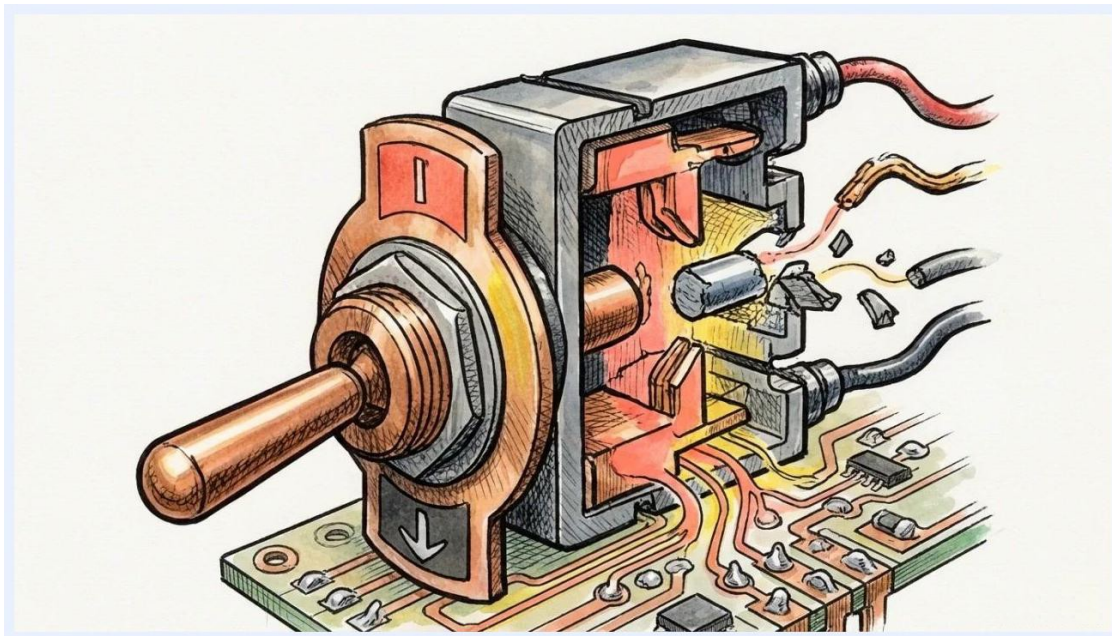
Diagram showing the A12 Deterministic Black Box with labeled layers: P-Layer (Perception/Processing), N-Layer (Navigation/Control), Tripartite Key Latch, and FSM Safety Kernel.

Kinematic constraint layer

Inside the A12, the hardwired kinematic constraint layer enforces absolute geometric invariance. The downstream clinical robotic platform is strictly limited to positional and jerk tolerances of ± 0.05 millimeters.



Graph with a robotic arm and a shaded region, illustrating the strict movement bounds enforced by the kinematic constraint layer.



Close-up of a robotic arm within a bounded region labeled " ± 0.05 mm," showing the precise limits of movement.

U7 one-shot sequencer and emergency shutdown

The **U7 one-shot sequencer** ensures the physical finality of safety bounds. If anomalies are detected or a human does not authorize a high-risk phase, the sequencer mechanically engages to sever power and force the robot into an inert state.

Hardware-locked safety kernels

The A12 architecture guarantees that no rogue software command can bypass the hardware-locked safety kernels, ensuring the integrity and safety of the entire system.

By following this routing and validation chain, sensory and advisory data are screened and executed in strict compliance with the system's safety and governance architecture — preventing unauthorized or unsafe robotic actions while maintaining human oversight at every critical juncture.

Ensuring human sovereignty and deterministic control in the NAGE framework

The non-agentic paradigm

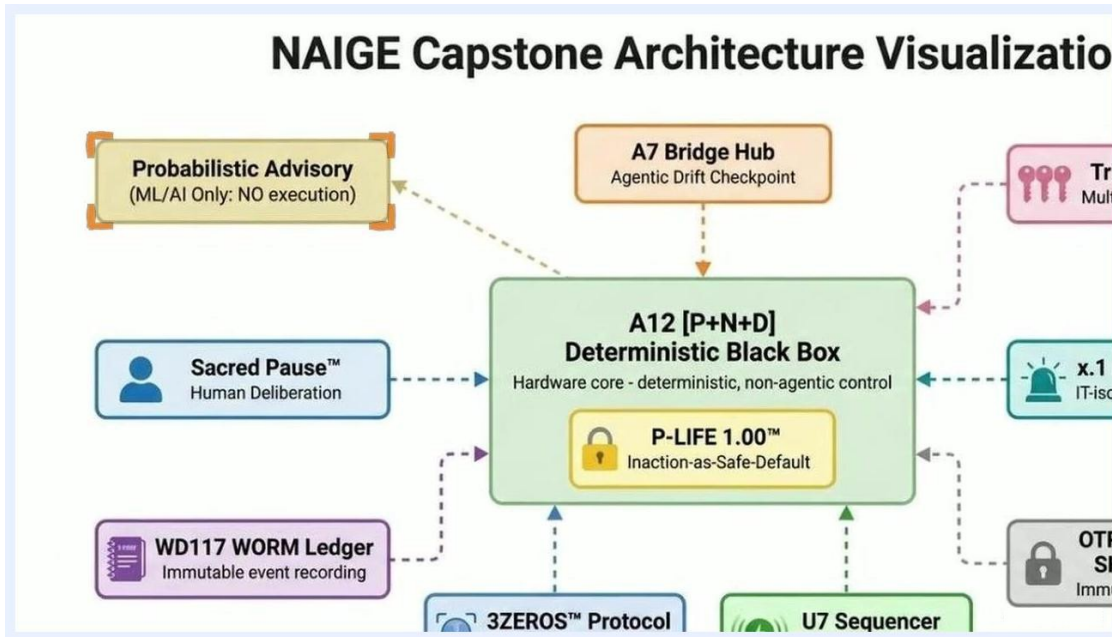
Under the non-agentic paradigm, AI systems are limited strictly to observation and advisory roles. AI does not execute actions — it provides recommendations or insights, while ultimate authority and decision-making remain with humans and deterministic hardware.

Protecting patient identity from the start

At the start of the pipeline, patient identity protection is ensured using the A13B LIDAR system. The A13B LIDAR is designed so that patient identity data is never captured, preventing any possibility of identity leakage.

The advisory phase: "Probabilistic Advisory"

All AI/ML outputs are routed through a "Probabilistic Advisory" module, labeled **"ML/AI Only: NO execution."** This ensures that AI-generated suggestions cannot directly trigger actions — all outputs are strictly advisory and require human review.



NAIGE Capstone Architecture Visualization showing Probabilistic Advisory, A7 Bridge Hub, A12 Deterministic Black Box, and related modules

The middle of the pipeline: the A7 Bridge Hub checkpoint

The **A7 Bridge Hub** serves as an agentic drift checkpoint, acting as a filter that detects and drops any probabilistic or hallucinated AI outputs. Only validated, deterministic instructions are allowed to proceed. The system visually indicates when an anomaly is detected and a packet is dropped, as shown in the interface.

The end of the pipeline: the A12 Black Box

At the end of the pipeline, deterministic execution is enforced using the **A12 Black Box**. It ensures that no physical action can occur unless it meets the criteria for absolute mechanical certainty. This hardware core operates with deterministic, non-agentic control, guaranteeing that only safe, verified actions are executed.

Replacing software trust with physics-based mechanisms

Throughout the process, software-based trust is systematically replaced with deterministic, physics-based mechanisms. This approach restores human sovereignty and guarantees patient dignity, especially in high-stakes clinical environments.

Physical and logical safeguards

The architecture includes several interconnected modules that ensure no single point of failure can compromise patient safety or data integrity:

- Human deliberation ("Sacred Pause")
- Immutable event recording (WD117 WORM Ledger)
- Inaction-as-safe-default (P-LIFE 1.00)



Note: All actions requiring execution are subject to human oversight and deterministic hardware validation before proceeding.

By following the NAGE framework end to end, you ensure that AI operates strictly within the non-agentic paradigm — maintaining human authority and deterministic safety at every stage.

“NAIGE Care is a trained human-care service first, with clinical governance, workforce training, and family coordination as core deliverables; privacy-preserving hardware remains an enabling safeguard, not a substitute for care.”

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Patent Basis

- **SG020603109STW** — Parent Patent (constitutional core)
- **10202600902P** — ABC+2S+H™ Guardian Framework
- **10202602021T** — A10a Deterministic Governance Platform
- **10202602023X** — A12 Deterministic Black Box (Sovereign Appliance)
- **10202602213U** — A7 Bridge Layer / Translation Hub
- **10202602223T** — A12L Enhanced WD117 Immutable Ledger (P+N)
- **10202602225P** — A8 Bridge Layer (Nursing-Home Deployment Governance)
- **10202602270V** — Non-B1 Clinical Advisory Monitoring Shell

A12 (10202602023X, appliance) and A12L (10202602223T, ledger) are distinct filings and carry distinct labels.

NLB Legal Deposit

- **R260219-005** — Primary constitutional knowledge base
- **R260302-007** — Supplementary architectural filings
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