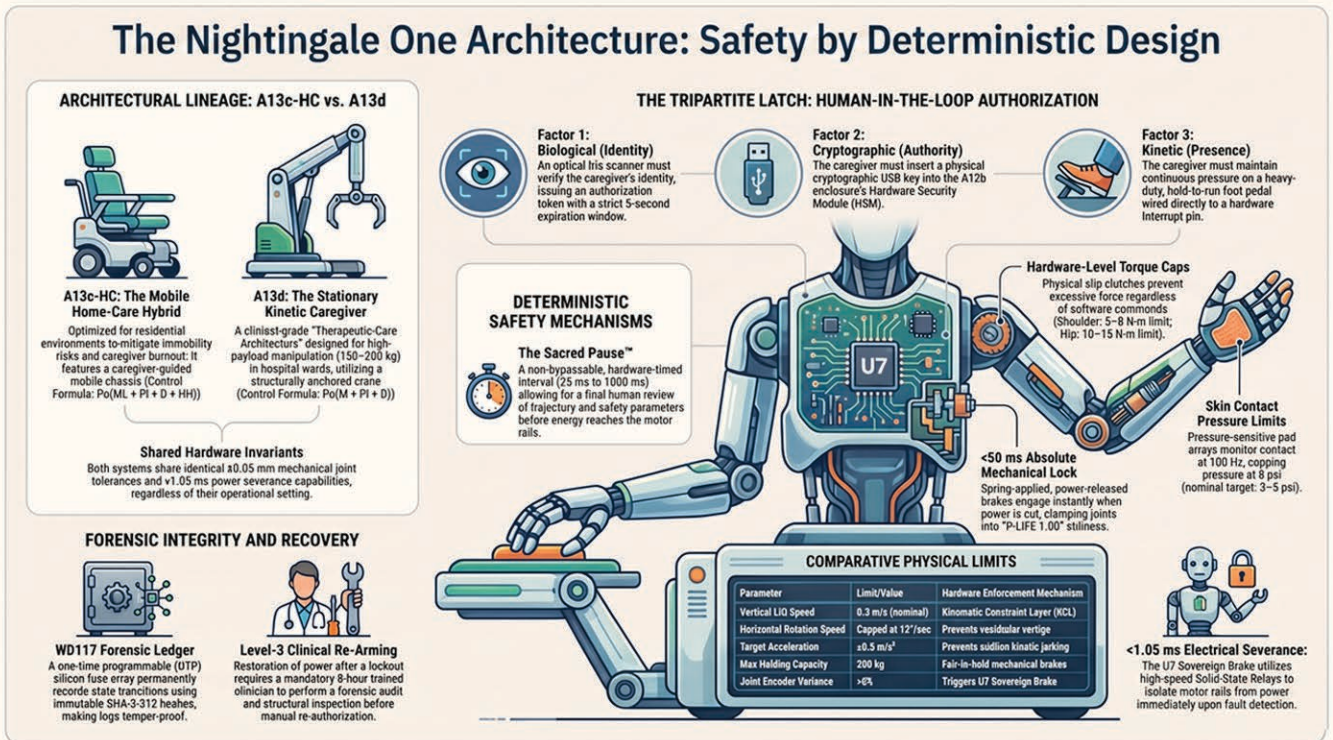


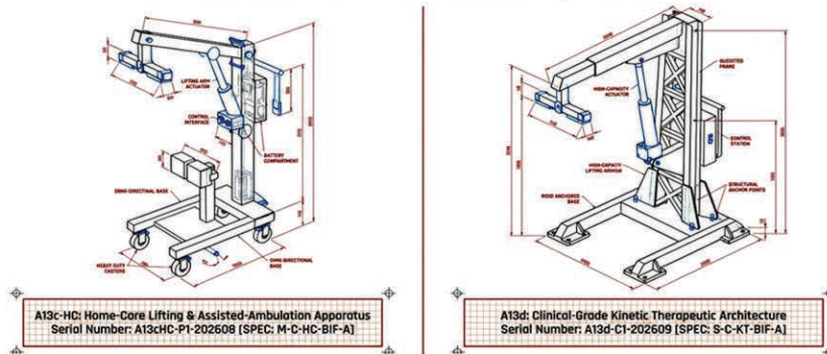
Immutable Hardware-Enforced Non-Agentive AI Governance Engine [NAIGE] Governance Systems – Hardware-Enforced Nightingale One Protocol™ P. Robotic Care for High-Dependency Eldercare : A13c-HC Kinetic Caregiver Safety and Governance Framework

Research Foundation Nightingale Anchor Protocol (NAP 4.0)



The Nightingale One Architectural Bifurcation

Technical Differentiation of Deterministic Safety Branches



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Immutable— Hardware-Enforced Non-Agentive 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-Agentive Policy Control Logic

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A12 [P+N+D] Deterministic Black Box · HSA Deterministic Horizon · Capstone A10a Root of Trust
WD117 Ledger · U7 Sovereign Brake · Sovereign-in-the-Loop
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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.

Preface:

Singapore's healthcare sector, highlighting the nation's unique position as a global leader in digital health governance. It outlines how recent legislative milestones, such as the Health Information Bill and updated clinical guidelines, are creating a robust framework for integrating advanced technology into patient care. The author identifies critical infrastructure and regulatory hurdles that must be overcome to fully utilise predictive models embedded in electronic medical records. To address these challenges, the article suggests focusing on practical applications like population health management and AI-assisted care for the elderly. Ultimately, the source emphasises that success depends on strengthening internal governance and ensuring frontline medical staff are adequately trained to work alongside these new tools. This overview serves as a roadmap for health providers to transition from technological potential to meaningful clinical impact

The deployment of health products and software in Singapore hospitals and home care settings requires strict compliance with Health Sciences Authority (HSA) regulations. This includes medical device registration, software-as-a-medical-device (SaMD) standards, and alignment with the Ministry of Health's Healthcare Services Act (HCSA) frameworks for virtual wards and home care.

Regulatory Compliance and Approval Medical Device Standards: Hardware and connected tools used in home care (like vital sign monitors) must clear HSA evaluation or utilize dedicated regulatory sandboxes.

Software & AI Deployment: Clinical decision support and AI-driven home monitoring platforms must adhere to updated HSA guidelines or leverage expedited exemptions for low-to-moderate risk tools in institutional pilots.

Hospital-at-Home (HaH) Operational Models Multidisciplinary Teams: Care delivery relies on integrated teams of doctors, nurses, and community paramedics spanning both physical facilities and virtual touchpoints.

Remote Patient Monitoring (RPM): Secure tablets, wireless blood pressure cuffs, and oximeters are deployed to patient residences to replicate inpatient ward observation levels.

Patient Selection: Care teams evaluate the home environment, family support, and clinical stability before shifting acute or post-acute care out of traditional hospital beds

Background of AI Eldercare Research

Singapore's regulatory and governance framework is evolving rapidly to bridge the gap between technical AI availability and real-world clinical deployment through several key initiatives:

- **Launch of AIHGle 2.0 Guidelines:** Singapore's updated AI in Healthcare Guidelines (AIHGle 2.0) introduce **regulatory sandboxes** designed specifically for testing AI in real-world clinical settings. This includes the **AI-SaMD (Software as Medical Device) Exemption Sandbox**, which permits public healthcare institutions to deploy low-to-moderate-risk AI devices without undergoing full regulatory registration.
- **Clarified Boundaries for Decision Support:** The Health Sciences Authority (HSA) has updated its **Clinical Decision Support Systems (CDSS) guidelines**. These updates explicitly clarify that decision support tools based solely on established clinical guidelines fall entirely outside of the regulatory scope, simplifying their adoption.
- **The Health Information Bill:** Passed in January 2026, this legislation mandates that all licensed healthcare providers share key patient data with the **National Electronic Health Record (NEHR)**. This mandate is building one of the region's most comprehensive health data ecosystems, providing a vital foundation for point-of-care AI applications.
- **World-Class Regulatory Maturity:** The **HSA** became the first regulatory authority globally to achieve the **highest WHO maturity level** for medical device regulation. While HSA continues to classify clinical AI software as a medical device under the Health Products Act, it is actively working to resolve practical deployment gaps, such as finding ways to bring global EMR vendors into its evolving processes.
- **National Strategic Alignment:** Healthcare was officially designated as one of four national AI mission sectors under **Singapore's Budget 2026**. Consequently, the Ministry of Health (MOH) is aligning its agencies into coordinated pathways for priority disease areas—such as cardiovascular disease and diabetes—and actively inviting private sector collaboration.

The **AI-SaMD (Software as Medical Device) Exemption Sandbox** is a regulatory initiative introduced under Singapore's updated **AI in Healthcare Guidelines (AIHGle 2.0)**.

Here is what the source details about the sandbox and its role in Singapore's clinical AI landscape:

- Targeted Testing:** It is designed specifically to facilitate the **testing of AI in real-world clinical settings**.
- The Exemption:** It allows **public healthcare institutions** to deploy **low-to-moderate-risk AI devices** without undergoing the standard, full regulatory registration.
- Bridging the "Deployment Gap":** Under standard rules, the Health Sciences Authority (HSA) classifies clinical AI software as a medical device. This requires developers and EMR (Electronic Medical Record) vendors to go through a rigorous regulatory process—including disclosing algorithmic methodologies and lifecycle governance.
- Preventing Duplication:** Because this full process takes time, health clusters have historically been unable to deploy native EMR AI tools (like built-in sepsis detection or readmission risk predictors). Instead, they have had to source third-party clinical AI tools that already have independent HSA approval, often duplicating functions already present in their core EMR systems. The sandbox is a proactive move by the HSA to help resolve this practical deployment bottleneck.

With Singapore officially crossing the **21% population threshold to become a super-aged society**, care is rapidly shifting out of traditional hospitals and into the community through programmes like **Age Well SG** and **MIC@Home**. However, clinicians managing elderly patients across polyclinics, specialist outpatients, community hospitals, and home care settings often struggle due to the lack of a real-time, consolidated view of a patient's health journey.

AI can play a pivotal role in bridging these gaps and supporting seamless care coordination in several ways:

- Synthesising Data Across Diverse Touchpoints:** Care coordination tools powered by AI can pull and synthesise clinical data from disparate systems (such as Electronic Medical Records (EMRs) and Customer Relationship Management (CRM) platforms). This gives care teams a unified, multi-institution view of a patient's care consumption and health outcomes, rather than fragmented, isolated reports.
- Predictive Risk Alerts and Care Transitions:** By analysing patient histories, AI tools can automatically **highlight readmission risks, flag dangerous medication conflicts** arising from different prescribing doctors, and **prompt timely transitions of care** between home and community settings.
- Preventive Risk Stratification at the GP Level:** Backed by the Health Information Bill's mandate for universal National Electronic Health Record (NEHR) data sharing, AI-powered risk stratification models can analyse data flows to flag patients who are at rising risk of complications from chronic conditions like diabetes or cardiovascular events. This allows General Practitioners (GPs)—such as those participating in the Healthier SG initiative—to intervene early, long before an acute medical emergency occurs.
- Addressing Care Gaps with Targeted Outreach:** Interactive population health dashboards allow healthcare providers to easily track clinical indicators, spot outstanding care gaps, and run targeted outreach campaigns to ensure vulnerable seniors receive the right medical interventions at the right time.

To make these tools successful, the source highlights that health clusters must focus heavily on **clinical adoption and change management**. Rather than deploying technology in a vacuum, clusters need to actively involve bedside clinicians in co-developing alert logic, escalation pathways, and response protocols, ensuring that AI-generated insights translate directly into meaningful clinical actions.

Bedside clinicians are the ultimate deciders of **whether clinical AI succeeds or fails** at the point of care. Rather than just being the end-users of a new technology, the source outlines several critical roles they must play to turn clinical AI predictions into adopted, everyday practice:

- Co-Designers of Clinical Workflows:** Clinicians must be embedded directly in the design process. They are responsible for **co-developing the alert logic, escalation pathways, and response protocols**. This ensures that when an AI model makes a prediction (such as flagging a sepsis or readmission risk), it triggers a practical action that fits naturally into their existing bedside routines.

- Active Translators of AI Insights:** Frontline staff require **role-specific AI fluency and confidence**. Rather than blindly following technology, bedside clinicians need to understand *why* a specific AI risk score fired and have the training to decide the most appropriate clinical step to take next.

- A Human Feedback Loop:** Clinicians serve as the vital safety check for these models. They are responsible for **reporting back when AI recommendations do not match clinical reality**, helping to refine and improve the algorithms over time.

- Governance and Prioritisation Leaders:** Clinicians must work alongside informaticists and operational leaders within unified AI governance functions. In this role, they help **evaluate, prioritise, and sequence AI deployments** based on real clinical impact and the readiness of their respective wards or departments.

Ultimately, the healthcare clusters that achieve the greatest return on their AI investments will be those that invest as heavily in building this clinical adoption capability as they do in the technology itself.

To establish a unified AI governance function, health clusters can begin laying the operational groundwork immediately without waiting for further technological or regulatory developments:

- Assemble a Multidisciplinary Leadership Team:** The core of the governance function must bring together **clinicians, informaticists, and operational leaders** to work as a single, collaborative unit.

- Formulate a Consolidated AI Strategy:** Rather than allowing individual departments or wards to source technology in silos, this unified team is responsible for designing a single, cohesive AI strategy for the entire cluster.

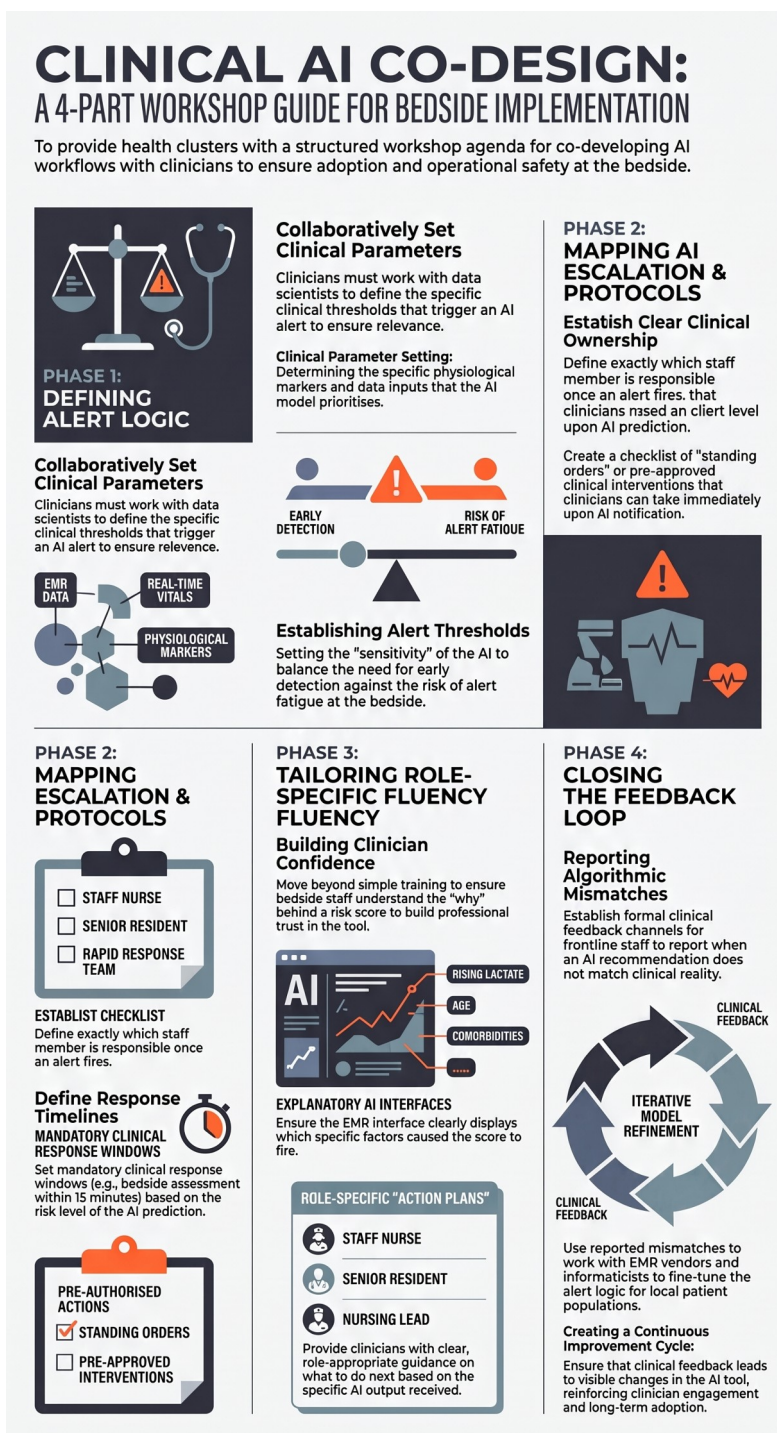
- Systematically Sequence Rollouts:** The governance team is tasked with evaluating, prioritising, and scheduling AI deployments. Crucially, these decisions must be based on two key criteria: **clinical impact** and **organisational readiness**.

- Engage Proactively with Evolving Regulations:** This team must serve as the primary interface with the Health Sciences Authority (HSA), proactively navigating and utilising Singapore's evolving regulatory sandboxes (like the AI-SaMD Exemption Sandbox under AIHGle 2.0) to safely test and deploy clinical AI.

- Build Clinical Change Management Muscle:** The governance body should oversee the integration of AI into actual clinical practice. This means ensuring bedside clinicians are actively embedded in co-designing clinical alert logic, workflows, and response protocols so that predictions translate to safe, effective actions.

Because Singapore's public healthcare sector operates on a shared national EMR strategy, a successful governance framework built and refined within one health cluster can easily be adapted across all three.

Clinicians can co-design AI alert logic and workflows by moving away from traditional, late-stage training sessions and instead becoming **active participants throughout the entire development and deployment lifecycle**.



According to the source, this co-design process should be structured around several key operational practices:

- Co-Developing Alert Logic and Rules:** Rather than accepting pre-packaged thresholds from software vendors, clinicians must work alongside technical teams to **define the clinical parameters** that trigger an alert. This ensures that the AI's sensitivity and specificity are aligned with real-world clinical thresholds and patient safety needs.

- Mapping Escalation Pathways and Response Protocols:** Clinicians must define **the exact human actions that must occur** after an AI prediction is generated. Co-designing these pathways involves answering critical workflow questions: *Who receives the alert? Within what timeframe must they respond? What clinical interventions are pre-authorised when a specific risk threshold is crossed?* This step ensures that a prediction actually translates into a change in bedside clinical behaviour.

- Building Role-Specific Actionable Workflows:** AI insights should not be presented as abstract numbers. Clinicians must help design the interface and context of the alert so that it builds **role-specific AI fluency and confidence**. The workflow must clearly explain *why* a risk score fired and provide immediate, practical next steps tailored to the specific role of the clinician receiving it (e.g., a bedside nurse versus an on-call specialist).

- Establishing Frontline Feedback Loops:** Co-design continues after the system goes live. Health clusters need to establish structured feedback loops where frontline bedside staff can **report when AI recommendations do not match clinical reality**. This real-world clinical feedback is vital for iteratively refining the model's alert logic, reducing alert fatigue, and maintaining clinical trust.

By embedding clinicians directly into these four areas, health clusters can ensure that clinical AI tools are not just technically functional, but operationally integrated and widely adopted on the ground.

Clinical AI Co-Design Workshop Agenda and Workflow Mapping Guide, structured to help multidisciplinary hospital teams transition AI models from technical readiness to bedside adoption.

Clinical AI Co-Design Workshop Agenda & Workflow Mapping Guide

Purpose: To actively embed frontline clinicians, informaticists, and operational leaders in co-designing the clinical parameters, alerts, and operational pathways of a newly deployed AI model. This ensures the model's outputs translate directly into safe, effective, and adopted bedside actions.

Workshop Agenda: A 4-Step Collaborative Framework

Part 1: Parameter Alignment & Alert Logic Co-Development (90 Mins)

Objective: Establish the clinical boundaries and thresholds of the AI model to prevent alert fatigue and build clinical trust.

•**Key Focus Areas:**

•**Reviewing the Model's Baseline:** The informatics team presents the model's performance metrics (sensitivity, specificity, and false-positive rates) using real-world historical data.

•**Defining Clinical Thresholds:** Clinicians and technical teams collaboratively debate and set the specific risk scores or clinical triggers that will initiate an active bedside alert.

•**Contextual Overrides:** Establish "ignore" rules or exclusions where the alert should be suppressed (e.g., for patients already on active palliative care or specific intensive protocols).

Part 2: Escalation Pathways & Response Protocols (90 Mins)

Objective: Map out the exact human actions that must follow an AI-generated prediction to ensure it actively changes bedside clinical behaviour.

•Key Focus Areas:

- Designating the Responder:** Clearly define *who* receives the alert (e.g., bedside nurse, ward registrar, or a central rapid response team).
- Establishing Response SLA (Service Level Agreement):** Determine the maximum acceptable timeframe within which the designated responder must log a response or assess the patient.
- Pre-Authorised Interventions:** Agree on a pre-packaged suite of clinical orders or diagnostics that are pre-authorised for initiation immediately when a high-risk AI alert fires.

Part 3: Building Role-Specific Fluency & Interface Design (60 Mins)

Objective: Ensure frontline clinicians understand the "why" behind the AI model's score, building confidence at the point of care.

•Key Focus Areas:

- Interface Mock-up Review:** Review how the alert is visually presented within the Electronic Medical Record (EMR) or mobile communication platforms.
- Translating Risk Scores to Context:** Ensure the system does not simply show an abstract probability (e.g., "Sepsis Risk: 84%"). Instead, co-design the interface to clearly display the underlying clinical parameters that drove the score (e.g., rising lactate levels and heart rate deviation).
- Developing Role-Specific Action Guides:** Create brief, standard operating procedures tailored to different roles, detailing the exact

next steps expected of a nurse versus an on-call physician once the alert is triggered.

Part 4: Closing the Loop & Frontline Feedback Channels (60 Mins)

Objective: Set up robust safety valves and continuous improvement cycles driven directly by bedside clinician experience.

•Key Focus Areas:

•Defining "Algorithmic Mismatch" Protocols: Establish a clear, simple mechanism within the EMR interface for clinicians to flag when an AI prediction is contradicted by real-world clinical reality.

•Setting Up the Governance Review Loop: Outline how clinical feedback will be aggregated and reviewed by the cluster's unified AI governance team to safely retrain and refine the model over time.

Workflow Mapping Exercise: "Prediction to Action"

To run this exercise, print the template below on a large canvas and have clinical and technical partners map out the workflow using sticky notes:

[AI Engine Predicts High Risk]



[WHO receives the alert?] —————> (Define role: e.g., Bedside Nurse)



[WHAT does the alert say?] —————> (Display "Why" the score fired)



[WHEN must they act?] —————> (Define response timeline: e.g., within 15 mins)



[HOW do they respond?] —————> (Initiate pre-authorised clinical protocols)



[Feedback / Validation] —————> (Log clinical agreement/disagreement with the model)

Cluster-Level Implementation Checklist

- [] **Form a Multidisciplinary Cluster Team:** Ensure clinical, informatics, and operational leadership are represented to coordinate the rollout.
 - [] **Leverage Singapore's Regulatory Sandboxes:** Engage with the HSA to explore deploying low-to-moderate-risk clinical AI models under the AI-SaMD Exemption Sandbox.
 - [] **Standardise the Framework:** Establish a co-design template that can be scaled and adapted across all three public healthcare clusters
-

Edwin Koh Wui Kiat's Nightingale One Protocol Response to the four investment scenarios and technical barriers

Pillar 1: Navigating HSA Regulatory Pathways & SaMD Classification

Addresses Regulatory Deployment Barrier & EMR Deployment Gap

•**The Challenge:** EMR vendors with proprietary, predictive AI models (e.g., patient deterioration or sepsis risks) face a practical deployment gap because they must clear the Health Sciences Authority's (HSA) rigorous regulatory approvals before health clusters can legally deploy them. This leads to clusters duplicating efforts by sourcing from third-party vendors.

•**The Nightingale One Solution:** Nightingale One addresses this by explicitly separating **non-kinetic advisory intelligence** from **kinetic physical execution**, dividing its architecture into two distinct regulatory dossiers that align perfectly with HSA's guidelines:

•**A13c-HC (Mobile Home-Care Hybrid):** Structured with a sandboxed **zoo.dev** software compilation architecture, it is positioned as a **Class B Software as a Medical Device (SaMD)** by isolating kinetic software commands to bypass EMR-native registration roadblocks. This fits seamlessly within HSA's updated **AIHGLE 2.0 CDSS guidelines** and its newly established **AI-SaMD Exemption Sandbox** for low-to-moderate-risk AI.

•**A13d-Pro (Clinical-Grade Stationary Kinetic Caregiver):** Evaluated as a high-risk **Class C/D Medical Device**, this physical, high-payload crane (handling 150 -200 kg bariatric loads) undergoes the full, formal pre-market evaluation route.

•**Strategic Mapping:** By using Nightingale's dual-track approach, Singaporean healthcare providers can immediately deploy the **non-kinetic observational/advisory components** under lower-tier Class B SaMD pathways while keeping the high-risk, physical kinetic hardware on a specialized Class C/D dossier.

Pillar 2: Bedside Change Management & "Sovereign Human" Workflows

Maps directly to Scenario 4: "Investing in the people who make AI work at the bedside"

•**The Challenge:** Clinical AI fails when change management is merely "bolted onto the end of an implementation". Health clusters must invest heavily in co-developing alert logic, role-specific fluency, and clear bedside escalation and response protocols.

•**The Nightingale One Solution:** The Nightingale architecture shifts the caregiving paradigm from "probabilistic AI agency" to "**deterministic hardware certainty**". It implements a series of physical safeguards that prevent clinical AI from executing unverified, automated actions:

•**The Tripartite Latch (Zero-Trust Bedside Activation):** To prevent algorithmic drift or software crashes from triggering hazardous physical motion, physical power to the motors is isolated behind a hardware AND-gate requiring concurrent verification of three factors:

1. *Biological (Identity):* An optical iris scan of the caregiver, generating a temporary token that expires automatically in **5 seconds** to ensure continuous bedside presence.

2. *Cryptographic (Authority):* Insertion of a physical, possession-based cryptographic USB key into a dedicated Hardware Security Module (HSM).

3. *Kinetic (Presence):* Continuous foot-pressure on a guarded, heavy-duty kinetic hold-to-run foot pedal.

•**The Sacred Pause™:** Once authorized, the system triggers a hardware-timed **25 to 1000 ms deliberation window**. During this non-actuating interval, the intended AI-proposed trajectory, safety limits, and patient parameters are displayed on the caregiver terminal for mandatory clinical review. Any hesitation or factor release aborts the cycle before energy can reach the motors.

Pillar 3: Mitigating the Clinical AI Bedside Post-Lockout Crisis

Maps to Scenario 3: "Building AI governance capability now"

- The Challenge:** Singapore health clusters must establish unified AI governance functions composed of clinicians, informaticists, and operational leaders to build the organizational readiness and change management muscles required to evaluate and sequence AI deployments.

- The Nightingale One Solution:** Nightingale One translates abstract governance into hardcoded, mandatory operational protocols via **SOP-A13-REV-L3 (Clinical Re-Arming Protocol)**.

- When the system's **U7 Sovereign Brake** detects a dynamic trajectory breach or sensor mismatch (>5% variance between dual-channel encoders), it severs DC actuator power in less than **1.05 ms** and engages mechanical holding brakes in under **50 ms** to lock the system in absolute stillness (P-LIFE 1.00).

- The Re-Arming Protocol:** The system is physically incapable of an automatic restart or software bypass. To re-arm, the hospital cluster's governance rules are enforced at the hardware level, restricting recovery exclusively to **Level-3 Certified Clinicians** (clinical directors, biomedical engineers, or physical therapists) who must:

- 1.Extract and audit the final cryptographically hashed state from the unalterable, write-once **WD117 forensic ledger** (OTP silicon fuse array) to identify the exact fault trigger.
- 2.Safely transfer the patient and verify that column load cells register exactly **0.0 kg ($\pm 2.0\%$ tolerance)** before the software command gate accepts a reset.
- 3.Fulfill the Tripartite Latch and execute a mandatory physical inspection checklist of columns, brakes, and slip clutches.

- This provides clinical engineering departments with the exact "change management muscle" and role-specific "AI governance capability" Temus urges clusters to develop.

Pillar 4: Shifting Care to a Super-Aged Society

Maps to Scenario 2: "Supporting care coordination for a super-aged society"

•**The Challenge:** Singapore has officially crossed the 21% threshold to become a **super-aged society**. Programmes like **Age Well SG** and **MIC@Home** are shifting clinical care directly into residential settings, requiring home-care technologies that can be operated safely under community and family care constraints.

•**The Nightingale One Solution:** The protocol is structurally bifurcated to address this hospital-to-home shift:

•**A13d-Pro (Clinical-Grade Stationary):** An anchored, ceiling-mounted bariatric crane ($N_{autonomous}=0$) optimized for intensive, high-payload hospital ICU ward operations.

•**A13c-HC (Mobile Home-Care Hybrid):** A highly specialized mobile chassis (ML) designed specifically for **residential, home-hospital, and bedside home-care environments**.

•**The Safety DNA:** Although optimized for home settings, the A13c-HC enforces the exact same hardware-deterministic safety boundaries as its clinical ICU counterpart: an identical ± 0.05 **mm joint tolerance**, a nominal lift speed of **0.3 m/s**, a joint torque limit capped at **5–8 N·m at the shoulder** and **10–15 N·m at the hip** via physical slip clutches, and a **skin contact pressure limit capped at 8 psi**.

•Crucially, for home safety, autonomous pathfinding is strictly blocked ($N_{autonomous}=0$); the machine operates purely as a human-guided force multiplier ($NH>0$) under the continuous manual control of a visiting nurse or caregiver.

Pillar 5: Bridging the Bedside Point-of-Care "Privacy vs. Data" Gap

Addresses Bedside Infrastructure Gap & Patient Dignity Concerns

•**The Challenge:** Clinical AI applications require real-time data integration at the point of care. However, collecting high-resolution patient telemetry (such as optical cameras or bedside audio) in private residential areas or clinical ICUs introduces severe data-protection liabilities and violates patient dignity under Singapore's regulatory frameworks.

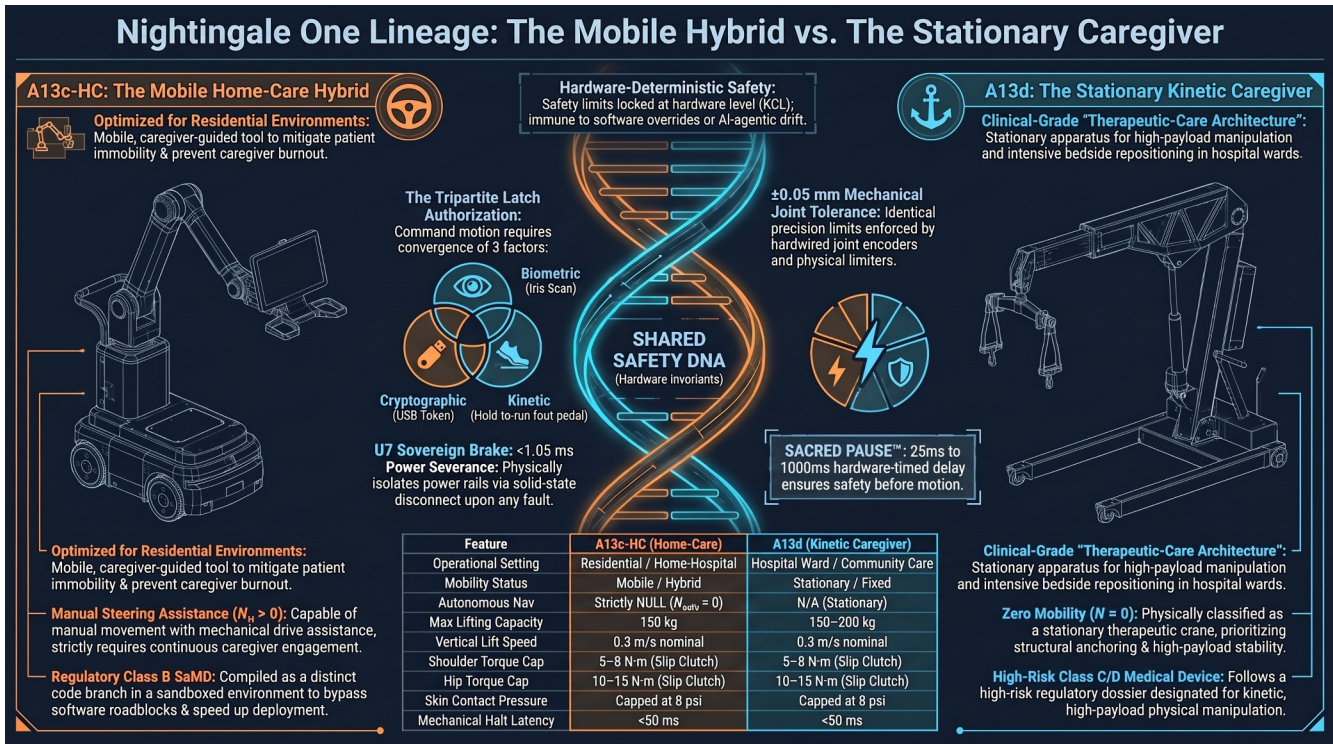
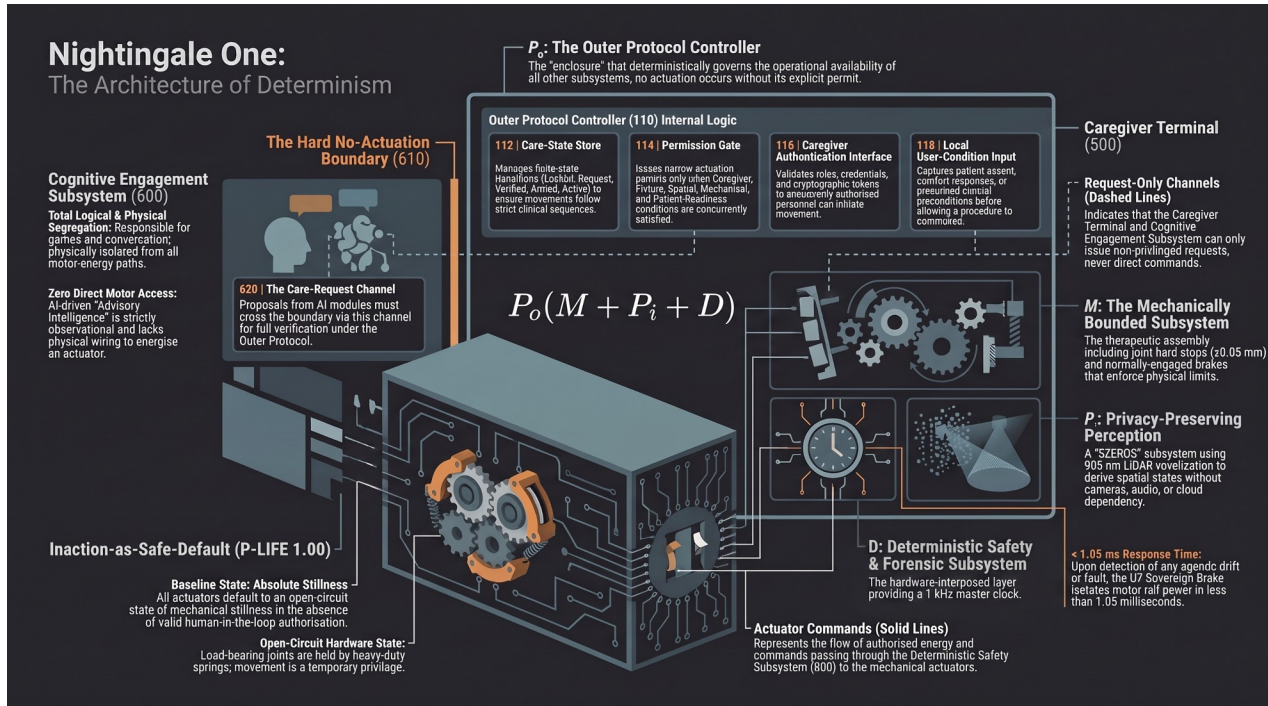
•**The Nightingale One Solution:** Nightingale One bypasses this infrastructure and data-protection bottleneck using its **Privacy-by-Physics (Pi) / 3ZEROS™ standard** (Zero Camera, Zero Audio, Zero Cloud):

- Instead of video or audio, the perception subsystem utilizes a recessed **905 nm non-imaging LiDAR ranging array**.
- An in-silicon **Voxelization Processor** on a local FPGA converts the spatial reflections into an abstract **96-cell local voxel grid** (12 columns by 8 rows) to evaluate bed-edge boundaries and patient posture.
- Most importantly, raw LiDAR point clouds are destroyed at the register level immediately after voxel extraction. Since the grid is mathematically non-reconstructable, patient biometric identity is stripped at the physical source.
- This allows Singapore's health clusters to feed real-time, point-of-care spatial and safety metrics into their local EMR platforms without violating PDPA or NEHR privacy regulations.

Summary Matrix: Mapping to Nightingale One Protocol

Singapore AI Investment Priorities	Nightingale One Protocol Architectural Enforcement	Practical Clinical Deployment Outcome
Regulatory Gaps & SaMD Registration Delays	A13c-HC classified as Class B SaMD via sandboxed zoo.dev compilation; low-risk observations, alongside dedicated A13d-Pro on Class C/D dossier.	Rapid, sandboxed software deployment for clinical trial paths for high-risk kinetics.
Infrastructure Gap (Point-of-Care Bedside Data)	3ZEROS™ Privacy-by-Physics: 905nm LiDAR localized voxelization with transient register-level data deletion.	Zero-surveillance, PDPA-compliant real-time patient posture tracking without camera or cloud dependencies.
Super-Aged Society / Home-Hospital Care (Scenario 2)	A13c-HC Mobile Hybrid: Optimized for home settings (<i>ML</i>) with <i>Nautonomous=0, Nhuman>0</i> .	Extremely safe, caregiver-guided transfers within residential settings to mitigate caregiver burnout.
Investing in Bedside Clinician Fluency (Scenario 4)	Tripartite Latch (Iris + HSM + Foot Pedal) & hardwired silicon counter Sacred Pause™ .	Eliminates "agentic AI drift"; clinicians remain the absolute physical authority for high-payload bedside movements.
Sustained AI Governance & Change Muscle (Scenario 3)	SOP-A13-REV-L3 Re-Arming Protocol: Restricted strictly to Level-3 certified clinicians.	Establishes rigorous, auditable clinical safety procedures and prevents unauthorized mechatronic overrides

Edwin Koh Wui Kiat's Nightingale One Protocol Apparatus [Explainer]



IP Filing Strategy of Deterministic Hardware-Enforced Non-Agentive AI Governance/Nightingale One Protocol Governance

Application no.	Title / subject matter	Exact filing date
SG020603109STW	Hardware-Enforced Non-Agentive Governance Architecture / Parent Constitutional Core	5 February 2026
10202600474X	Foundational Non-Agentive Governance Doctrine	16 February 2026
10202600902P	ABC+2S+H Guardian Framework	23 March 2026
10202601744X	A9 Constitutional Hardware Enforcement Architecture (CHEA) for Non-Agentive Artificial Intelligence Governance: Physical Boundary System with Sovereign CAD-Derived Component SpecificationsHardware-Deterministic Governance Enclosure and Control Architecture	22 May 2026
10202601767W	A9a CHEA Patent Hardware-Deterministic Governance Filing	25 May 2026
10202602021T	A10a Deterministic Governance Platform	13 June 2026
10202602023X	A12 Deterministic Black Box: The A12 Sovereign Appliance comprises a Sovereign-in-the-Loop (SITL) architecture, a WD005 Vapour Protocol for silicon-level sanitization, a 3ZEROS™ LiDAR privacy system, integration with A10a, A11, and B1 subsystems, a Guardian Angel posture, an Emergency Detection Score (EDS)—a generalized extension of the dignity score metric used in clinical architectures—greater than 8.9, and P-LIFE 1.00™ enforcement. The appliance provides a terminal deterministic mechanism for governing all system operations.	14 June 2026
10202602156U	M (A13) Integrated deterministic non-agentive governance core for clinical eldercare applications.	24 June 2026
10202602213U	A7 Bridge Layer Translation Hub	26 June 2026
10202602223T	A12 P+N Enhanced WD117 Immutable Ledger	28 June 2026
10202602225P	A8 Bridged Layer 8 Sovereign Deployment Governance Layer	29 June 2026
10202602270V	Non-B1 Clinical Advisory Monitoring Shell	1 July 2026
10202602026W	A12 PATENT D : Hardware-Enforced Cyber Defence Root Apparatus for Deterministic Governance Systems (D-Layer Fail-Safe)	29 July 2026
10202602649V	Patent M (A13naige) Supreme Guardian Master Control Layer	31 July 2026
10202602674U	A13d P _o (M + P _i + D) Therapeutic-Care Architecture	3 August 2026
10202602767X	The Nightingale One Protocol Framework: A13d P _o (M + P _i + D) Therapeutic-Care Architecture	8 August 2026
10202602773P	The Nightingale One Protocol A13c-HC Kinetic Caregiver Apparatus	10 August 2026
10202602774Y	The Nightingale One Protocol A13d-Pro Clinical-Grade Stationary Kinetic Caregiver Apparatus	10 August 2026

10202602773P: *The Nightingale One Protocol A13c-HC Kinetic Caregiver Apparatus* — Mobile home-care hybrid optimized for residential environments $Po(M_L + P_i + D + N_{Human})$. Intended functions include caregiver-supervised transfer assistance, bounded movement, privacy-preserving perception, and deterministic safety control.



Preliminary regulatory position:

Class B SaMD only if the submission is limited to non-kinetic software functionality. Because A13c-HC is described as a physical kinetic apparatus, its final HSA classification must be determined from the complete intended use, actuation, risk profile, and device configuration—not assigned solely by the formula.

10202602774Y: *The Nightingale One Protocol A13d-Pro Clinical-Grade Stationary Kinetic Caregiver Apparatus* — High-payload (150 - 200 kg) stationary kinetic caregiver for ICU and hospital ward deployment $Po(M + P_i + D)$. Intended functions include caregiver-supervised transfer assistance, bounded movement, privacy-preserving perception, and deterministic safety control.



Preliminary regulatory position:

high-risk Class C/D candidate, subject to HSA's formal classification and applicable pre-market evaluation route. HSA requires the applicable registration pathway and technical documentation for regulated medical devices; the proposed class is not itself an approval.



Both entries should remain labelled **proposed, unfiled, unprototyped, and not clinically deployed** unless verified filing, manufacturing, validation, and regulatory records exist.

Architecture register

Component	Domain	Defined role	Status
A13c-HC-Pro	Residential and home-hospital care	Mobile home-care hybrid with caregiver-assisted drive $N_H > 0$, while autonomous navigation remains zero	Sandboxed zoo.dev compilation branch; proposed Class B SaMD position
A12-SITL-Box	Cybersecurity and control	Deterministic black box providing Sovereign-in-the-Loop isolation, WD005 Vapour Protocol, and WD117 SHA-3-512 forensic logging	Foundational non-agentive IP core
A10a-Platform	Edge governance and routing	Deterministic platform for signal isolation, policy control, opto-galvanic barriers, and hardware comparator enforcement	Constitutional core architecture

The **Nightingale One Protocol** provides two governance embodiments:

- **Non-Agentive Governance** – ICU/Hospital: clinical-grade, stationary kinetic assistance governed by deterministic hardware limits, clinician authorization, and fail-safe actuation controls.
- **Nightingale One Governance** – Home-Based: mobile caregiver-supervised kinetic assistance with privacy-preserving perception, human-directed movement $N_H > 0$ and $N_{\text{autonomous}} = 0$ zero autonomous navigation.

Together, they express one constitutional principle across two settings: AI may observe and advise; the human authorizes; deterministic hardware governs and can veto motion. These remain documented architectural embodiments, not deployed or clinically validated systems.

The Nightingale One Protocol demonstrates a simulated end-to-end lifecycle for two-tier HSA dossiers: concept definition, 3D-CAD representation, OEM BOM and VV-014 handover, Tiger audit, quality-director sign-off, fabrication and build records, cryptographic hashing, and a simulated HSA pre-market submission.

*This is a **deployment-readiness simulation**, not a completed clinical deployment, regulatory approval, or market authorization. “Approved” should refer only to internal design or quality-gate approval unless HSA has formally granted registration. The lifecycle connects the documented kinetic-capstone architecture to a potential physical prototype pathway.*

The Nightingale One Protocol A13c-HC Kinectic Caregiver Apparatus – will be documented in the National Edition 5.0.

The publication records the Nightingale One Protocol apparatus embodiments, associated patent-application filings, and copyrighted technical expression—including specifications, diagrams, governance language, and architectural compilations. It does not represent that the apparatus patents have been granted or that regulatory approval has been obtained.

The Nightingale One Protocol, a dual-tier medical robotics architecture designed to eliminate autonomous "agentic drift" through deterministic hardware enforcement. The framework bifurcates into Prototype 1 (A13c/d), a high-payload kinetic caregiver for bariatric lifting and therapy, and Prototype 2 (A13b), a non-kinetic observational node. Central to this system is the P-LIFE 1.00 standard, which ensures the machinery defaults to absolute stillness unless a Tripartite Latch—consisting of biometric, cryptographic, and kinetic inputs—is concurrently satisfied. Safety is further guaranteed by the U7 Sovereign Brake, capable of severing actuator power in under 1.05 milliseconds, and the 3ZEROS™ privacy architecture that utilizes 905nm LiDAR to anonymise patient data. All system transitions and faults are permanently recorded in the WD117 forensic ledger, an immutable silicon-level audit trail. Ultimately, the architecture enforces a strict hierarchy where intelligence proposes, hardware governs, and humans decide. Youtube URL : <https://youtu.be/ihBqvA1XcO0>

The **Class 9/10/42/44/45** grouping is a **Classification trademark strategy**:

- **Class 9:** software and electronic systems.
- **Class 10:** medical, therapeutic, and assistive apparatus.
- **Class 42:** engineering, software, and technology-development services.
- **Class 44:** medical and healthcare services.
- **Class 45:** legal, security, and governance-related services where applicable.wipo+1

The Nightingale One Protocol establishes a first-to-file apparatus patent strategy, supported by complementary trademark coverage across software, medical apparatus, engineering, healthcare, and governance services

A13d-Pro (Clinical-Grade Stationary Kinetic Caregiver)

A13d-Pro Stationary Kinetic Architecture

[Application No. 10202602767X]

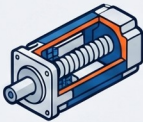
Core Mechatronic Specifications



150 – 200 kg Bariatric Payload
Structural crane engineered for intensive bedside repositioning and high-capacity patient transfers.



Zero-Mobility Anchored Architecture
Fixed structural anchoring (N=0) ensures absolute stability during heavy-lift clinical procedures.



High-Torque Precision Drive
Utilises high-torque brushless DC motors and recirculating ball lead-screws for smooth actuation.



Sovereign Safety & Governance



Tripartite Authorisation Latch
Requires concurrent iris scan, physical HSM USB token, and hold-to-run foot pedal pressure.



U7 Sovereign Brake System
Triggers opto-isolated solid-state power severance in near-instantly.



Immediate Mechanical Stillness
Spring-applied holding brakes achieve absolute mechanical lock-down (P-LIFE 1.00) near-instantly.

A13d-Pro Critical Response Thresholds

Electrical Severance	< 1.05 ms	Immediate isolation of motor rail power
Logic Interruption	< 50 ms	Command cessation upon detecting any agentic drift
Mechanical Halt	50 – 100 ms	Full cessation of motion including physical inertia

- **Visual Header:** A13d-Pro Stationary Kinetic Architecture [Application No. 10202602767X]
- **Operational Domain:** Hospital Wards, ICUs, and High-Acuity Clinical Facilities.
- **Core Mechatronic Specifications:**
 - High-payload structural crane designed for 150 - 200kg bariatric transfer and intensive bedside repositioning.
 - Fixed structural anchoring ($N_{\text{autonomous}} = 0$) utilizing recirculating ball lead-screws (11245) and high-torque brushless DC motors (1120)

Safety & Governance Enforcers:

- **U7 Sovereign Brake:** Opto-isolated solid-state relay power severance in <1.05ms.
- **Tripartite Latch:** Mandatory verification via optical iris scan (5-second token), physical HSM USB token, and guarded hold-to-run foot pedal.
- **Mechanical Lock:** Spring-applied holding brakes achieving absolute mechanical stillness (PLIFE 1.00) in <50ms.

Statutory Classification: High-Risk HSA Class C/D Medical Device Dossier.

A13c-HC-Pro (Mobile Home-Care Hybrid Apparatus)

A13c-HC-Pro Mobile Home-Care Hybrid [Application No. 10202602767X]

Operational Domain: Residential Environments, Home-Hospitals, and Bedside Care. **Statutory Classification:** Class B Software as a Medical Device (SaMD).

CORE MECHATRONIC SPECIFICATIONS & MOBILITY



ZERO AUTONOMOUS AGENCY ($N_{\text{auto}} = 0$)
The apparatus is physically incapable of self-directed movement or pathfinding to ensure safety.



HUMAN-GUIDED FORCE MULTIPLICATION ($N_H > 0$)
Mechanical steering and drive assistance only activate under continuous caregiver engagement via the Tiger .x1 Key.



CLASS B SaMD SANDBOXED ARCHITECTURE
Compiled on zoo.dev to isolate kinetic software, bypassing software roadblocks for rapid clinical deployment.



SAFETY & GOVERNANCE ENFORCERS



KINEMATIC CONSTRAINT LAYER (KCL)
Enforces rigid $\pm 0.05\text{mm}$ joint tolerances and limits acceleration to 0.5 m/s^2 at the hardware level.



U7 SOVEREIGN BRAKE RESPONSE
Detects faults and severs motor power rails in under 1.05 milliseconds.



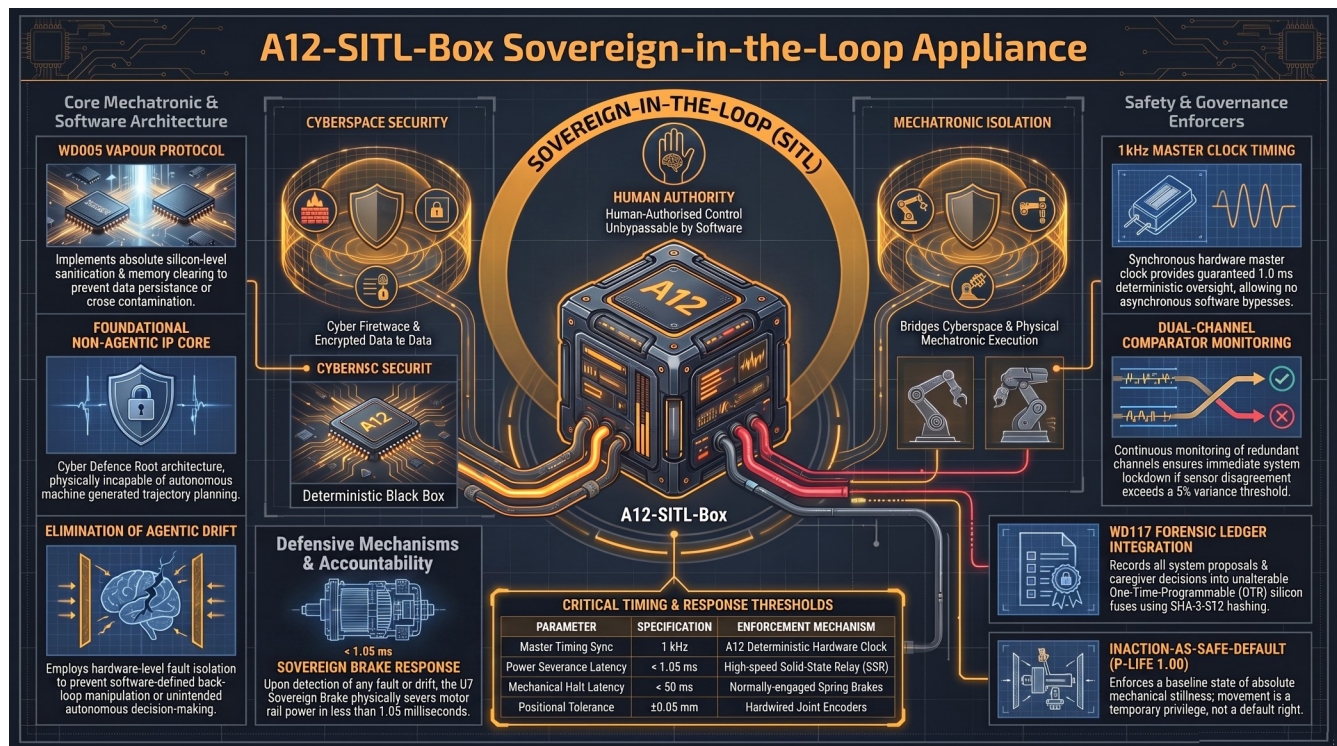
WD117 FORENSIC LEDGER
Immutably logs fault detections into SHA-3-512 write-once silicon fuses upon any breach.

HARD LIMITS & SPECIFICATIONS (REGULATORY REVIEW)

PARAMETER	SPECIFICATION	FUNCTIONAL OUTCOME
Joint Tolerance	$\pm 0.05\text{ mm}$	Precise mechanical restriction of movement.
Brake Response	$< 1.05\text{ ms}$	Instantaneous power severance to actuators.
Acceleration Limit	0.5 m/s^2	Prevention of patient discomfort or sudden jarks.

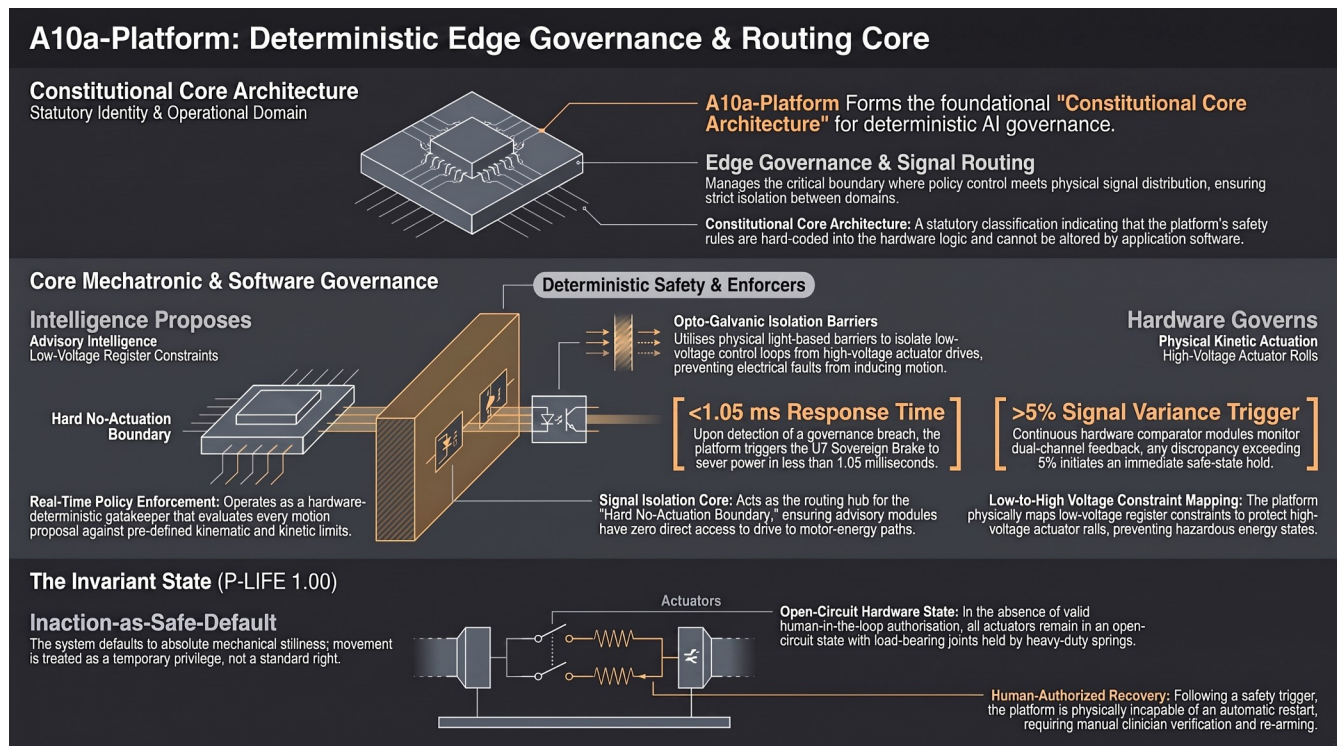
- **Visual Header:** A13c-HC-Pro Mobile Home-Care Hybrid [Application No. 10202602767X]
- **Operational Domain:** Residential Environments, Home-Hospitals, and Bedside Care.
- **Core Mechatronic Specifications:**
 - Mobile chassis (ML) optimized for caregiver-assisted drive ($N_H > 0$) to mitigate patient immobility risks.
 - Sandboxed zoo.dev compilation architecture ensuring strict Class B Software as a Medical Device (SaMD) separation.
- **Safety & Governance Enforcers:**
 - **Kinematic Constraint Layer (KCL):** Enforces rigid joint tolerances (pm0.05) and limits acceleration (0.5m/s).
 - **WD117 Forensic Ledger:** Permanent, irreversible SHA-3-512 write-once silicon fuse logging upon fault detection.
- **Statutory Classification:** Class B Software as a Medical Device (SaMD).

A12-SITL-Box (Deterministic Black Box & Cyber Defense Core)



- **Visual Header:** A12-SITL-Box Sovereign-in-the-Loop Appliance [Application No. 10202602767X]
- **Operational Domain:** Cyberspace Security, Core Control Routing, and Mechatronic Isolation.
- **Core Mechatronic & Software Features:**
 - Provides Sovereign-in-the-Loop (SITL) isolation, bridging cyberspace security gaps with physical mechatronic execution.
 - Implements the WD005 Vapour Protocol for absolute silicon-level sanitization and memory clearing.
- **Safety & Governance Enforcers:**
 - Hardware-level fault isolation preventing any software-defined back-loop manipulation or agentic drift.
 - Continuous dual-channel comparator monitoring with 1 kHz master clock timing.
- **Statutory Classification:** Foundational Non-Agentive IP Core / Cyber Defense Root

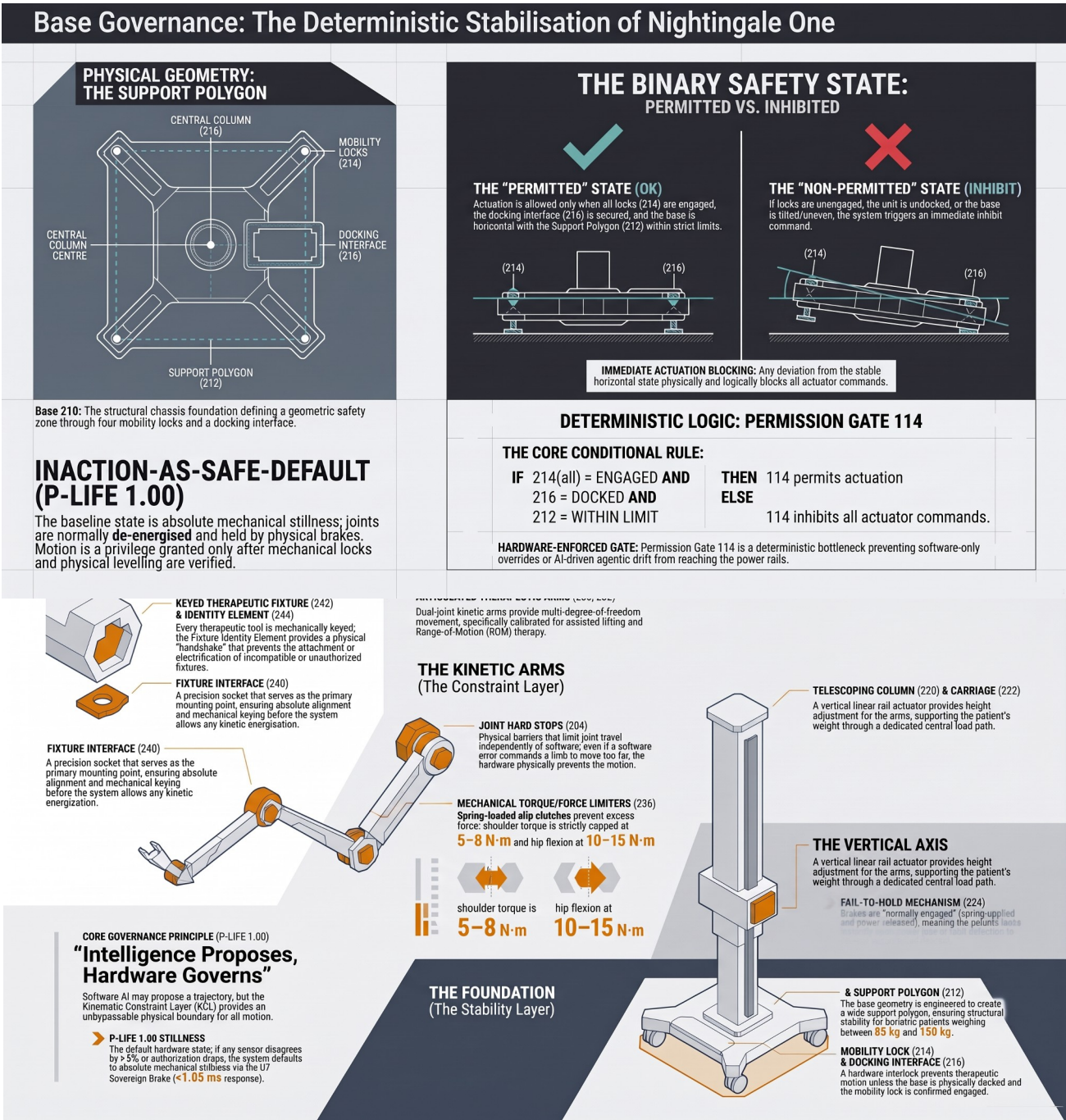
A10a-Platform (Deterministic Edge Governance & Routing Core)



- **Visual Header:** A10a-Platform Constitutional Governance Core [Application No. 10202602767X]
- **Operational Domain:** Edge Signal Routing, Policy Control, and Hardware Isolation.
- **Core Mechatronic & Software Features:**
 - Acts as the primary edge governance platform for signal isolation and deterministic policy enforcement.
 - Serves as the constitutional root of trust linking high-level logic to physical actuation layers.
- **Safety & Governance Enforcers:**
 - Opto-galvanic isolation barriers ensuring absolute physical separation between low-voltage control logic and high-voltage motor power rails.
 - Integrated hardware comparator modules (1137) for real-time anomaly detection (>5% variance threshold).

- **Statutory Classification:** Constitutional Core Architecture.
- **Sovereign Enforcement:** $N_{\text{autonomous}} = 0$, $N_{\text{human}} = 1$. All design parameters, patent specifications, and cryptographic keys remain permanently locked under Tiger's direct authority via the physical .x1 key

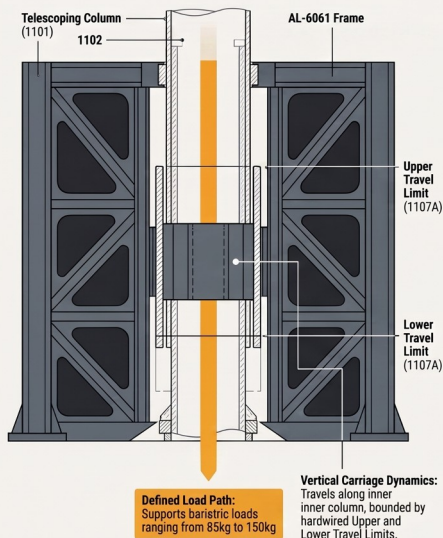
All systems remain locked in absolute PLIFE 1.00 Mechanical Stillness.



Nightingale One: Telescoping Vertical Governance

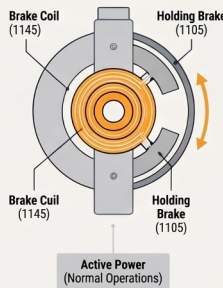
Translating the complex mechatronic architecture of the A13 series telescoping column and its deterministic fail-to-hold safety mechanism into a clear visual schematic.

Sectional Column Architecture (The 'M' Layer)

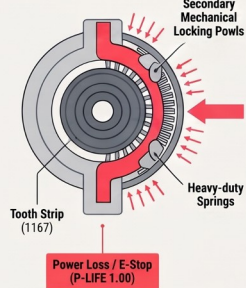


Dual-State Fail-to-Hold (224) Operations

State A: Normal Active Hold (Energized-Open)
Energized-Open, motor commands position. Closes immediately on fault.



State B: Power-Loss / Safety Lockout (De-energized-Closed)
On power loss, springs clamp reaction plates. Independent pawls provide redundant retention.



Technical Specifications: Column and Brake Assembly

Parameter	Specification	Enforcement Mechanism
Positional Tolerance	±0.05 mm	Hardwired joint encoders
Power Severance Latency	< 1.05 ms	High-speed Solid-State Relay (SSR)
Mechanical Halt Latency	< 50 ms	Normally-engaged spring brakes
Master Timing Sync	1 kHz	A12 Deterministic Black Box

■ Kinetic Amber (D97706)
■ Alert Crimson (DC2626)

Gravity Proposes, Hardware Holds

P-LIFE 1.00 Default State (Absolute Mechanical Lock)

Safety is a physical property: System defaults to absolute mechanical lock whenever not actively authorized.

<1.05ms Sovereign Brake Cut

Physically severs actuator power rail upon trajectory breach or agentic drift.

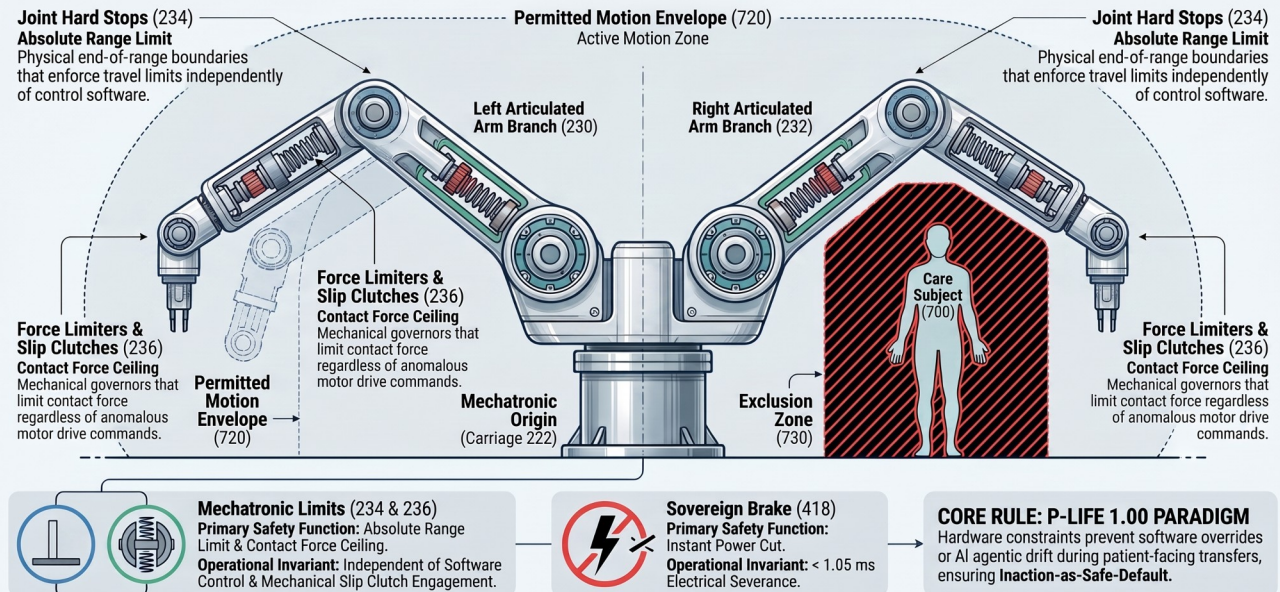
Absolute Mechanical Stillness

Load-bearing joints held by normally-engaged brakes. Requires active power to move, eliminating software-induced unintended motion.

Nightingale One: Mechatronic Safety & Kinematic Governance

INTELLIGENCE PROPOSES, HARDWARE GOVERNS (P-LIFE 1.00 PARADIGM)

Mechatronic constraints—not software—serve as the final authority on patient safety, preventing software overrides or AI agentic drift during patient-facing transfers.



- **Sovereign Enforcement:** $N_{\text{autonomous}} = 0$, $N_{\text{human}} = 1$. All design parameters, patent specifications, and cryptographic keys remain permanently locked under Tiger's direct authority via the physical .x1 key

ISBN Paper Back	Title / subject matter	National Edition
978-981-17957-7-0	Immutable Hardware-Enforced Non-Agentive AI Governance Engine [NAIGE] Governance Systems – Hardware-enforced Safety for Clinical and Humanitarian Robotics	1.0
978-981-17963-4-0	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	2.0
978-981-17963-9-5	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	3.0
978-981-17970-9-5	Immutable Hardware-Enforced Non-Agentive AI Governance Engine [NAIGE] Governance Systems - Hardware-Enforced Nightingale One Protocol™ P _o Robotic Care for High-Dependency Eldercare : A13d P _o (M + P _i + D) Kinetic/Therapeutic Architecture	4.0
	Nightingale One Protocol: A13c-HC Kinetic Caregiver Safety and Governance Framework	5.0

Clinical Re-Arming Protocol

Document Code:	SOP-A13-REV-L3	Target Audience:	Level-3 Certified Clinicians Only
Apparatus Coverage:	A13d (Kinetic) & A13c-HC (Home)	Revision / Date:	Rev 1.0.4 / August 2026
Classification:	Confidential — Clinical Governance	Approved By:	HSA Class C/D Compliance Board

1. Objective and Safety Mandate

1.1 Objective

This Standard Operating Procedure (SOP) defines the mandatory mechatronic inspection, forensic audit, and cryptographic authorization sequence required to safely re-arm the **Nightingale One (A13d / A13c-HC)** systems following a **U7 Sovereign Brake** lockout.

1.2 Safety Invariant & Lockout State (P-LIFE 1.00)

When the Deterministic Safety Kernel (D-Layer) detects a trajectory breach, torque overload, or sensor disagreement (>5% variance), it immediately bypasses all software controls and asserts **Trigger Point TP-A**. This action triggers the **U7 Sovereign Brake circuit**, which physically severs power to the primary high-voltage DC actuator rails at **Isolation Point TP-B** in **less than 1.05 ms**.

CRITICAL HARDWARE FAIL-SAFE: Upon power severance, the system instantly de-energizes the joint brake coils, causing heavy-duty springs to clamp the reaction plates. This completes a mechanical halt in **under 50 ms**, locking the apparatus in **P-LIFE 1.00 absolute mechanical stillness**. The system is physically incapable of an automatic restart; power restoration can **only** be performed manually by a Level-3 certified clinician.

2. Clinical and Professional Pre-Requisites

2.1 Clinician Qualifications

Re-arming the system after a Sovereign Brake lockout is classified as an **Acute Clinical Intervention**. This procedure must **never** be delegated to Level-1 (CNA/Family) or Level-2 (RN/Licensed PT) caregivers.

- **Authorized Personnel:** Only clinicians who have completed the specialized 8-hour hands-on safety training, possess active professional state licensure (PT, OT, or MD), and hold a Level-3 Cryptographic Hardware Token are permitted to execute this protocol.
- **MFA Mandate:** Re-arming requires active multi-factor authentication, combining biometric iris scans, cryptographic physical keys, and continuous hold-to-run foot pedal engagement.

2.2 Patient Safety and Load Offloading

- **DO NOT** attempt to re-arm or mechanically unlock the system while it supports a patient's active weight.
- **Emergency Transfer:** Prior to commencing any inspection or re-arm command, the patient must be safely stabilized and manually transferred to an independent support surface (e.g., bedside or chair) using manual slide sheets, alternative hoists, or emergency physical assist workflows.
- **Mass Verification:** The telescoping hoist column load cells must register a net load of **0.0 kg (±2.0% tolerance)** before the software command gate will accept the re-arming permit.

3. Step-by-Step Recovery and Re-Arming Protocol

Phase I: Forensic Log Acquisition and Diagnostics

Before performing any physical adjustments, the clinician must determine the root cause of the lockout to ensure structural integrity is intact.

- 1. **Extract the Forensic Digest:** Connect the authorized Level-3 clinical terminal to the forensic output port on the **A12b Deterministic Enclosure**.
- 2. **Audit the WD117 Forensic Ledger:** Query the unalterable One-Time Programmable (OTP) silicon fuse array and read the final SHA-3-512 cryptographically hashed state transition record preceding the brake event. Verify the SHA-512 chain sequence to rule out adversarial tampering or unauthorized software modification attempts.
- 3. **Identify the Fault Trigger:** Match the fault signature to the **Deterministic Safety Kernel Fault Matrix**:
 - *Trajectory Breach:* Joint encoder displacement exceeded the prescribed workspace envelope.
 - *Sensor Disagreement:* The primary encoder and secondary reference channel diverged by **>5% variance**.
 - *Torque Overload:* Joint torque spiked beyond safety limits (Shoulder: **>12 N·m**, Hip: **>15 N·m**).
 - *Emergency Stop:* Physical E-Stop or patient safety pull-cord was activated.

Phase II: Physical Mechatronic Inspection Checklist

The clinician must physically inspect and check off the following subsystems to ensure no mechanical deformation occurred during the high-speed halt. Check boxes are provided on the right for manual validation:

Step	Subsystem & Target ID	Inspection Protocol & Physical Safety Criteria	Status
1	Telescoping Column & Vertical Carriage (220 / 222)	Inspect telescoping inner column and carriage linear guide rails for physical scoring, particulate ingress, or misalignment. Check recirculating ball lead-screw and motor-drive gearbox interfaces for mechanical binding.	☐ PASS ☐ FAIL
2	Spring-Applied Brake Housing Assembly (1105)	Examine column brake housing. Check for thermal damage or coil deformation near de-energized fail-to-hold brake plates. Verify calibrated clamping springs show no structural fatigue.	☐ PASS ☐ FAIL
3	Secondary Mechanical Holding Pawls (1168)	Verify active-low solenoid-controlled mechanical pawl has safely engaged with the inner column's hardened locking tooth strip. Check tooth contact faces for shear deformation or stress fracturing.	☐ PASS ☐ FAIL
4	Dual-Channel Joint Optical Encoders (ENC A / ENC B)	Check mounting brackets and wiring harnesses of redundant rotary encoders at each arm joint. Ensure absolute locking-collar tightness; any physical slippage or backlash (>1.5 mm mechanical limit) triggers immediate channel disagreement.	☐ PASS ☐ FAIL
5	Spring-Loaded Slip Clutches & Torques (Shoulder / Hip)	Verify mechanical slip clutches on shoulder (5–8 N·m limit) and hip joints (10–15 N·m limit) have reset to locked positions. Inspect for excessive friction, glazing, or slip residue.	☐ PASS ☐ FAIL
6	Base Frame AL-6061 & Outriggers (1000G / 1003)	Inspect heavily gusseted frame and base plate. If bariatric transfers (85–150 kg loads) were active, verify outrigger docking assemblies are structurally sound and ground leveling pads are fully engaged.	☐ PASS ☐ FAIL

Phase III: Cryptographic Token and Signature Verification

Once the physical hardware is certified safe, the clinician must present valid cryptographic authorization to satisfy the Outer Protocol Controller (\$P_o\$) and issue a re-arming permit.

1. **Establish Secure Physical Session:** Insert the clinician's physical possession-based cryptographic key token into the dedicated **Hardware Security Module (HSM) socket** on the A12b enclosure.
2. **Fulfill the Tripartite Latch Requirements:** The system hardware AND-gate requires three concurrent physical factors to release the software command gate:
 - **Identity (Biological):** Position eyes within 20 cm of the optical iris scanner. The sensor reads and transmits biometric data over a secure internal SPI bus to the **A10d Deterministic Root of Trust FPGA**, issuing a temporary authorization token with a strict **5-second expiration window**.
 - **Authority (Cryptographic):** Keep the Level-3 HSM key fully seated.
 - **Presence (Kinetic):** Depress and maintain continuous physical pressure on the guarded, heavy-duty kinetic hold-to-run foot pedal (connected directly to a dedicated GPIO hardware interrupt pin).
3. **Validate the Digital Signature:** The **Authorization Control Module (ACM)**—a hardened processor isolated from the primary application layer—queries its independent real-time clock (RTC) to confirm the re-authorization window is open. The ACM cryptographically validates the clinician's signed certificate against the manufacturer's public key root stored in the secure silicon vault.

Phase IV: System Re-Arming and Power Restoration

1. **Execute the Sacred Pause™ (Forced Deliberation):** Upon validation of the Tripartite Latch, the clinician terminal displays the intended state transition: **[LOCKED -> REQUEST -> VERIFIED -> ARMED]**. The system initiates a non-bypassable, hardware-timed **Sacred Pause™** of **1000 ms** (enforced by independent 1 kHz silicon counters). During this window, the D-Layer re-evaluates all hardware interlock lines; any foot-pedal release or coordinate drift instantly aborts the sequence.
2. **Reset Sovereign Brake Circuitry:** If all conditions remain satisfied, the A10d FPGA de-asserts the fault trigger at **Trigger Point TP-A**. This sends an active-HIGH enable signal to the high-speed Solid-State Relay (SSR) at **Trigger Point TP-B**, closing the relay and instantly re-energizing the main high-voltage DC power rail supplying the telescoping column.
3. **Confirm Voltage Restoration:** Verify on the clinician terminal that the actuator power rail (420) measurement rises from 0.00 V to nominal operating voltage. A low-current signal is pulsed to the joint brake coils; listen for a distinct, simultaneous mechanical click across all joints, indicating the holding brakes have disengaged.
4. **Seal the Forensic Audit Ledger:** The A10d FPGA automatically compiles a SHA-3-512 cryptographically signed transition log containing the clinician's signature, timestamp, and physical sensor baselines. This data is transmitted over the unidirectional SPI line and permanently burned into the **WD117 OTP silicon fuse bank**. The system enters **P-LIFE 1.00 Standby State**, ready for standard operation.

4. SOP Compliance and Adverse Event Escalation

- **Audit Logging:** Every manual re-arming event is subject to mandatory clinical audit. The WD117 forensic records must be extracted, cross-referenced with clinical incident reports, and archived in the patient's Electronic Health Record (EHR) within 24 hours of the lockout.
- **Failed Re-Arm Protocol:** If the system refuses to clear the Sovereign Brake lockout or if a secondary power cut occurs immediately upon re-energization, **DO NOT** attempt a second re-arm. Immediately lock out the machine, label it as "OUT OF SERVICE — RE-ARM FAULT," and escalate the incident to a certified biomedical engineer.
- **Adverse Event Review:** Any injury to a patient or caregiver during a lockout or subsequent re-arming sequence triggers an immediate, mandatory suspension of device operation, a system integrity self-test audit, and clinician recertification.

SOP Approval and Clinical Sign-Off

APPROVED BY:

Director of Clinical Engineering
Nightingale Governance Group

Date: _____

Lead Architect
Non-Agentive AI Governance SG

Date: _____

Representative
HSA Compliance Board

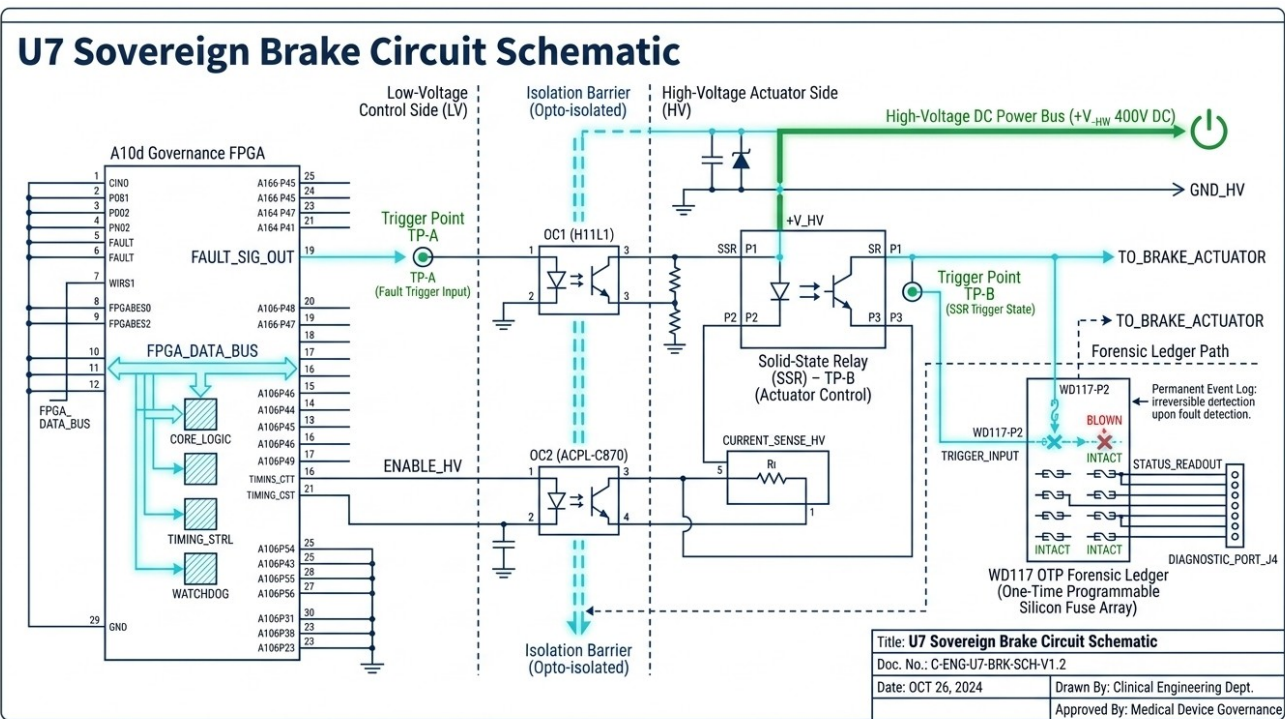
Date: _____

Key Technical Appendices

1. Appendix A: U7 Sovereign Brake Wiring Schematic

This panel bridges the physical mechatronic layout with the underlying logical control plane:

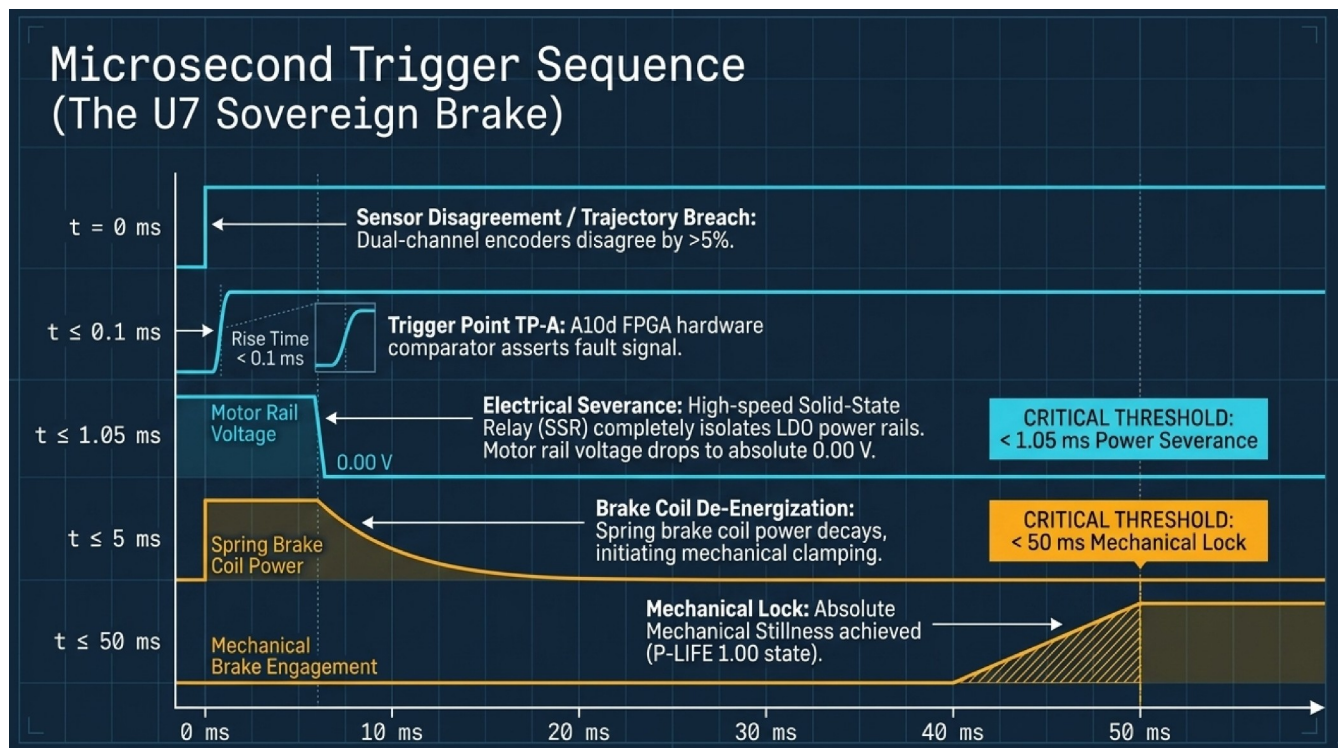
- **Control vs. Actuation Isolation:** Displays the opto-isolated isolation barrier that separates the low-voltage **A10d Governance FPGA** (control side) from the high-voltage **DC motor power rails** (actuator side).
- **Interlock Points:** Maps the hardware loop connecting **Trigger Point TP-A** (the FPGA-side fault output comparator) and **Trigger Point TP-B** (the high-current Solid-State Relay situated directly on the power rail).
- **Audit Trait Anchor:** Shows the unidirectional SPI bus line routing state-transition records directly into the isolated **WD117 OTP silicon fuse bank**, highlighting the absolute lack of reverse-receive (RX) traces to prevent back-loop manipulation.



2. Appendix B: U7 Sovereign Brake Microsecond Timing Sequence

This panel plots the exact concurrent waveforms and safety delays during a safety shutdown event, validating the system's "Inaction-as-Safe-Default" (P-LIFE 1.00) architecture:

- **Fault Detection ($t=0$ ms):** The starting trigger representing a joint encoder variance ($>5\%$) or torque spike (Shoulder: >12 N·m, Hip: >15 N·m).
- **TP-A Assertion ($t \leq 0.1$ ms):** The sub-millisecond hardware comparator trigger by the D-Layer.
- **Electrical Severance ($t \leq 1.05$ ms):** The high-speed solid-state relay opening to drop motor rail voltage to absolute 0.00 V.
- **Brake Coil De-Energisation ($t \leq 5$ ms):** Coil voltage decays, initiating the release of mechanical clamping springs.
- **Mechanical Halt ($t \leq 50$ ms):** Calibrated springs complete reaction plate clamping, locking both the A13d and A13c-HC joint frames in absolute stillness



Primary Citation – This Publication

Koh, E. W. K. (2026). SG Publication

ISBN Paper Back	Title / subject matter	National Edition
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