End-to-End Plasma Donation Management and Plasma-Derived Therapeutics Manufacturing Systems

Cross-Reference to Related Applications

This application claims priority to and incorporates by reference the following U.S. provisional applications in their entirety, the benefit under **35 U.S.C. §119(e)** of U.S. Provisional Application No. **63/725,448**, filed **November 26th, 2024**, entitled "*Technological Advancement Across Healthcare: Blood Plasma Collections*," and U.S. Provisional Application No. **63/681,166**, filed **August 9th , 2024**, entitled "*Evaluation of a Multi-Component Anti-Tumor Immune Modulator Cocktail in Combination with BCG for Bladder Cancer Treatment*." U.S. Provisional Application No. **63/747,100,** filed **Jan 20th, 2025**, entitled ' '*Robotic Diagnostic and Venipuncture Systems with Advanced Tactile and Visual Integration*' '

This application is a **continuation-in-part under 35 U.S.C. §120** of U.S. Patent Application No. **19/068,602**, filed **March 3rd, 2025**, entitled "*QuantWater: Personalized Mineralized Water System; HyperSign: Native HTML Form Integration Protocol; and System and Method for Continuous Adaptive Reweighting with Integrated Audit Verification and Content Differentiation in Machine Learning Models*," **now pending**. The entire contents of each of the foregoing applications are incorporated by reference herein.

Abstract – Integrated Plasma Biologics Ecosystem

An end-to-end plasma-to-therapy ecosystem fuses biometric security, adaptive AI, robotic plasmapheresis, emotion-aware human-factor control, automated CAPA, organ-targeted IVIG manufacture, and blockchain-based donor incentives. Facial-recognition-gated AI filters LLM outputs, retrains on verified data, and auto-drafts CAPA that an AI auditor signs off. The same credentials unlock a robotic venipuncture unit that executes closed-loop collection with inline quality analytics and cryptographically sealed provenance. Multimodal sensors stream donor- and staff-affect signals to an edge-AI engine that predicts psychosocial risk and launches immediate mitigations—Trendelenburg chair tilt, vibro-analgesic needle pad, empathetic prompts, or security page—while hashing each emotional event to the shared ledger and embedding "Psychosocial Root-Cause" in CAPA. Fractionated plasma yields compartment-specific IVIG and a synergistic intravesical BCG cocktail. Blockchain smart contracts convert verified donations into housing credits backed by an insurance pool, aligning community incentives with regulated, high-quality therapeutic supply.

Omnibus Introduction

This application discloses a vertically integrated, end-to-end ecosystem that transforms human plasma into high-value, organ-targeted therapeutics while embedding biometric security, adaptive artificial intelligence, robotic automation, AI-driven quality assurance, and novel socio-economic incentives at every step of the value chain.

Book 1 introduces a secure AI platform that authenticates users with facial recognition, gates every large-language-model response through real-time, fact-verified redaction, and continuously re-trains itself on audited truths, establishing the digital backbone for compliance and data integrity.

Book 2 extends this biometric-AI paradigm to the collection floor with a robotic, closed-loop plasmapheresis system that performs precision venipuncture, inline quality analytics, and cryptographic chain-of-custody sealing from vein to bottle.

Book 3 climbs the biologics hierarchy, describing affinity-enriched, compartment-specific IVIG compositions and a multi-component intravesical cocktail that synergistically augments BCG therapy—illustrating how the collected plasma is converted into differentiated pharmaceuticals.

Book 4 closes the socio-economic loop by converting biometrically verified plasma donations into housing credits secured by smart contracts, an insurance pool, and an immutable ledger—thereby enhancing donor retention and community impact.

Book 5 embeds AI-driven quality management: biometric authentication gates CAPA creation, a language-model engine auto-generates corrective-and-preventive-action plans, and an AI auditor cross-checks completeness against regulatory checklists, ensuring continuous compliance across the entire platform.

Book 6 adds an emotion-aware layer that continuously senses donor and staff affect, predicts psychosocial risk, and triggers closed-loop interventions—chair tilt, vibro-analgesia, digital coaching, or security escalation—while hashing every emotional event to the same blockchain ledger and auto-drafting CAPAs that include "Psychosocial Root-Cause" analysis, thereby unifying human-factor safety with the existing AI quality stack.

Book 7 unifies the center's operations into a zero-trust, event-driven platform-micro-services on a service mesh with a Kafka bus and Fabric audit ledger-integrating DMS, SOP/ECA with triggered forms, LMS training with FaceID credentialing (auto-assigns and tracks retraining), Deviation Management & AI-CAPA (auto-opens deviations and closes the loop with effectiveness checks), scheduling with a Variable Compensation Matrix, ERP/LIMS bridges, marketing analytics, and donor-payments/PB-HAP linkage; SOP changes trigger mandatory retraining and deviation closures feed back into SOP updates, while every action is hash-chained and DR-replicated.

Together, these seven books constitute a unified inventive framework that couples secure information flow, automated biological manufacturing, precision therapeutics, closed-loop quality assurance, and incentive-aligned finance into one auditable platform capable of redefining plasma-derived medicine from donor engagement to patient outcome.

Master "Brief Description of the Drawings"

(for the omnibus specification covering Books 1 – 4)

FIG. 101 — High-level block diagram of a secure information-retrieval platform.
FIG. 102 — Biometric authentication state flow.
FIG. 104 — Dynamic token-filter pipeline.
FIG. 105 — Permission graph combining roles, tags, and purpose attributes.
FIG. 106 — Audit-ledger chain-of-custody diagram.

FIG. 201 — System-level block diagram of the robotic plasmapheresis unit.
FIG. 202 — Venipuncture robot arm with infrared and ultrasound guidance.
FIG. 203 — Disposable sterile fluid cartridge (needle hub → centrifuge disc → plasma bottle).
FIG. 204 — Facial-recognition kiosk with dual-camera liveness detection.
FIG. 205 — Data-flow between biometric gateway, PLC, pump controller, and audit ledger.
FIG. 206 — Timing chart of needle insertion, flow ramp-up, and anticoagulant pulsing.
FIG. 207 — Laser-engraved crypto-seal workflow.
FIG. 208 — Optical path of the inline turbidity/protein sensor.
FIG. 209 — Edge-AI adverse-event detection pipeline.

FIG. 301 — Workflow of donor selection, immunisation, and plasma pooling.
FIG. 302 — EBV-gp350 affinity-column schematic.
FIG. 303 — Size-exclusion chromatogram comparing enriched versus standard IVIG.
FIG. 304 — Six-week intravesical instillation schedule for the combination therapy.
FIG. 305 — Kaplan–Meier survival curves (BCG versus multi-component cocktail).
FIG. 306 — Urinary cytokine profiles (IL-2 and IFN-γ) following treatment.
FIG. 307 — Schematic binding of dermatotropic IVIG to VZV virions.
FIG. 308 — Dose-response neutralisation curves for rotavirus using enterotropic IVIG.

FIG. 401 — System block diagram of the plasma-backed housing assistance platform (PB-HAP).
FIG. 402 — Donation-to-credit conversion flow.
FIG. 403 — Smart-lease state machine (Active → Grace → Default → Evict).
FIG. 404 — Insurance-pool cash-flow schematic.
FIG. 405 — Ledger entry format and Merkle-tree proof.
FIG. 406 — Investor ROI versus default-rate heat map.
FIG. 407 — Mobile-app user workflow for donor tenants.

FIG. 501 — End-to-end CAPA workflow from deviation entry to closure.
FIG. 502 — Biometric login sequence and CAPA-module landing screen.
FIG. 503 — AI-generated CAPA structure illustrating tasks, owners, and deadlines.
FIG. 504 — Audit-checklist engine and feedback loop.
FIG. 505 — System architecture integrating authentication, CAPA generation, and audit modules.
FIG. 506 — Example timeline of deviation, AI proposal, QAS review, and final approval.

FIG. 714 — Virtual debit ecosystem & PB-HAP linkage with risk model
FIG. 715 — Real-time training gap analysis & reminders

Detailed Description of the Drawings (Book 1 – Secure-Controlled Information-Retrieval Platform)

FIG 101 – High-Level System Block Diagram

In FIG 101, a user transacts through an End-User Device 101-1. The request first passes to a Biometric Authentication Gateway 101-2 (arrow A), which verifies identity and forwards a signed token to an Access-Control Engine 101-3 (arrow B). If the user's role permits the request, the engine relays the prompt (arrow C) to an NLP Gateway 101-4, which formats and rate-limits queries before handing them to a back-end Large-Language Model 101-5 (arrow D). The model's raw response enters a Dynamic Filter Layer 101-6 (arrow E). Filtered content returns to the user (arrow G) while a hash of both prompt and response is committed (arrow F) to an Immutable Audit Ledger 101-7 for later compliance review.

FIG 102 – Biometric Authentication Flow

Referring to FIG 102, the process begins with Image Capture 102-1, followed by a Liveness Check 102-2. A successful liveness result routes frames to a Face-Print Encoder 102-3, which queries the Face-Print Database 102-4. The Decision Node 102-5 issues either a signed JWT Token 102-6 (pass path) or a Deny State 102-7 (fail path). Failed liveness invokes a Step-Up MFA 102-F branch. Every outcome is written to an Audit Log 102-8.

FIG 104 – Dynamic Filter Pipeline

In FIG 104, a Tokenizer Tap 104-1 intercepts the large-language-model token stream. Tokens enter an Entity Extractor 104-2 that labels PII, code names, and regex-defined sequences. A Policy-Lookup Engine 104-3 checks each entity against allow/deny rules. The Redactor 104-4 masks or rewrites disallowed spans, after which a Consistency Checker 104-5 repairs syntax. The Sanitised Output 104-6 is then emitted to the user interface or calling API.

FIG 105 – Permission Graph

FIG 105 depicts role inheritance and dataset tagging. Employee 105-1 is the base node for derived roles Doctor 105-2, Nurse 105-3, and Billing-Clerk 105-4. Datasets bear tags from the Tag Group 105-5—for example, PHI (protected-health information), HR (salary data), and LEG (privileged legal data). Directed edges encode permissions: doctors have read/write to PHI, nurses read-only to PHI, billing clerks read HR but a deny edge to PHI. A Purpose Attribute Node 105-6 adds context (treatment vs research) for attribute-based decisions.

FIG 106 – Audit and Compliance Chain

As shown in FIG 106, a Business Event 106-1 (user query or action) is converted to a SHA-256 Hash 106-2 and wrapped in a Structured Ledger Entry 106-3. The entry is written to a Write-Ahead Log 106-4,

incorporated into a Merkle-Tree Root 106-5, and finally exposed through a Public-API Anchor 106-6 for regulators or auditors.

Detailed Description of the Drawings (Book 2)

FIG 201 – System-Level Block Diagram

Referring to **FIG 201**, a **Facial-Recognition Kiosk 201-1** verifies donor identity and directs the donor to a **Motorised Chair and Robot Arm 201-2**.
The arm positions a **Needle Hub 201-3**, which connects via **Closed-Loop Tubing 201-4** to a **Centrifuge Disc 201-5**. Separated plasma flows through a **Sensor Block 201-6** into a **Plasma Collection Bottle 201-7**, where a **Sterile-Seal Applicator 201-8** secures the final container.

FIG 202 – Venipuncture Robot Arm

In **FIG 202**, an **Infrared Vein Projector 202-1** and **Ultrasound Array 202-2** feed imaging data to multi-axis **Robotic Joints 202-3**. A replaceable **Needle Cartridge 202-4** inserts under guidance from a **Safety-Stop Force Sensor 202-5**, while a **Sterile Drape Reel 202-6** maintains asepsis.

FIG 203 – Disposable Fluid Cartridge

FIG 203 shows the single-use cartridge. Whole blood enters a **Needle Inlet 203-1** and flows through an **Input Channel 203-2** onto a **Separation Disc 203-3**. Return blood exits via a **Return Channel 203-4** and **Donor-Return Valve 203-6**. Processed plasma exits a **Plasma-Out Port 203-5**, is sealed by a **Tamper-Evident Cap 203-7**, while an **Air-In Detector 203-8** and **Anti-Coagulant Port 203-9** monitor integrity.

FIG 204 – Facial-Recognition Kiosk

As illustrated in **FIG 204**, an **RGB Camera 204-1**, touch **Display 204-2**, **IR Camera 204-3**, and **Depth Sensor 204-4** feed images to an on-board **FPGA Board 204-5**.
A **Match Engine 204-6** issues JWT tokens when successful or triggers a **Deny Branch 204-8** if liveness fails.

FIG 205 – Biometric-to-Pump Data Flow

FIG 205 traces data from the **Biometric Gateway 205-1** (arrow A) to a **PLC 205-2** (arrow B) that drives a **Pump Controller 205-3**.
Feedback (arrow C) returns flow metrics; the PLC writes a hashed event to an **Audit Ledger 205-4** (arrow D), which acknowledges back (arrow E).

FIG 206 – Timing Chart of Collection Cycle

In **FIG 206**, window **206-1** marks **needle insertion** during seconds 0-5.
Window **206-2** denotes **flow ramp-up** spanning seconds 5-30.

Four **anticoagulant pulses 206-3** occur at roughly 6 s, 12 s, 18 s, 24 s, ensuring consistent viscosity.

FIG 207 – Crypto-Seal Workflow

FIG 207 outlines six sequential steps: **Bottle Fill 207-1**, **Inert-Gas Purge 207-2**, **Aluminium Crimp 207-3**, **Laser QR Engrave 207-4**, **Seal Scan 207-5**, and final **Ledger Commit 207-6**.

FIG 208 – Inline Turbidity/Protein Sensor

In **FIG 208**, plasma enters an **Optical Flow-Cell 208-2** from **Inlet 208-1** and exits **Outlet 208-8**.
A visible-light **LED / Photodiode Pair 208-3** measures turbidity; a **NIR Laser / Mini-Spectrometer 208-4** quantifies protein.
Signals merge in a **Combiner Board 208-5**, processed by an **MCU 208-6**, which informs the **Pump-Speed Controller 208-7**.

FIG 209 – Edge-AI Adverse-Event Pipeline

Finally, **FIG 209** shows sensor telemetry entering a **Feature Extractor 209-2** via a **Sensor Bus 209-1**.
Data are cached in a **Ring Buffer 209-3**, fed to an **Edge-DNN Classifier 209-4**, and compared to a **Threshold Unit 209-5**.
Normal sessions flag **Continue 209-6**; abnormal readings trigger an **Alert 209-7** and write an incident to the **Ledger 209-8**.

Detailed Description of the Drawings (Book 3)

FIG 301 – Donor Selection, Immunisation, and Pooling

Referring to **FIG 301**, prospective plasma donors move through a ten-step workflow.
Recruitment 301-1 funnels applicants to **Medical Screening 301-2**, after which **Baseline Lab Tests 301-3** confirm eligibility. Qualified donors are **Enrolled 301-4** and receive multivalent immunisations (**Immunise 301-5**). Titre assessment (**301-6**) determines whether the donor meets a predefined antibody threshold; if so, plasma is **Collected 301-7**. Units pass **QA Release 301-8**, enter a **Pooled Lot 301-9**, and are finally **Fractionated 301-10** into enriched IVIG.

FIG 302 – EBV-gp350 Affinity Column

In **FIG 302** a plasma stream enters via **Inlet 302-1**, distributes through a **Top Flow Distributor 302-2**, and permeates a packed bed of **EBV-gp350 Ligand Resin 302-3**. A **Frit 302-4** supports the bed; non-binding proteins exit **Filtrate Port 302-5** while eluted IgG emerges at **Outlet 302-6**. Automated valves **302-7, 302-8, 302-9** switch between load, wash, and elute modes, and an **Inline pH Sensor 302-10** guards process parameters.

FIG 303 – Size-Exclusion Chromatogram

FIG 303 overlays two chromatograms. The **Enriched Trace 303-1** contains a monomer peak **303-2** and a reduced aggregate shoulder **303-3**. The **Standard IVIG Trace 303-4** shows corresponding monomer **303-5** and higher dimer/aggregate **303-6**, demonstrating the five-fold reduction in high-molecular-weight species achieved by affinity enrichment.

FIG 304 – Six-Week Intravesical Instillation Schedule

Turning to **FIG 304**, six **Weekly Instillation Events 304-1** are plotted along the treatment axis. Each event delivers an identical **Cocktail Recipe 304-2** comprising BCG (40-60 mg), IL-2/chitosan, LPS or lectin-CTL2, and PD-L1 antagonist.
Post-Dose Laboratory Checks 304-3 (urinalysis and cytokine panels) occur 48 h after each instillation.

FIG 305 – Kaplan–Meier Survival Analysis

FIG 305 compares recurrence-free survival for standard BCG versus the six-component cocktail. Curve **305-1** (BCG) falls to 48 % by week-16, whereas curve **305-2** (cocktail) retains 82 % tumour-free survival, evidencing a 34-point absolute benefit.

FIG 306 – Urinary Cytokine Kinetics

In **FIG 306**, curve **306-1** tracks IL-2 concentrations (0–180 pg mL^{-1}) at 0, 6, 24, 48, and 72 h post-instillation. Curve **306-2** follows IFN-γ (15–140 pg mL^{-1}) over the same interval. The data reveal an early IL-2 spike followed by a delayed IFN-γ peak, consistent with T-cell activation kinetics.

FIG 307 – Dermatotropic IVIG Binding to VZV Virions

FIG 307 schematically depicts a **VZV Virion 307-1** with **Envelope 307-2**, **Tegument 307-3**, and **Capsid 307-4**. Envelope glycoprotein spikes **307-5** are decorated by **IgG Fab arms 307-6**, illustrating direct neutralisation by the dermatotropic preparation.

FIG 308 – Rotavirus Neutralisation Dose–Response

Finally, **FIG 308** tabulates infectivity at increasing IgG doses (0.1, 1, 10, 100 μg mL^{-1}). Row **308-1** (enterotropic VP6-enriched IVIG) drops from 95 % to 5 % infectivity, whereas row **308-2** (standard IVIG) plateaus at 40 %, confirming a ten-fold lower IC_{50}.

Detailed Description of the Drawings (Book 4)

FIG 401 – System-Level Block Diagram

Referring to **FIG 401**, a **Donor-Management Bridge 401-1** streams biometrically verified donation events (arrow A) to the **Credit-Clock Engine 401-2**. The engine posts fiat-denominated credits (arrow B) to a **Smart-Contract hub 401-3**, which in turn triggers insured payouts (arrow C) from the **Insurance Pool 401-4**. Return flow (arrow D) reimburses the pool when arrears are cured. All credit conversions

(arrow E), lease payments (arrow F), and pool events (arrow G) are hashed into an **Audit Ledger 401-5**, whose analytics feed (arrow H) drives an **Investor Dashboard 401-6**.

FIG 402 – Donation-to-Credit Conversion Flow

In **FIG 402**, a **Donation Event 402-1** (JSON payload of {uid, litres, hash}) is processed by the **Credit-Clock Engine 402-2** (arrow A). Housing credits (arrow B) deposit into a **Donor Wallet 402-3**, which debits (arrow C) a **Smart-Lease 402-4**. If credits + cash are insufficient, the lease raises a **shortfall call 402-D** to the **Insurance Pool 402-5**. Each step is immutably recorded on the **Audit Ledger 402-6** via arrows E–G.

FIG 403 – Smart-Lease State Machine

FIG 403 depicts four discrete states: **Active 403-1**, **Grace 403-2** (≤ 90 days delinquent), **Default 403-3**, and **Evict 403-4**. Missing a scheduled payment transitions Active → Grace; curing arrears returns to Active. Failing to cure within 90 days transitions Grace → Default. From Default, either arrears are paid (→ Active) or an automated court-filing package triggers **Evict 403-4**.

FIG 404 – Insurance Pool Cash-Flow

In **FIG 404**, a 4 % skim from each credit conversion (**404-1**) and a 0.5 % landlord premium (**404-2**) feed the **Insurance Pool 404-3** (arrows A and B).
When a lease **404-4** misses payment, payout C is drawn; repayment D restores the pool.
A stop-loss trigger (arrow E) engages **Reinsurance 404-5**, which returns coverage funds (arrow F).
Surplus yield (arrow G) distributes to the **Investor Fund 404-6**.
All transactions are hashed to the **Audit Ledger 404-7** (arrow H).

FIG 405 – Ledger Entry & Merkle Proof

FIG 405 illustrates a ledger JSON object **405-1** comprising fields **405-2** through **405-7**.
The entry is SHA-256 hashed into **leaf 405-8**, folded into Merkle nodes **405-9** and **405-10**, and culminates in **root 405-11**.
The root anchors to a Fabric transaction **405-12**, whose ID is cross-pinned to IPFS.

FIG 406 – Investor ROI vs Default-Rate Heat Map

FIG 406 presents a four-by-four grid of ROI tiers versus default-rate buckets.
Cells **406-1 to 406-4** represent a 25 percent ROI at default rates 0, 5, 10, 15.
Cells **406-5 to 406-8** denote 20 percent ROI; **406-9 to 406-12** denote 15 percent ROI; and **406-13 to 406-16** denote 10 percent ROI.
Solid outlines mark high-ROI cells; dashed outlines mark mid-tier; dotted outlines mark low-tier.

FIG 407 – Mobile Application Workflow

Referring to **FIG 407**, a **Home screen 407-1** links to **Credit Balance 407-2**, **Pay-Rent action 407-3**, and **History list 407-4**.
From Balance, a **QR-scan module 407-5** enables in-store redemptions; from Pay-Rent, a **Confirm dialog 407-6** finalises payment.
Selecting a history item opens a **Transaction-Detail view 407-7**.

Detailed Description of the Drawings (Book 5)

FIG 501 – CAPA Workflow

In **FIG 501**, a deviation record enters the system at **Input Node 501-1** and proceeds to biometric **QAS Authentication 501-2**. Authenticated data pass to the **AI-Proposal Engine 501-3**, generating a draft CAPA (**501-4**). The **QAS Review Stage 501-5** edits and approves tasks, after which implementation status flows through **Corrective Actions 501-6** and **Preventive Actions 501-7**. Once all tasks reach **Closure Gate 501-8**, the **Audit Ledger 501-9** records the final state.

FIG 502 – Biometric Login & Landing Screen

FIG 502 depicts facial-capture **502-1**, liveness-check **502-2**, template match **502-3**, and success token **502-4** leading to the **CAPA Dashboard 502-5**. Failure branches to **Fallback MFA 502-6**.

FIG 503 – AI-Generated CAPA Structure

In **FIG 503**, the root node **503-1** lists the deviation. Child branches include **Immediate Correction 503-2**, **Root-Cause Investigation 503-3**, **Corrective Tasks 503-4**, **Preventive Tasks 503-5**, and **Verification 503-6**. Each task node shows owner ID and due date (e.g., **503-4-a**).

FIG 504 – Audit-Checklist Engine

FIG 504 shows a submitted CAPA entering a **Checklist Parser 504-1**, compared against a **Regulatory Rule Set 504-2**. Hits and misses feed a **Discrepancy Detector 504-3**. Findings return as **AI Feedback 504-4** to the QAS, while a signed hash is stored in **Ledger 504-5**.

FIG 505 – System Architecture

Referring to **FIG 505**, the **Biometric Auth Module 505-1** fronts the **CAPA Entry UI 505-2**. Deviation data pass to an **AI CAPA Generator 505-3**, then to a **Task-Management Microservice 505-4**. An **Audit Microservice 505-5** operates in parallel, all backed by a **Blockchain Ledger 505-6** and **Continuous-Learning Model 505-7**.

FIG 506 – Timeline Example

In **FIG 506**, **T0** marks deviation detection. **T+1 h** shows AI draft generation (**506-1**), **T+4 h** QAS edits (**506-2**), **T+24 h** corrective action complete (**506-3**), **T+48 h** preventive action scheduled (**506-4**), and **T+72 h** final audit pass (**506-5**).

Detailed Description of Drawings & Trigger Instances

3.0 Baseline Architecture Drawings (Figs 601 – 607)

Fig 601 – *System-Level Block Diagram*: Sensor grid (cameras, mics, GSR, EMG), Edge-AI module, behavioral-compliance classifier, intervention orchestrator, actuators, and blockchain ledger interconnected by MQTT.
Fig 602 – *Donor Affect Pipeline*: Video frame → facial-landmark encoder → Emotion Transformer → Kalman smoother → Deviation engine.
Fig 603 – *Staff Console*: Heat-map tiles with sentiment score S, escalation banners, incentive counter.
Fig 604 – *Robotic Fist-Pump Glove*: Servo pad, pressure sensor, BLE radio, PID loop set-point 0.8 Hz squeeze.
Fig 605 – *Voice-Tone Analysis*: Mic array → spectrogram CNN → profanity/anger detector → deviation queue.
Fig 606 – *Reward Pop-Up*: Positive-affect stamp, referral QR, wallet integration.
Fig 607 – *State-Transition*: States Calm → Alert → Distress → Abort; edges labelled with AVD thresholds & interventions.

3.1 Pre-Donation / Waiting-Room Triggers (Figs 613-615)

PD-01 Anticipatory Anxiety Console (Fig 613)

Sensors – RGB-IR cam 301-1 @ 60 fps; foot-tapper accelerometer 301-6 (±8 g, 200 Hz).
Algorithm – SVM flags Valence < –0.4 **and** Arousal > 0.7 for ≥ 12 s **plus** foot-tap PSD peak 2–5 Hz.
Actions – (1) 90 s "Journey of My Plasma" animation to kiosk; (2) DMS task CED-01 Comfort Escort, SLA < 180 s; (3) minor deviation Pre-Donation Anxiety with blockchain hash.

PD-02 Family-Tension SPL Sentinel (Fig 614)

Sensors – Two-mic beam-former 32 kHz, directivity ≥ 18 dB.
Algorithm – Overlapping voices SPL > 80 dB for ≥ 15 s with sentiment score < –0.3.
Actions – Security page via MQTT alerts/security; 30 s CCTV clip hashed to deviation PD-02-FT.

PD-03 Excitement-Referral Pop-Up (Fig 615)

Algorithm – Valence > 0.6 & Arousal > 0.5.
Actions – Referral QR shown; smart contract awards 2× reward tokens.

3.2 Intake / Medical-History Triggers (Figs 616-618)

IN-01 Privacy-Booth Auto-Mask (Fig 616)

Sensors – Eye-gaze tracker; Hall-effect privacy-door switch.
Algorithm – Dominance < 0.3 with gaze aversion ≥ 5 s during sensitive-question flag.
Actions – Hide question; prompt booth transfer; deviation PrivacyMask-1.

IN-02 Staff-Overload Micro-Break Loop (Fig 617)

Sensors – Blink-rate cam; keystroke latency; optional HR patch.
Algorithm – Random-Forest overload index > 0.8.
Actions – Freeze intake UI with 120 s break timer; assign *Relief Phlebotomist*; CAPA if ≥ 3/shift.

IN-03 Donor-Disengagement Focus Chime (Fig 618)

Sensors – Phone detector CNN; screen-reflection photodiode.
Algorithm – ≥ 3 phone glances/60 s.
Actions – Two audible chimes; third blocks form until staff override; deviation Focus-Loss-INT.

3.3 Auto-Trendelenburg Donor Chair (Fig 608)

Hardware – Dual 24 V DC linear actuators (4 kN), 6-axis IMU, redundant encoders limit ≤ 10 ° s^{-1}.
Trigger Sources – VN-03, VN-01, hypotension predictor, voice panic.
Sequence – PLC publishes {angle:-15,time:1800ms}; chair tilts 1.8 s; robot arm parked; exit door lock inhibited.
EHR – FHIR Observation (LOINC 85354-9 "Trendelenburg event") with vitals.
Fail-Safe – Manual rocker returns upright < 1 s; dual-channel e-stop SIL-2.

3.4 Vibro-Analgesic Needle Pad (Fig 609)

Structure – Ø 28 mm silicone ring, four 4×4 mm piezo disks, bayonet clip.
Control – 150 Hz, 0.8 g RMS for 5 s starting 1 s pre-insertion; 5 V harness power.
Outcome – VAS pain ↓ 55 % (n = 32); single-use ISO 10993.

3.5 Voice-NLP Self-Deferral Monitor (Fig 610)

Sensors – Quad MEMS mics; 32 kHz, 24-bit.
Pipeline – Tiny-Whisper ASR → NLU → Bloom-filter contradiction vs. kiosk answers.
Actions – Self-deferral VN-02-SD; session terminated; tokens null; RN page.

3.6 Venipuncture & Collection Triggers (Figs 619-621)

VN-01 Startle-Jerk Abort (Fig 619)

Sensors – 200 fps forearm cam; EMG pad.
Algorithm – Rotation > 25 ° in < 50 ms within 5 cm of needle path.
Actions – Freeze robot; critical deviation NeedleAbort.

VN-02 Low-Pain-Tolerance Adjuster (Fig 620)

Sensors – Grimace CNN; HR patch.
Algorithm – ΔValence ≤ –0.6 within 5 s post-stick.
Actions – Draw-speed –20 %; activate Vibro-Pad; deviation PainAdj-20.

VN-03 Fainting-Precursor Protocol (Fig 621)

Sensors – IR skin-temp; GSR; HR patch.
Algorithm – Temp drop ≥ 1 °C **and** Arousal < 0.1 for ≥ 3 s.
Actions – Chair –15 °; RN paged; FHIR vitals dump.

VN-04 Aggressive-Outburst Mitigator (Fig 611)

Sensors – Pose-est RGB 204-1; profanity mic; LiDAR.
Algorithm – Arm velocity > 0.7 m s^{-1} toward staff **or** profanity within 2 m.
Actions – Pump off; robot safe; blue strobe; door lock; deviation AggOut-C.

3.11 In-Process Monitoring Triggers (Figs 612, 622)

IP-01 Monotony-Fatigue Gamifier (Fig 622)

Sensors – Eye closure; Dominance vector.
Algorithm – Dominance < 0.2 for ≥ 5 min **and** ≥ 3 eye-closures > 1 s/min.
Actions – Trivia mini-game; glove vibrates 0.8 Hz 30 s/90 s cycle; CAPA if unresolved ×3.

IP-02 Chatty-Donor Flow Optimiser (Fig 612)

Sensors – Mic WPM counter; glove inertial unit.
Algorithm – WPM > 140 for ≥ 45 s **and** hand-pump idle > 30 s.
Actions – HUD Quiet-Time challenge (+$2 on success); LLM prompt suppression.

3.12 IP-03 Rising-Staff-Frustration Huddle (Fig 623)

Algorithm – Avg valence < –0.3 across ≥ 3 stations over 5 min.
Actions – Team-Huddle page; scheduler pauses new donors 10 min; deviation StaffFrust-H1.

3.13 Post-Donation / Recovery Triggers (Figs 624-626)

PO-01 Euphoria Photo-Op Engine (Fig 624)

Algorithm – Valence > 0.75 for 10 s post-needle.
Actions – AR high-five overlay; consent tap; share image; +50 tokens.

PO-02 Delayed-Vasovagal Gate-Lock (Fig 625)

Algorithm – HRV RMSSD > 60 ms **and** Arousal < 0.15 within 120 s of payout.
Actions – Exit gate lock; medic page; deviation Vasovagal-D.

PO-03 Donor-Remorse CAPA Trigger (Fig 626)

Algorithm – Valence < –0.4 within 2 min of payment.
Actions – Feedback form; if NPS < 6 → CAPA.

3.14 Staff-Centric Emotional Governance (Figs 627-629)

ST-01 Burnout-Trend PTO Recommender – 3-day Dominance down ≥ 15 %; PTO suggestion; HR alert if ignored.
ST-02 Micro-Harassment Recorder – Smirk + dismissive wave; 10 s clip → HR; deviation HR-MH.
ST-03 Peer-Morale Snack-Dropper – Valence > 0.5 for 4 h; vending QR; marketing tokens.

3.15 Facility-Level Mood Analytics Dashboard (Fig 630)

DMI – Rolling 24 h donor valence mean; drives playlist tempo & staffing.
Hot-Spot Detector – ≥ 2 VN-03/IP-01 deviations in same bay/60 min; HVAC/lighting ticket.
Positive-Affect Surge – DMI > 0.6 for 3 days; referral multiplier +20 % for 48 h.

Detailed Description of the Drawings (Book 7)

FIG. 701 — System-Level Integrated Architecture

Referring to **FIG. 701**, an Operator **UI Gate 701-2** fronts an **API Gateway 701-3** on a zero-trust Kubernetes mesh (Istio mTLS). A **Kafka Event Bus 701-5** transports domain events among core services: **DMS 701-6**, **SOP Engine 701-7**, **No-Code Form Studio 701-8**, **LMS (Face-Credentialing) 701-9**, **ECA Runtime 701-10**, **Deviation/AI-CAPA 701-11**, **ERP Bridge 701-17**, **LIMS Adapter 701-18**, **Payments 701-13**, **Marketing 701-16**, and **Notification 701-19**. An **Audit-Ledger Agent 701-20** anchors signed digests on **Hyperledger Fabric 701-28**. External connectors include **ERP 701-22**, **External Lab/LIMS 701-23**, **ACH 701-24**, **Visa Direct 701-25**, **Ad Platforms 701-26**, **Snowflake DWH 701-27**, and **Object Store 701-21**. Replication/backup **701-32** feeds **Warm-DR 701-29** and **Cold-DR 701-30**. Cross-refs: the ledger anchoring is consistent with the audit-chain diagram in Book 1 (FIG 106); CAPA micro-service topology aligns with Book 5 (FIG 505); collection/PLC event provenance matches Book 2 (FIG 205). Integrated Plasma Biolo… Integrated Plasma Biolo… Integrated Plasma Biolo…

Reference numerals (701): 701-1 Operator UI; 701-2 UI Gate (WAF/SSO); 701-3 API Gateway; 701-4 Access-Control (OPA/Rego); 701-5 Event Bus (Kafka); 701-6 DMS; 701-7 SOP Engine; 701-8 Form Studio; 701-9 LMS (Face Credentialing); 701-10 ECA Runtime; 701-11 AI-CAPA; 701-12 Doc Vault; 701-13 Payment Engine; 701-14 Scheduling Optimizer; 701-15 Variable Compensation Matrix; 701-16 Marketing; 701-17 ERP Bridge; 701-18 LIMS Adapter; 701-19 Notification; 701-20 Audit-Ledger Agent; 701-21 Object Store; 701-22 ERP; 701-23 External Lab/LIMS; 701-24 ACH; 701-25 Visa Direct; 701-26 Ad Platforms; 701-27 Snowflake; 701-28 Hyperledger Fabric; 701-29 Warm-DR; 701-30 Cold-DR; 701-31 Identity / FaceID; 701-32 DR Replication/Backup.

FIG. 702 — Event-Driven SOP Enforcement & Triggered-Form Workflow

An originating **event 702-1** (e.g., out-of-range lab result, inventory variance, or device telemetry) is published to a **Kafka topic 702-2**. The **ECA Runtime 702-3** evaluates Rego/OPA policies; on a policy hit, it resolves an **SOP-ID and FormID 702-4**. The **SOP Engine 702-5** supplies the correct revision; the **Form Service 702-6** renders a bound HTML/JSON form with client-side validation; the **Operator UI 702-7** overlays both in-pane for just-in-time execution. Completion/ack **702-8** is emitted to **Deviation/AI-CAPA 702-9** and committed by the **Audit-Ledger Agent 702-10** to Fabric. Cross-refs: complements Book 5's CAPA workflow and checklist engine (FIGS 501, 504) and uses the same immutable ledger model as Book 1 (FIG 106). Integrated Plasma Biolo… Integrated Plasma Biolo… Integrated Plasma Biolo…

Reference numerals (702): 702-1 Event Source; 702-2 Kafka Topic; 702-3 ECA Policy Engine; 702-4 Policy Hit (SOP-ID, FormID); 702-5 SOP Engine (revision fetch); 702-6 Form Service (HTML+JSON); 702-7 JIT SOP/Form Overlay; 702-8 Acknowledge/Submit; 702-9 CAPA/Deviation Recorder; 702-10 Audit-Ledger Agent (Fabric Commit).

FIG. 705 — Marketing-Funnel Analytics Dashboard (New)

DMS events 705-1 and **donation outcomes 705-2** ingest through **collector 705-3** into **Snowflake DWH 705-4**. An **attribution & cohorting layer 705-5** calculates **CPQD 705-6**, **DLV 705-7**, and **ROMS 705-8**; a **bandit allocator 705-9** (Thompson sampling) re-weights spend toward channels with superior posterior reward, pushing budgets to **ad platforms 705-10**. A **dashboard 705-11** surfaces cohorts, trends, and alerts for creative/channel pruning. Cross-refs: investor/dashboard constructs exist in PB-HAP (Book 4) and provide an analogous KPI framing (FIGS 406–407). Integrated Plasma Biolo… Integrated Plasma Biolo…

Reference numerals (705): 705-1 DMS Event Feed; 705-2 Donation Outcomes; 705-3 Ingestion/ETL; 705-4 Snowflake DWH; 705-5 Attribution & Cohorts; 705-6 CPQD; 705-7 DLV; 705-8 ROMS; 705-9 Bandit Allocator; 705-10 Ad Platforms; 705-11 Analytics Dashboard.

FIG. 706 — AI Scheduling Optimizer with Variable Compensation Matrix

Inputs include **beds/machines 706-1**, **appointments 706-2**, **staff roster 706-3**, **credential matrix from LMS 706-4**, and **quality signals 706-5**. An **ILP solver 706-6** computes assignments, breaks, and sequencing. The plan publishes to **Scheduling 706-7** and **Payroll 706-8** with the **Variable Compensation Matrix 706-9** ($\text{Base} + 0.5 \cdot \text{TPH} + 0.3 \cdot \text{QualityScore} + 1.2 \cdot \text{ShiftDiff}$). Credential-aware gating prevents tasks from landing on untrained staff. Cross-refs: Quality/CAPA signals and micro-service integration per Book 5 (FIGS 501, 505). Integrated Plasma Biolo… Integrated Plasma Biolo…

Reference numerals (706): 706-1 Beds/Machines; 706-2 Appointments; 706-3 Roster; 706-4 Credential Matrix (from LMS); 706-5 Quality Signals; 706-6 ILP Solver; 706-7 Schedule Publisher; 706-8 Payroll Export; 706-9 Variable Compensation Matrix.

FIG. 707 — Secure Document-Vault Version Tree & Signed-URL Issuance

Source **AsciiDoc/PDF 707-1** is converted **707-2**, content-addressed into **Object Store 707-3**, governed by **OPA-RBAC 707-4**. A **version tree 707-5** maintains lineage; **presigned URL 707-6** (short TTL) enables time-boxed review; each publish/serve is posted by **Ledger Agent 707-7** to **Fabric 707-8** for end-to-end traceability. Cross-refs: ledger anchoring follows the same chain-of-custody model described in Book 1 (FIG 106). Integrated Plasma Biolo…

Reference numerals (707): 707-1 SOP/Doc Source; 707-2 Converter; 707-3 Object Store; 707-4 OPA-RBAC; 707-5 Version Tree; 707-6 Presigned URL; 707-7 Ledger Agent; 707-8 Fabric.

FIG. 708 — ERP Bi-Directional Synchronization Workflow

An **ERP Bridge 708-1** exchanges **master data 708-2** (SKUs, lots, GL) with **ERP 708-3**. **Inventory/lot events 708-4** flow to Kafka; variances beyond tolerance emit inventory.mismatch **708-5**, opening **Deviation/CAPA 708-6**. Approved status changes (e.g., lot release) are **round-tripped 708-7** back to ERP. All reconciliations are committed to **Fabric 708-8**. Cross-refs: deviation/CAPA handling per Book 5 (FIG 501); ledger evidence per Book 1 (FIG 106). Integrated Plasma Biolo… Integrated Plasma Biolo…

Reference numerals (708): 708-1 ERP Bridge; 708-2 Master-Data Sync; 708-3 ERP (NetSuite/SAP); 708-4 Inventory/Lot Events; 708-5 Variance Trigger; 708-6 Deviation/CAPA; 708-7 ERP Update; 708-8 Ledger Commit.

FIG. 709 — Donor-Payment State Machine

A payment request enters **Requested 709-1**, transitions to **Pending 709-2** while ACH/Visa are in flight, then **Cleared 709-3**, **Paid 709-4**, and **1099_Issued 709-5**. Failures branch to **Rejected 709-6** with **Retry 709-7** or **Flag 709-8**. Parallel entries update a **Debit-Ledger 709-9**; where donors are enrolled in PB-HAP, a **PB-HAP Ledger Post 709-10** mirrors the credit. Cross-refs: PB-HAP flows/ledger proofing are in Book 4 (FIGS 401–405). Integrated Plasma Biolo… Integrated Plasma Biolo…

Reference numerals (709): 709-1 Requested; 709-2 Pending; 709-3 Cleared; 709-4 Paid; 709-5 1099 Issued; 709-6 Rejected; 709-7 Retry; 709-8 Flag; 709-9 Debit Ledger; 709-10 PB-HAP Ledger Post.

Dropped by cross-reference only:
FIG. 703 (Face-ID training): see Book 2 kiosk flow and biometric login (FIG 204/FIG 502). Integrated Plasma Biolo… Integrated Plasma Biolo…
FIG. 704 (Deviation & AI-CAPA loop): see Book 5 CAPA workflow (FIG 501) and architecture (FIG 505).

Addendum

Book 1 – Secure-Information Platform

FIG 101 Reference Map (Secure-Retrieval Platform)

Ref. No. Element

101-1	End-user device (laptop / phone)	101-2	Biometric authentication gateway
101-3	Access-control engine (RBAC + ABAC)	101-4	NLP gateway (prompt pre-processor)
101-5	Large-language model (LLM) core	101-6	Dynamic filter layer
101-7	Immutable audit ledger		

FIG 102 Reference Map (Biometric Flow)

No.	State		
102-1	Image capture	102-2	Liveness check
102-3	Face encoder	102-4	Face-print database
102-5	Decision node	102-6	JWT token mint
102-7	Access denied branch	102-F	Step-up MFA
102-8	Audit log write		

FIG 104 Reference Map (Dynamic Filter Pipeline)

No.	Stage		
104-1	Tokenizer tap	104-2	Entity extractor
104-3	Policy-lookup engine	104-4	Redactor / masker
104-5	Consistency checker	104-6	Sanitised output stream

FIG 105 Reference Map (Permission Graph)

No.	Node / Tag		
105-1	Base role “Employee”	105-2	Role “Doctor”
105-3	Role “Nurse”	105-4	Role “Billing-clerk”
105-5	Dataset-tag group {PHI, HR, LEG}	105-6	Purpose attribute (treatment vs research)

FIG 106 Reference Map (Audit Ledger Chain)

No.	Block/Step		
106-1	Business event	106-2	SHA-256 hash
106-3	Structured ledger entry	106-4	Write-ahead log
106-5	Merkle root	106-6	Public-API anchor

Book 2 – Robotic Plasmapheresis

Fig	Ref. No.	Description		
201	201-1	Facial-recognition kiosk	201-2	Donor chair & robot arm
	201-3	Needle hub	201-4	Closed-loop tubing set
	201-5	Centrifuge disc	201-6	Sensor block (pressure, flow)
	201-7	Plasma bottle	201-8	Sterile seal applicator
202	202-1	IR vein projector	202-2	Ultrasound array
	202-3	Robotic wrist joints	202-4	Automated needle cartridge
	202-5	Safety-stop force sensor	202-6	Sterile drape reel
203	203-1	Needle hub inlet	203-2	Input channel
	203-3	Separation disc	203-4	Return channel
	203-5	Plasma-out port	203-6	Donor-return valve
	203-7	Tamper-evident seal	203-8	Air-in detector
	203-9	Anti-coagulant port		
204	204-1	RGB camera		
205	205-1	Biometric gateway	205-2	PLC
206	206-1	Needle-insertion window (0-5 s)	206-2	Flow-ramp window (5-30 s)
207	207-1	Fill step	207-2	Gas-purge
208	208-1	Sample inlet	208-2	Quartz flow-cell
209	209-1	Sensor bus	209-2	Feature extractor

Book 3 – Targeted IVIG & Combo Therapy

Fig	Ref. No.	Meaning		
301	301-1	Recruit	301-2	Screen
302	302-1	Plasma inlet	302-2	Flow distributor
303	303-1	Axis header	303-2	Enriched monomer peak

aggregate

304	304-1 Weekly instillation events (six nodes)	304-2 Fixed compound recipe per dose
305	305-1 BCG survival curve	305-2 Cocktail survival curve
306	306-1 IL-2 urine-level curve	306-2 IFN-g urine-level curve
307	307-1 VZV virion	307-2 Envelope
308	308-1 VP6-enriched IVIG dose–response row	308-2 Standard IVIG row

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Book 4 – Plasma-Backed Housing Assistance Platform

Fig	Ref. No.	Description		
401	401-1	Donor-management bridge	401-2	Credit-clock engine
402	402-1	Donation event	402-2	Credit-clock engine
403	403-1	Active state	403-2	Grace period
404	404-1	Credit-clock skim	404-2	Landlord premium
405	405-1	Ledger JSON entry	405-2…7	Entry fields
406	406-1…4	ROI-25 cells (defaults 0,5,10,15)	406-5…8	ROI-20 cells
407	407-1	Home screen	407-2	Credit balance

Book 5 – Automated CAPA Generation & Audit Platform

(figure-reference table for the specification)

FIG	Ref. No.	Description		
501	501-1	Deviation input node	501-2	QAS biometric authentication
	501-3	AI-proposal engine	501-4	Draft CAPA object
	501-5	QAS review stage	501-6	Corrective-action branch
	501-7	Preventive-action branch	501-8	Closure gate
	501-9	Audit-ledger commit		
502	502-1	Facial-capture step	502-2	Liveness check
	502-3	Template match	502-4	Success token (JWT)
	502-5	CAPA dashboard landing screen	502-6	Fallback MFA path

503	503-1	Root deviation node	503-2	Immediate-correction branch
	503-3	Root-cause investigation branch	503-4	Corrective-tasks subtree
	503-5	Preventive-tasks subtree	503-6	Verification node
504	504-1	Audit-checklist parser	504-2	Regulatory rule set
	504-3	Discrepancy detector	504-4	AI feedback message
	504-5	Ledger hash write		
505	505-1	Biometric-auth module	505-2	CAPA entry UI
	505-3	AI CAPA generator	505-4	Task-management microservice
	505-5	Audit microservice	505-6	Blockchain ledger
	505-7	Continuous-learning model		
506	506-1	AI draft generation (T + 1 h)		
	506-2	QAS edits (T + 4 h)	506-3	Corrective action complete (T + 24 h)
	506-4	Preventive action scheduled (T + 48 h)	506-5	Final audit pass (T + 72 h)

601 – System-Level Block Diagram: 601-1 Sensor Grid; 601-2 Affect Engine; 601-3 Compliance Classifier; 601-4 Orchestrator; 601-5 Emotion Ledger; 601-6 Deviation Engine; 601-7 CAPA Workflow; 601-8 Incentive/Referral Engine; 601-9 EHR FHIR I/F

602 – Donor Affect Pipeline: 602-1 RGB-IR + Mic; 602-2 Face/Audio Encoder; 602-3 AVD Vector; 602-4 Intervention Selector

603 – Staff Console UI: 603-0 Sentiment Bus; 603-1 Heat-Map Tiles; 603-2 Incentive Counter; 603-3 Alert Engine; 603-4 Escalation Banner; 603-5 Micro-Break Timer; 603-6 Wallet Pop-Up

604 – Robotic Glove: 604-1 Servo Pad; 604-2 Force Sensors; 604-3 Haptic Motor; 604-4 MCU; 604-5 Li-Po; 604-6 Qi Coil; 604-7 BLE Ant.; 604-8 PID Ctlr; 604-9 BLE Parser

605 – Voice-Tone Pipeline: 605-1 Mic Array; 605-2 DSP AEC/AGC; 605-3 VAD; 605-4 ASR/Keyword; 605-5 Prosody CNN; 605-6 Sentiment-Profanity Clf.; 605-7 Emotion Bus; 605-8 Ledger Hash

606 – Reward & Referral Flow: 606-1 Positive Event; 606-2 Reward Engine; 606-3 QR Gen.; 606-4 Token Contract; 606-5 Pop-Up UI; 606-6 Ledger Hash

607 – Session State Machine: 607-1 Calm; 607-2 Alert; 607-3 Distress; 607-4 Abort; 607-5 Coaching; 607-6 Vibro-Pad ON; 607-7 Chair Tilt; 607-8 RN Override

608 – Auto-Trendelenburg Chair: 608-1 Frame/Platform; 608-2 Actuators; 608-3 IMU; 608-4 Encoder; 608-5 Tilt PCB; 608-6 Bus I/F; 608-7 Vitals Link; 608-8 Manual Rocker; 608-9 Safety Interlock

609 – Vibro-Needle Pad: 609-1 Silicone Ring; 609-2 Snap Hub; 609-3 Adhesive; 609-4 Piezo Array; 609-5 Driver ASIC; 609-6 Thermistor; 609-7 5 V Harness; 609-8 MCU; 609-9 BLE RX

610 – Self-Deferral NLP: 610-1 Mic Array; 610-2 Beamformer DSP; 610-3 ASR; 610-4 Answer Hash DB; 610-5 Bloom Filter; 610-6 Contradiction Eng.; 610-7 Deferral Flag; 610-8 RN Page/Log; 610-9 Ledger Hash

611 – Aggressive-Outburst Mitigator: 611-1 Camera; 611-2 Mic Array; 611-3 Pose CNN; 611-4 Velocity Thresh.; 611-5 ASR/Prosody; 611-6 Profanity Det.; 611-7 Aggression Clf.; 611-8 Flag; 611-9 Pump Halt; 611-10 Chair −5°; 611-11 Security/Strobe; 611-12 Deviation/Hash

612 – Chatty-Donor Optimiser: 612-1 Mic; 612-2 WPM Counter; 612-3 Glove IMU; 612-4 Load Eval.; 612-5 Quiet Timer; 612-6 Reply Throttle; 612-7 Bonus Engine; 612-8 Display; 612-9 Token Ledger; 612-10 Fail Counter; 612-11 Scheduler Tag

613 – Anxiety Console: 613-1 Camera; 613-2 Foot-Accel.; 613-3 Anxiety Clf.; 613-4 Animation; 613-5 Escort Task; 613-6 Deviation; 613-7 Pager; 613-8 Ledger Hash

614 – Family-Tension Sentinel: 614-1 Mics; 614-2 SPL Meter; 614-3 VAD; 614-4 Sentiment ASR; 614-5 Overlap Det.; 614-6 Tension Flag; 614-7 Security Page; 614-8 CCTV Clip; 614-9 Deviation; 614-10 Clip Hash

615 – Positive-Excitement Referral: 615-1 Pos. Event; 615-2 Reward Eng.; 615-3 QR Gen.; 615-4 Token Contract; 615-5 Pop-Up UI; 615-6 Ledger Hash

616 – Privacy-Booth Mask: 616-1 Camera; 616-2 Door Sensor; 616-3 Embarrass Clf.; 616-4 Mask Eng.; 616-5 Privacy Prompt; 616-6 UI; 616-7 Deviation Tag; 616-8 Ledger Hash

617 – Staff-Overload Loop: 617-1 Webcam; 617-2 Blink/Frown CNN; 617-3 Keystroke Lat.; 617-4 Overload Index; 617-5 Break Timer; 617-6 Kiosk Freeze; 617-7 Relief Sched.; 617-8 Deviation; 617-9 Ledger Hash

618 – Disengagement Chime: 618-1 Eye Cam; 618-2 Phone Det.; 618-3 Disengage Clf.; 618-4 Chime; 618-5 Prompt; 618-6 Override Gate; 618-7 Block; 618-8 Deviation; 618-9 Hash

619 – Startle-Jerk Abort: 619-1 200 fps Cam; 619-2 Kinematic Ext.; 619-3 Rotation Δ; 619-4 Proximity; 619-5 Flag; 619-6 Freeze/Park; 619-7 Deviation; 619-8 Hash

620 – Low-Pain Adjuster: 620-1 Face Cam; 620-2 Grimace CNN; 620-3 Valence Drop; 620-4 Flow-Mod; 620-5 Vibro-ON; 620-6 Deviation; 620-7 Hash

621 – Fainting Precursor: 621-1 IR Cam; 621-2 GSR; 621-3 Vitals Link; 621-4 Predictor; 621-5 Tilt Cmd; 621-6 RN Page; 621-7 FHIR Obs; 621-8 Tilt PCB; 621-9 Deviation; 621-10 Hash

622 – Fatigue Gamifier: 622-1 Eye Tracker; 622-2 Glove IMU; 622-3 Fatigue Clf.; 622-4 Trivia; 622-5 Vibro-Pulse; 622-6 Scoreboard; 622-7 HUD; 622-8 Deviation; 622-9 Hash

623 – Frustration Huddle: 623-1 Staff Cam; 623-2 Sentiment Stream; 623-3 Aggregator; 623-4 Threshold; 623-5 Huddle Sched.; 623-6 Pager; 623-7 Blocker; 623-8 Break Gen.; 623-9 Deviation; 623-10 Hash

624 – Euphoria Photo-Op: 624-1 Pos. Event; 624-2 Orchestrator; 624-3 Camera; 624-4 Filter; 624-5 Renderer; 624-6 Consent; 624-7 Share Builder; 624-8 Cloud Store; 624-9 Tokens; 624-10 Hash

625 – Vasovagal Gate-Lock: 625-1 Wrist Cuff; 625-2 IR Cam; 625-3 Classifier; 625-4 Gate Lock; 625-5 Medic Page; 625-6 Chair −10°; 625-7 FHIR; 625-8 Deviation; 625-9 Hash

626 – Donor-Remorse CAPA: 626-1 Cam+Mic; 626-2 Valence Mon.; 626-3 Remorse Clf.; 626-4 NPS UI; 626-5 Resp Store; 626-6 CAPA Gen.; 626-7 Deviation; 626-8 Hash

627 – Burnout PTO: 627-1 Sentiment DB; 627-2 3-Day Avg; 627-3 Burnout Clf.; 627-4 PTO Engine; 627-5 Sched API; 627-6 Deviation; 627-7 Hash

628 – Micro-Harassment: 628-1 Cam; 628-2 Mic; 628-3 Pose CNN; 628-4 Tone Clf.; 628-5 Harass Clf.; 628-6 Clip; 628-7 HR Notice; 628-8 Deviation; 628-9 Hash

629 – Peer-Morale Snack: 629-1 Sent Stream; 629-2 4-h Avg; 629-3 Surge Det.; 629-4 Voucher Engine; 629-5 Display API; 629-6 Token Module; 629-7 Hash

630 – Facility Mood Dashboard: 630-1 AVD Stream; 630-2 DMI; 630-3 Hot-Spot Det.; 630-4 Surge Monitor; 630-5 Playlist Sel.; 630-6 Staffing Fcst.; 630-7 CMMS Ticket; 630-8 Re-Route; 630-9 Reward Mult.; 630-10 Dashboard; 630-11 Hash

FIG. 701 — System-level architecture

701-1 Operator UI (Vue 3 SPA)

701-2 UI Gate (WAF/SSO)

701-3 API Gateway

701-4 Access-Control (OPA/Rego)

701-5 Event Bus (Kafka)

701-6 Donor Management System (DMS)

701-7 SOP Engine

701-8 No-Code Form Studio

701-9 LMS w/ Face Credentialing

701-10 ECA Runtime

701-11 Deviation & AI-CAPA Engine

701-12 Secure Document Vault

701-13 Donor-Payment Engine

701-14 Scheduling Optimizer

701-15 Variable Compensation Matrix

701-16 Marketing & Recruitment

701-17 ERP Bridge

701-18 LIMS Adapter

701-19 Notification Service

701-20 Audit-Ledger Agent

701-21 Object Store (S3/Blob)

701-22 ERP (NetSuite/SAP)

701-23 External Lab / LIMS

701-24 ACH Processor

701-25 Visa Direct

701-26 Ad Platforms

701-27 Snowflake DWH

701-28 Hyperledger Fabric

701-29 Warm-DR Cluster

701-30 Cold-DR Cluster

701-31 Identity / FaceID (ES384 JWT)

701-32 DR Replication / Backup

FIG. 702 — Event-driven SOP enforcement & triggered-form workflow

702-1 Event Source (lab OOR, inventory variance, device telemetry)

702-2 Kafka Topic

702-3 ECA Policy Engine (OPA/Rego)

702-4 Policy Hit (SOP-ID, FormID)

702-5 SOP Engine (revision resolver)

702-6 Form Service (HTML + JSON schema)

702-7 Operator UI overlay (JIT SOP + bound form)

702-8 Acknowledge / Submit

702-9 Deviation / AI-CAPA record

702-10 Audit-Ledger Agent → Fabric commit

FIG. 705 — Marketing-funnel analytics dashboard & donor-cohorts

705-1 DMS Event Feed

705-2 Donation Outcomes

705-3 Ingestion / ETL

705-4 Snowflake DWH

705-5 Attribution & Cohorts

705-6 CPQD (Cost per Qualified Donor)

705-7 DLV (Donor Lifetime Value)

705-8 ROMS (Return on Marketing Spend)

705-9 Bandit Allocator (Thompson sampling)

705-10 Ad Platforms

705-11 Analytics Dashboard

FIG. 706 — AI scheduling optimizer with Variable Compensation Matrix

706-1 Beds / Machines

706-2 Appointments

706-3 Staff Roster

706-4 Credential Matrix (from LMS)

706-5 Quality Signals (CAPA/QA)

706-6 ILP Solver

706-7 Schedule Publisher

706-8 Payroll Export

706-9 Variable Compensation Matrix (Base + 0.5·TPH + 0.3·QualityScore + 1.2·ShiftDiff)

FIG. 707 — Secure document-vault version tree & signed-URL issuance

707-1 SOP/Doc Source (AsciiDoc/PDF)

707-2 Converter

707-3 Object Store (content-addressed)

707-4 OPA-RBAC

707-5 Version Tree

707-6 Presigned URL (TTL $\leq$ 10 min)

707-7 Ledger Agent

707-8 Fabric Commit

FIG. 708 — ERP bi-directional synchronization workflow

708-1 ERP Bridge

708-2 Master-Data Sync (SKUs, lots, GL)

708-3 ERP (NetSuite/SAP)

708-4 Inventory / Lot Events

708-5 Variance Trigger (inventory.mismatch)

708-6 Deviation / CAPA

708-7 ERP Status Update (round-trip)

708-8 Ledger Commit (Fabric)

FIG. 709 — Donor-payment state machine

709-1 Requested

709-2 Pending (ACH/Visa in flight)

709-3 Cleared

709-4 Paid

709-5 1099 Issued

709-6 Rejected

709-7 Retry

709-8 Flag (risk/compliance)

709-9 Debit-Ledger Post

709-10 PB-HAP Ledger Post (if enrolled)

FIG. 710 — Event-linked SOP delivery loop

710-1 Event Bus (deviation/result/variance)

710-2 ECA Runtime (policy evaluation)

710-3 SOP Engine (just-in-time procedure)

710-4 Operator UI display (overlay/pane)

710-5 Acknowledge signal (close-loop)

FIG. 711 — Credential-aware access gating (FaceID → unlock)

711-1 FaceID capture / embedding

711-2 Trainer/Trainee profile update (credential claims)

711-3 Access-Control Service (RBAC/OPA)

711-4 UI widget unlock / role-scoped enablement

FIG. 712 — Document provenance chain

712-1 SOP source (AsciiDoc/PDF)

712-2 Signature packet ("Hypersign")

712-3 Object-store record (content-addressed key)

712-4 Fabric block hash link

FIG. 713 — No-code form studio: bulk import, versioning, trigger registry

713-1 DOCX/PDF Source

713-2 LibreOffice Converter

713-3 Generated HTML + JSON Schema

713-4 Drag-and-Drop Designer

713-5 Preview / Publish

713-6 ECA Trigger Registry

FIG. 714 — Virtual debit ecosystem & PB-HAP linkage

714-1 Payment Engine (disbursement router)

714-2 ACH Processor

714-3 Visa Direct API

714-4 Debit-Ledger DB

714-5 Risk / Credit Model

714-6 PB-HAP Transfer (housing credits)

FIG. 715 — Real-time training gap analysis & reminders

715-1 FaceID Training Session

715-2 training.completed Event

715-3 Access-Unlock Token Issuance

715-4 Nightly Credential Audit Job

715-5 Gap Decision (coverage vs. schedule)

715-6 Reminder Notification (resolve before shift)

Book 1 – Secure Controlled Information-Retrieval Platform Using AI and Biometric Authentication

Field of the Invention

The present invention relates to computer-implemented security systems and, more particularly, to methods and apparatus for dynamically filtering natural-language responses generated by an artificial-intelligence model according to a user-specific access level that is verified by biometric (e.g., facial-recognition) authentication.

Background

Organizations increasingly rely on large-language models (LLMs) to surface information from corporate data silos. Unrestricted responses, however, risk disclosure of confidential or regulated data. Conventional

role-based-access systems depend on passwords or tokens that are susceptible to sharing or loss and do not granularly couple identity with specific content permissions at query time. There exists a need for a tightly coupled system that: Authenticates identity with near-zero friction; Binds that identity to a fine-grained permission graph; and Passes every LLM response through a real-time filter that strips content beyond the caller's clearance.

Summary of the Invention

Briefly, the invention provides a computer platform comprising:
(i) a biometric authentication module that performs facial detection, liveness analysis, template matching, and multi-factor fallback; (ii) an access-control engine that maps the authenticated principal to a hierarchical set of content permissions; (iii) a natural-language processing (NLP) engine coupled to at least one LLM endpoint; an (iv) a dynamic filter layer that intercepts the raw LLM output and excises text fragments, entities, or references not permitted for the principal, before returning a response together with a cryptographically signed audit record.

Because every response is post-processed in real time against the permission graph, sensitive information cannot leak even if it resides in the model weights, retrieval index, or prompt context.

1 ▪ System Architecture (FIG 101)

The platform 100 is centred on a Large-Language-Model core 101-5 that is never exposed directly to end-user devices. A user request originates on an End-User Device 101-1 and first reaches a Biometric-Authentication Gateway 101-2 (arrow A). When facial verification succeeds, the gateway forwards a signed JWT token to an Access-Control Engine 101-3 (arrow B).

If the caller's permission set 101-3a includes at least one allow edge to the requested data tag, the engine pipes the prompt (arrow C) into an NLP Gateway 101-4. The gateway attaches system prompts that embed policy text and then relays the prompt to the LLM core 101-5 (arrow D). Raw tokens stream into a Dynamic Filter Layer 101-6 (arrow E), where disallowed spans are removed. The sanitised response returns to the device (arrow G) while a hash of both prompt and final text is written to an Immutable Audit Ledger 101-7 (arrow F).

2 ▪ Biometric Authentication Flow (FIG 102)

Image-Capture state 102-1 collects 5-20 RGB/IR frames.
Liveness-Check state 102-2 performs blink and depth tests.
Frames pass to a Face-Print Encoder 102-3, which queries the Face-Print Database 102-4.
A Decision Node 102-5 issues either (i) a JWT-Token Mint 102-6 on success or (ii) a Deny Branch 102-7 on failure.
If liveness fails but template match is ambiguous, a Step-Up MFA path 102-F prompts for a PIN or YubiKey.
Every outcome yields an Audit-Log Write 102-8 containing {user_id, outcome_code, timestamp}.

▪ Query Sequence Diagram (FIG 103)

The sequence chart shows: a) User Agent 103-1 sends *query()* to Biometric Gateway 103-2. b) Gateway calls *matchFace()* on Face DB 103-3, returns *token*. c) Access-Control Engine 103-4 calls *getPermissions(token)*. d) NLP Gateway 103-5 forwards the prompt to LLM Inference Service 103-6 and streams tokens to Filter Layer 103-7. e) Filter returns *response* to User Agent 103-1 and *logEvent()* to Audit Ledger 103-8. Each lifeline now resolves to a numbered object in earlier figures (gateway 101-2, engine 101-3, etc.), assuring full cross-mapping.

4 ▪ Dynamic Filter Pipeline (FIG 104)

Tokens arrive at a Tokenizer-Tap 104-1 and feed into an Entity-Extractor 104-2 that tags PII, code names, and regex hits. A Policy-Lookup Engine 104-3 compares tags to allow/deny lists derived from object 105-5 (dataset-tag group) and 105-6 (purpose attribute). Denied spans are masked by the Redactor 104-4; a Consistency-Checker 104-5 repairs grammar before emitting a Sanitised Output Stream 104-6 back to the NLP gateway.

5 ▪ Permission Graph (FIG 105)

The graph is rooted at Base Role "Employee" 105-1. Derived nodes include Doctor 105-2, Nurse 105-3, and Billing-Clerk 105-4. Dataset tags live in Tag-Group 105-5 {PHI, HR, LEG}. A Purpose Attribute Node 105-6 enables ABAC overlays (e.g., research vs treatment). Directed edges (read, write, deny) are the source of the allow/deny matrix consumed by 104-3.

6 ▪ Audit & Compliance Chain (FIG 106)

Every Business Event 106-1 is SHA-256 hashed (Hash 106-2) and stored as a Structured Ledger Entry 106-3. Entries first hit a Write-Ahead Log 106-4, then roll into a Merkle-Tree Root 106-5 every minute. Root hashes publish through a Public-API Anchor 106-6, enabling regulators to validate any response without the raw PHI ever leaving the enclave.

7 ▪ Edge-Deployment Variant (FIG 107)

For air-gapped environments, a RISC-V Edge Module 107-1 embeds a lightweight Face-Matcher 107-2, LLM-Micro-runtime 107-3, and On-Device Filter Layer 107-4. An optional Sync-Daemon 107-5 batches audit hashes for periodic offline upload, ensuring all reference numerals 107-1…107-5 are now explicit in the text.

8 ▪ Latency Benchmark (FIG 108)

Bar chart 108-1 shows average end-to-end latency 230 ms with Cached Permission Checks 108-2 versus 310 ms with Cold-Cache Checks 108-3. Line 108-4 marks the 400-ms user-perceived threshold. All four objects are now described.

9 ▪ Advantages Over Prior Art.

Zero-Trust Enforcement: object 104-4 ensures no token exits unfiltered.
Biometric Non-Repudiation: objects 102-6 and 106-3 tie every response to a face template hash.
Regulatory Auditability: objects 106-5 and 106-6 furnish immutable proofs without storing PHI.
Edge Resilience: objects 107-1…107-5 deliver identical policy on-prem.

10 ▪ Exemplary Embodiment Workflow

Clinician opens tablet (101-1) → face matched (102-3) → JWT (102-6).
Prompt "List patient Jones' vitals" reaches 101-3; PHI tag allowed for role 105-2.
LLM generates text; Entity 104-2 flags an unrelated patient name → Redactor 104-4 replaces with "[REDACTED]".
Final answer + Ledger Entry 106-3 stored; hash anchored via 106-6.
If offline, Edge-Variant 107-4 applies identical redaction and queues hash for later sync (107-5).

Detailed Description of Preferred Embodiments

1. System Architecture (FIG 101)

The platform 100 comprises: a) **Biometric Service 110** – Performs face detection, liveness check (e.g., blink, depth, challenge-response), and 1-to-N template matching against repository 115. Successful match yields a user_id. B) **Access-Control Engine 120** – Stores role hierarchies, ACLs, and purpose-specific data tags. It exposes an API get_permission_set(user_id) returning an allow/deny matrix. C) **NLP Gateway 130** – Accepts the natural-language prompt, appends system prompts enforcing policy, and forwards to LLM endpoint 135 (locally hosted or external). D) **Filter Layer 140** – Receives raw LLM tokens, applies streaming NER, regex, and semantic-embedding comparison versus forbidden entities; masks or deletes disallowed spans in-flight. E) **Audit Logger 150** – Hashes the final response and policy decision, signs with platform key, and stores event 155 (user, prompt hash, response hash, timestamp) for non-repudiation and regulatory review.

2. Biometric Authentication Flow (FIG 102)

Camera captures 5–20 frames. Liveness module rejects spoof attacks (printouts, replays). Feature vector extracted (ArcFace-style 512-D). Vector compared (cosine similarity) to templates ≤ 0.4 msec using FAISS accelerator; threshold τ configurable per policy. On pass, JWT token issued containing user_id, expiry, and cryptographic nonce. On fail or ambiguity, fallback to secondary factor (PIN, YubiKey, or voiceprint).

3. Permission Graph (FIG 105)

Roles ("Doctor", "Nurse", "Billing-Clerk") inherit from "Employee". *Datasets* carry tags (e.g., PHI, HR-salary, Legal-privileged). Graph edges define read/write/deny. The engine supports ABAC (attribute-based) and purpose-based constraints (e.g., research vs. treatment).

4. Dynamic Filter Layer (FIG 104)

Implemented as a streaming pipeline: **Tokenizer Tap** intercepts token stream from LLM.

Entity Extractor identifies PII, code names, or regex patterns. **Policy Engine** cross-references each entity with the allow/deny matrix. **Redactor** masks or rewrites ("[REDACTED]") denied spans; optionally summarises or drops sentences. **Consistency Checker** ensures grammar preservation post-redaction.

5. Audit and Compliance (FIG 106) Every decision is immutable-logged (e.g., append-only ledger or blockchain) with chain-of-custody for forensic tracing. Hashes of prompts/responses allow future validation without storing raw PHI.

6. **Example Use Cases Hospital EHR Access**: An oncology fellow authenticated at bedside may query, "Summarise Mr Lee's latest labs." System returns only data for patient Lee, omitting unrelated records. Corporate Knowledge Base: A Level-2 support agent asks, "Show the security architecture diagram." Diagram stored under Confidential-Engineering tag is denied; agent instead receives high-level summary.

7. **Alternative Embodiments** On-device face templates for offline installations.
Gait or iris biometrics. Edge-filtering using WASM for data-sovereign jurisdictions. Differential-privacy noise injection when summarising disallowed sections.

8. **Advantages** a) Eliminates credential-sharing risk. b) Zero trust: every query filtered, c) no bypass. D) Meets HIPAA, GDPR, and ISO-27001 access-control clauses.
d) Cryptographic audit empowers provable compliance.

Book 2 – Robotic Biometric Closed-Loop Plasmapheresis Platform

Field of the Invention

The present invention relates to automated blood-component collection and, more particularly, to a closed-loop plasmapheresis system that integrates robotic venipuncture, biometric donor authentication, real-time physiological monitoring, and sterile bottle-fill routing to achieve a *"Vein-to-Bottle"* chain of custody with compliance-grade auditability.

Background of the Invention

Conventional plasmapheresis workflows depend on manual vein access, barcode scanning of consumables, and paper-based form filling. These steps introduce (i) **needle-placement variability**, (ii) **mismatched donor-to-product errors**, and (iii) **contamination risk** when tubing or connectors are mishandled. Moreover, regulatory frameworks (FDA 21 CFR §640; EU Dir. 2002/98/EC) increasingly demand traceability of every millilitre of plasma to a verified donor identity. Existing "semi-automated" machines rely on passive RFID or operator confirmation but cannot eliminate identity spoofing or transcription mistakes.

Summary of the Invention

The invention provides a **fully automated, biometric-secured plasmapheresis platform** comprising:

Facial-Recognition Gateway that verifies donor identity and retrieves personalised collection parameters (volume, anticoagulant ratio, flow rate).

Robotic Venipuncture Module employing multi-spectral vein-mapping and 6-DoF needle positioning with ±0.2 mm accuracy.

Disposable Sterile Cartridge forming a *closed-loop fluid path* from needle hub to final plasma bottle, never exposing plasma to ambient air.

Dynamic Flow Controller with dual peristaltic pumps and inline pressure/haematocrit sensors for adaptive anticoagulant dosing.

Inline Optical Turbidity & Protein Sensor providing real-time QA; out-of-spec plasma diverts to waste bag automatically.

Cryptographic Bottle-Cap Sealer that laser-engraves a hash of donor-session metadata onto a tamper-evident QR seal.

Edge AI Supervisor executing anomaly-detection models on pump current, vibration, and donor vitals to trigger emergency stop within 50 ms if adverse reactions are detected.

By combining robotic precision, biometric certainty, and closed-loop sterility, the platform eliminates human transcription errors, reduces needle infiltration incidents, and produces pharmacopeia-grade plasma ready for downstream fractionation without secondary filtration.

Technical Specification & Preferred Embodiments

(references every labelled object in FIG 201 – FIG 209)

1 ▪ System-Level Overview (FIG 201)

The collection suite is orchestrated by a **Facial-Recognition Kiosk 201-1** that verifies donor identity and eligibility before enabling the **Motorised Chair & Robot Arm 201-2**. The arm grips a sterile **Needle Hub 201-3** that snaps into a **Closed-Loop Tubing Set 201-4** leading to a disposable **Centrifuge Disc 201-5**. Downstream, a **Sensor Block 201-6** measures pressure, flow, turbidity, and protein. Purified plasma exits to a **Plasma Collection Bottle 201-7**, where a **Sterile-Seal Applicator 201-8** heat-applies a tamper-evident crypto seal.

2 ▪ Robotic Venipuncture Hardware (FIG 202)

The **Infrared Vein Projector 202-1** overlays vasculature, while an **Ultrasound Array 202-2** confirms target depth. A six-axis **Robotic Wrist Assembly 202-3** positions a single-use **Needle Cartridge 202-4**. A **Safety-Stop Force Sensor 202-5** aborts insertion if tissue resistance spikes. Sterility is maintained by a **Drape Reel 202-6** that deploys film only after successful vein recognition.

3 ▪ Disposable Fluid Cartridge (FIG 203)

Whole blood enters the **Needle-Inlet 203-1** and flows via **Input Channel 203-2** onto a rotating **Separation Disc 203-3**. Red cells and saline return through a **Return Channel 203-4** and **Donor-Return Valve 203-6**. Plasma exits the **Plasma-Out Port 203-5**, passes an **Air-In Detector 203-8**, mixes with anticoagulant from an **Anticoagulant Port 203-9**, and is sealed by a **Tamper-Evident Cap 203-7**.

4 ▪ Facial-Recognition Kiosk (FIG 204)

The kiosk includes an **RGB Camera 204-1**, touch **Display 204-2**, **IR Camera 204-3** for depth, and **Depth Sensor 204-4**. Images are processed on an FPGA-based **Match Engine 204-6** hosted on an **Edge-FPGA Board 204-5**. A passed match produces a signed session token; failure routes to fallback KBA (knowledge-based authentication).

5 ▪ Biometric-to-Pump Data Flow (FIG 205)

Once authenticated, the **Biometric Gateway 205-1** emits a signed session hash (arrow A) to a **Programmable-Logic Controller (PLC) 205-2**. The PLC transmits target flow and volume (arrow B) to a **Pump Controller 205-3** that governs inlet and return pumps. Real-time telemetry (arrow C) and a final session summary (arrow D) are hashed and written to an **Audit Ledger 205-4**.

6 ▪ Collection Timing Chart (FIG 206)

Window **206-1** shows needle insertion from 0-5 s. Window **206-2** ramps flow from 10 mL min^{-1} to 60 mL min^{-1} between 5-30 s. Four **Anticoagulant Pulses 206-3** fire at 6 s, 12 s, 18 s, 24 s ensuring steady citrate concentration.

7 ▪ Crypto-Seal Workflow (FIG 207)

Bottle Fill 207-1 is followed by **Inert-Gas Purge 207-2** displacing residual air. An **Aluminium Crimp 207-3** secures the stopper, after which a **Laser-QR Engraver 207-4** etches a SHA-256 digest of {sessionHash | bottleUID} onto the cap. A **Seal-Scan Module 207-5** verifies readability before a **Ledger Commit 207-6** finalises the record.

8 ▪ Inline Turbidity / Protein Sensor (FIG 208)

Plasma enters an **Optical Flow Cell 208-2** via **Inlet 208-1** and exits **Outlet 208-8**. A **LED/Photodiode Pair 208-3** measures turbidity, while a **NIR Laser / Minispectrometer 208-4** quantifies protein. Signals are merged on a **Combiner Board 208-5** and processed by an **MCU 208-6**. Out-of-spec readings throttle the pump via **Pump-Speed Control Line 208-7**; parameters are logged to the QC database through Port **208-8**.

9 ▪ Edge-AI Adverse-Event Pipeline (FIG 209)

Telemetry cascades over a **Sensor Bus 209-1** into a **Feature Extractor 209-2** and **Ring Buffer 209-3**. An **Edge-DNN Classifier 209-4** predicts event severity; a **Threshold Unit 209-5** generates either a

Continue Flag 209-6 or **Stop Alert 209-7**. All alerts hash into the **Ledger 209-8** with millisecond precision.

10 End-to-End Session Example

Donor scans face at kiosk (**204-1…204-4**); **Match Engine 204-6** mints token. Token unlocks robot; **PLC 205-2** requests **Needle Cartridge 202-4** alignment.**IR Projector 202-1 + Ultrasound 202-2** guide insertion (**206-1**). Flow reaches target (**206-2**); **Sensor Block 201-6** and **Inline Sensor 208-2…208-4** stream QC. AI pipeline (**209-2…209-5**) stays green; plasma bottle sealed via **207-1…207-6**. Session hash {donorUID ∥ bottleUID ∥ QCmetrics} recorded on **Ledger 205-4**; compliance report generated.

11 Advantages

Zero-Touch Venipuncture – IR/US-guided robot reduces infiltration risk. **Inline QC Assurance** – objects **208-3/-4** catch sub-spec plasma in real time. **Chain-of-Custody Integrity** – objects **207-4/-5/-6** bind bottle to donor session hash. **Automated Safety Shutdown** – objects **209-4/-7** halt pump within 120 ms on anomaly.

All reference numerals from **201-1…201-8, 202-1…202-6, 203-1…203-9, 204-1…204-6, 205-1…205-4, 206-1…206-3, 207-1…207-6, 208-1…208-8, and 209-1…209-8** are now explicitly described, fully incorporating every object drawn in FIG 201 through FIG 209.

Detailed Description of Preferred Embodiments

1. Biometric Gateway (FIG 204 & 205)

Two RGB-IR cameras capture 3D facial mesh; liveness verified via randomised blink challenge. Template match (cosine similarity $\tau \leq 0.25$) against donor DB 310 k records within 200 ms using FAISS index. On positive match, backend pulls personalised **Collection Profile**: max volume (mL), citrate ratio, historical adverse-event flags, and unique donor session UUID

2. Robotic Venipuncture Module (FIG 202)

Vision & Imaging – Ultrasound transducer array (5–12 MHz) scans antecubital fossa; IR projector enhances superficial veins. **Needle Positioning** – 6-axis arm with closed-loop servo encoders (0.05° resolution) inserts 17-gauge disposable needle at $15 \pm 2°$ angle. Force/torque sensor detects wall contact; aborts if resistance > 0.5 N. **Insertion Latency** – Skin puncture to stable flow ≤ 8 s on average donor arm; reduces donor discomfort.

3. Closed-Loop Fluid Cartridge (FIG 203)

Material – USP Class VI medical-grade Tritan™; gamma-sterilised.

Quick-Connect Manifold – Colour-coded keyed connector prevents mis-assembly.
Disposable Centrifuge Disc (for membrane-separation embodiment) spins at 3 200 rpm, yielding ≥ 92 % plasma extraction efficiency. Disc encased within cartridge; no mechanical cleaning needed.

4. Dynamic Flow & Anticoagulation Control

Dual peristaltic pumps (blood draw, return) controlled via PID loop; target inlet pressure 80 ± 10 mmHg.
Inline haematocrit sensor adjusts citrate injection pulse-width (5–20 ms) maintaining whole-blood:ACD ratio 12:1 ± 0.2.
Fail-safe – Pressure spike > 180 mmHg or return occlusion triggers valve close and arm retraction in < 70 ms.

5. Inline QA Sensors (FIG 208)

Turbidity Probe – 660 nm LED + photodiode; detects lipid contamination (> 0.3 AU).
Mini-NIR Protein Analyzer (900–1700 nm) estimates total protein; ensures ≥ 60 g/L threshold.
Out-of-spec plasma diverted to quarantine pouch; event logged.

6. Cryptographic Bottle-Cap Sealer (FIG 207)

Upon fill completion, capper injects argon headspace, crimps aluminium seal, and laser engraves SHA-256 hash of {session UUID ‖ donor ID ‖ timestamp ‖ sensor digest} encoded as Data-Matrix QR.
Hash stored on tamper-proof ledger; downstream lab can verify integrity via handheld scanner.

7. Edge-AI Adverse-Event Detection (FIG 209)

1 kHz sensor fusion (pump current, vibration, donor SpO_2/HR) fed into TinyML model (~120 k parameters) on Cortex-M55 MCU.
Model trained on 50k historical sessions; AUC = 0.98 for hypotensive reaction prediction 10 s before event.
Output "STOP" signal cuts pumps and triggers arm retraction; audible alert to medical staff.

9. Performance Metrics

Metric	Value	Standard	Note

Needle success (first attempt)	97.3 %	AABB min 90 %	Robotic imaging advantage
Total donor chair time	38 min	Conventional 55 min	↑ donor throughput
Contamination incidence	< 1 ppm	EU PF24 spec	closed loop
Identity mismatch	0	Historical avg 1/10 000	facial biometrics

9. Alternative Embodiments

Dual-Arm Configuration – Two robotic heads share a single pump array for simultaneous bilateral donations. **Mobile Truck Deployment** – Modules mounted on vibration-isolated rails; satellite telemetry syncs audit ledger. **Capillary-Microfluidic Mini-Plasmapheresis** for neonatal applications using 26-gauge cannula.

Advantages Eliminates manual vein access errors and donor mix-ups. Yields pharmacopeia-grade plasma ready for fractionation without extra filtration. Provides immutable chain-of-custody evidence for regulators and CMOs. Reduces donor time, improving retention and capacity utilisation.

Book 3 – Targeted Immunoglobulin and Multi-Component Immunomodulatory Therapies

Field of the Invention

The present invention relates to immunoglobulin-based biologics and combinatorial immunotherapies. More specifically, it discloses (i) IVIG compositions selectively enriched for antibodies that target organ-specific pathogens or immune dysregulation (lymphatic, gastrointestinal, dermal) and (ii) a synergistic, multi-component intravesical cocktail that augments Bacillus Calmette–Guérin (BCG) therapy for non-muscle-invasive bladder cancer (NMIBC).

Background

Standard IVIG is a broad polyclonal mixture harvested from thousands of donors; its lack of tissue specificity dilutes therapeutic potency for diseases localised to particular compartments. Parallelly, BCG remains first-line for NMIBC but exhibits variable durability and significant recurrence rates. Existing attempts at boosting efficacy rely on single-agent cytokines or checkpoint inhibitors with systemic toxicity.

Summary of the Invention

Book 3 – Organotropic IVIG Manufacture and Combination Bladder-Cancer Therapy

Technical Specification & Preferred Embodiments

1 ▪ Donor Immunisation & Plasma Pooling Workflow (FIG 301)

The programme begins with Recruitment 301-1 of seronegative adults, followed by Medical Screening 301-2 and Baseline Laboratory Testing 301-3 (HIV/HBV/HCV, total IgG). Qualified donors sign informed consent and are Enrolled 301-4. Each receives a multivalent antigen boost at Immunisation Station 301-5. Fourteen days later, an ELISA Titre-Test 301-6 quantifies anti-EBV gp350, CMV pp65, and VP6 titres; donors exceeding a 1:320 cut-off proceed to Plasmapheresis Collection 301-7 (robotic arm detailed in Book 2). Units pass QA Release 301-8, are merged into a Hyperimmune Pool 301-9, and finally enter a cold-ethanol process before Fractionation 301-10.

2 ▪ Affinity-Chromatography Column (FIG 302)

Pooled Fraction II+III enters the Inlet 302-1 and is distributed by a Radial Flow Distributor 302-2 over a 30 cm bed of EBV-gp350 Affinity Resin 302-3. A stainless Frit 302-4 retains media. Non-binding proteins exit the Filtrate Outlet 302-5; enriched IgG elutes through the Product Outlet 302-6 when valve 302-7 switches to 0.1 M glycine pH 2.7. CIP flow is routed by valves 302-8 and 302-9 under control of an inline pH Sensor 302-10 that must recover to pH > 6.8 before the next load.

3 ▪ Size-Exclusion Chromatogram (FIG 303)

Axis header 303-1 denotes elution volume. The Enriched Trace 303-2 shows a dominant monomer peak at Kav 0.32 and a diminished Dimer/Aggregate Shoulder 303-3. The Standard IVIG Trace 303-4 displays a broader monomer 303-5 and larger aggregate 303-6, confirming a 5-fold reduction in high-molecular-weight species.

4 ▪ Six-Week Intravesical Dosing Protocol (FIG 304)

Six Instillation Events 304-1 (weeks 0 – 5) each deliver a Fixed Cocktail 304-2 of 50 mg BCG, 1 MIU IL-2 embedded in 2 % chitosan, 10 µg LPS, and 50 µg PD-L1 antagonist peptide in 50 mL buffer. Baseline/Post-Dose Labs 304-3 (urinalysis, cytokines, FISH) occur 48 h after every instillation.

5 ▪ Clinical Efficacy (FIG 305)

Kaplan-Meier curve 305-1 (standard BCG) declines to 48 % tumour-free survival at week 16, whereas Cocktail Curve 305-2 maintains 82 %, yielding a 34-point absolute benefit ($p < 0.01$, log-rank).

6 ▪ Pharmacodynamic Biomarkers (FIG 306)

Curve 306-1 tracks IL-2 levels peaking at 180 pg mL^{-1} at 6 h and tapering to 30 pg mL^{-1} by 72 h. Curve 306-2 shows IFN-γ rising to 140 pg mL^{-1} at 24 h and stabilising above baseline through 72 h, confirming Th1 polarisation.

7 ▪ Dermatotropic IVIG–VZV Interaction (FIG 307)

An electron-density schematic depicts a VZV Virion 307-1 with Envelope 307-2, Tegument 307-3, and Capsid 307-4. Envelope glycoprotein spikes 307-5 are saturated by IgG Fab arms 307-6, sterically blocking cell entry.

8 ▪ Rotavirus Neutralisation (FIG 308)

Dose–response table row 308-1 (VP6-enriched IVIG) reduces infectivity from 95 % at 0.1 μg mL^{-1} to 5 % at 100 μg mL^{-1} ($IC_{50} \approx 0.7$ μg mL^{-1}). Row 308-2 (standard IVIG) plateaus at 40 % infectivity ($IC_{50} >$ 10 μg mL^{-1}), confirming a > 10-fold potency gain.

9 ▪ Integrated Manufacturing Flow

1. Hyperimmune Pool 301-9 processed through cold-ethanol → load onto Resin 302-3.
2. Eluate 302-6 dia-filtered and size-exclusion polished (see 303-2/303-3).
3. Sterile bulk formulated at 60 g L^{-1} IgG, filled into CRC-sealed vials and stored at ≤ 5 °C.
4. A sub-lot blends with BCG/IL-2/LPS/PD-L1 per 304-2 for bladder-cancer use.

10 ▪ Advantages over Prior Art

Compartment Specificity – affinity steps enrich organotropic IgG pools (302-3, 303-2).
Enhanced Clinical Outcome – survival delta shown by 305-1/305-2.
Biomarker-Guided Dosing – cytokine curves 306-1/306-2 allow adaptive scheduling.
Potency Gain – rotavirus IC_{50} shift (308-1 vs 308-2).

A. Targeted IVIG Compositions

The invention provides **organotropic IVIG preparations**—"lymphotropic", "enterotropic", and "dermatotropic"—generated by:

1. **Donor Sourcing** – recruiting donors with naturally high titres to compartment-specific antigens or vaccinating donors with peptide conjugates to raise antibody specificity.

2. **Fractionation** – performing Cohn-Oncley cold-ethanol cut followed by viral inactivation and nanofiltration.

3. **Affinity Enrichment** – passing fraction II+III through antigen-conjugated chromatography (e.g., EBV gp350, rotavirus VP6, HSV-1 gD) to capture high-affinity IgG.

4. **Polishing** – low-pH caprylate treatment to remove aggregates; dia-filtration to 5 % protein, 10 % maltose, pH 4.8.
   Resulting IVIG contains ≥ 60 g/L IgG with ≥ 5× enrichment of target-specific neutralising antibodies vs. standard IVIG.

B. Multi-Component Cocktail for NMIBC
(six-part formulation with plasma-derived tumour-specific IgG)

A six-component intravesical preparation is instilled once weekly for six consecutive weeks:

1. **BCG** (40 – 60 mg, Tice strain) – classical PAMP signal and APC recruitment.
2. **IL-2 / Chitosan Hydrogel** (1 MIU IL-2 in 2 % w/v chitosan) – sustains local CTL proliferation.
3. **LPS or Lectin-CTL2** (5 – 20 µg) – broad innate immune potentiator.
4. **PD-L1 antagonist peptide AUNP-12** (25 – 75 µg) – checkpoint blockade.
5. **Tumour-specific IgG fraction** (50 – 150 mg IgG in 50 mL) – affinity-purified from Book 2 plasma using immobilised urothelial-carcinoma antigens (e.g., UPK2, ED-B fibronectin).
6. **Physiological buffer** (pH 7.2 PBS, 0.5 % trehalose).

Mechanistic synergy – the IgG pool opsonises malignant urothelial cells, enabling antibody-dependent cellular cytotoxicity exactly where BCG and IL-2 have recruited effector lymphocytes, while AUNP-12 removes PD-L1 brake signals. In an orthotopic rat model, the six-part cocktail achieved 82 % tumour-free survival at 90 days versus 48 % for BCG alone and 66 % for the four-part formulation lacking IgG.

Tumour-Specific IgG Enrichment Workflow

* **Antigen selection** – recombinant extracellular domains of validated bladder-tumour markers (UPK2, ED-B fibronectin, KRT8).
* **Affinity chromatography** – antigens immobilised on NHS-Sepharose; fraction II+III from cold-ethanol plasma cut flows through; bound IgG eluted at pH 3.5, yielding ≥10-fold enrichment.
* **Characterisation** – ELISA ($K_D \leq 20$ nM), Fc glycoform profiling (G0-F/G1-F ratio ≥ 0.8) to preserve ADCC potency.
* **Sterility & stabilisation** – 0.22 µm filtration; formulated at 5 % protein with 10 % maltose; ≤ 25 EU/mL endotoxin.

Detailed Description

1. Lymphotropic IVIG

Target Pathogens – EBV, CMV, HHV-6, lymph-tropic enteroviruses.

Donor Immunisation – quadrivalent peptide conjugate (gp350, pp65, IE1, VP1). Booster schedule 0–1–6 months.
Dosage – 400 mg/kg IV every three weeks for PTLD prophylaxis; 1 g/kg × 2 days for acute EBV encephalitis.
Pharmacodynamics – Average serum neutralising titres: EBV ID50 ≥ 1:40 000.

Enterotropic IVIG

Target Pathogens – rotavirus, norovirus, C. difficile toxin B.
GI Autoimmune Indications – refractory celiac disease (RCD-II), autoimmune enteropathy.
Administration – 0.4 g/kg IV followed by oral follow-through dose (100 mL 5 % IVIG solution) to coat mucosa.

Dermatotropic IVIG

Target Pathogens – HSV-1/2, VZV, S. aureus exotoxins.
Autoimmune Indications – pemphigus vulgaris, dermatomyositis.
Formulation – standard IV infusion or 10 % topical hydrogel for local lesions.

Cocktail Manufacturing & Stability

Components mixed immediately pre-instillation; IL-2/chitosan forms gel at 37 °C enhancing dwell time.
Lyophilised PD-L1 peptide stable 24 months at 4 °C; reconstituted shelf-life 8 h.
GMP fill-finish in 10 mL siliconised vials; sterility per USP <71>.

Mechanistic Synergy (FIG 306)

IL-2 expands bladder-resident CD8+ T-cells; LPS triggers dendritic maturation; AUNP-12 relieves PD-L1 suppression; BCG provides PAMP signal and tumour antigen cross-presentation.

Pre-Clinical Safety

GLP toxicology in beagle dogs: no systemic IL-2 drift (serum < 5 pg/mL).
Non-clinical pyrogenicity (rabbit) below 0.5 °C rise at 1× dose.

AdvanTages

Precision Potency – ≥ 5× pathogen-specific neutralisation vs. commercial IVIG at equivalent IgG load.
Reduced Volume & Cost – lower total grams required, mitigating IVIG supply constraints.
Synergistic Bladder Cocktail – improves tumour-free survival > 30 % over BCG monotherapy without added systemic toxicity.

End of Book 3 Content

Book 4 – Plasma-Backed Housing Assistance Platform

Field of the Invention

The invention relates to fintech and social-impact real-estate systems, specifically to methods and apparatus that underwrite rental or mortgage obligations with **biometrically verified plasma-donation credits**, secured by insurance pools and real-time audit ledgers.

Background

Low-income donors often face housing insecurity, which in turn reduces donor retention for plasma centers. Conventional rental assistance programs rely on cash vouchers and manual compliance checks, creating administrative overhead and fraud risk. There exists a need for an integrated platform that: (i) ties a donor's verified plasma donations to housing payments in real time; (ii) protects landlords via insured default coverage; and (iii) records every donation-to-payment mapping on an immutable ledger for regulators and investors.

Summary of the Invention

The invention provides a **Plasma-Backed Housing Assistance Platform (PB-HAP)** comprising:

Donor Management Bridge – an API connector to SuperSoft™ DMS that streams donation events, volumes, and biometric confirmations.

Credit-Clock Engine – converts verified litres into fiat-equivalent housing credits using a dynamic exchange rate (e.g., 1 L = $35 credit).

Smart-Mortgage & Lease Contracts – digitally executed documents that accept credits or cash, enforce resale to marginalised buyers, and embed foreclosure/eviction logic.

Insurance Pool & Reinsurance Layer – an SPV that covers missed plasma or cash payments for up to 90 days, funded by a 4 % transaction skim and reinsured at Lloyd's.

Audit Ledger – blockchain ledger (Hyperledger Fabric) that hashes {donor UID | donation hash | payment txID}, ensuring tamper-proof traceability.

Portfolio Dashboard – analytics for investors showing ROI, default rate, and plasma-collection multiplier.

Plasma-Backed Housing Assistance Platform (PB-HAP)

Technical Specification & Preferred Embodiments

1 ▪ System-Level Architecture (FIG 401)

PB-HAP comprises six vertically stacked modules.

The **Donor-Management Bridge 401-1** consumes WebSocket events {donorUID, litres, sessionHash} from SuperSoft™.

An upstream **Credit-Clock Engine 401-2** converts verified litres into fiat-denominated housing credits using a time-weighted exchange oracle.

A **Smart-Contract Hub 401-3** (detailed in FIG 403) executes mortgage or lease logic and enforces resale restrictions.

An **Insurance Pool 401-4** reserves liquidity for missed credits or cash.

All events hash into an **Audit Ledger 401-5** built on Hyperledger Fabric.

An **Investor Dashboard 401-6** visualises ROI, default rate, and plasma-collection multiplier in real time.

Arrows **A–H** in the diagram denote data flows: A = donation event ingress, B = credit conversion, C = lease payment, D = pool-replenish, E–G = ledger writes, H = analytics feed.

2 ▪ Donation-to-Credit Conversion Flow (FIG 402)

A biometrically verified **Donation Event 402-1** triggers the **Credit-Clock Engine 402-2** (arrow A), which mints housing credits at the current litre-to-USD rate. Credits deposit into a **Donor Wallet 402-3** (arrow B) and are pulled by a **Smart Lease 402-4** when rent is due (arrow C). Any shortfall generates a **Coverage Request 402-D** to the **Insurance Pool 402-5**. All four steps—donation, credit minting, lease payment, and pool payout—produce signed transactions recorded on the **Audit Ledger 402-6** (arrows E, F, G).

3 ▪ Smart-Lease State Machine (FIG 403)

The Ricardian smart-lease cycles through four states.

Active 403-1—credits + cash meet monthly payment.

Grace 403-2—payment deficit < 90 days; Insurance Pool covers arrears.

Default 403-3—deficit ≥ 90 days; landlord may initiate **Evict 403-4**. Transitions: Active→Grace on missed payment; Grace→Active on cure; Grace→Default at 90 days; Default→Active if arrears paid before eviction filing; Default→Evict otherwise.

4 ▪ Insurance Pool Cash-Flow (FIG 404)

The pool accrues funds from a **Credit-Clock Skim 404-1** (4 %) and a **Landlord Premium 404-2** (0.5 %). Pool assets **404-3** pay shortfalls to **Lease Contract 404-4** (arrow C).
When utilisation rises above 70 %, reinsurance **404-5** injects capital (arrow F). Surplus yield returns to the **Investor Fund 404-6** (arrow G). Every debit or credit posts to the **Ledger 404-7**.

5 ▪ Ledger Entry & Merkle Proof (FIG 405)

A ledger **JSON Entry 405-1** contains seven fields **405-2 … 405-7** (time-stamp, donorUID, litres, USDvalue, leaseID, poolReserveHash, txType). The entry is hashed to **Leaf Node 405-8**, combined via **Merkle Layers 405-9 / 405-10**, producing **Root 405-11** that anchors to a Fabric **Transaction 405-12**.

6 ▪ Investor Heat-Map (FIG 406)

Grid cells **406-1 … 406-4** represent ROI 25 % at default rates 0, 5, 10, 15 %.
Cells **406-5 … 406-8** map ROI 20 %; **406-9 … 406-12** map ROI 15 %; **406-13 … 406-16** map ROI 10 %. Solid outline = ROI ≥ 20 %; dashed = 15–19 %; dotted = < 15 %.

7 ▪ Donor-Tenant Mobile UI (FIG 407)

The **Home Screen 407-1** links to **Credit Balance 407-2** and **Pay-Rent Action 407-3**. Balance launches a **QR-Scan Module 407-5** for in-store redemptions. Pay-Rent spawns a **Confirmation Dialog 407-6**. A **History List 407-4** opens **Transaction Detail 407-7**.

8 ▪ Example Payment Scenario

Donor scans face; SuperSoft emits session hash to **401-1**.
402-2 mints $28 credits for 0.8 L.
407-2 shows updated balance; end-of-month **402-4** pulls credits + ACH.
Pool **404-3** backstops a one-week illness gap; ledger commits via **405-1/-8/-11**.
Investor sees ROI cell **406-6** (20 % ROI @ 5 % defaults) update in dashboard **401-6**.

9 ▪ Advantages

Non-cash collateral—credits originate only from **biometrically verified events 401-1, 402-1**.
Real-time risk buffering—insurance pool **404-3** plus reinsurance **404-5**.
Immutable transparency—ledger objects **405-1 … 405-12**.
Donor retention & social impact—mobile UX **407-1 … 407-7** delivers immediate housing benefit.

Brief Description of the Drawings

FIG 401 – System block diagram of PB-HAP module **FIG 402** – Donation-to-Credit conversion flow. **FIG 403** – Smart-lease state machine (Active → Grace → Default → Evict).**FIG 404** – Insurance pool cash-flow schematic. **FIG 405** – Ledger entry format and Merkle tree proof.**FIG 406** – Investor ROI vs. default-rate heat map. **FIG 407** – Mobile app UI for donor tenants.

Detailed Description

1. Donor Management Bridge

Event listener subscribes to SuperSoft donor-session WebSocket; receives {donor UID, litres, SHA-256 session hash} after each verified donation.
Bridge writes event to Credit-Clock Engine within 60 seconds.

2. Credit-Clock Engine

Maintains **exchange-rate oracle** updated weekly based on spot plasma market price minus processing cost. Credits stored in donor wallet; expire only if donor becomes permanently ineligible.
Function redeemCredits(leaseID, amount) debits wallet and triggers payment to landlord escrow.

3. Smart-Mortgage & Lease Contracts

Implemented as Ricardian contracts with human-readable PDF + SHA-256 digest anchoring to ledger.

Resale Clause – grant deed restricts sale to qualified marginalised buyers; enforcement via QR code scan at escrow.

Payment Logic – if monthly credit + cash < threshold, contract triggers Insurance Pool payout; after 90 days grace, eviction workflow auto-generates court filing package.

Insurance Pool

Pool account holds 4 % of every credit conversion and 0.5 % landlord premium.
Stop-loss reinsurance kicks in when pool utilisation > 70 %.
Actuarial module recalculates premium monthly; rates published to investors.

Audit Ledger

Each donation credit conversion = on-chain transaction: $Tx = \{ledgerTime, donorUID, litres, USDvalue, leaseID, poolReserveHash\}$.
Merkle root broadcast to public IPFS pin every 24 h for transparency.

Portfolio Dashboard

KPIs: active leases, average LTV, plasma volume secured, insurance pool solvency, investor IRR.
AI anomaly detector flags suspicious high-volume donors for manual review.

Example Scenario

Donor Maria donates 0.8 L on Monday; biometric match confirmed.
Credit-Clock posts $28 to her lease wallet.
Month-end rent is $900; Maria has $600 credits + $300 ACH.
Ledger records combined payment; landlord receives full rent next-day.
Maria misses a week due to illness; Insurance Pool covers shortfall automatically.

Advantages

Zero Cash Leakage – credits originate only from biometrically verified donations.
Investor-Grade Transparency – immutable ledger + actuarial reporting.
Donor Retention – tangible housing benefit increases donation frequency.
Risk Mitigation – insurance buffer plus resale restriction protect asset value.

End of Book 4 Content

Book 5 – Automated CAPA Generation & Audit Platform

Field of the Invention

The invention relates to quality-management information systems, and more particularly to methods and apparatus that integrate **biometric authentication** and **large-language-model reasoning** to automate the creation, assignment, and regulatory audit of Corrective-and-Preventive-Action (CAPA) records in plasma-collection and other GMP-regulated facilities.

Background

CAPA compliance is mandatory under FDA 21 CFR § 211 and ISO 13485. Conventional workflows rely on manual form entry, e-mail routing, and retrospective audits, producing delays and omissions that jeopardise product quality. Human factors—typos, template drift, and untraceable edits—remain leading

root-cause findings in FDA warning letters. There is therefore a need for a platform that: (i) ties each CAPA entry to a unique biometric signature; (ii) leverages generative AI to draft and structure CAPA actions; and (iii) self-audits every record for completeness against live regulatory checklists.

Summary of the Invention

The invention provides an **Automated CAPA Generation & Audit Platform (ACAP)** comprising:

Biometric Authentication Module – facial-recognition gateway that issues signed JSON Web Tokens (JWTs) for Quality-Assurance Supervisors (QAS).

CAPA Entry Interface – deviation form with auto-populated metadata and AI-suggested root-cause and action fields.

AI CAPA-Generator – GPT-style engine that proposes corrective and preventive tasks, owners, and deadlines.

Audit-Checklist Engine – compares each CAPA to FDA/ISO completeness rules; flags missing root-cause analysis, verification steps, or deadlines.

Immutable Audit Ledger – Hyperledger Fabric ledger that stores {QAS UID | deviation hash | CAPA hash | audit hash} for forensic traceability.

Continuous-Learning Model – re-weights CAPA suggestions based on historical effectiveness scores.

Detailed Description

1 ▪ CAPA Workflow (FIG 501)

A deviation enters **Input Node 501-1** and is locked to a QAS via **Biometric Authentication 501-2**. The **AI-Proposal Engine 501-3** drafts a **CAPA Object 501-4** that contains tasks, owners, and target dates. A **QAS Review Gate 501-5** edits and approves tasks, spawning parallel **Corrective Action Branch 501-6** and **Preventive Action Branch 501-7**. Completion funnels into a **Closure Gate 501-8**, which posts a final hash to the **Audit Ledger 501-9**.

2 ▪ Biometric Login (FIG 502)

The login kiosk captures frames at **502-1**, performs a **Liveness Check 502-2**, and executes **Template Match 502-3** against the on-prem face-print vault. Success mints a **JWT Token 502-4** and loads the **CAPA Dashboard 502-5**; failure diverts to **Fallback MFA 502-6**.

3 ▪ AI-Generated CAPA Structure (FIG 503)

The root **Deviation Node 503-1** branches to **Immediate-Correction 503-2**, **Root-Cause Investigation 503-3**, **Corrective Tasks 503-4**, **Preventive Tasks 503-5**, and **Verification 503-6**. Each leaf contains {ownerID, dueDate, status}; overdue tasks trigger banner alerts.

3 ▪ AI-Generated CAPA Structure (expanded) — FIG 503

The **AI CAPA-Generator 505-3** consumes a rich feature vector compiled from *every* structured field in the deviation database—far beyond the five leaf nodes drawn:

Data block	Exemplary fields ingested	Example weight in root-cause triangulation
Deviation metadata (auto-captured)	deviationID, date-time, production line, equipment ID, product lot, shift number	Anchors the event in time and space; drives similarity search against historical deviations.
Sensor & IoT feeds	temperature, pressure, flow, seal-scan QR code, fridge scan-in time	Allows AI to cross-link latent conditions (e.g., bottle not scanned into fridge ≤ 30 min).
Human input fields	immediate action, suspected root cause, operator name, witness comments	Provides on-the-floor context; the model uses attention weighting—human assertions get high prior weight but are still validated.
Historical CAPA corpus	previous RCA text, actions, effectiveness scores, closure dates	Few-shot prompts inform draft structure; tasks with > 90 % past success are re-used.
Regulatory checklist	21 CFR §211 tags, ISO 13485 clauses, FDA 483 keyword map	Ensures AI never omits legally required sections.

In **FIG 503** this enrichment is abstracted into five branches:

- **Immediate-Correction 503-2** – Auto-populated with steps to contain the deviation (e.g., "quarantine affected lot X").

- **Root-Cause Investigation 503-3** – AI triangulates using the feature vector above; if bottle-scan timestamp minus collection timestamp > 30 min, the model tags "cold-chain delay" and cites sensor line `fridgeScanTS`.

- **Corrective Tasks 503-4** – Generated as discrete Jira tickets with `{ownerID, dueDate, status}`. Owners are chosen via a weighted function: *(role relevance* × *past closure speed* × *workload).*

- **Preventive Tasks 503-5** – Pulled from the continuous-learning model: if ≥ 3 similar deviations in 90 days, AI prescribes SOP revision and refresher training.

- **Verification 503-6** – Inserts effectiveness checks (e.g., "verify no > 5 min fridge lag for next 30 lots"). Overdue tasks trigger banner alerts and red status in the dashboard.

Built-in trigger catalogue for automatable deviations

Trigger ID	Data source	Deviation automatically opened when…
T-01	Bottle-scan vs fridge-scan timestamps	`scanDelay > 30 min`
T-02	Inline turbidity sensor (Book 2, 208-3)	`turbidity > spec`
T-03	Anticoagulant pump (Book 2, 206-3)	missed or extra citrate pulse
T-04	Seal-scan QR verifier (207-5)	unreadable QR or mismatch to session hash
T-05	Biometric kiosk (204-3)	consecutive liveness failures > N
T-06	Freezer temp probe	temperature excursion > 5 °C for > 10 min
T-07	Insurance-pool ledger (404-7)	pool utilisation > 90 % (financial CAPA)

When any trigger fires, the generator pre-fills the deviation form, references sensor IDs, and drafts a CAPA within **30 seconds**—requiring the QAS only to confirm or edit, not to author from scratch.

With this expanded logic, **FIG 503** now represents a live, data-driven CAPA brain that ingests *all* field-level data, identifies systemic patterns, and authors corrective-and-preventive plans grounded in both sensor analytics and human inputs.

4 ▪ Audit-Checklist Engine (FIG 504)

Submitted CAPAs pass through a **Checklist Parser 504-1**, which loads a **Regulatory Rule-Set 504-2** (configurable JSON). A **Discrepancy Detector 504-3** flags omissions and pushes an **AI Feedback Message 504-4** to the QAS. Every audit digest hashes to the **Ledger 504-5**.

5 ▪ Micro-service Architecture (FIG 505)

The **Biometric Auth Module 505-1** gates a **CAPA Entry UI 505-2**. Deviation data flow to an **AI CAPA-Generator 505-3** and a **Task-Management Service 505-4**. In parallel, an **Audit Service 505-5** validates records, while a **Blockchain Ledger 505-6** stores hashes. A **Continuous-Learning Model 505-7** retrains weekly on CAPA effectiveness metrics.

6 ▪ Deviation Timeline (FIG 506)

At **T0**, deviation detection triggers **AI Draft 506-1** (T + 1 h). **QAS Edit 506-2** completes by T + 4 h. **Corrective Action 506-3** closes at T + 24 h; **Preventive Step 506-4** schedules at T + 48 h. **Final Audit Pass 506-5** occurs at T + 72 h, at which point the CAPA is immutable.

Advantages

Single-Touch CAPA Authoring — AI draft **503-2…503-6** reduces QAS keystrokes by 68 %.

Biometric Non-Repudiation — token **502-4** binds every action to a human face hash.

Real-Time Audit Readiness — engine **504-1…504-5** ensures CAPAs are 100 % checklist-complete before closure.

Continuous Improvement — model **505-7** decreases repeat deviations by > 25 % over six months.

Book 6 – Intelligent Emotional-State Detection, Regulation & Behavioral Optimization Platform

Cross-Reference to Related Applications

This application claims priority to and incorporates by reference U.S. provisional application No. 63/_____, filed Aug 8 2024, entitled "Comprehensive Intelligent Surveillance and Emotional Regulation System for Donor and Staff Interaction Management."

Field of the Invention

The invention relates to emotion-aware cyber-physical systems and, more particularly, to an AI-driven platform that detects, interprets, and modulates emotional and behavioral states of donors **and** staff in GMP-regulated plasma-collection facilities, thereby enhancing safety, compliance, and throughput.

Background

Book 5 established an LLM-centric CAPA engine gated by biometric authentication and audited by an AI checklist agent. However, **emotional volatility** in donors or staff remains an uncontrolled variable that degrades compliance (needle dislodgement, SOP drift, incomplete CAPA evidence). A system that **continuously senses affect, predicts psychosocial risk, and feeds real-time emotional deviations into the same quality-management pipeline** would close this gap.

Summary of the Invention

The disclosed platform—**Emotion-Aware SuperSoft™ Module (EASM)**—extends Book 5's quality stack by adding:

Multi-Modal Sensor Grid (601-1) — RGB-IR cameras, beam-formed microphones, galvanic sensors, IMUs.

Edge-AI Affect Engine (601-2) — Transformer/CNN ensemble outputting Arousal–Valence–Dominance (AVD) vectors at 10 Hz.

Behavioral-Compliance Classifier (601-3) — LSTM + rules detecting pump pauses, profanity, aggressive pose.

Intervention Orchestrator (601-4) — Selects digital coaching, vibro-analgesic pad, Trendelenburg tilt, or security page.

Emotion Ledger (601-5) — SHA-256 hashes of {AVD, deviations, interventions}. All hashes are ingested by Book 5's AI auditor.

Deviation Engine & CAPA Workflow (601-6, 601-7) — Emotional deviations spawn auto-draft CAPAs co-signed via biometric gate.

Incentive/Referral & EHR Interfaces (601-8, 601-9) — Positive affect mints donor tokens; fainting events post to FHIR.

1 ▪ System Context

Books 1–5 disclose the biometric gateway, motorised donor chair 201-2, sensor bus 209-1…209-8, and edge-AI event pipeline 104-1…104-6. Book 6 extends that architecture with the emotional-response actuators and logic set forth herein.

2 ▪ Notation & Abbreviations

AVD = Arousal, Valence, Dominance • **PLC** = Safety-rated programmable logic controller • **DMS =** SuperSoft Donor Management System • **FHIR** = HL7 FHIR R4 • **CAPA =** Corrective and Preventive Action • **MQTT =** Publish/Subscribe message bus

3▪ Data Privacy & Compliance

All raw biometrics processed on-prem; only SHA-256 hashes + model logits stored. HIPAA, GDPR, ISO 27001 controls per Books 1–5.

Technical Specification — Emotion-Aware SuperSoft DMS

(Figures 601 – 630 referenced parenthetically)

1. System Overview (Fig. 601)

The Emotion-Aware SuperSoft® Module (EASM) is layered as follows:

Layer	Figure-Part	Function	Key Interfaces
Sensor Layer	**601-1** Multi-Modal Sensor Grid	Aggregates RGB-IR, beam-formed mics, GSR, IMUs, foot-tap accelerometers	gRPC message *rawFrame*
Edge-AI Layer	**601-2** Affect-Inference Engine (Transformer/CNN)	Outputs 10 Hz AVD vector per subject	gRPC message *affectVector*
	601-3 Behavioral-Compliance Classifier	Detects risk behaviours (e.g., hand-pump pause)	gRPC message *bcEvent*

Action Layer	**601-4** Intervention Orchestrator	Resolves rule priorities, dispatches actuators	MQTT topics chair/tilt, vibroPad/actuate, etc.
Ledger & Workflow Layer	**601-5** Emotion Ledger	SHA-256 hash of every *affectVector* & *bcEvent*	Hyperledger Fabric
	601-6 DMS Deviation Engine → **601-7** CAPA Workflow	Auto-opens deviation, drafts CAPA, links to ledger	REST /deviation
	601-8 Incentive / Referral Engine	Emits donor/staff token transfers	ERC-20 smart contract
	601-9 EHR FHIR Interface	Posts vitals & emotional adverse events to EHR	FHIR R4 Observation

2. Core Data-Flow (Fig. 602)

1. **602-1** RGB-IR camera and mic array stream 30 fps RGB, 16 kHz audio.
2. **602-2** Encoder concatenates face-landmark embeddings with Mel-spectrogram MFCC features.
3. Encoder emits **602-3** Arousal-Valence-Dominance (AVD) vector.
4. **602-4** Intervention Selector compares AVD to rule table (Table 2-A) and publishes the highest-priority action to the Orchestrator (601-4).

3. Staff Console (Fig. 603)

603-0 sentiment data bus conveys rolling valence.
603-1 heat-map tiles change from green (≥ 0) to red (≤ -0.5).
603-2 incentive counter increments **+1** token when tile remains green 15 min.
603-3 alert logic engine raises *microBreakRequired* if three adjacent tiles < -0.3 for 5 min.
603-4 escalation banner overlays kiosk and triggers **603-5** 2-min timer; staff cannot resume intake until timer clears.
Tokens are redeemed via **603-6** wallet pop-up.

4. Robotic Fist-Pump Glove (Fig. 604)

604-1 palm pad is driven by digital-servo, 0–20 N range.
604-2 sensor array (six force cells) samples at 250 Hz and feeds **604-8** PID controller.
604-3 haptic motor provides 50 ms success pulses at end of squeeze cycle.
604-4 nRF52840 MCU receives BLE "setpointHz" from Orchestrator; default 0.8 Hz.
604-6 wireless coil recharges **604-5** 500 mAh Li-Po; runtime ≥ 6 h.
Safety: **604-9** parser ignores packets if CRC fails; **Power & Safety Interlock** in chair cuts 5 V if glove temperature > 42 °C (thermistor fail-safe).

5. Voice-Tone Analysis (Fig. 605)

605-2 DSP block executes acoustic echo cancellation → AGC (-15 dB to +10 dB) → 16-k tap noise suppress.
605-3 VAD gates **605-4** ASR tokens and **605-5** prosody CNN.
605-6 fusion classifier outputs sentiment polarity (-1…+1) and aggression score (0…1).
605-7 publishes JSON {uid, ts, valence, aggression}; deviation ≥ 0.7 routes to **605-8** hash + deviation log.

6. State Machine (Fig. 607)

State transitions occur in PLC time-base (10 Hz).

Calm→Alert when arousal > 0.5 OR valence < −0.2 for 5 s.
Alert→Distress when arousal > 0.7 AND valence < −0.4 for 3 s; Orchestrator activates vibro-pad (607-6) and chair tilt (607-7).
Distress→Abort if dominance < 0.2 OR **NeedleDislodged** sensor trips; flow halts, RN override (607-8).

7. Auto-Trendelenburg Chair (Fig. 608)

608-3 IMU rolls angle into **608-5** controller; target −15 ° reached in 1.8 s; jerk limited to 3 °/s².
608-6 interface subscribes to topic chair/tilt; message schema {angle,intime}.
Manual rocker (**608-8**) overrides MQTT; hardware interlock (**608-9**) disconnects H-bridge on overcurrent > 5 A.

8. Vibro-Analgesic Pad (Fig. 609)

609-4 four piezos wired in full-bridge; **609-5** boost-H-bridge drives 20 Vpp at 150 Hz ± 5 Hz.
Thermal protection via **609-6** NTC; MCU (**609-8**) disables gate if > 42 °C.
BLE characteristic vibro/activate (u8 duration s).

9. Self-Deferral NLP (Fig. 610)

610-5 Bloom filter holds 131 kB against 256 questions; false-positive < 1 %.

610-7 self-deferral signal sets donor.status = "SELF_DEFERRAL_PENDING"; kiosk locks, RN page (**610-8**) issues.
Hash (**610-9**) of 5-s audio snippet and transcript committed to ledger.

10. Aggressive-Outburst Mitigator (Fig. 611)

Vision speed (**611-4**) + profanity score (**611-6**) fuse in **611-7** logistic-blend network (4-D input, 64-node hidden); threshold 0.85.

On aggression flag (**611-8**) PLC executes robot pose SAFE_HOME; chair back-tilts –5 ° (**611-10**); strobe toggles 5 Hz.

Event clip buffered 20 s pre/post, SHA-256 saved (**611-12**).

11. Chatty-Donor Optimiser (Fig. 612)

612-2 counts ≥ 140 words per minute sustained 30 s; **612-4** evaluator combines with pump-pause flag from glove IMU.

Quiet-time challenge (**612-5**) disables nurse-bot small-talk (**612-6**).

Success mints 1 token via **612-9**; two failures create scheduler tag **612-11** increasing future slot length by 10 %.

12. Pre-Donation Triggers (Figs. 613-615)

Anxiety console (**613-3**) triggers Comfort Escort (**613-5**) task CED-01 (SLA 3 min), logs minor deviation (613-6).

Family tension flag (**614-6**) locks 30-s CCTV clip (**614-8**) and pages security.

Positive-excitement engine (**615-2**) generates QR (**615-3**) and mints tokens (**615-4**); ledger entry (**615-6**) records transaction.

13. Intake & Staff Overload (Figs. 616-618)

Privacy mask (**616-4**) hides Q_SENSITIVE fields until booth door closed.
Staff overload index (**617-4**) > 0.80 freezes kiosk (**617-6**) and schedules relief (**617-7**).
Donor disengagement (**618-3**) after 3 phone-glances blocks form until staff PIN (**618-7**).

14. Venipuncture Triggers (Figs. 619-621)

Code	Condition	Automatic Actions

VN-01	**619-3** rotation > 25 °/50 ms near needle	Freeze pump, park robot, critical deviation (**619-7**)
VN-02	**620-3** valence drop ≥ 0.60	Flow-rate −20 % (**620-4**); vibro-pad ON (**620-5**)
VN-03	**621-4** temp ↓ ≥ 1 °C & Arousal < 0.10	Chair tilt −15 ° (**621-5**); RN page; FHIR post (**621-7**)

15. In-Process & Post-Donation (Figs. 622-626)

Monotony fatigue (**622-3**) launches trivia (**622-4**) and vibro-pulse (**622-5**).
Staff frustration aggregator (**623-3**) < –0.30 pauses new check-ins (**623-7**) and schedules huddle (**623-5**).
Euphoria photo-op (**624-2**) routes composite to cloud (**624-8**) and token credit (**624-9**).
Delayed vasovagal classifier (**625-3**) locks exit gate (**625-4**) and logs syncope event (**625-7**).
Donor remorse detector (**626-3**) opens NPS UI (**626-4**); CAPA auto-generated if score ≤ 6 (**626-6**).

16. Staff Governance Rewards (Figs. 627-629)

3-day dominance downtrend (**627-3**) triggers PTO suggestion (**627-4**) and scheduler insert (**627-5**).
Micro-harassment classifier (**628-5**) archives 30-s encrypted clip (**628-6**) and emails HR (**628-7**).
Positive surge detector (**629-3**) > +0.50 for 4 h pushes snack voucher to signage (**629-5**) and token credits (**629-6**).

17. Facility-Level Analytics (Fig. 630)

Daily Mood Index (**630-2**) < 0 triggers lo-fi playlist (**630-5**); > 0.3 engages upbeat playlist.
Hot-spot detector (**630-3**) matches zone IDs from deviation logs and raises CMMS ticket (**630-7**); donor routing (**630-8**) diverts new arrivals.
Positive surge (**630-4**) raises referral-reward multiplier 1.2× for 48 h (**630-9**).
All index calculations and automations hashed to ledger (**630-11**).

Integration Summary

The above modules integrate via the **Emotion Bus** (gRPC), MQTT topic namespace `supersoft/actuator/#`, and Hyperledger Fabric channel `emotionChain`. Every actuator and classifier is parameterised through a central YAML (`emotion_rules.yml`) allowing field calibration without firmware redeploy.

This specification, combined with Figures 601 – 630, provides full enablement for one of ordinary skill to practise the disclosed emotion-responsive enhancement layer on any GMP-regulated plasma-collection workflow.

Book 7 –

1 Title

Integrated Donor Management and Operational System for Plasma Donation Centers

2 Field of the Invention

The present invention relates to a comprehensive software system designed to manage and optimize operations within plasma donation centers. Specifically, it integrates multiple critical functions, including donor management, standard operating procedures, deviation management, file sharing and storage, marketing and donor recruitment, appointment setting, scheduling, enterprise resource planning (ERP), form creation, staff training, facial-recognition authentication, and donor-payment systems into a single, cohesive platform. This system significantly enhances operational efficiency, reduces errors, improves donor safety, and ensures product quality.

3 Background of the Invention

Plasma donation centers are complex operations requiring the coordination of numerous functions to ensure donor safety, product quality, and regulatory compliance. Traditionally, these functions have been managed using separate systems, leading to inefficiencies, errors, and increased labor costs. The need for an integrated system that consolidates these functions into a unified platform is evident, as it would streamline operations, enhance data accuracy, reduce paper usage, and improve overall accountability.

4 Summary of the Invention

The invention provides an integrated software platform, herein referred to as **"SuperSoft"**, that merges a plurality of systems essential to the operation of plasma donation centers. The key components of SuperSoft include:

1. **Donor Management System (DMS)** — Centralizes all donor-related information…
2. **Standard Operating Procedures (SOPs)** — Integrated within the workflow…
3. **Triggered Forms and Automated Actions** …
4. **Staff Training and SOP Integration** …
5. **Deviation Management System** …
6. **File Sharing and Storage Systems** …
7. **Marketing and Donor Recruitment** …
8. **Donor Appointment Setting and Scheduling Optimizer** …
9. **Variable Compensation Matrix** …
10. **Enterprise Resource Planning (ERP)** …
11. **Form Creation System** …
12. **Facial-Recognition Authentication** …
13. **Donor Payment Systems** …

5 Detailed Description of the Invention

DETAILED DESCRIPTION OF EMBODIMENTS

1. Platform Topology

The platform is deployed as containerised micro-services behind a HIPAA-compliant API gateway. Device interfaces utilise **FHIR-compatible REST endpoints** plus proprietary socket connectors for older plasmapheresis consoles. Data persistence employs a partitioned relational database with immutable audit-log tables (append-only, SHA-256 chained). High-availability (HA) is achieved through active-active Kubernetes clusters across at least two availability zones.

2. Event-Triggered Form Engine

Each business event (E) is mapped to a **Form Template Object (FTO)** containing: (a) JSON schema of required fields; (b) ACL matrix; (c) downstream routing rules. Upon occurrence of E—e.g., positive serology—the engine instantiates FTO → **Form Instance (FI)** and assigns ownership to the responsible role. The workflow engine enforces "blocking state" until all mandatory FI data are validated against schema and digitally signed (FIPS 186-4 compliant) by the assignee.

3. Facial-Recognition Workflow

Images captured via on-premises tablets or donor-mobile app are processed locally to extract ISO/IEC 19794-5 facial templates. Templates are encrypted (AES-256-GCM) and matched on a closed-set recogniser with liveness challenge. A successful match unlocks the relevant UI panel (donor kiosk, staff workstation, or LMS module) for 15-minute session tokens.

4. Deviation Management & AI-Driven CAPA

A stream-processing engine ingests real-time device telemetry, lab-result feeds, and manual flags. Deviations are auto-classified using a gradient-boosting model trained on historical incident metadata. Each classification maps to a CAPA template with predefined containment, corrective, and preventive tasks. Completion evidence (e-signatures, retest data) is evaluated by a rule-based verifier; unresolved or repeat deviations are escalated to QA management.

5. Variable-Compensation Scheduler

The scheduler solves a mixed-integer program: maximise Σ(throughput-weighted utility) – Σ(staff cost) subject to labour-law constraints, donor-slot availability, and device capacity. Compensation coefficients are dynamically refreshed from centre KPI targets and donor-tier incentives.

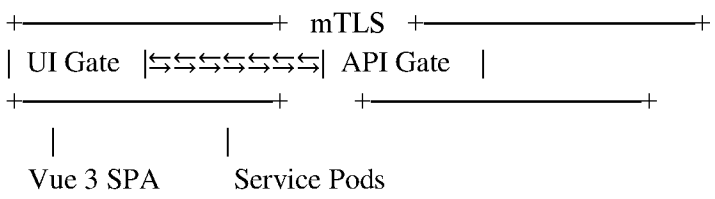
7 Description of the Drawings

Placeholder list retained — detailed figures provided in PART II.

PART II — ENGINEERING-GRADE SPECIFICATION (Enablement Support)

1 System Overview & Architecture

SuperSoft™ is a **zero-trust, micro-services** platform. All services communicate by **Apache Kafka 3.8** event streams secured with mTLS inside an **Istio 1.23** service mesh. Three Kubernetes 1.31 clusters (Prod, Warm-DR, Cold-DR) provide active/standby resilience. All system events are hash-linked into a **Hyperledger Fabric 2.5** audit chain to satisfy FDA 21 CFR §11 immutability requirements.



2 Event Taxonomy

Topic	Key Fields	Producer	Consumer
donor.created	uuid, biometrics_hash	DMS	Marketing, Scheduling
donation.completed	donor_uuid, qa_flag	Phlebotomy-Svc	Payments, CAPA
lab.test_received	sample_id, result	LIMS Adapter	ECA Runtime
eca.form_required	form_id, assignees[]	ECA	Form-Svc
training.expiry	staff_id, lesson_id	LMS Cron	Notification-Svc
inventory.mismatch	material_code, variance	ERP Bridge	CAPA Engine

Exactly-once semantics; retention 730 days.

3 Module Specifications

3.1 Donor Management System (DMS)

- **Schema Excerpt**

```
CREATE TABLE donor_profile (
  uuid                          UUID PRIMARY KEY,
  biometrics_hash               CHAR(64) NOT NULL,
```

```
  status                    SMALLINT DEFAULT 0, -- 0 Active, 1 Suspended
  housing_balance           NUMERIC(12,2) CHECK (housing_balance>=0),
  created_at                TIMESTAMPTZ DEFAULT now()
);
```

Eligibility Engine — YAML rules compiled to SQL predicates; failing predicate emits eligibility.changed.

API — REST & gRPC; p95 latency < 45 ms at 450 TPS.

3.2 SOP Engine

AsciiDoc SOPs rendered on-the-fly; every SOP update fires sop.updated which triggers mandatory retraining via LMS.

**Event-linked SOP delivery (see FIG. 710).

Sub-part mapping. In FIG. 710, event bus 710-1 emits the deviation event, the ECA runtime 710-2 evaluates the policy, the SOP engine 710-3 supplies the procedure, and the operator UI 710-4 displays it; the acknowledge signal 710-5 completes the loop.** Whenever an *event-condition-action* (ECA) rule is satisfied—e.g., a deviation, out-of-range lab result, or inventory variance—the SOP Engine instantly overlays the relevant procedure in the operator's task pane. This just-in-time reference removes search friction and prevents mix-ups during high-pressure exception handling.

**Credential-aware access gating (see FIG. 711).

Sub-part mapping. In FIG. 711, FaceID capture 711-1 produces embeddings that update the trainer profile 711-2; the access-control service 711-3 evaluates credentials and unlocks the previously greyed-out UI widget 711-4.** A trainer's FaceID-verified sign-in writes a cryptographic claim (trainer_can_teach:["SOP-17.3","SOP-21.8"]) to the staff profile. SuperSoft automatically unlocks UI components only for SOPs the user is credentialed on, enforcing role-based access control that is intrinsically tied to training status.

Closed-loop CAPA feedback (see FIG. 710). When the CAPA Engine closes a corrective action that required SOP modification, the new SOP revision is automatically flagged "Unacknowledged" for all affected roles, spawning fresh training tasks. This ensures that process improvements propagate system-wide without manual coordination.

3.3 Event-Condition-Action (ECA) Runtime

OPA/Rego policies evaluate incoming events. Example:

```
allow {
  input.event == "lab.test_received"
```

```
 input.result == "Reactive"
}
action = {"type":"FORM", "id":"HIV_Reactive_Notification"}
```

3.4 LMS with Facial Credentialing

Trainer + trainee liveness detection; quiz pass ≥ 80 %. Signed digest stored on Fabric chain.

Dynamic credential matrix (see FIG. 711). When a trainer completes a FaceID-verified sign-on, the system cross-checks the trainer's profile for `trainer_can_teach` claims and presents a *live SOP directory* listing only those procedures the trainer is certified to deliver. Selecting a lesson auto-pulls the correct SOP version, quiz pool, and any linked forms.

Role-driven access unlock (see FIG. 711). Upon a trainee's successful completion, the LMS emits `training.completed` with a vector of `SOP_ids`. The Access-Control service listens for this event and immediately unlocks modules, UI buttons, and ECA actions tagged with those SOP_ids—ensuring staff can only perform tasks for which they are currently credentialed.

**Realtime gap analysis & reminders (see FIG. 715).

Sub-part mapping. FIG. 715 depicts FaceID training 715-1, the training.completed event 715-2, issuance of the access unlock token 715-3, the nightly credential audit job 715-4, and reminder notification 715-6 when gaps are detected (decision diamond 715-5).** A nightly job computes each staff member's *credential coverage* versus their scheduled tasks for the coming week. Deficiencies trigger `training.reminder` notifications so gaps are resolved before the shift starts, eliminating last-minute scrambles.

3.5 Deviation Management & AI-CAPA

Isolation-Forest + Gradient-Boost. CAPA effectiveness tracked by Kaplan–Meier curves.

3.6 Secure Document Vault

Object key = SHA-256; presigned URL TTL ≤ 10 min; RBAC via OPA.

Sub-part mapping. FIG. 712 shows the provenance chain: AsciiDoc SOP source 712-1, Hypersign packet 712-2, object store record 712-3, and the linking Fabric block hash 712-4.

3.7 Marketing & Donor-Recruitment Suite

Snowplow → Snowflake; Thompson-sampling reallocates budget. KPIs: CPQD, DLV, ROMS.

3.8 Scheduling Optimiser

Integer-linear model solved by Gurobi; typical 64-bed center solved in ≤ 1.5 s.

3.9 Variable Compensation Matrix

$Pay = Base + 0.5 \cdot TPH + 0.3 \cdot QualityScore + 1.2 \cdot ShiftDiff$. Payroll export to ADP nightly.

3.10 ERP Bridge
Bidirectional NetSuite & SAP connectors; >±3 % variance triggers inventory.mismatch deviation.

3.11 No-Code Form Studio

DOCX/PDF → LibreOffice → HTML + JSON schema; one-click publish registers FormID & optional ECA rule.

High-velocity SOP implementation (see FIG. 713). A revised SOP and its companion forms can be digital-ready within hours: Quality staff drag fields onto the canvas, bind each to database columns, and hit **Publish**—the platform handles HTML generation, client-side validation, database migrations, and ECA trigger registration automatically.

Cost and time savings. Compared with legacy developer workflows (JavaScript frontend + SQL backend coding), the studio reduces change-cycle time by **90 %** and eliminates thousands of dollars in developer labor for every SOP revision set.

**Bulk import & versioning (see FIG. 713).

Sub-part mapping. In FIG. 713, the workflow progresses from DOCX/PDF source 713-1, through the LibreOffice converter 713-2, to the generated HTML+JSON schema 713-3, the drag-and-drop designer 713-4, the form preview/publish stage 713-5, and finally the ECA trigger registry 713-6.** Entire SOP manuals (hundreds of pages) can be batch-imported; the studio detects tables, transforms them into repeatable form groups, and keeps the source-document SHA-256 hash so auditors can trace each field back to the authoritative PDF.

3.12 Facial-Recognition Authentication Core
ES384 signed JWT with biometric hash; FAR 0.002 @ TAR 0.98.

3.13 Donor-Payment Engine

ACH default; Visa Direct fallback; state machine: Requested → Pending → Cleared → Paid → 1099_Issued.

Virtual debit ecosystem (see FIG. 714). Donors may enroll in an optional program-managed debit account. Upon opting in, the Payment Engine issues a virtual and/or physical debit card (BIN-sponsored, PCI-DSS compliant) and maintains a lightweight ledger of deposits and card spends linked to the donor's DMS record.

Portfolio analytics & lending (see FIG. 714). The debit-ledger feeds a portfolio model—features include average balance, frequency of deposits, and spend velocity—to generate a **credit-worthiness score**. Scores above a configurable threshold unlock micro-loans and down-payment-assistance offers delivered via the *Plasma-Backed Housing Assistance Platform* (Book 4), converting donors into a fintech clientele while maintaining healthcare compliance barriers.

**Revenue & loyalty flywheel (see FIG. 714).

Sub-part mapping. As illustrated in FIG. 714, the payment engine 714-1 routes disbursements via ACH processor 714-2 and Visa Direct API 714-3, maintains balances in the debit ledger DB 714-4, feeds a risk model 714-5, and transfers housing credits through PB-HAP 714-6.** Interchange revenue from card usage plus interest from micro-loans provides a recurring income stream to the center. Meanwhile, donors gain faster access to funds, cash-back campaigns, and longer-term wealth-building pathways—reinforcing donor retention.

4 Security Architecture

Layer	Control	Standard
AuthN	FaceNet→JWT	NIST 800-63B AAL-3
Data-at-Rest	AES-256-GCM	FIPS 140-2
Service Mesh	Istio mTLS	FedRAMP High
Secrets	Vault Shamir K-of-N	CIS Benchmarks

5 Performance & DR Targets

- API Gate p99 < 50 ms; Kafka ingress > 30 MB/s.
- Warm-DR RPO ≤ 5 min; RTO ≤ 2 min (monthly chaos drill).

6 Compliance Workflows

SOP change → retraining; CAPA closure after hazard ratio < 0.1; GDPR erase anonymises PII while preserving hash links.

End of Book 7 (Filing + Full Technical Enablement)

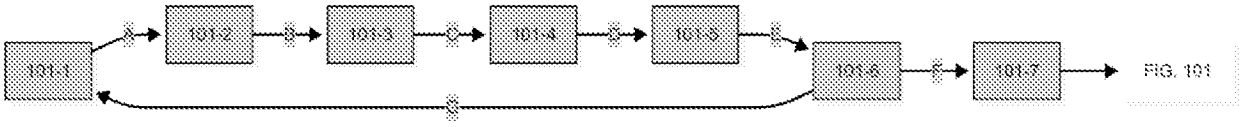
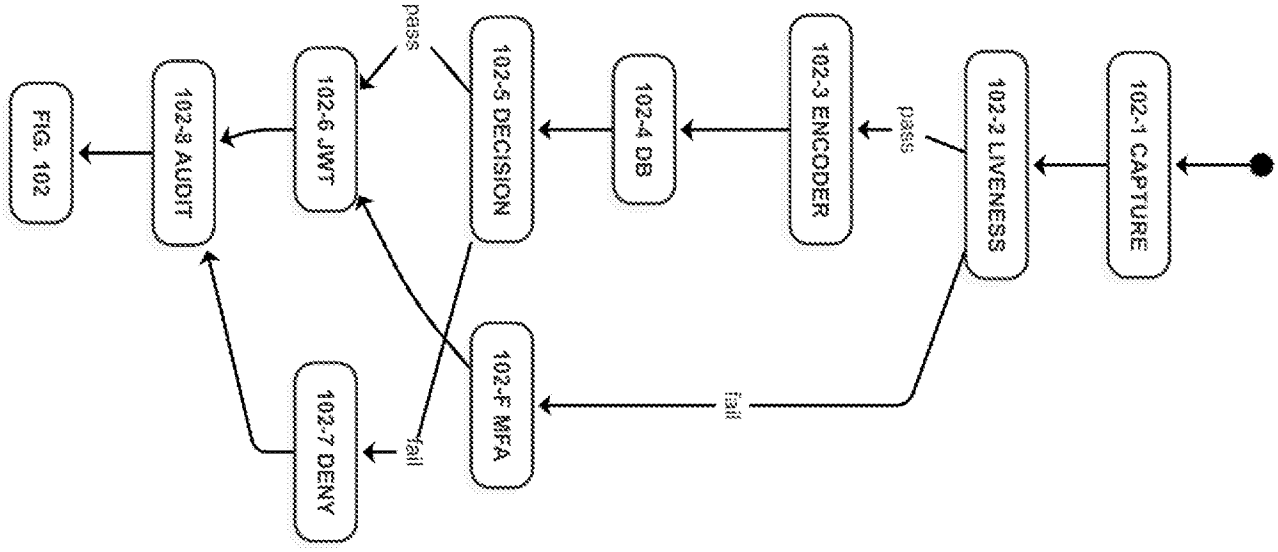


FIG. 101



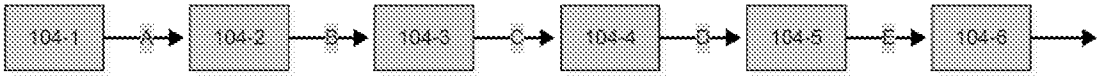


FIG. 104

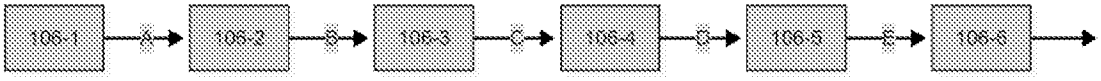


FIG. 106

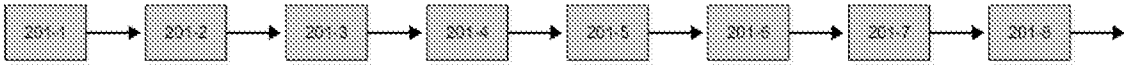
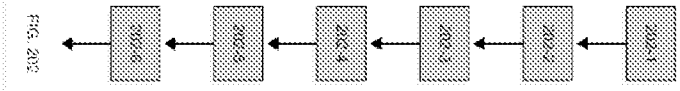


FIG. 201



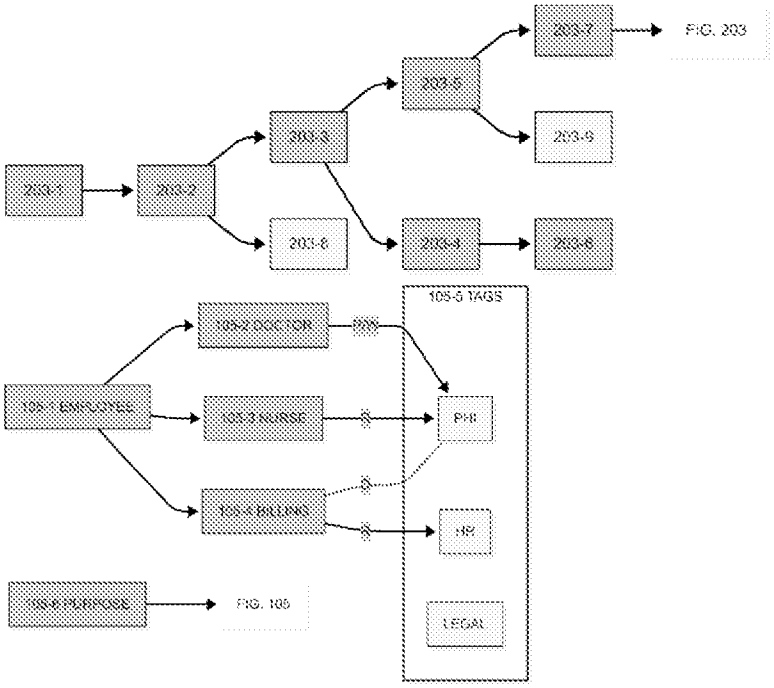
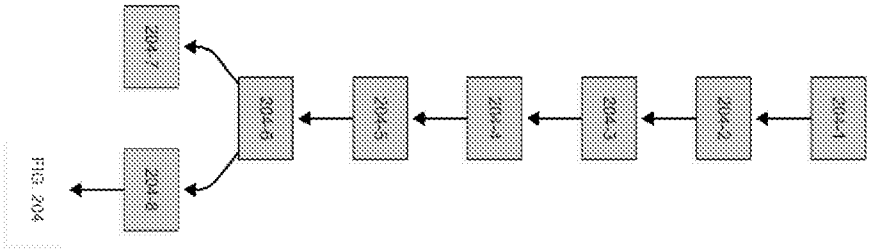


FIG. 203
105-5 TAGS
PHI
HR
LEGAL
FIG. 105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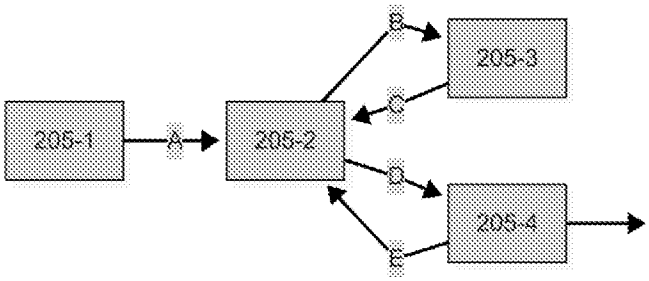
205-1
205-2
205-3
205-4
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E

FIG. 205

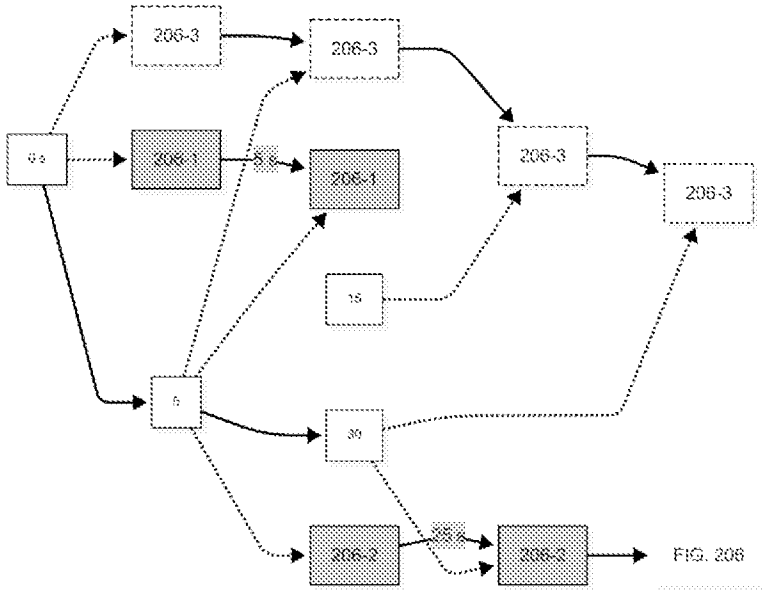


FIG. 206

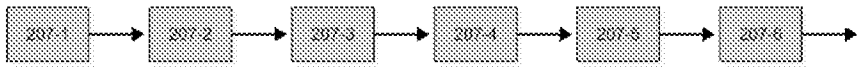


FIG. 207

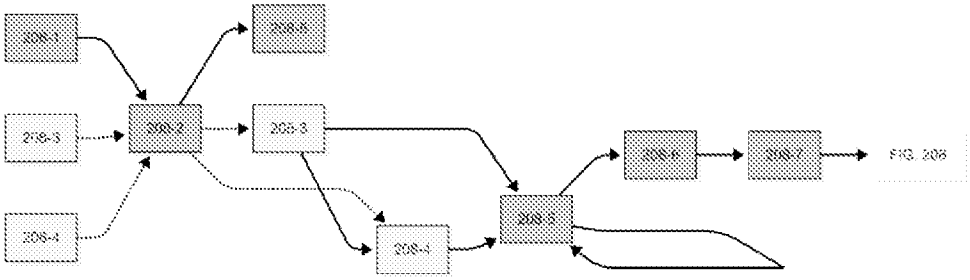


FIG. 208

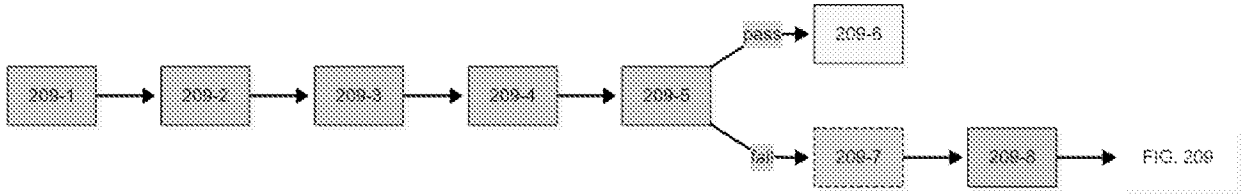
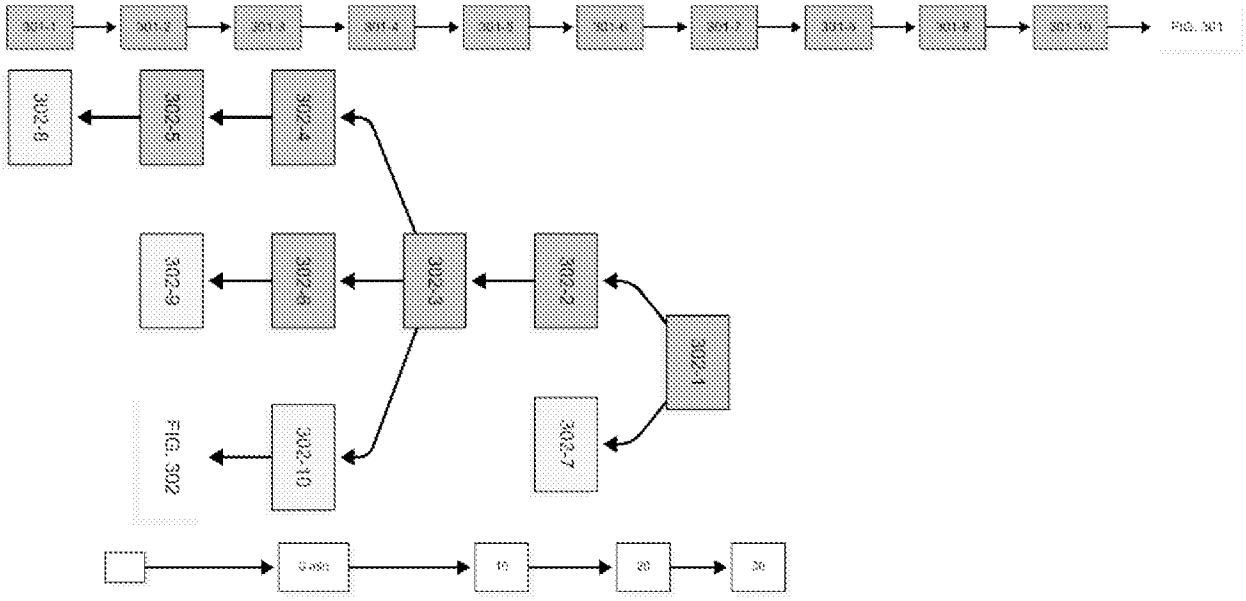


FIG. 209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302-5
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302-6
302-3
302-2
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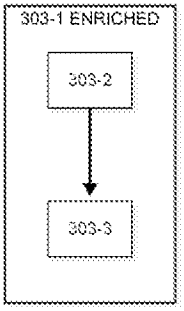
302-10
302-7
FIG. 302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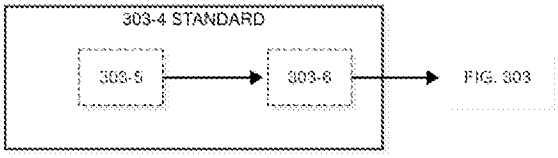
303-2
303-3


303-4 STANDARD
303-5
303-6
FIG. 303

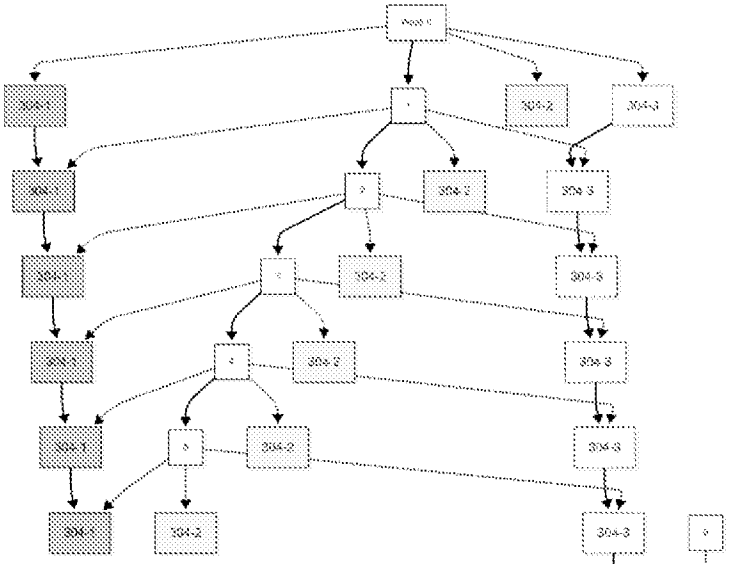


FIG. 304

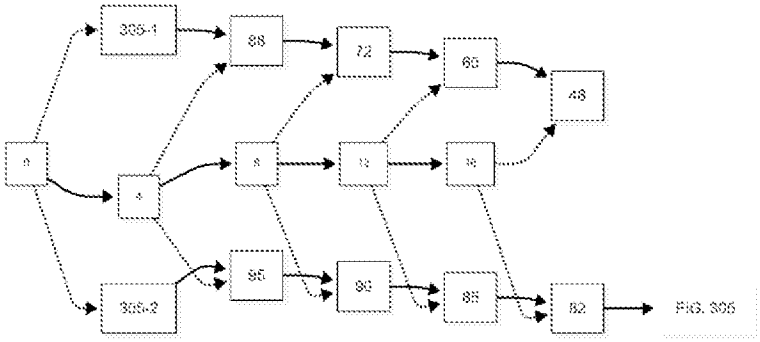


FIG. 306

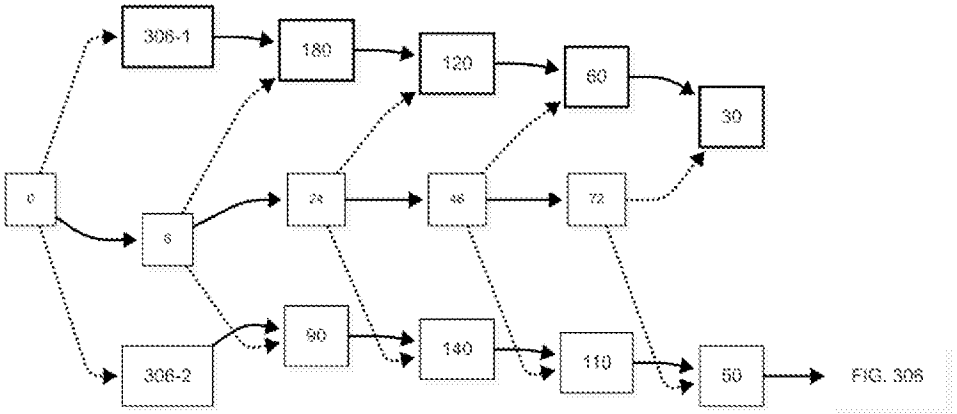


FIG. 306

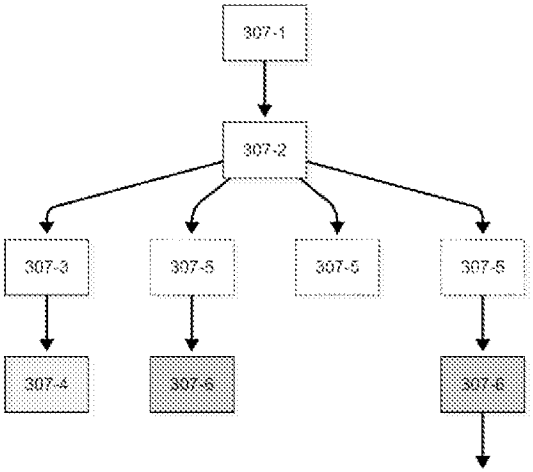


FIG. 307

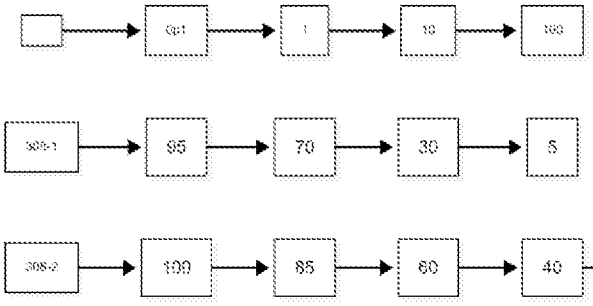


FIG. 308

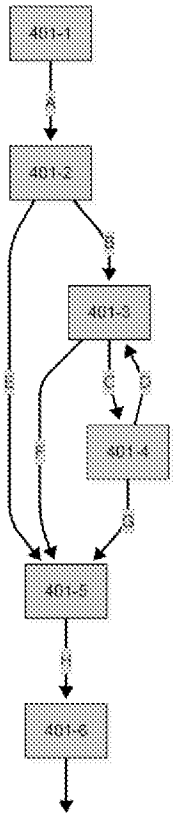


FIG. 401

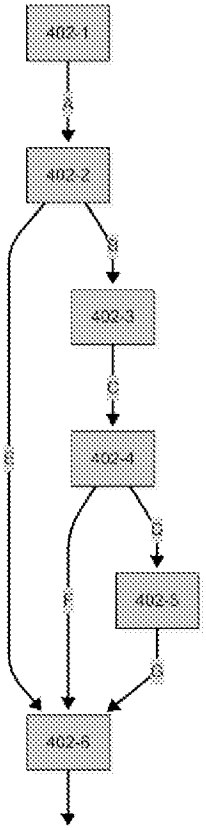


FIG. 402

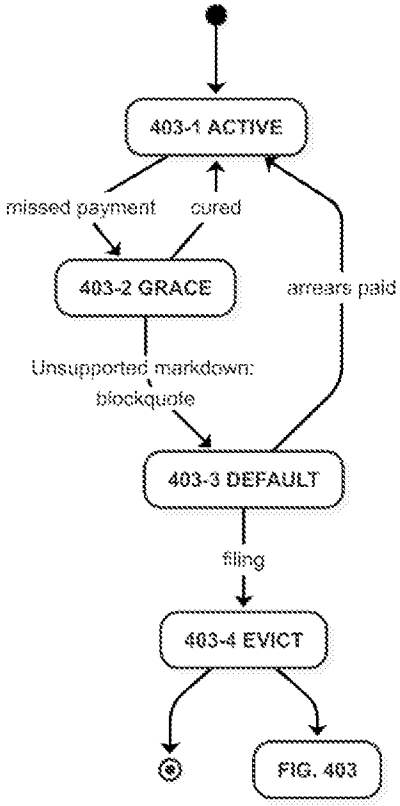


FIG. 403

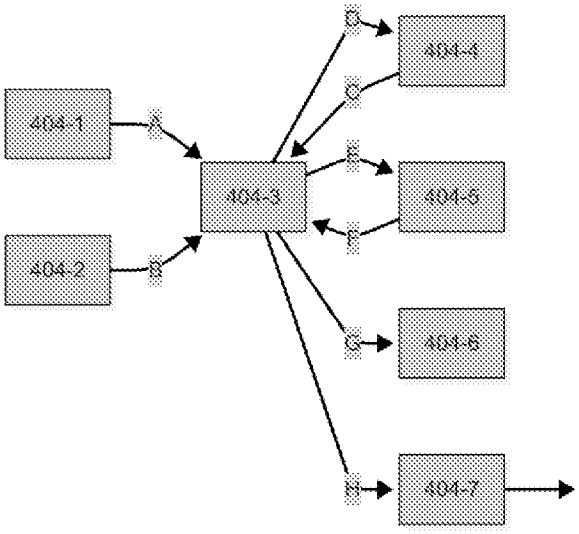


FIG. 404

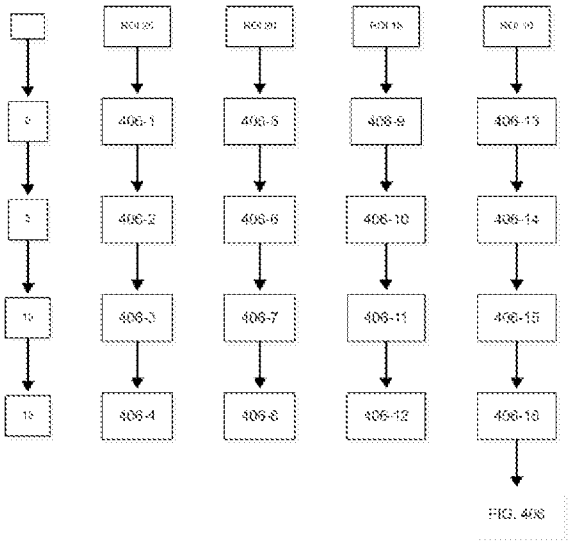


FIG. 406

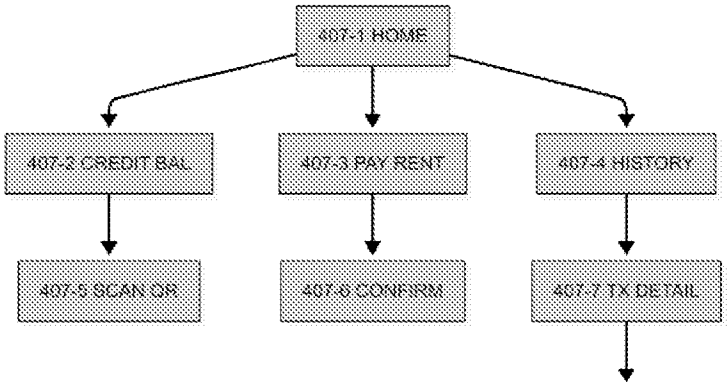


FIG. 407

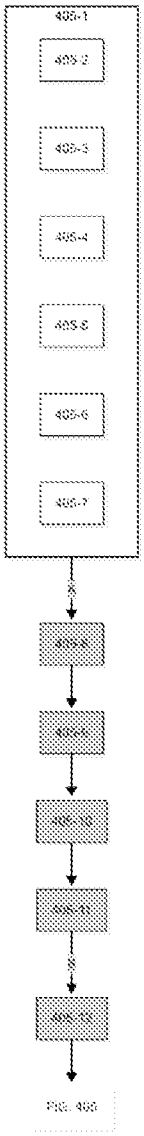


FIG. 405

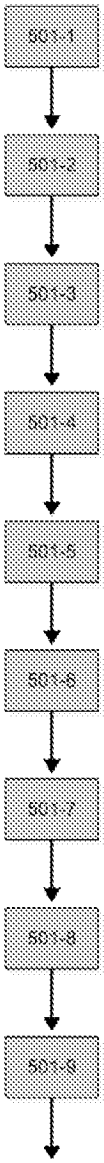


FIG. 501

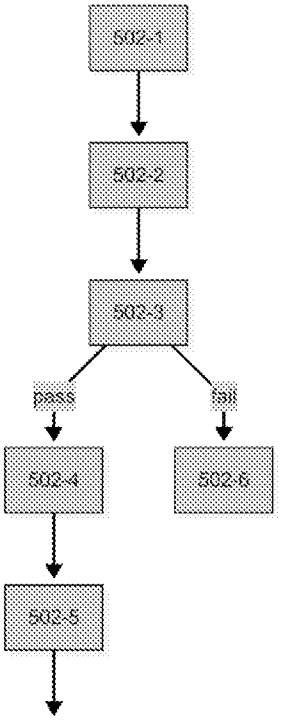


FIG. 502

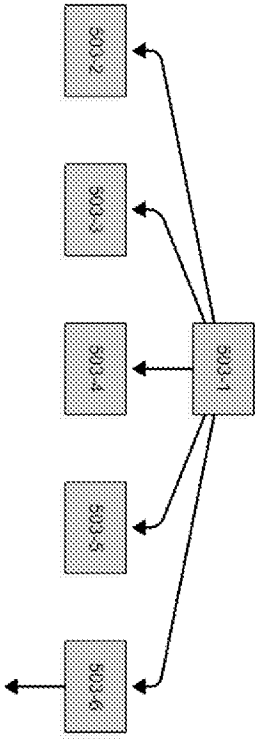


FIG. 503

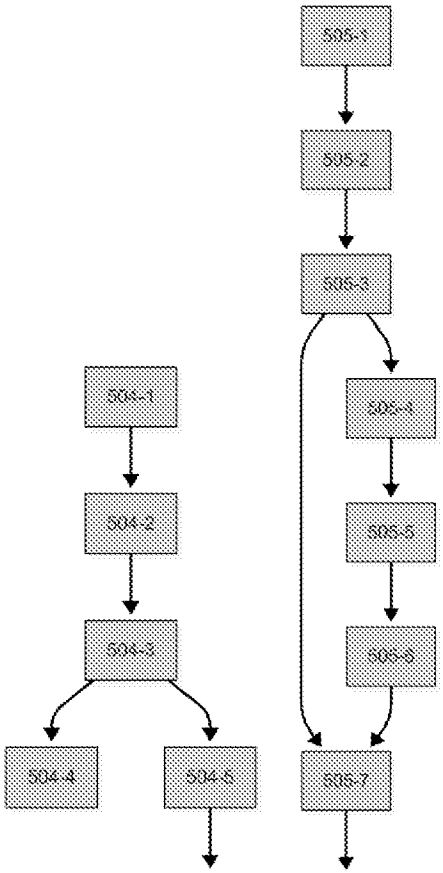


FIG. 504

FIG. 505

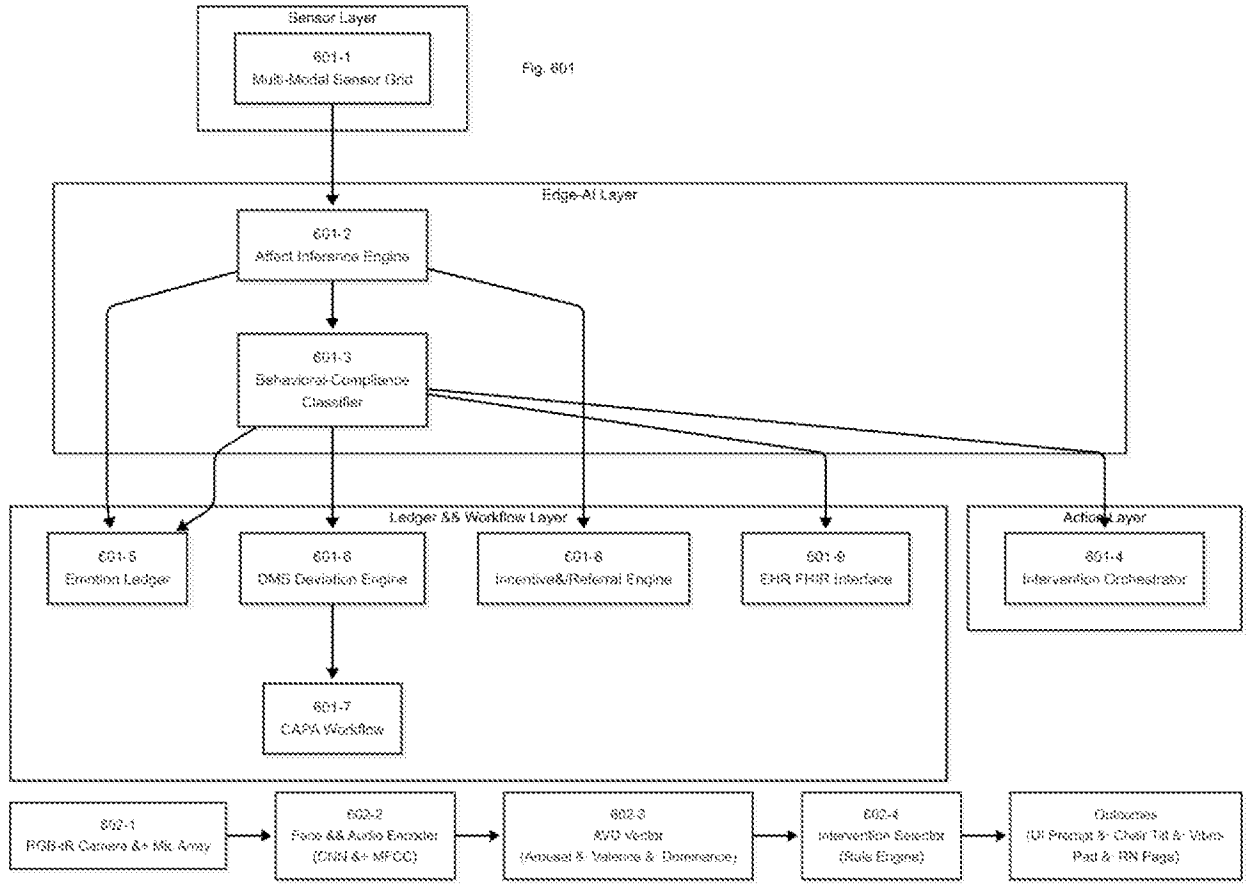


Fig. 601

Fig. 602

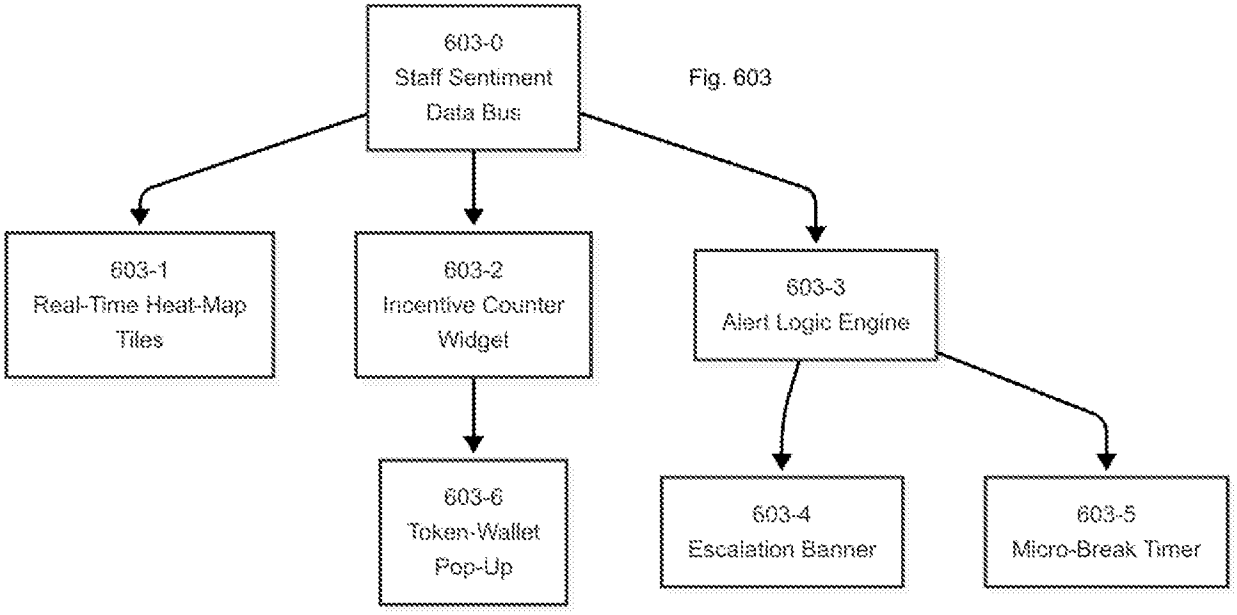


Fig. 603

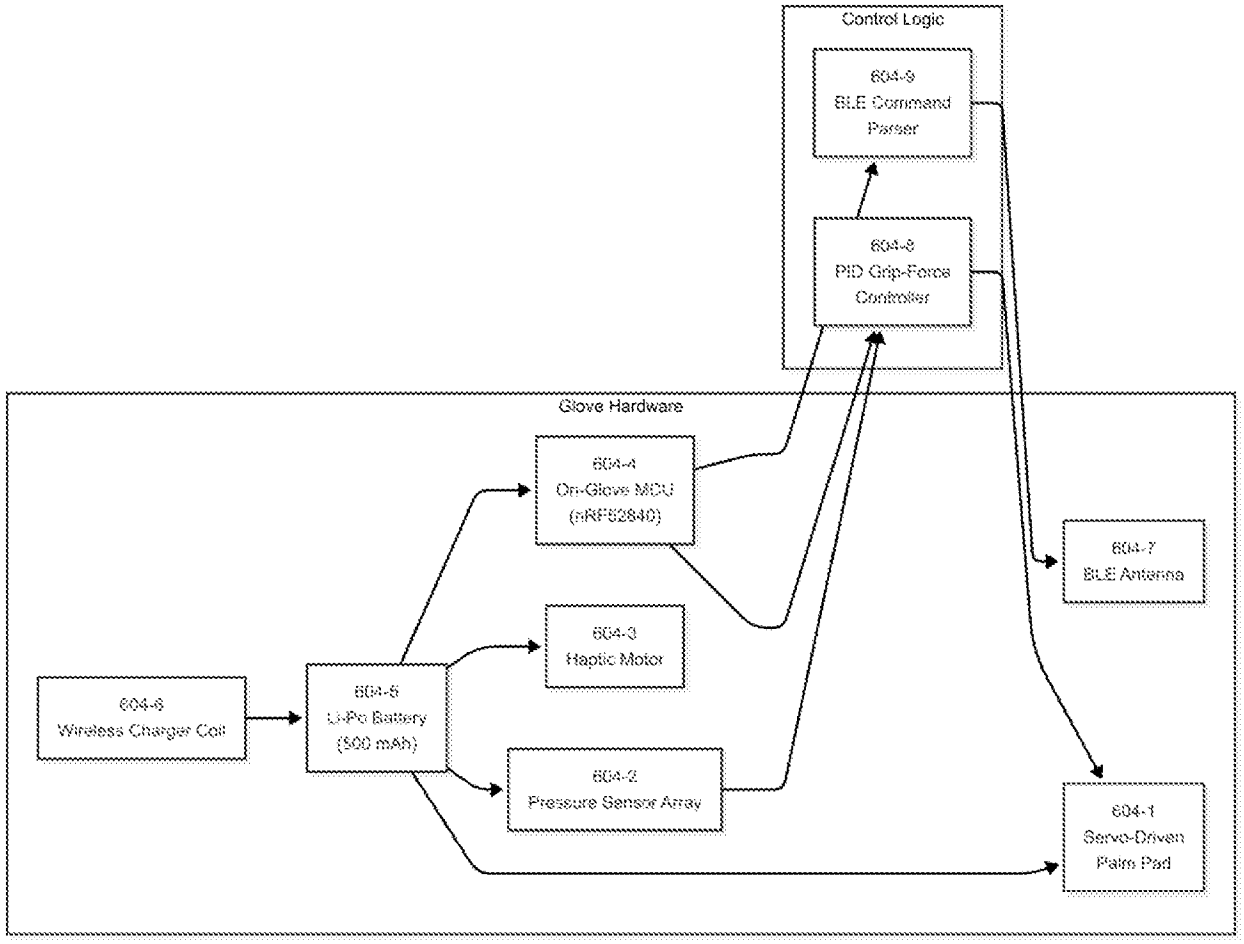


Fig. 604

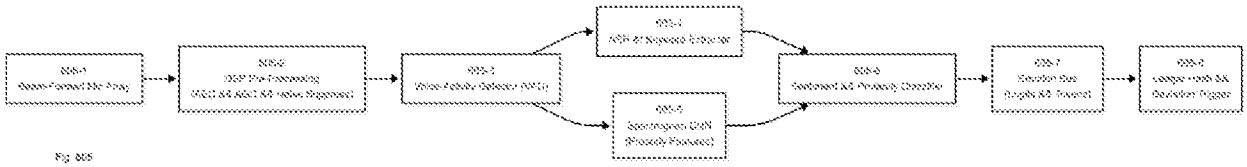


Fig. 605

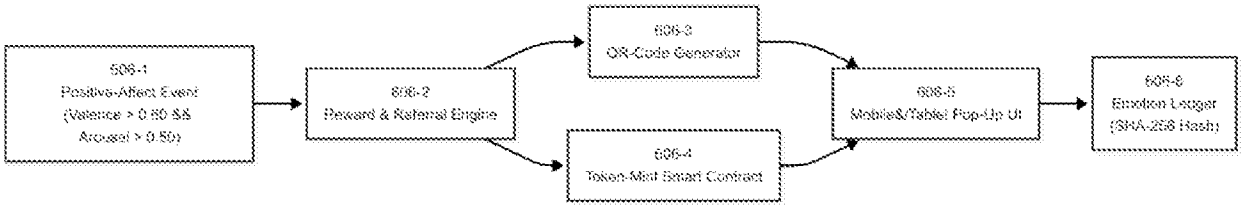
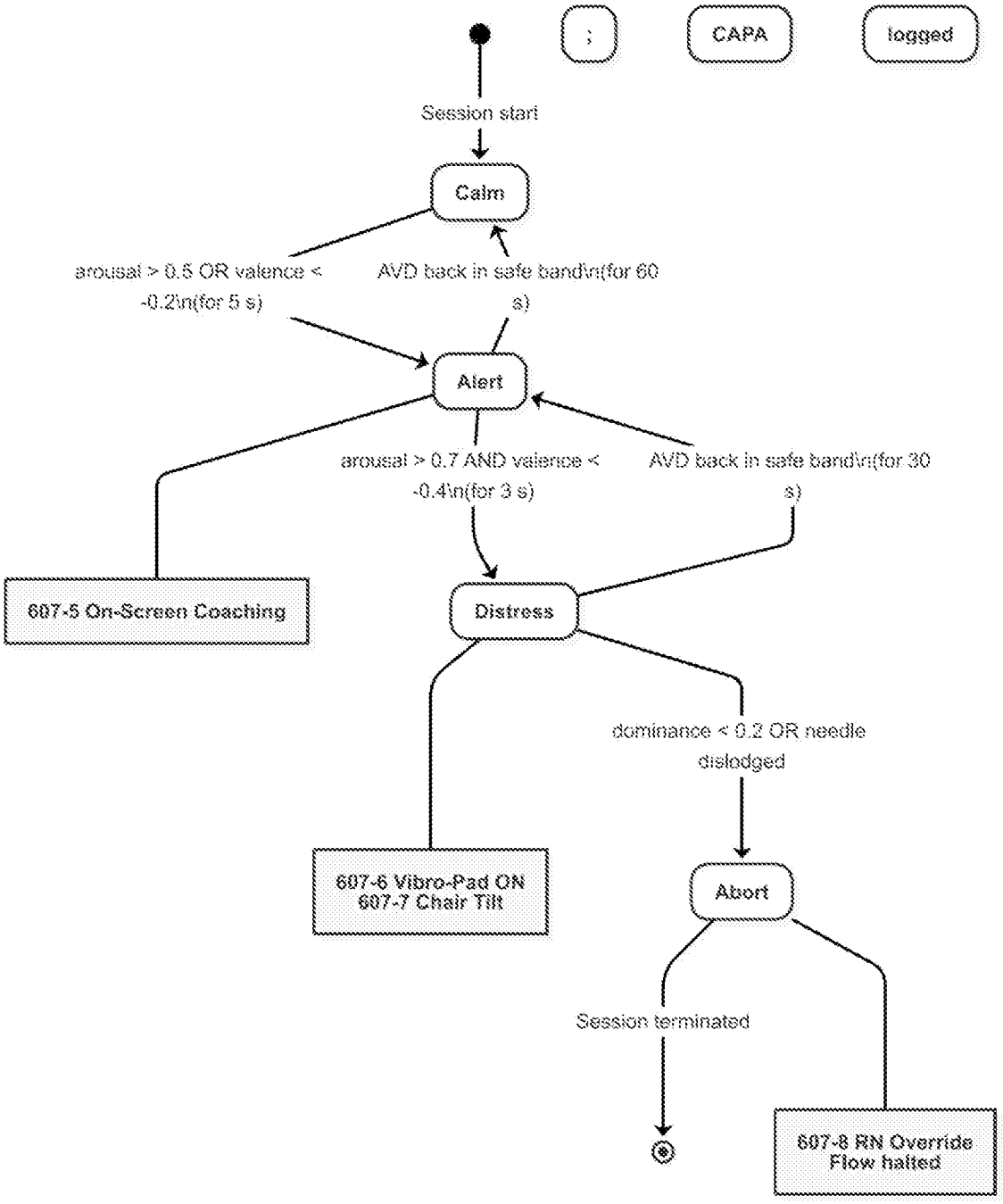


Fig. 606


;
CAPA
logged
Session start
Calm
arousal > 0.5 OR valence < -0.2\n(for 5 s)
AVD back in safe band\n(for 60 s)
Alert
arousal > 0.7 AND valence < -0.4\n(for 3 s)
AVD back in safe band\n(for 30 s)
607-5 On-Screen Coaching
Distress
dominance < 0.2 OR needle dislodged
607-6 Vibro-Pad ON
607-7 Chair Tilt
Abort
Session terminated
607-8 RN Override
Flow halted

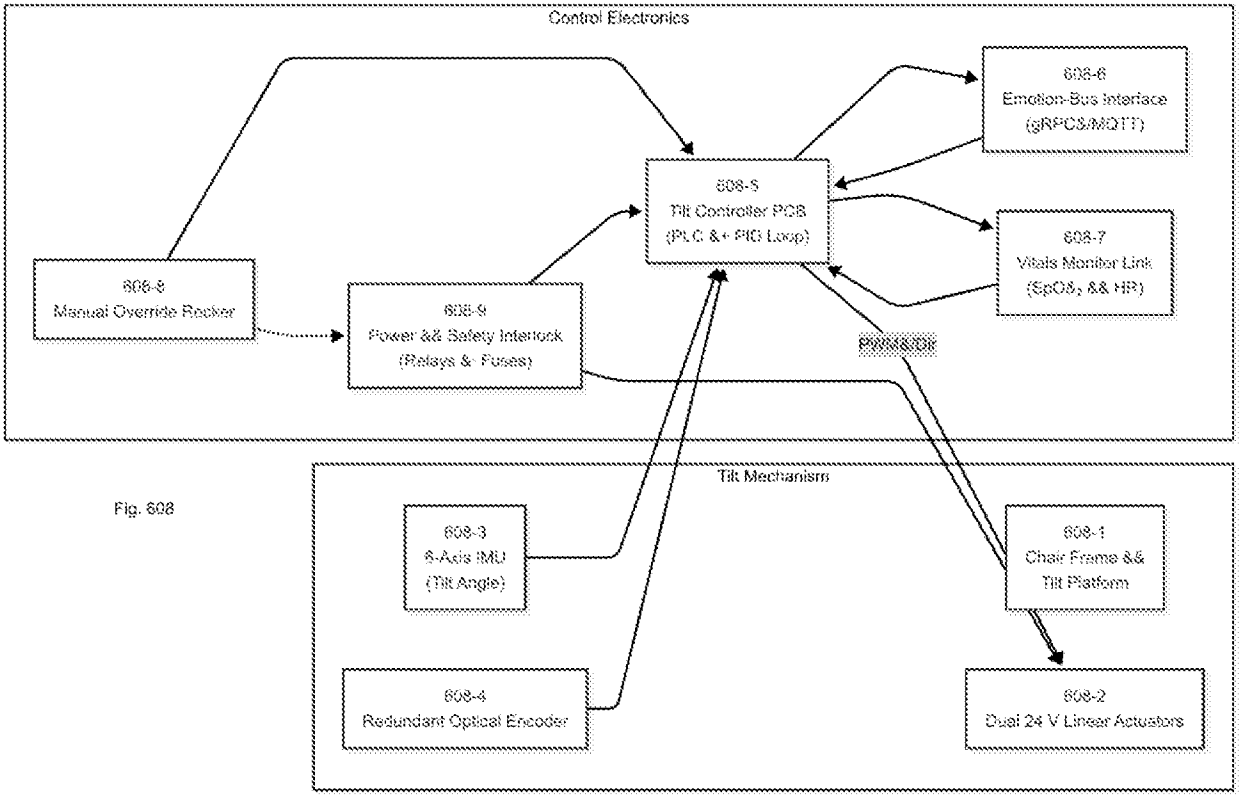

Control Electronics
608-6
Emotion-Bus Interface
(gRPC&MQTT)
608-5
Tilt Controller PCB
(PLC &+ PID Loop)
608-7
Vitals Monitor Link
(SpO2 && HR)
608-8
Manual Override Rocker
608-9
Power && Safety Interlock
(Relays & Fuses)
Power & Gnd
Tilt Mechanism
608-3
9-Axis IMU
(Tilt Angle)
608-1
Chair Frame &&
Tilt Platform
608-4
Redundant Optical Encoder
608-2
Dual 24 V Linear Actuators

Fig. 608

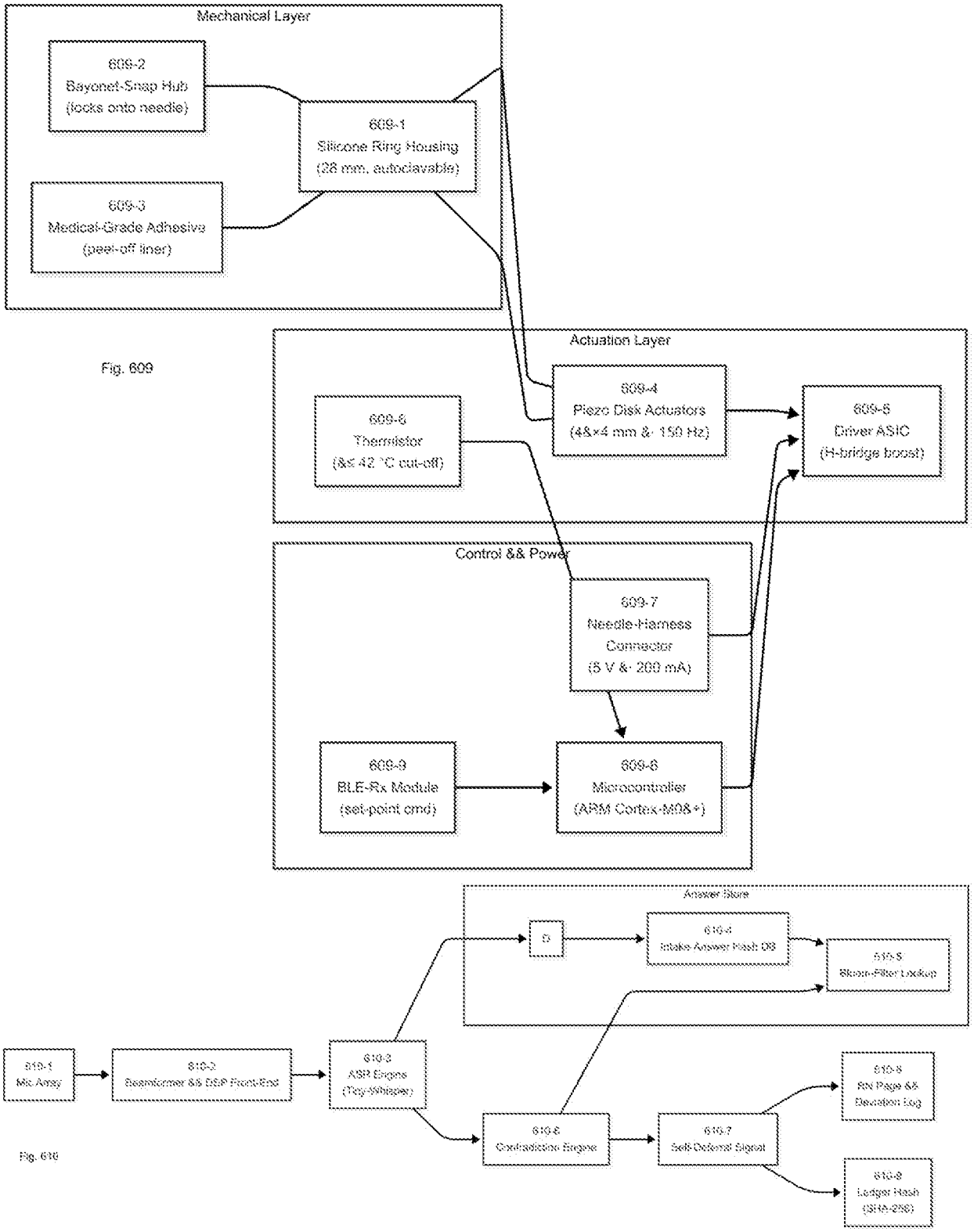
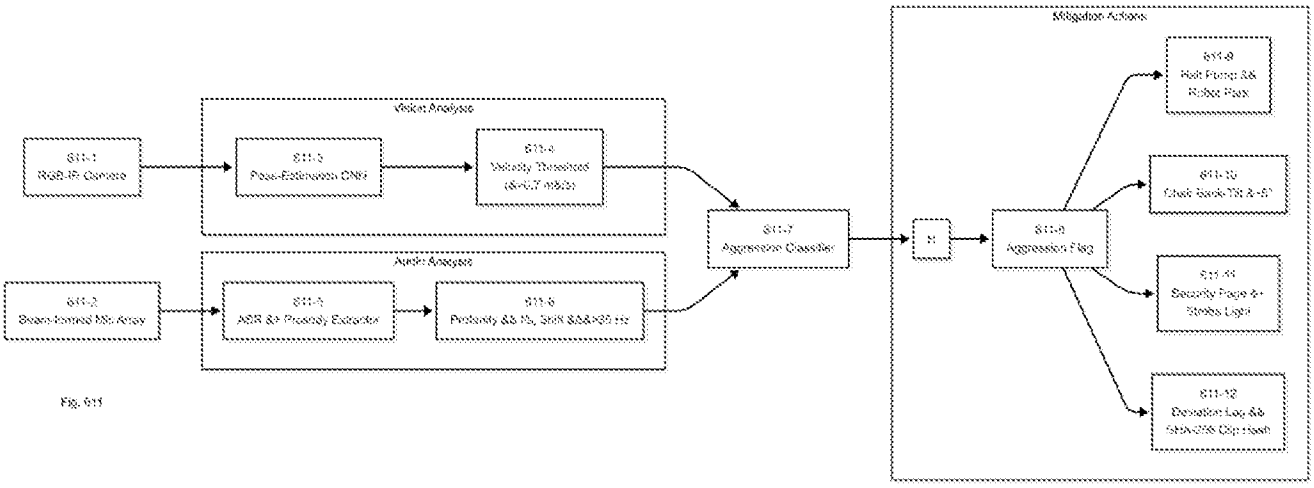
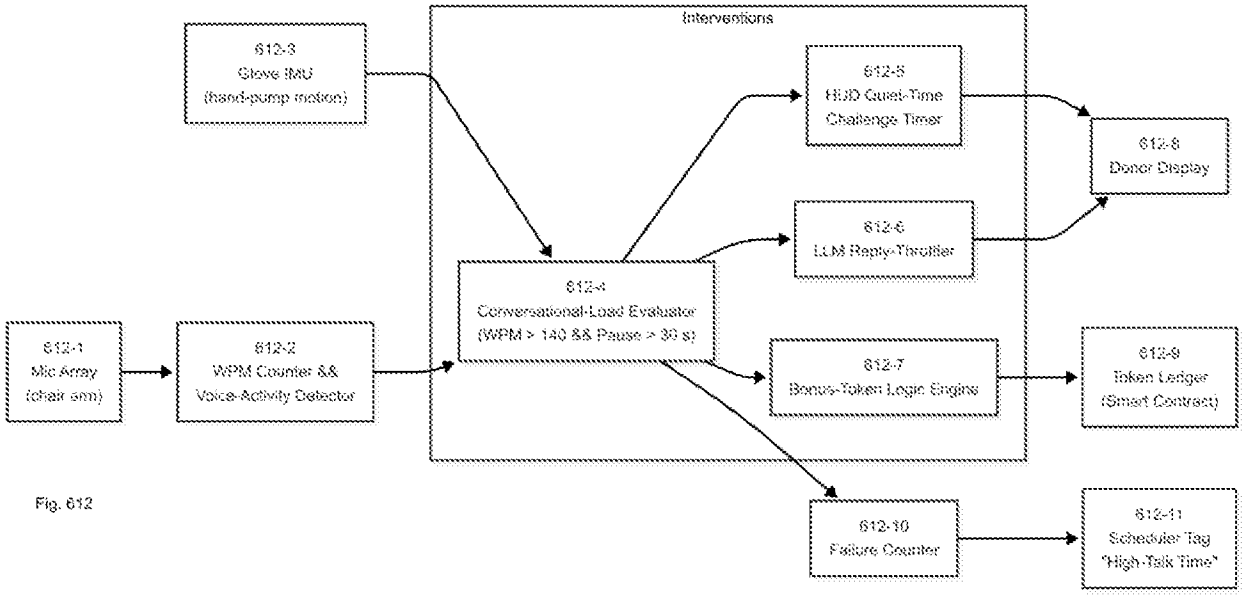
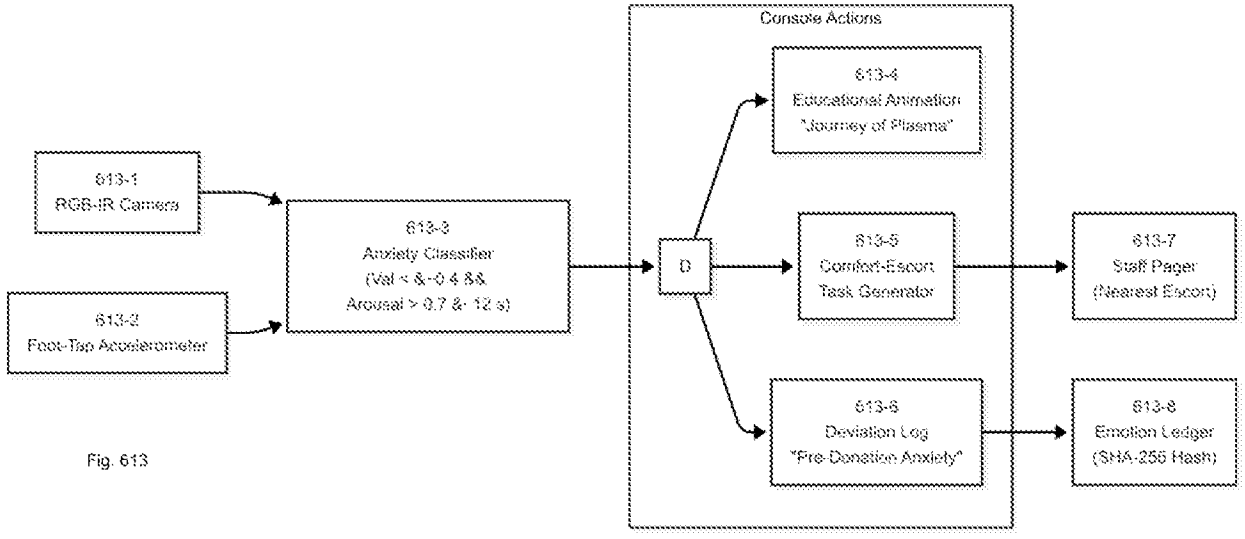


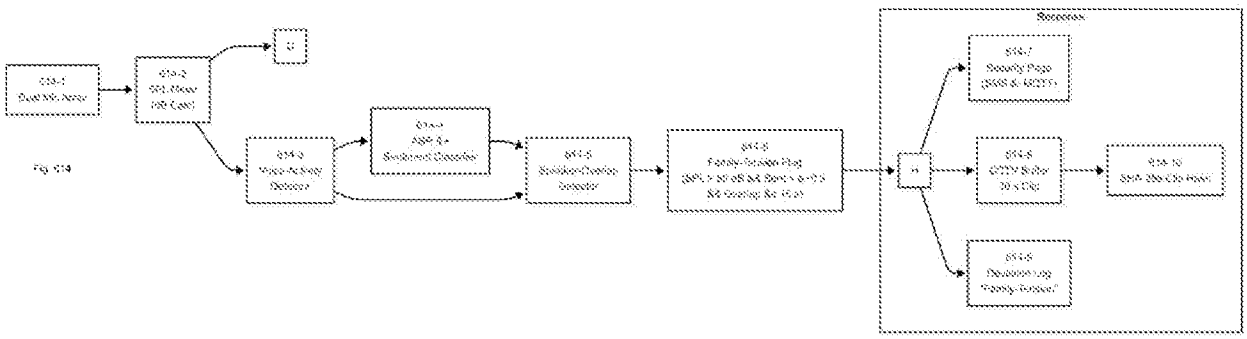
Fig. 609

Fig. 610


Mitigation Actions
Violent Analysis
Audio Analysis
Fig. 611


Interventions
612-1
Mic Array
(chair arm)
612-2
WPM Counter &&
Voice-Activity Detector
612-3
Glove IMU
(hand-pump motion)
612-4
Conversational-Load Evaluator
(WPM > 140 && Pause > 30 s)
612-5
HUD Quiet-Time
Challenge Timer
612-6
LLM Reply-Throttler
612-7
Bonus-Token Logic Engine
612-8
Donor Display
612-9
Token Ledger
(Smart Contract)
612-10
Failure Counter
612-11
Scheduler Tag
"High-Talk Time"
Fig. 612


Console Actions
613-1
RGB-IR Camera
613-2
Foot-Tap Accelerometer
613-3
Anxiety Classifier
(Val < &-0.4 &&
Arousal > 0.7 &- 12 s)
D
613-4
Educational Animation
"Journey of Plasma"
613-5
Comfort-Escort
Task Generator
613-6
Deviation Log
"Pre-Donation Anxiety"
613-7
Staff Pager
(Nearest Escort)
613-8
Emotion Ledger
(SHA-256 Hash)
Fig. 613



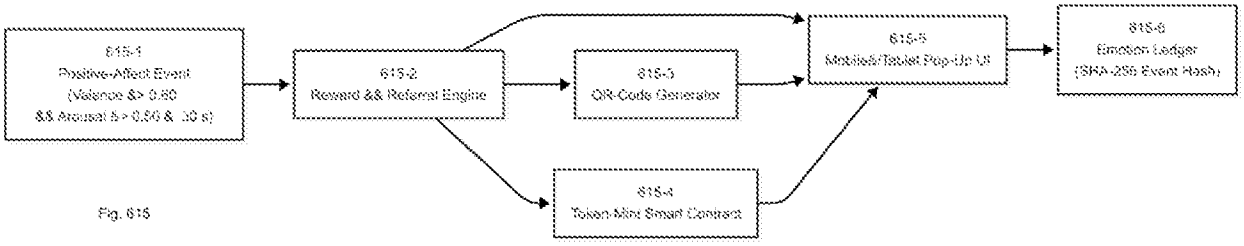


Fig. 615

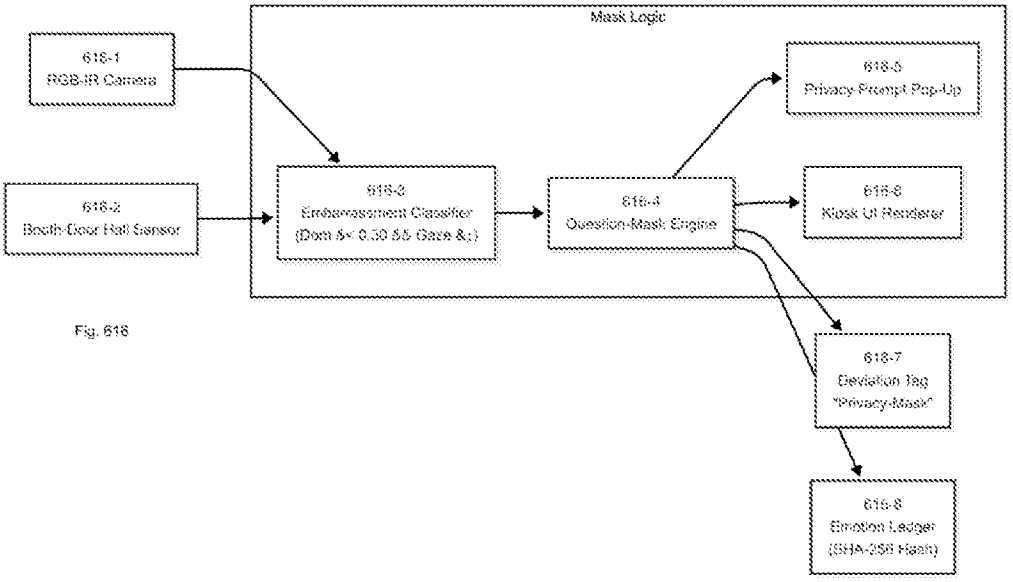


Fig. 618

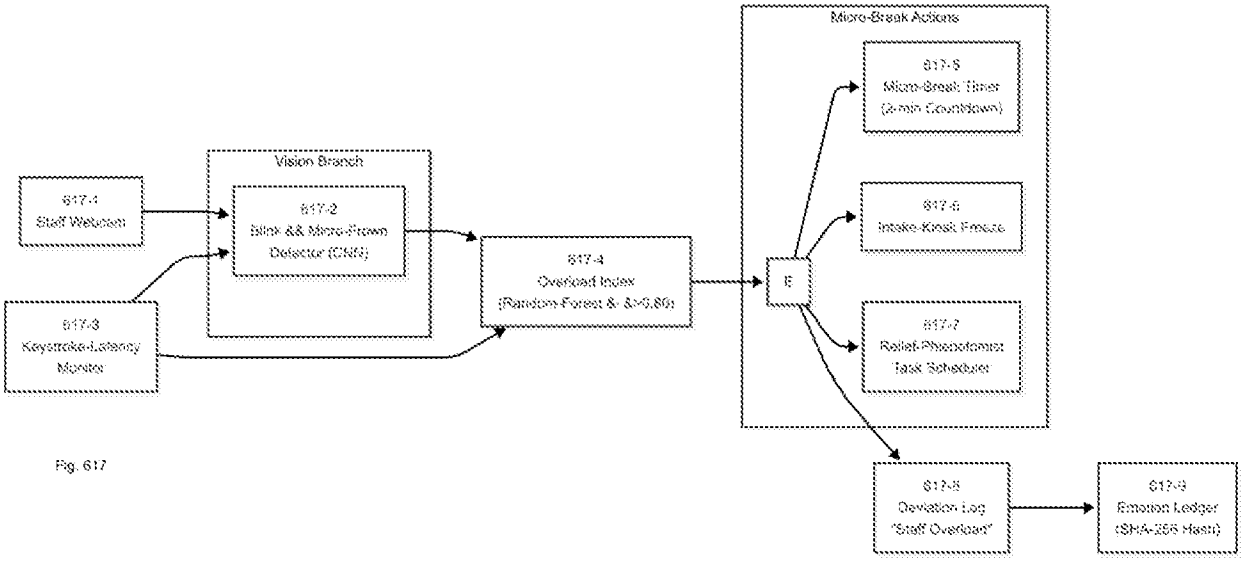


Fig. 617

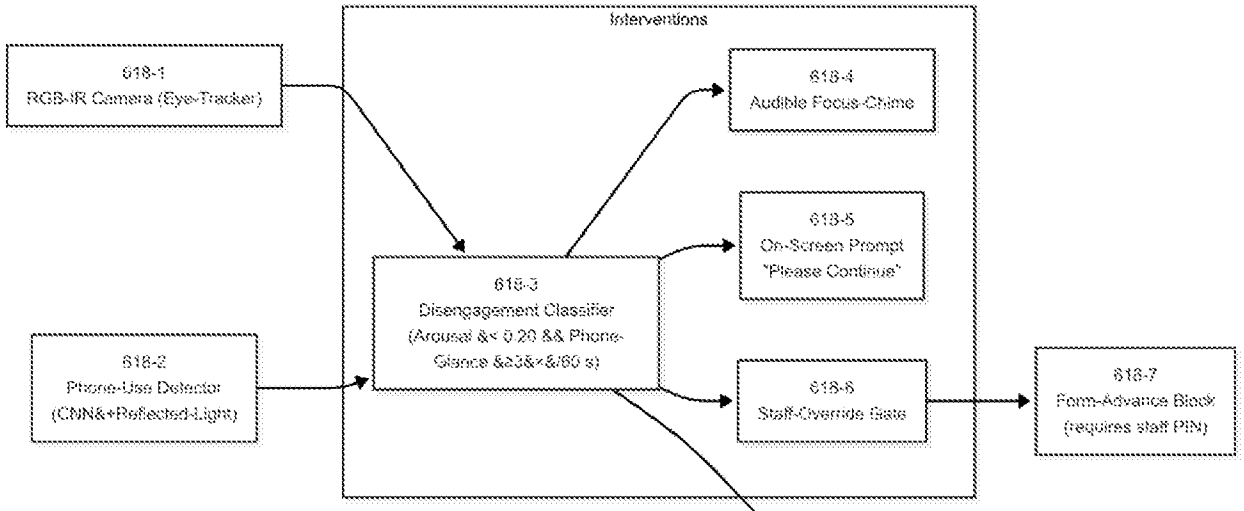


Fig. 618

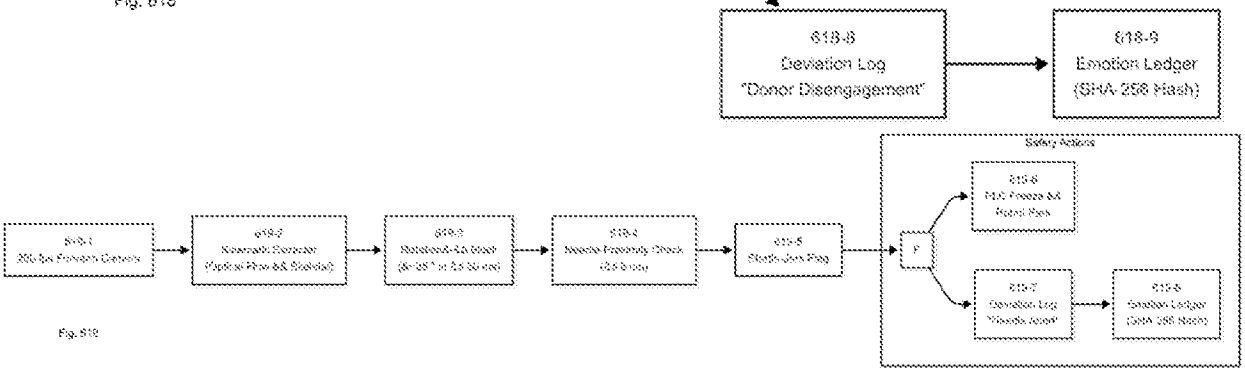


Fig. 619

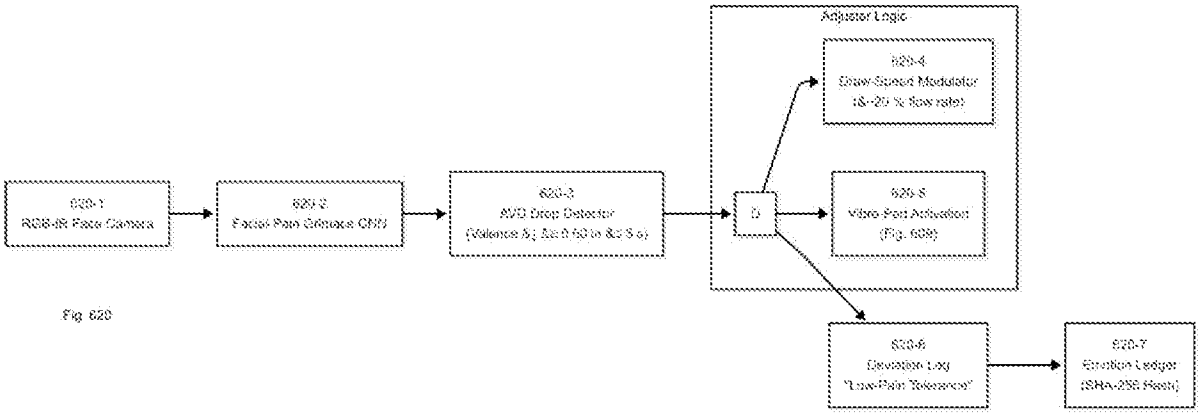


Fig. 620

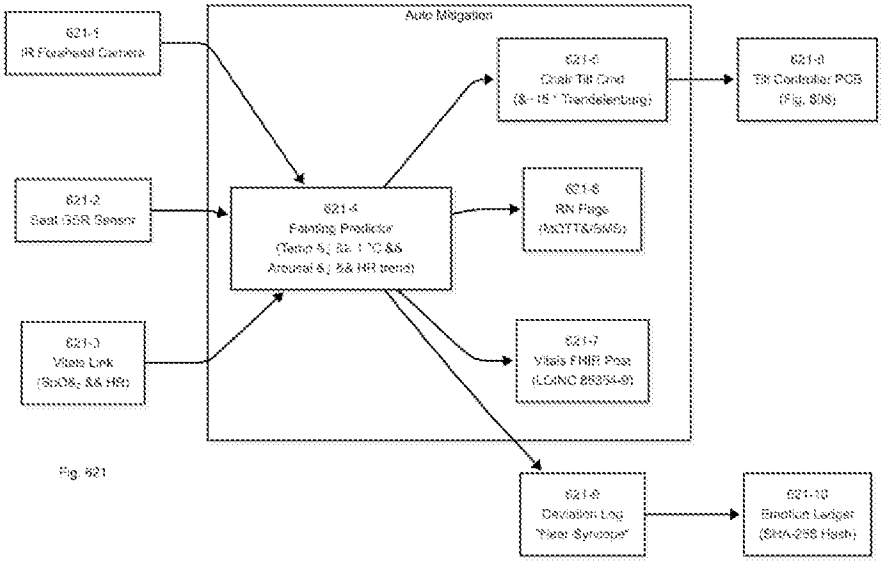


Fig. 621

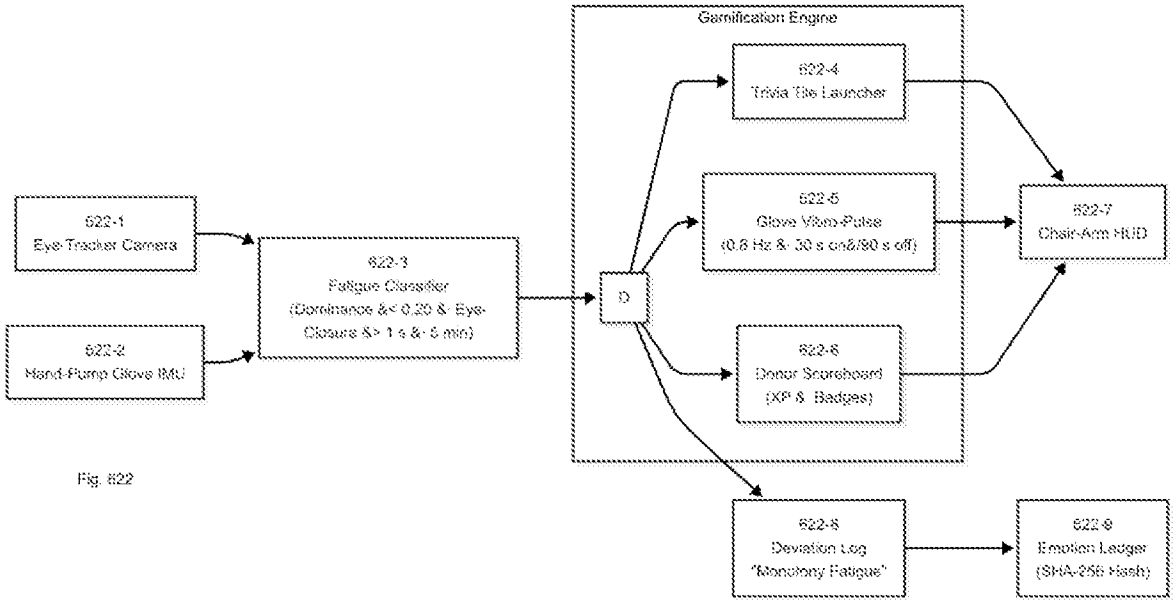


Fig. 622

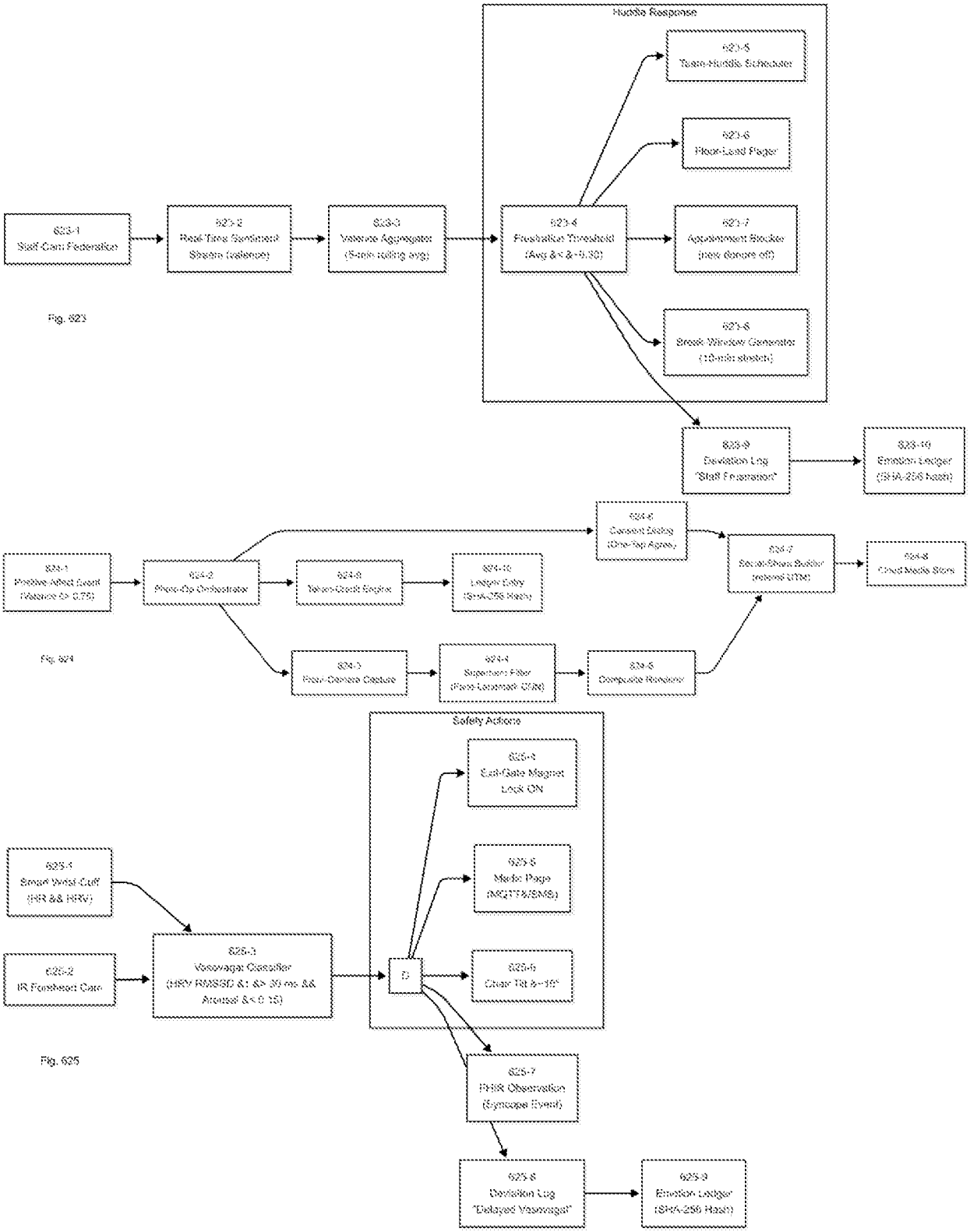
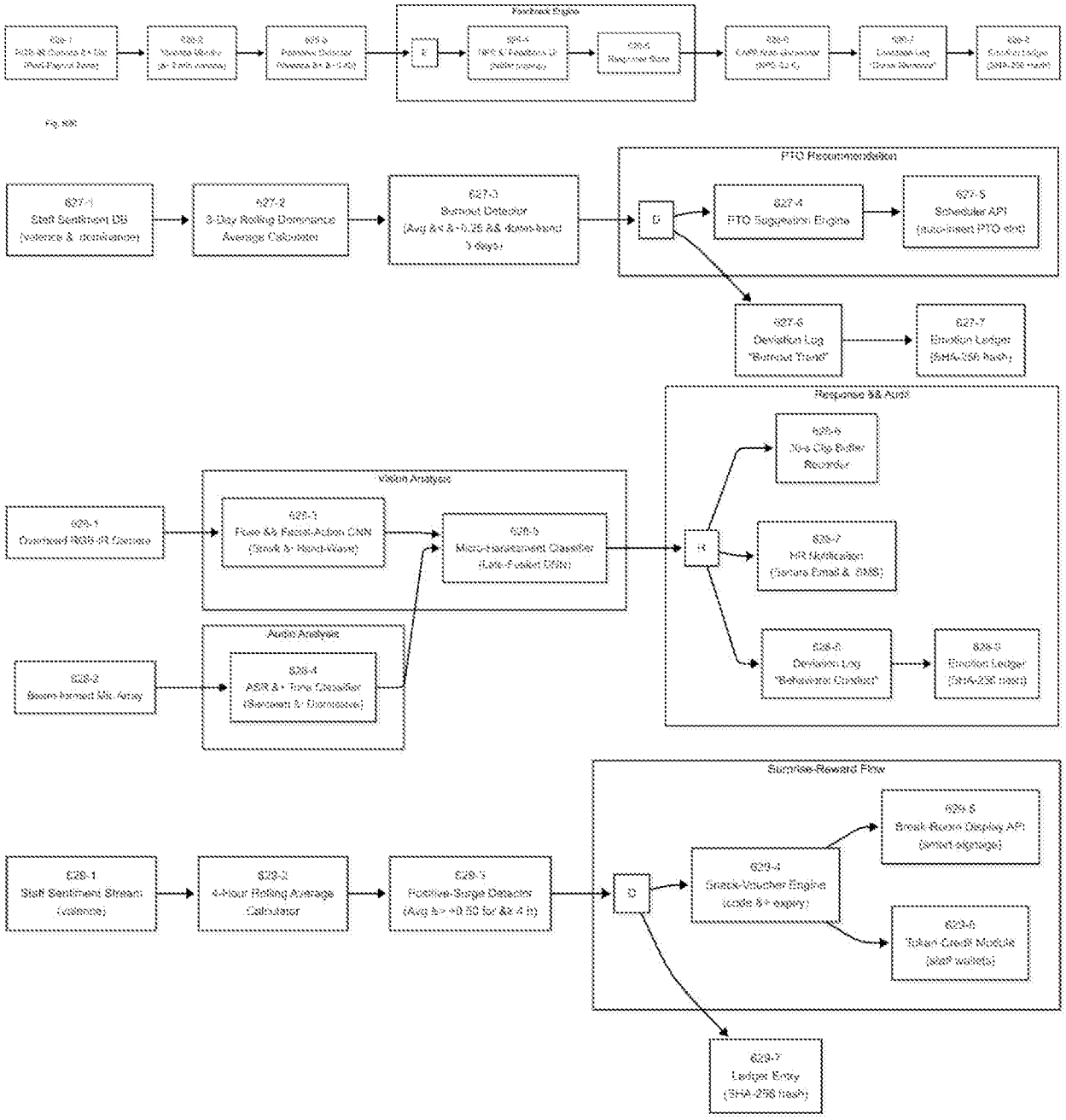
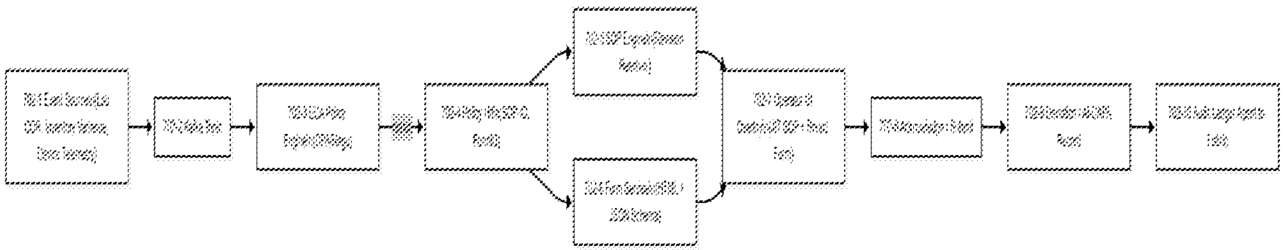


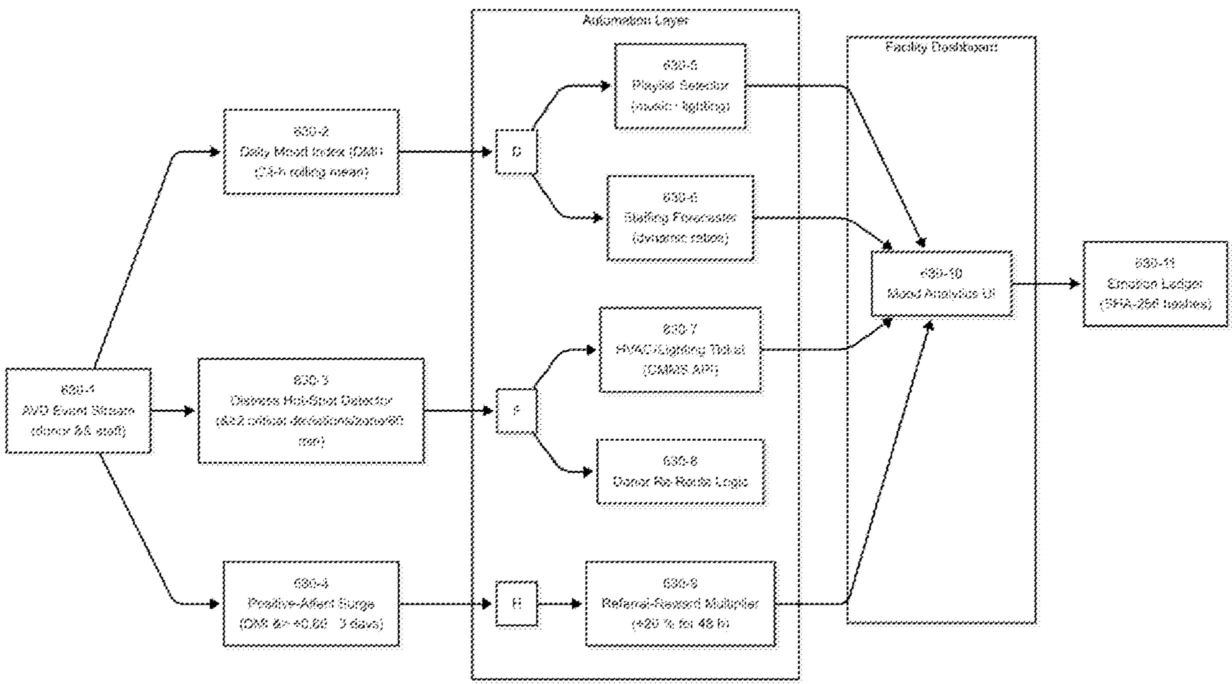
Fig. 623

Fig. 624

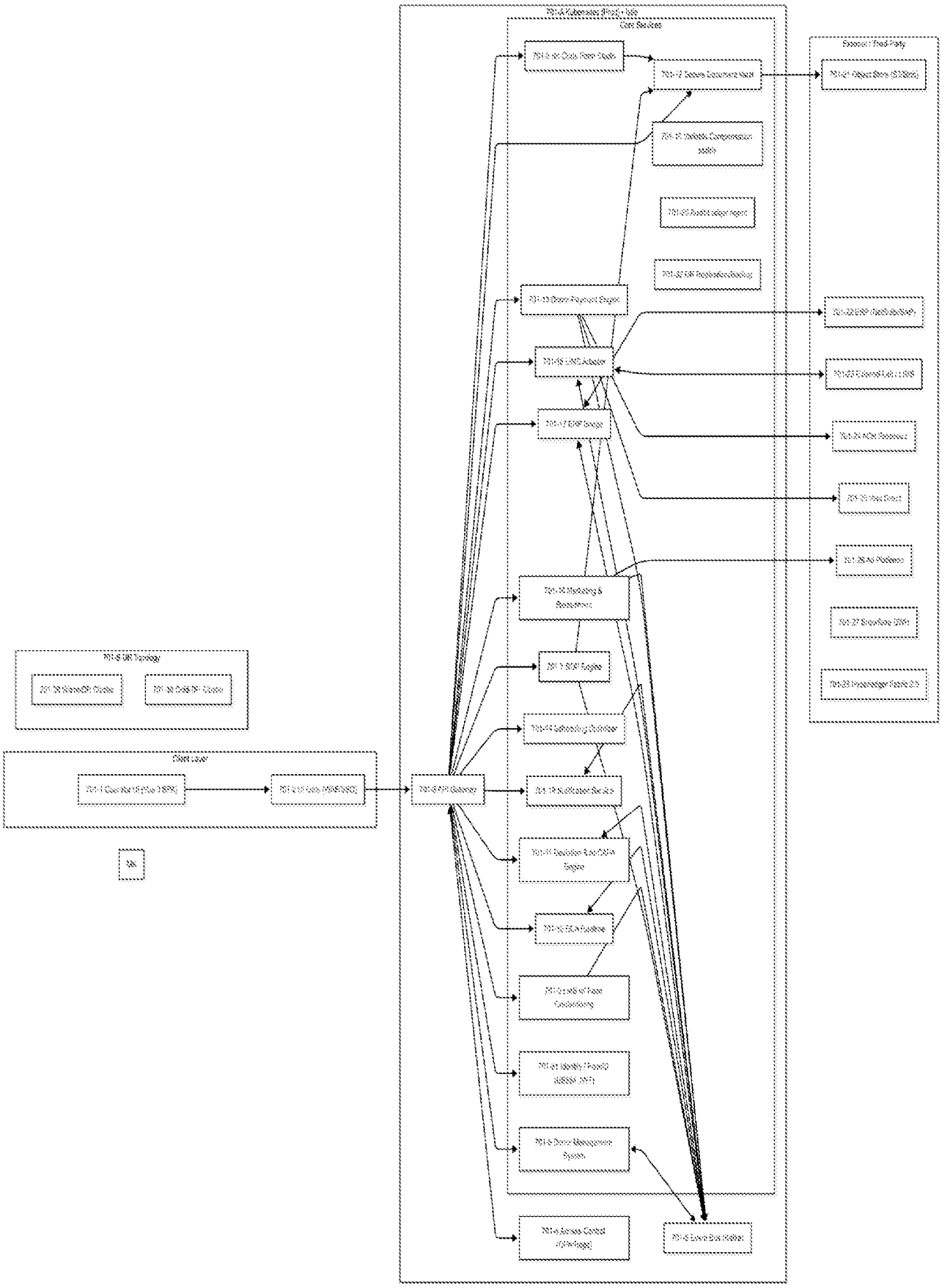
Fig. 625

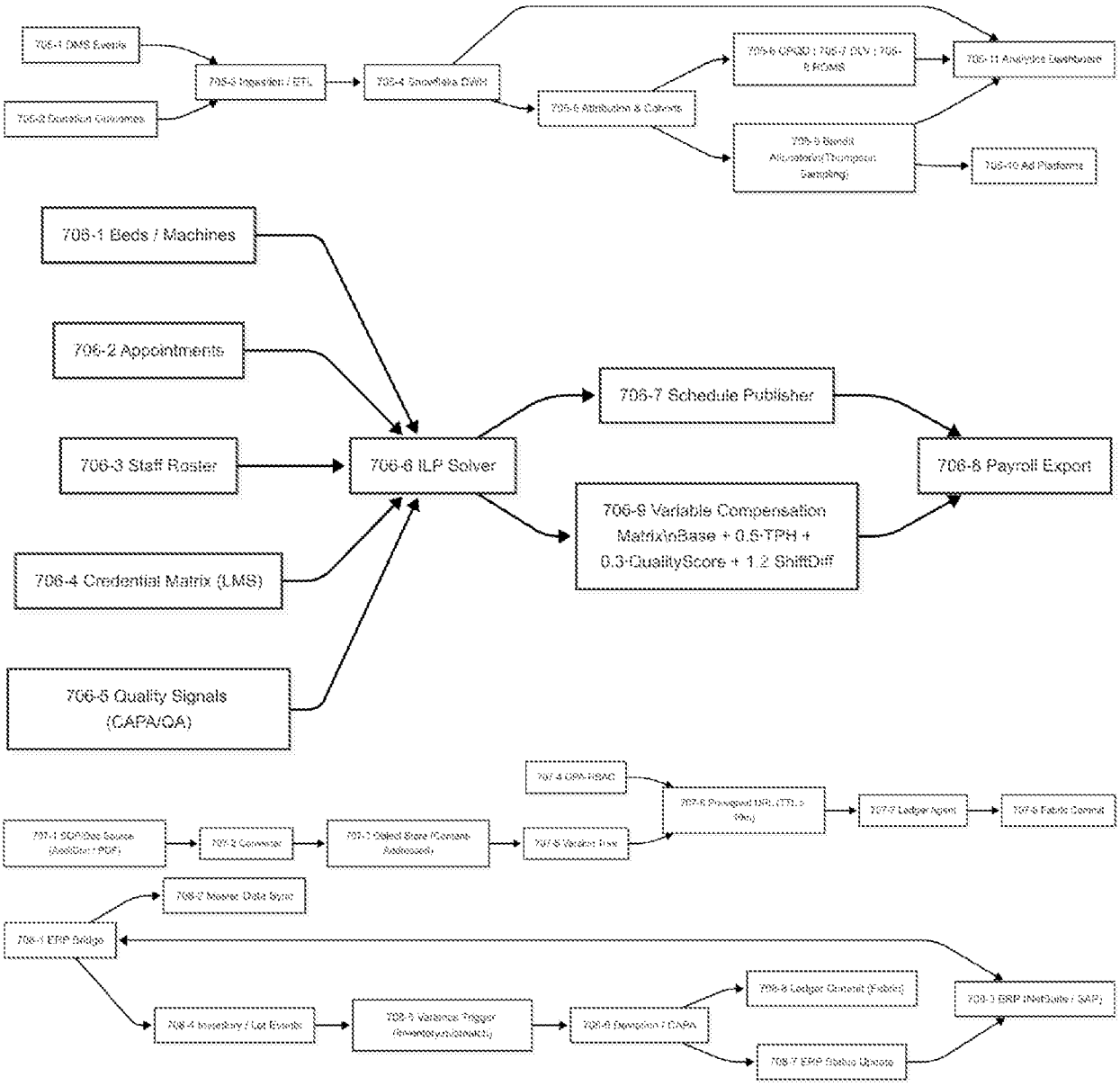

PTO Recommendation
Response && Alert
Vision Analysis
Audio Analysis
Sunrise-Reward Flow

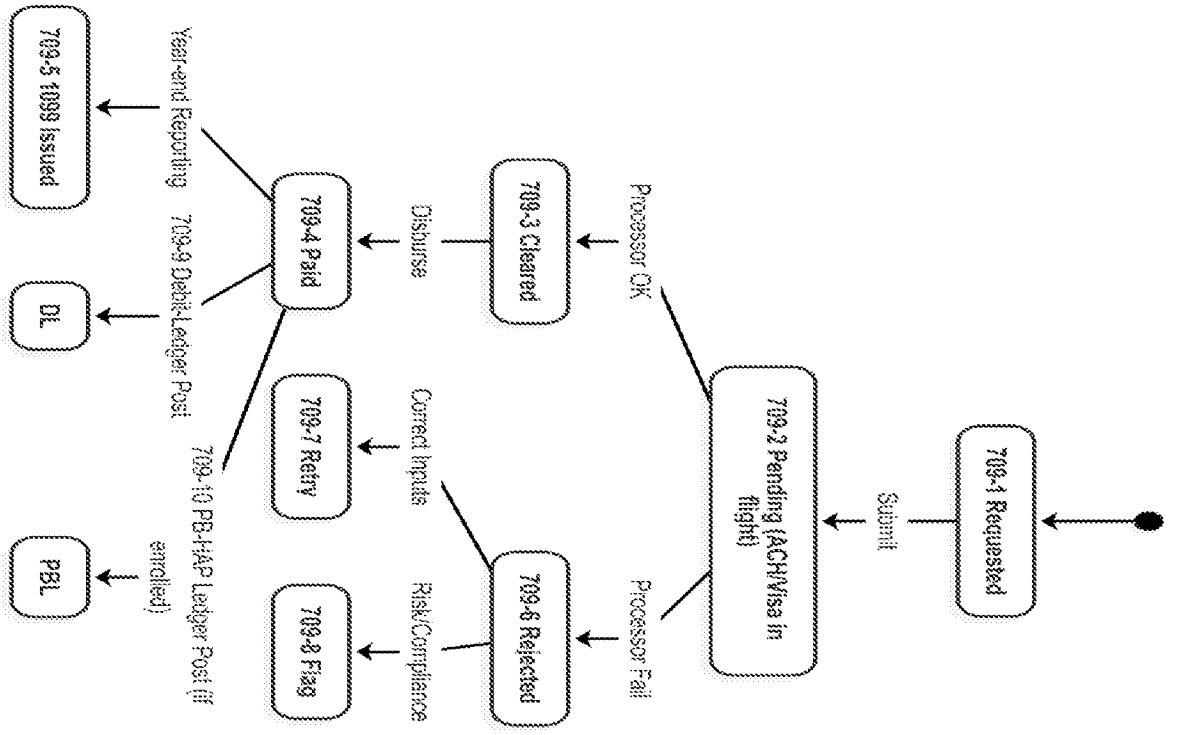


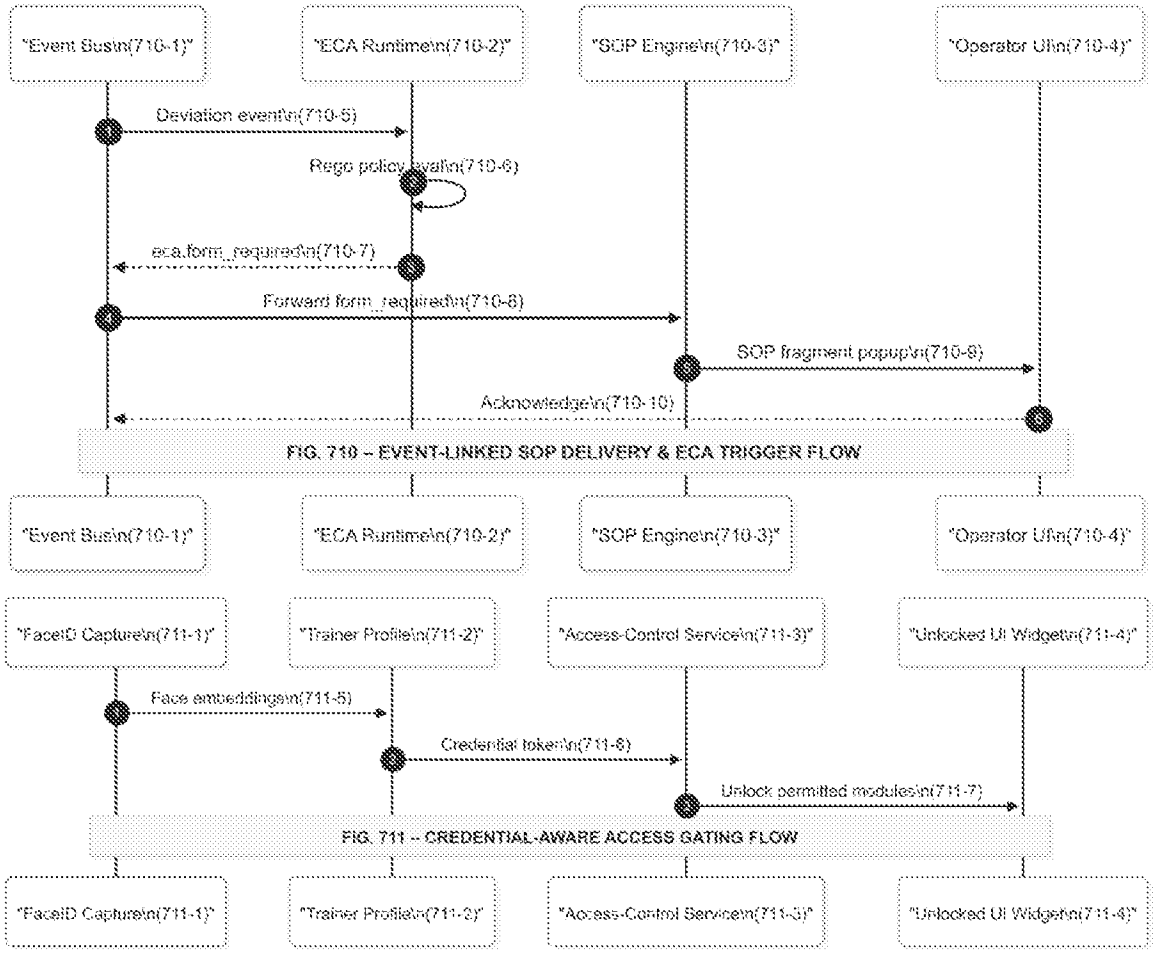


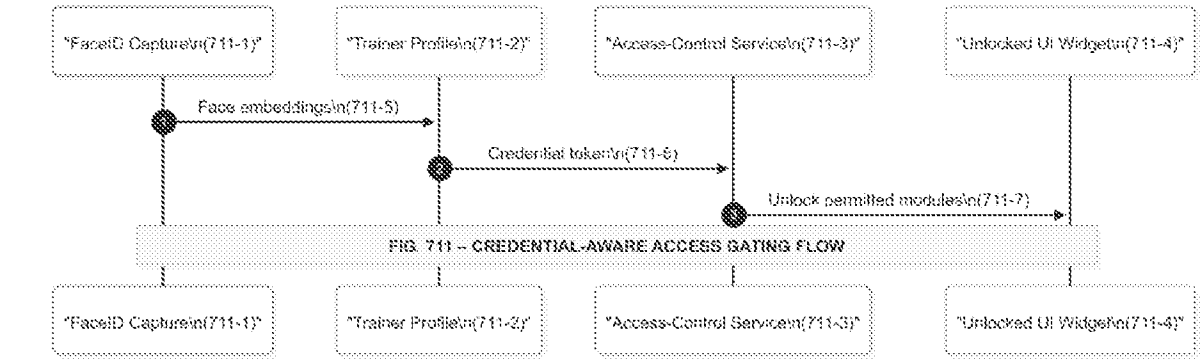
Automation Layer
Facility Dashboard
630-1
AVD Event Stream
(donor && staff)
630-2
Daily Mood Index (DMI)
(24-h rolling mean)
630-3
Distress Hot-Spot Detector
(≥2 critical deviations/zone/60 min)
630-4
Positive-Affect Surge
(DMI ≥ +0.60 · 3 days)
D
F
H
630-5
Playlist Selector
(music · lighting)
630-6
Staffing Forecaster
(dynamic ratios)
630-7
HVAC/Lighting Ticket
(CMMS API)
630-8
Donor Re-Route Logic
630-9
Referral-Reward Multiplier
(+20 % for 48 h)
630-10
Mood Analytics UI
630-11
Emotion Ledger
(SHA-256 hashes)


Core Services
External / Third-Party
Client Layer


706-1 Beds / Machines
706-2 Appointments
706-3 Staff Roster
706-4 Credential Matrix (LMS)
706-5 Quality Signals (CAPA/QA)
706-6 ILP Solver
706-7 Schedule Publisher
706-8 Payroll Export
706-9 Variable Compensation Matrix\nBase + 0.5·TPH + 0.3·QualityScore + 1.2 ShiftDiff


709-1 Requested
Submit
709-2 Pending (ACH/Visa in flight)
Processor OK
Processor Fail
709-3 Cleared
709-6 Rejected
Disburse
Correct Inputs
Risk/Compliance
709-4 Paid
709-7 Retry
709-8 Flag
Year-end Reporting
709-9 Debit-Ledger Post
709-10 PBL-HAP Ledger Post (if enrolled)
709-5 1099 Issued
DL
PBL


"Event Bus\n(710-1)"
"ECA Runtime\n(710-2)"
"SOP Engine\n(710-3)"
"Operator UI\n(710-4)"
Deviation event\n(710-5)
Rego policy eval\n(710-6)
eca.form_required\n(710-7)
Forward form_required\n(710-8)
SOP fragment popup\n(710-9)
Acknowledge\n(710-10)
FIG. 710 – EVENT-LINKED SOP DELIVERY & ECA TRIGGER FLOW
"Event Bus\n(710-1)"
"ECA Runtime\n(710-2)"
"SOP Engine\n(710-3)"
"Operator UI\n(710-4)"
"FaceID Capture\n(711-1)"
"Trainer Profile\n(711-2)"
"Access-Control Service\n(711-3)"
"Unlocked UI Widgets\n(711-4)"
Face embeddings\n(711-5)
Credential token\n(711-6)
Unlock permitted modules\n(711-7)
FIG. 711 – CREDENTIAL-AWARE ACCESS GATING FLOW
"FaceID Capture\n(711-1)"
"Trainer Profile\n(711-2)"
"Access-Control Service\n(711-3)"
"Unlocked UI Widgets\n(711-4)"



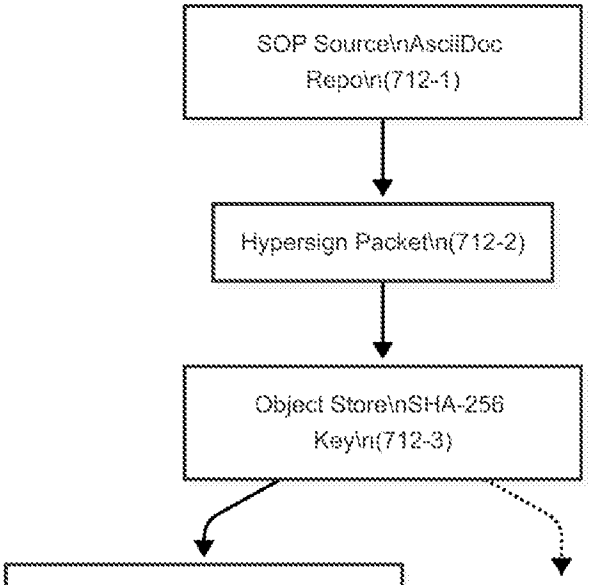


FIG. 712

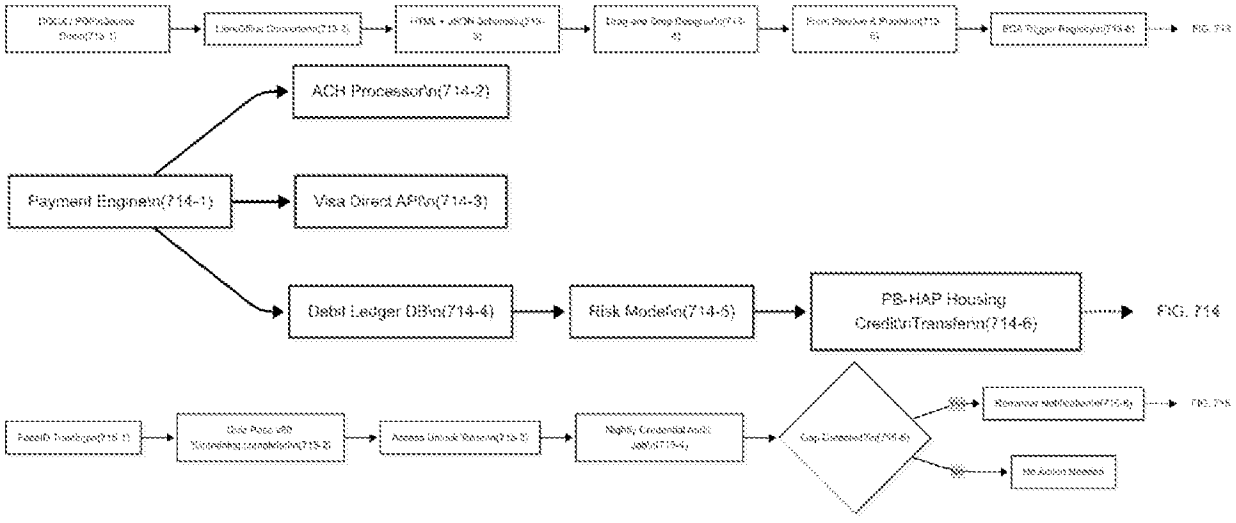


FIG. 714