Claims

1. **An adaptive medication infusion system**, comprising:
   – at least one infusion pump channel configured to deliver a drug to a subject, each pump channel including a replaceable smart cartridge with a fluid reservoir and an on-cartridge memory storing a **drug identifier** and associated dosing parameters;
   – a **base drug library (G0)** stored in a controller, the base library containing predefined hard and soft dose limits and rules for a plurality of medications;
   – a **dynamic overlay library (G1)** maintained by the controller, the overlay containing patient-specific dose limit adjustments and learned pharmacodynamic parameters for the one or more drugs being infused;
   – one or more patient **sensors** providing real-time physiological data of the subject; and
   – a hierarchical **controller** operatively connected to the pump channel and sensors, the controller being programmed to (i) retrieve the drug identifier and dosing parameters from the cartridge memory, (ii) supervise the infusion pump according to a multi-layer safety and control algorithm, and (iii) automatically update the G1 overlay in response to the subject's data;
   wherein the controller's multi-layer algorithm comprises at least: a **safety override layer** that immediately interrupts or modifies infusion if a measured patient parameter or infusion command violates a critical safety threshold, a **guard-rail layer** that enforces dosing constraints from the G0 base library and G1 overlay (including inter-drug incompatibility rules and dose maxima) during routine operation, and a **control optimization layer** that adjusts infusion rates within those constraints to achieve target therapeutic outcomes for the subject.

2. **The system of claim 1**, wherein each smart cartridge's memory stores (a) a unique drug class code and concentration, (b) an upper dosage limit per unit time and a maximum cumulative dose, (c) one or more defined **μ-band** dose ranges for safe probing, and (d) an incompatibility list or interaction vector referencing other drug classes[107][64]; and the controller automatically **disables actuation** of a cartridge if its class code conflicts with an active cartridge's class per said incompatibility list or if dispensing the next dose would exceed said maximum cumulative dose[15][16].

3. **The system of claim 1**, wherein the guard-rail layer uses a stored **conflict-graph** to arbitrate multiple simultaneous infusions such that a higher-priority infusion command can suppress or scale down a lower-priority infusion to prevent harmful drug–drug or drug–condition interactions. **Wherein** the controller, on every control cycle, evaluates each cartridge's identifier and current patient state against a set of rules, and **suppresses actuation of a second cartridge** when those rules predict a harmful interaction with a first cartridge's drug or with a current physiologic condition of the patient[13][16] (for example, automatically pausing an electrolyte infusion when a conflicting hormone infusion is active to maintain safe ion ratios).

4. **The system of claim 1**, wherein the controller includes a learning module configured to perform **sub-threshold micro-dosing** during stable conditions and thereby update a patient-specific dose–response model. **Wherein** each controlled variable or analyte has at

least one micro-threshold band (μ-band) stored in the overlay, and when the measured value lies within that band, the controller injects a patterned micro-dose perturbation that is ≤5% of the normal dose range[5], measures the patient's response, and uses the result to adjust a Jacobian matrix representing the patient's coupling between drugs and physiological responses[108][109]. **Wherein** the updated Jacobian coefficients are thereafter applied by the guard-rail and optimization layers to personalize dosing decisions for the patient.

5. **The system of claim 4**, **wherein** the learning module applies a **confidence gating** criterion such that a newly identified patient-specific coefficient is only accepted (and integrated into the G1 overlay limits) once its estimated confidence interval is sufficiently narrow relative to population variability[110][8]. **Wherein** during learning, the safety override and guard layers remain active such that any probe dose that begins to push a value outside of safe bounds is immediately clipped or aborted.

6. **The system of claim 1**, **wherein** each infusion pump channel further comprises a built-in **flow sensor or stroke counter**, and the controller or cartridge microcontroller includes an actuator-feedback verifier that raises a fault signal if a discrepancy greater than a predetermined tolerance (5% for at least 3 seconds) is detected between commanded dose and actual delivered dose[89][90]. **Wherein** upon such a fault or any hardware anomaly, the safety override layer transitions the system into a fail-safe state that closes a valve or otherwise prevents further infusion on that channel.

7. **The system of claim 1**, **wherein** the hierarchical controller is implemented on a bedside computing device in communication with a hospital network, and the system further comprises interfaces for interoperability, including:
– an **HL7 interface** to receive patient data (such as weight, age, lab results) and medication orders from an electronic health record system, which the controller uses to initialize or adjust the drug library overlay (for example, updating weight-normalized dose limits in G1 based on the patient's recorded weight); and
– an **IEEE 11073 or IHE PCD compliant interface** to transmit infusion pump events and alarms to external systems and to receive remote commands, thereby enabling the dynamic infusion system to integrate with existing infusion pump frameworks and central monitoring stations.

8. **The system of claim 1**, **wherein** each smart cartridge is configured as a **safety lockout device** such that it cannot be reused or loaded with a different drug without detection. **Wherein** the cartridge comprises a physical tamper-evident feature and an electronic identifier linked to that feature[41][42], such that removal or opening of the cartridge causes a permanent change in its memory (or a certificate invalidation) that the controller checks on insertion and, if tampering is detected, the controller refuses to operate that cartridge.

9. **An infusion control method** for personalized medication delivery, comprising:
(a) **loading** a baseline drug library into a pump controller, the library specifying standard dosing limits and safety rules for each medication;
(b) **detecting** the coupling of a drug infusion cartridge to the system, reading a digital identifier and stored parameters from the cartridge's memory;

(c) **retrieving** patient-specific data including at least one patient physiological measurement and patient attributes (weight, diagnoses, etc.);
(d) **initializing** a patient-specific drug profile by adjusting the baseline library limits based on the patient data to form a starting overlay (for example, scaling dose limits by weight or contraindicating certain drug pairs given patient's condition);
(e) **automatically controlling** the infusion pump to deliver the drug, wherein a control algorithm updates the pump command at regular intervals to approach a target clinical effect (e.g., a target concentration or vital sign);
(f) during said control, **monitoring** the patient's physiological measurements in real time and enforcing safety constraints before each pump command is executed – including blocking any command that would violate the drug's current safe dosage range or cause a defined unsafe interaction;
(g) **periodically refining** the patient-specific drug profile by analyzing the patient's responses: when the patient is stable, injecting a micro-scale test dose change and measuring the response to estimate the patient's sensitivity, then updating the overlay limits or model coefficients accordingly; and
(h) **logging** all infusion events, adjustments, and any safety override occurrences in a secure audit log.
Whereby, the method provides closed-loop infusion regulation that learns and adapts to the individual patient while continuously preventing dosing that exceeds either institutional guidelines or the patient's real-time tolerance.

10. **The method of claim 9**, further comprising an **override process** wherein if a clinician inputs an override request (to exceed a soft limit or silence an alarm), the system authenticates the request and, if authorized, temporarily suspends enforcement of the corresponding guard-rail for a predetermined duration or dose amount[19][111]. **Wherein** the method includes automatically reactivating full safety enforcement once the override period expires (or the dose amount is delivered)[18][101], and recording the identity, reason, and duration of the override in the audit log[22].

11. **The method of claim 9**, wherein in step (f) the safety constraints include maintaining defined **multi-drug ratio limits**. **Wherein** the method involves solving a set of inequalities or quadratic constraints relating multiple infusion rates – for example, ensuring that the ratio of infusion rates of drug A and drug B stays within a safe range or that the product of two ion concentrations (Ca × P) does not exceed a precipitation threshold – and adjusting the pump commands of involved drugs if needed to satisfy those constraints before execution.

12. **The method of claim 9**, wherein the secure audit log of step (h) is implemented as an **immutable ledger** in which each new event record is cryptographically linked to the previous record (forming a hash chain)[36][37]. **Wherein** the method includes periodically anchoring the ledger to an external trusted system (for instance, by submitting Merkle roots to a blockchain or write-once storage) such that any tampering with past infusion data would be detectable.

13. **The method of claim 9**, applied to **ICU medication control** for a human patient, **wherein** the infusion cartridge is delivering a critical care drug and the physiological

measurement is a corresponding vital sign or lab value. In an embodiment, the method controls a vasopressor infusion using continuous blood pressure readings, a sedation drug using processed EEG or BIS index, and an insulin infusion using blood glucose measurements – all concurrently – and coordinates these loops to avoid cross-interference (e.g., preventing sedative-induced hypotension by preemptively adjusting vasopressor) while maintaining each target within a clinician-specified range.

14. **The method of claim 9**, applied to a **multi-fluid industrial process**, **wherein** the "patient" is replaced by an industrial process system and the "drugs" are process reagents delivered by analogous pump cartridges. The method controls multiple reagent additions (such as pH adjusters, nutrients, catalysts) based on sensor feedback from the process (pH, temperature, turbidity, etc.), using the same hierarchical safety architecture to enforce process parameter limits and prevent incompatible chemical additions[75][76]. **Wherein** the dynamic library overlay is used to optimize the process recipe in real time, and all adjustments are logged for batch record-keeping.

15. **A computerized infusion control apparatus**, comprising a non-transitory memory and one or more processors configured by software instructions to perform the steps of: (i) acquiring patient data and drug library data, (ii) executing a tiered decision algorithm that outputs infusion rate commands while performing real-time safety checks and adaptive model updates, and (iii) interfacing with infusion pump hardware and hospital information systems to carry out and document the therapy. **Wherein** the software includes distinct modules corresponding to a **Safety Arbiter**, a **Dosing Optimizer**, and a **Learning Engine**, which communicate such that the Safety Arbiter can override or constrain any command from the Optimizer according to rule sets and current model parameters, and the Learning Engine adjusts said model parameters only within allowed safe margins[112][14]. **Wherein** any update to software or library data is cryptographically verified against the audit log before deployment to ensure system integrity[113][114].

16. **The apparatus of claim 15**, further comprising a user interface that displays, for each infusion channel, a current status (running, temporarily overridden, or locked-out) and remaining safe dose range. **Wherein** the interface implements a color-coded scheme (green for normal operation, amber for override active, red for safety lockout) consistent with medical alarm standards[62][115] and provides means for an authorized user to initiate an override or adjust a target within predefined bounds, with all such interactions requiring secure user authentication.

17. **The apparatus of claim 15**, wherein each smart infusion cartridge associated with the apparatus includes at least one **on-cartridge sensor** (selected from: pressure sensor, optical sensor, electrical conductivity sensor, chemical analyte sensor) that monitors either the drug solution or patient's fluid and reports to the controller, allowing the apparatus to detect issues like occlusions, air in line, drug degradation, or local physiological changes at the infusion site. **Wherein** the controller's safety module uses this sensor data as additional input to halt or modulate the pump (for example, stopping infusion if the in-line sensor detects an air bubble or if a drug concentration drifts outside expected range).

18. **The system of claim 1**, **wherein** if a battery or power failure occurs, the controller seamlessly enters a **monitor-only failsafe mode** in which it continues to record sensor data and retains all state information while suspending pump actuation until power is restored[88]. Upon restoration, the system is configured to either resume prior infusions safely (if within safe downtime limits) or prompt for clinician confirmation before restarting, thereby avoiding unintended bolus or lapse due to power interruption.

19. **The system of claim 1**, **wherein** the dynamic drug library overlay can be updated in a **fleet-wide manner**: the controller is network-connected and able to receive signed library configuration updates or machine learning model updates from a central server, and will apply such updates only after verifying a digital signature and ensuring compatibility with the audit ledger (e.g., verifying that the update hash matches an authorized entry)[116][117]. This allows continuous improvement of dosing algorithms across multiple devices while maintaining regulatory compliance.

20. **The system of claim 1**, **wherein** the total wearable or contact surface area of any patient-attached sensors for the closed-loop system is minimized such that the system supports at least 20 distinct sensing channels (biochemical, hemodynamic, etc.) with an aggregate skin contact area of under 60 cm^2[118][119]. This ensures the system's multi-sensor capability is achieved in a patient-comfortable form factor, for example by using stacked microfluidic patches and microneedle arrays.

21. **The smart infusion cartridge of claim 2**, **wherein** the cartridge's memory includes an expiration timestamp and the cartridge's microcontroller or the main controller automatically **locks out** the cartridge from operation if the current date/time exceeds the expiration (preventing use of expired or potentially degraded medications)[120][121]. **Wherein** the cartridge also tracks cumulative time at room temperature (for drugs that require cold storage) and can similarly trigger a lockout if stability limits are exceeded, thereby ensuring drug efficacy and safety.

22. **The smart infusion cartridge of claim 2**, **wherein** the cartridge is further equipped with an **on-board power source** (battery) and a low-energy wireless transmitter such that it can periodically broadcast its identity and status even when not plugged into a main controller. **Wherein** this facilitates inventory management and safety checks (e.g., a pharmacy scanner can query the cartridge on a shelf to verify its drug, concentration, and expiration prior to deployment).

23. **The system of claim 1**, **wherein** in a configuration with multiple infusion channels, the pump manifold and control hardware are constructed such that any single-point failure induces a safe fallback: for example, if the main controller unresponsive, each cartridge's local microcontroller will enter a self-regulation mode to prevent harm (such as reverting to a KVO – "keep vein open" minimal rate or shutting off if safe to do so). **Wherein** the system includes a **dual-bank firmware architecture** enabling fail-operational rollback, so that in the event of a detected software fault or corruption, the controller can reboot from a known-good firmware image without losing control of critical infusions[94][95].

24. **The method of claim 9**, **wherein** multiple closed-loop drug control processes are orchestrated such that when **sensor confidence deteriorates** (for instance, a sensor starts

showing excessive noise or drift), the system transitions that particular loop into a guarded state or open-loop. The method includes detecting sensor faults (e.g., via a self-calibration test or redundant sensor comparison) and then **pausing adaptive updates** for the affected parameter while possibly reverting to a safe default infusion rate until the sensor issue is resolved[122][123]. This ensures sensor errors do not propagate into erroneous dosing.

25. **The system of claim 1**, implemented as a **modular skid platform** comprising multiple intervention cartridges, wherein all preceding claims and descriptions directed to a human subject apply *mutatis mutandis* to industrial fluid processes in place of a patient[124][12]. In such embodiments, the same cartridge architecture, control logic, and safety hierarchy are used to manage processes like chemical reactors or bioreactors, providing adaptive, hierarchical control of reagents and conditions with full traceability and safety equivalent to the clinical scenario.

26. A non-intrusive network-tap apparatus (1900) configured to replicate pump traffic in real time, decode infusion parameters, and transmit said parameters to a remote adaptive-dose controller without altering the operation of the infusion pump.

27. The apparatus of claim 1 wherein the network-tap comprises an optical splitter that introduces < 1 dB link loss and requires no electrical break in the infusion-pump data path.

28. The method of using the apparatus of claim 1 further comprising automatically detecting a library-bypass condition and issuing a real-time alert to a pharmacy information system within 150 ms of the bypass event.

29. A system comprising the apparatus of claim 1, a closed-loop ML weight engine (40) as in the parent, and an immutable ledger (60) that records each captured packet and each corresponding dose-adjustment recommendation.