Claims:

Continuous Anti-Xa Sensor Cartridge + Closed-Loop Anticoagulation System

1. A replaceable microfluidic sensor cartridge for continuous measurement of anti-factor Xa activity in blood, the cartridge comprising:

   (a) a microfluidic bypass channel sized to couple in-line to an arterial catheter;

   (b) a working electrode functionalised with a heparin-specific, redox-labelled DNA aptamer that reversibly changes electron-transfer rate upon binding anti-Xa complexes;

   (c) a porous hydrogel layer overlaying the aptamer to reduce fouling and improve signal-to-noise;

   (d) an on-cartridge micro-pump configured to periodically draw fresh blood through the channel and purge spent sample;

   (e) non-volatile memory storing cartridge identity, calibration coefficients and hard dose-limit parameters; and

   (f) a keyed mechanical dock incorporating a one-way valve to prevent retrograde flow during hot-swap.

2. The cartridge of claim 1 wherein the working electrode comprises a thin-film gold micro-band patterned on a glass or polymer substrate and paired with on-chip reference and counter electrodes.

3. The cartridge of claim 1 wherein the hydrogel layer is poly(HEMA) ≈25 µm thick, UV-cured in situ to form a semi-permeable antifouling barrier.

4. The cartridge of claim 1 wherein the non-volatile memory further stores a usage-life timer and incompatibility flags that disable the closed loop if direct factor Xa inhibitors are detected in the medication record.

5. The cartridge of claim 1 further comprising an RFID tag carrying lot and shelf-life data; the host controller blocks loop activation if a checksum fails or remaining shelf-life is <24 h.

6. An integrated anticoagulation control system, comprising:

   (a) the cartridge of any preceding claim;

(b) a host controller that polls the cartridge over a digital bus, converts sensor current to anti-Xa concentration, and executes a proportional-integral-derivative or model-predictive algorithm to modulate a heparin infusion pump; and

(c) a secondary protamine infusion pump actuated by the controller to partially neutralise heparin when anti-Xa exceeds a preset threshold.

7. The system of claim 6 wherein the controller enforces absolute ceilings for heparin rate and protamine bolus stored on the cartridge memory, overriding algorithm output that would exceed the ceilings.

8. The system of claim 6 wherein a hierarchical knock-down safety matrix automatically reverts to a maintenance heparin rate and raises alarms upon any sensor or pump fault.

9. The system of claim 6 further comprising an automated flush and two-point calibration manifold with three solenoid valves and a micro-peristaltic pump that injects low- and high-standard calibrants every ≈8 h, the resulting coefficients broadcast to an arbitration layer that updates sensor confidence weights.

10. A method of closed-loop anticoagulation, comprising the steps of:

(i) diverting arterial blood through the cartridge of claim 1;

(ii) measuring anti-Xa concentration at least once per minute;

(iii) adjusting the heparin infusion rate in incremental steps proportional to the error between measured and target anti-Xa;

(iv) triggering a calculated protamine micro-dose when anti-Xa exceeds an overdose threshold; and

(v) logging every sensor datum, dose adjustment and alarm event to an audit-ready ledger.

11. The method of claim 10 wherein, upon detection of sensor drift beyond calibration bounds, the controller automatically initiates the flush/calibration cycle of claim 9, and if calibration fails, transitions to a safe open-loop heparin rate and alerts clinical staff.

12. The method of claim 10 wherein the controller reduces heparin infusion no faster than 10 % per minute and enforces a minimum anti-Xa of 0.1 IU mL^{-1} and a maximum of 1.0 IU mL^{-1}.

13. The system of claim 6 wherein multiple sensor cartridges (anti-Xa, citrate, calcium) share a common CAN or I^2C bus and publish factor values in a fifteen-column schema for arbitration with other therapy loops.

14. The cartridge of claim 1 wherein the working electrode region is re-zeroed every 12 h via an on-board saline flush to maintain calibration within ±10 % for at least 5 days of continuous use.

15. The cartridge of claim 1 wherein the microfluidic channel is heparin-coated and sized to withdraw <15 mL of blood per day at laminar flow to minimise anaemia risk.