7. Claims

7.1

System Claims

1. A clinical decision support system for managing infusion therapy alerts, the system comprising:

   – an alert detection module configured to monitor infusion pump data and patient data for a conflict condition indicative of a safety risk;

   – a notification interface configured to present an alert for the conflict condition to a clinician and to receive a clinician's input acknowledging or overriding the alert;

   – an event logging subsystem configured to record the clinician's acknowledgment or override input as an immutable audit entry with a timestamp , without modifying any infusion device operation;

   – a therapy state monitoring module configured to track, in real-time or at intervals, a status of an infusion therapy associated with the conflict condition and/or a patient physiological parameter related to the conflict condition; and

   – a conflict resolution engine configured to automatically update a status of the conflict condition from "active" to "resolved" only upon detecting that one or more resolution criteria are met, the resolution criteria comprising at least that an infusion pump delivering said therapy has been stopped or that said patient physiological parameter has returned to a safe range;

   wherein the system is configured such that a clinician's acknowledgment or override of the alert does not itself resolve the conflict condition, and the conflict remains marked as unresolved until the conflict resolution engine verifies that the underlying risk has been objectively mitigated.

2. The system of claim 1, wherein the event logging subsystem implements an append-only audit ledger that is cryptographically secured, such that each acknowledgment or override entry is hashed or digitally signed to ensure tamper-evident provenance of alert handling .

3. The system of claim 1, wherein the therapy state monitoring module polls infusion pump telemetry to determine a current infusion rate for each therapy involved in the conflict, and the conflict resolution engine marks the conflict resolved in response to detecting that all such infusion rates have been reduced to zero (indicating all implicated pumps

are off) .

4. The system of claim 1, wherein the notification interface comprises a wearable device application that allows the clinician to send an “Acknowledge” or “Override” command, and wherein acknowledgment of the alert by the clinician causes the system to suppress duplicate or secondary alerts for the same conflict condition while the conflict remains unresolved, without altering the ongoing infusion therapy.

5. The system of claim 1, wherein the system operates as a non-device clinical decision support tool that provides advisory alerts and logging without issuing any command to an infusion pump, such that all therapy adjustments are performed by the clinician and the system’s role is limited to monitoring and notification .

7.2

Method Claims

1. A method of managing a clinical alert for an infusion therapy in a non-device decision support system, the method comprising:

   (a) detecting a conflict condition based on infusion pump data or patient data that indicates a potential safety risk during an infusion;

   (b) generating an alert notification for the conflict condition and delivering it to a clinician’s user device;

   (c) receiving a user input from the clinician acknowledging or overriding the alert via the user device interface;

   (d) recording the clinician’s acknowledgment or override action as a timestamped event in an immutable audit trail, thereby logging the clinician’s intent without altering the infusion pump’s operation ;

   (e) allowing the infusion therapy to continue uninterrupted by any automatic system action in response to the user input (the system takes no device control action upon acknowledgment);

   (f) monitoring one or more parameters associated with the conflict condition after the acknowledgment, the parameters including an infusion pump status and/or a patient physiological measurement; and

   (g) marking the alert as resolved only when the monitoring determines that the infusion has been terminated or that the patient’s associated risk condition has abated, wherein

until such determination the alert remains in an active-unresolved state within the system.

2. The method of claim 1, further comprising the step of updating a conflict status indicator in the system from “unacknowledged” to “acknowledged” after step (c), and subsequently to “resolved” at step (g), wherein the transition to “resolved” is conditioned exclusively on the resolution of the underlying risk and not on the mere act of acknowledgment by the clinician.

3. The method of claim 1, wherein step (f) comprises periodically checking a current infusion rate of a pump delivering the therapy, and wherein step (g) comprises setting the alert to resolved when the current infusion rate is detected to be zero for all pumps involved in the conflict condition .

4. The method of claim 1, wherein step (d) of recording in an immutable audit trail comprises adding an entry to a hash-chained log, the entry including at least an identifier of the alert, the type of user action (“ACKNOWLEDGE” or “OVERRIDE”), the user’s identity, and a timestamp, such that any modification of the log entry would be detectable .

5. The method of claim 1, wherein the system refrains from issuing any infusion pump stop command or rate adjustment as part of steps (c)–(g), thereby conforming to a non-device CDS mode of operation in which the clinician’s acknowledgment is logged and the condition is monitored to closure, but all therapeutic interventions are manually performed by clinical staff