Claims

1. A computer-implemented method for controlled pausing of an active infusion in response to clinical conditions, the method comprising:

    - receiving a standing-order template defining at least one condition on a patient's clinical data and a corresponding pause directive for an infusion therapy, said standing-order template having been pre-approved by authorized medical personnel;

    - compiling the standing-order template into a machine-executable rule that specifies a threshold condition and an automated pause action for an infusion pump delivering medication to the patient;

    - monitoring, in real time, the patient's clinical data including laboratory results and/or physiological measurements while the infusion is in progress;

    - upon detecting that the threshold condition defined in the machine-executable rule is met by the patient's clinical data, verifying that the pause action is permitted within a predefined scope-of-authority for attending clinical staff and that the clinical data triggering the condition is valid;

    - automatically issuing a pause command to the infusion pump and/or generating an electronic instruction to pause the infusion, thereby temporarily halting the delivery of the medication to the patient;

    - triggering an alert to notify clinical staff of the pause event with details of the condition that was met; and

    - documenting the pause event in the patient's electronic health record as an execution of the standing order, including attributing the order authorization to the physician-of-record.

2. The method of claim 1, wherein compiling the standing-order template includes performing a scope-of-practice validation that restricts compiled directives to pause or hold actions, and excludes directives that would adjust medication dosage or initiate new therapy beyond the standing order, such that the compiled machine-executable rule enforces compliance with nursing scope-of-practice regulations.

3. The method of claim 1, wherein verifying the clinical data triggering the condition comprises filtering out unreliable laboratory values by detecting quality flags or improbable measurements in the lab results, and inhibiting the automated pause action if the triggering lab result is marked as contaminated or invalid .

4. The method of claim 1, further comprising, after issuing the pause command, initiating an escalation protocol if the pause alert is not acknowledged by a clinician within a predetermined time, the escalation protocol including transmitting additional alerts to a higher-level responder (charge nurse or supervising physician) and optionally to a rapid response team.

5. The method of claim 1, wherein triggering an alert to notify clinical staff comprises:

    - presenting an interruptive notification on at least one user interface associated with the patient's care (including an EHR workstation or a mobile device carried by a clinician), the notification indicating the infusion paused and the reason;

    - emitting an audible and/or visual alarm associated with the infusion pump or bedside monitors; and

    - sending a message to a secondary notification system selected from a group consisting of: a pager, a telephone alert, a dedicated caregiver communication device, or a mobile application.

6. The method of claim 1, wherein the documentation of the pause event in the patient's electronic health record is entered as an order or administration record update under the name of the practitioner who authorized the standing order (physician-of-record), and the method further includes prompting that practitioner to authenticate the order entry in accordance with medical record regulations .

7. The method of claim 1, further comprising resuming the infusion either automatically or under clinician control when the patient's clinical data returns to acceptable ranges, wherein any automatic recommendation to resume is provided as a suggestion subject to clinician confirmation, thereby maintaining clinician oversight on restarting therapy.

8. The method of claim 1, wherein the machine-executable rule is integrated into an electronic health record (EHR) system via a standards-based interface such that:

    - the monitoring of patient clinical data is achieved by receiving data through an HL7 or FHIR interface from the EHR or laboratory information system;

    - the pause command or instruction is transmitted via a FHIR Task resource or a similar EHR order entry to coordinate the pausing of the infusion; and

    - the alert to clinical staff is delivered through a CDS Hooks service that injects a decision support card or notification into the EHR workflow when the condition is met.

9. The method of claim 1, further comprising operating a failsafe mode in which, upon detection of unavailability of the computerized decision support system or network ("downtime"), the method:

    - suspends automated monitoring and pause actions;

    - notifies clinical staff that the SmartStop automated system is offline; and

    - defaults to a manual protocol wherein nurses or clinicians monitor the patient's condition and manually implement the standing-order directions, thereby ensuring continuity of care during system downtime.

10. The method of claim 1, further comprising recording an audit log entry for each step of the process, including timestamps for detection of the condition, issuance of the pause command, alert notifications sent, acknowledgments received, and infusion resumption, such that a complete chronological audit trail of the pause event is maintained for quality assurance and regulatory compliance.

11. A system for automatically pausing infusions based on patient-specific clinical criteria, the system comprising:

- one or more processors and memory storing program instructions;

- a template compiler module configured to receive one or more standing-order templates each defining conditional pause criteria for an infusion, and to generate corresponding machine-executable rules, each rule including: (i) a condition involving at least one clinical parameter of a patient, and (ii) an action to pause an identified infusion therapy;

- a data interface configured to integrate with a clinical data source and an infusion device controller, the data interface receiving real-time patient data including lab results and transmitting commands to infusion pumps;

- a rule engine (runtime module) executable by the one or more processors, the rule engine programmed to continuously evaluate the machine-executable rules against incoming patient data and to trigger pause actions when rule conditions are satisfied;

- a scope validation component that interworks with the compiler module and rule engine, the scope validation component storing predefined scope-of-practice rules and preventing or requiring authorization for any action by the rule engine that falls outside a permitted scope for non-physician clinicians;

- an alerting subsystem configured to generate and route alerts to clinical end-users upon a rule condition trigger, the alerts comprising at least a descriptive message of the pause event and being delivered via multiple channels including on-screen notifications and

secondary devices;

- a documentation module that automatically records each pause event as an entry in an electronic health record system, associating the event with a standing order from a licensed practitioner; and

- an audit log repository for storing detailed records of rule evaluations and system actions,

wherein the system is configured such that, in operation, an active infusion is automatically paused when a patient's clinical parameter crosses a predefined threshold and the pause action is within an authorized protocol, while all such events are communicated to staff and logged.

12. The system of claim 11, wherein the template compiler module is further configured to compile a set of related standing-order templates as an order set, and instantiate patient-specific rules from the order set by populating patient-specific threshold values and linking each instantiated rule to a common identifying record for the standing order set in a standing order registry (FIG. 6), enabling efficient updates and management of multiple pause directives for the patient.

13. The system of claim 11, wherein the data interface supports HL7 FHIR standards, such that the system can receive laboratory Observation resources and Medication Administration updates, and issue Device or Task commands to pause or resume infusions in a manner interoperable with external systems.

14. The system of claim 11, wherein the alerting subsystem comprises an escalation manager that tracks whether an alert has been acknowledged and, if not acknowledged within a preset time, automatically escalates the alert to additional personnel or roles according to a defined escalation ladder (including notifying a supervising clinician), as illustrated in FIG. 5.

15. The system of claim 11, wherein the documentation module is further configured to mark each pause action in the patient's record with the identity of the ordering physician or protocol author, and to flag the record for physician authentication if required, thereby ensuring that use of the standing order is documented and signed in compliance with hospital policy and 42 CFR §482.24(c)(3) .

16. The system of claim 11, wherein the audit log repository stores, for each pause event, data including the triggering condition details (e.g., lab name, value, timestamp), the rule identifier, the exact time the pause command was issued, user acknowledgments, notifications sent, and time of infusion restart, and wherein the system provides an interface to retrieve and review said audit data for regulatory audit or post-event analysis.

17. The system of claim 11, wherein the scope validation component comprises a rule set indicating that pause directives are automatically permitted under nurse protocols whereas dose changes or medication substitutions require additional approval, and the system either (a) blocks any automated action outside the pause/hold scope or (b) converts such actions into recommendations that must be manually approved by a prescribing practitioner.

18. The system of claim 11, further comprising a quality control module configured to evaluate incoming lab results for reliability, wherein the quality control module will inhibit the rule engine from pausing an infusion if the relevant lab result is flagged as unreliable or likely erroneous (including cases of hemolyzed samples or machine error flags), optionally prompting a repeat measurement instead of immediate action .

19. The system of claim 11, wherein the system is implemented as a clinical decision support software module that is compliant with FDA guidance for software as a medical device (SaMD), including features for user transparency (displaying the basis for each pause recommendation), the ability for clinicians to override or decline recommendations, and validation of performance on retrospective data to demonstrate safety and effectiveness.

20. The system of claim 11, wherein the system is further configured with a downtime mode, such that upon loss of connectivity to the hospital network or detection of system malfunction, the system:

    - automatically notifies users that the SmartStop automation is temporarily unavailable;

    - deactivates any pending automated rules to avoid uncertainty; and

    - provides access to the underlying standing order instructions in human-readable form so that clinicians can continue to manually follow the protocols until the system is restored.

21. A non-transitory computer-readable medium storing program instructions which, when executed by one or more processors in a clinical infusion management system, cause the system to perform the steps of:

    - obtaining a digitally encoded standing order that specifies a rule for pausing a medical infusion based on a patient's parameter threshold;

    - translating the standing order into an active monitoring rule in a rules engine, including embedding any threshold value and identifying the target infusion device;

- continuously receiving patient data updates from electronic medical record systems and/or device interfaces;

- evaluating the active monitoring rule against the patient data updates and detecting fulfillment of the threshold condition;

- validating that an automated pause of the infusion under the fulfilled condition is authorized according to at least one of: a clinician role's scope-of-practice, a prior approval by a medical committee, or a regulatory guideline;

- executing a pause operation on the infusion by either sending an electronic pause instruction to the infusion device or prompting a user to pause the device, effectively stopping the infusion in a timely manner;

- delivering an electronic notification regarding the pause to at least one clinician, the notification including the reason for pause and any required follow-up actions (such as contacting a provider or obtaining repeat labs);

- logging the event with details in a machine-readable audit file; and

- interfacing with an electronic health record to record the event as an implemented standing order under the ordering provider's record.

22. The computer-readable medium of claim 21, wherein the program instructions further cause the system to handle multiple rules simultaneously, and in cases where multiple infusions are running with separate pause rules, to prioritize or coordinate alerts such that critical alerts are highlighted over lesser priority ones, thereby preventing alert overload and ensuring the most urgent infusion is addressed first.

23. The computer-readable medium of claim 21, wherein the program instructions implement an escalation workflow such that if the initial notification delivered to a responsible clinician is not acted upon, subsequent notifications are automatically dispatched to alternate personnel according to pre-configured roles and timing, mirroring an escalation ladder protocol.

24. The computer-readable medium of claim 21, wherein the standing order is one element of an order set, and the program instructions allow updates to the standing order's parameters (threshold or action) to be made centrally and propagated by recompiling the order set, thereby updating the active monitoring rule without requiring software code changes.

25. The computer-readable medium of claim 21, wherein the program instructions further include instructions for an industrial process control mode, in which terms and roles are mapped from clinical to industrial (such that "patient data" corresponds to sensor data of

a process, and “clinician” corresponds to an operator), allowing the system to pause industrial processes (equipment or chemical infusions) when sensor thresholds are crossed under pre-approved safety protocols, with analogous alerting, logging, and role-based authorization checks for an industrial environment.

26. The computer-readable medium of claim 21, wherein the program instructions cause the system to comply with relevant regulatory standards by:

    - ensuring that each automated action is traceable to a human-authorized instruction (standing order) to satisfy legal requirements;

    - providing secure logs and data integrity checks (including timestamping events and preventing tampering with records) in accordance with 21 CFR Part 11 or similar regulations; and

    - incorporating user authentication and access controls for managing the standing-order templates and rules, such that only authorized medical staff can configure or modify the conditions under which automatic pauses occur.

27. The system of claim 11, wherein in a hospital-based embodiment the “attending clinical staff” is a nurse and the “authorized medical personnel” who pre-approves the standing order is a physician or other prescribing practitioner, and in an industrial-use embodiment the attending staff is a process operator and the authorized personnel is an engineer or supervisor, the system thereby being adaptable to enforce pause directives in both healthcare and industrial process contexts using the same core rule-based compiler and execution engine.