Microcontroller-Based Automated Drug Infusion and Monitoring System for Critical Care

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ABSTRACT

In critical care, the accurate delivery of drugs through vias is absolutely essential – failure to set the right occlusion time or to accurately recognise the period may generate a serious threat if the flow isn't completely released and is not delivered correctly, or if there is a programming error. This mini project is an Automatic infusion and automatic monitoring system using microcontroller which can be used as an academic prototype/single channel syringe-pump system. The clinician enters in a volume, concentration, a rate and volume to be infused, a safety controller validates the parameters entered by the clinician by comparing the parameters with the clinician's database of programmable drugs, and a stepper motor actuator is then enabled to work. All inputs – such as pressure, syringe position, delivered-volume, door, air-in-line and battery and optional physiological-monitor inputs – are sampled continuously. The embedded software features deterministic state machine, independent watchdog supervision, alarm latching, alarm/event logging and fail-safe motor shutdown. This programmed flow rate as a function of motor displacement is mathematically modeled, and volume being provided is calculated. These techniques will be validated in a usability review and calibration will be performed at the various flows, fault injection, power outage recovery and plausibility check of the sensors. This sample simulation was performed and a mean absolute flow error of less than 2 percent, for four nominal test flow rates, was achieved as well as all critical fault injections directed to a safe state. The values are provided for interesting purposes only and for demonstration of the project and are not to be interpreted as clinical value statements. The work focuses on the fact that although automation can help reduce repetitive programming and increase traceability, it can be utilized in conjunction with, but not as a replacement for, prescription verification, expert clinical judgment, formal risk management, electrical-safety testing, software validation and regulatory clearance.

Keywords: embedded system engineering, syringe/infusion pump, Patient monitoring/alarm management, medical-device safety, critical care and flow control.

How to cite this article: Kumar YR, Namassivaya N, Aruna M, Kharade JM, Thorushe MP. Microcontroller-based automated drug infusion and monitoring system for critical care. Int J Drug Deliv Technol. 2026;16(75s): 313-323. DOI: 10.25258/ijddt.16.75s.35

I. INTRODUCTION

Infusion pumps are particularly useful when higher accuracy and/or consistency is required in therapy than gravity would require and are a way for fluid and medication to be given at a controlled rate. Everything that constitutes "the intensive-care system" – from the pump to the administration set to the drug reservoirs to the network to the patient to the clinician and the workflow associated with them – is one system. Hence, a failure can occur at various points such as the hardware, software, disposables, data entry, communications or human interaction. The U. S. Food and Drug Administration recommends handling the entire infusion system, instead of just the pump mechanism [1]:

It's a controlled mechanical relocation of a previously analyzed prescription, by people competent. The automation only applies to flow execution, handling of alarms and surveillance. The prototype won't diagnose a patient, automatically choose a drug, an automatic dose, or a change in the drug regimen. Not critical care specific, but may be especially important in critical care, where technically good flow might not be clinically indicated and speed of clinical interpretation can be very important.

II. CLINICAL CONTEXT AND PROBLEM DEFINITION

A. Need for Controlled Infusion

The pest needs to be injected below ground for its control.

In critical care medicines can be administered using volumetric pumps, syringe pumps, via PCA or using dedicated controllers. The clinical prescription may be volume/unit time, kg/unit time, intermittent dose or volume over a period of time or it may be a weight normalised dose. Programmed value shall be declared unambiguously, and unambiguous relationships between programmed value and ordered value/sdrug value (in drug library) and between programmed value and pump rate and programmed concentration; shall be existing. He notes that modern, “smart” pumps can provide you with clinical advisories, soft and hard limits, drug libraries and dose error reduction – but not with programming and equipment failure.

B. Principal Failure Modes

Over-infusions can happen if there is an infusion unit error, free flow or a totally wrong understanding of an infusion unit. Under-infusion can be caused by occlusion (blockage) or empty reservoir, motor stall, depleted battery or closed clamp/excessive mechanical resistance. If the syringe, line and connections are highly compressed, it may take a long time for the pressure to be released, and it will take longer to push out the drug. Others that have to be discovered implicitly are air in the line, disengaged syringe, motor moving in a wrong direction (due to open door) or wrong syringe profile. There also factors dealing with humans: If you can't see the screen, too many alarms are given, there are steps to take to verify the alarm or limits are easily reached, then great electronics is negated [7].

Table 1: Critical-care infusion hazards and proposed safety responses

Hazard	Possible effect	Prototype response	Residual action
Occlusion	Delayed or interrupted therapy	Pressure trend and motor-load alarm; stop drive	Inspect line and clinical status
Air-in-line	Air delivery risk	Optical bubble input; latched alarm and clamp request	Prime or replace line
Wrong rate or unit	Over- or under-infusion	Drug-library range check and two-step confirmation	Clinician re-verification
Free flow / door open	Uncontrolled delivery	Door switch, anti-free-flow mechanism, safe stop	Secure set and restart workflow
Empty syringe	Therapy interruption	Plunger position and remaining-volume estimate	Replace prepared syringe
Power loss	Unexpected stop	Battery backup, event record, restart lockout	Clinical contingency plan

C. Project Aim

The aim is to develop an embedded prototype with low cost that might be proved to be right in actuator control, continuous monitoring of infusion parameters, early fault recognition, transparent and understandable alarm messages and auditable operation. It is considered as an engineering learning platform, only. If ever translation to the clinical application becomes a reality, it would involve the controlled design process, verified requirement, validated software, biocompatible/stainless components of fluid-path, normalization of electrical and electromagnetic safety by the control, usability validation, manufacturing controls and certification by the competent jurisdiction.

D. Scope and Boundaries

Project boundary is from the qualified prescriber where he/she has placed an order to the outlet and the display, where the prototype is monitored. On the outside the automation are still the "preparation of medicine" in the pharmaceutical industry, the "clinical access to the vessels" and the selection of the dose for each individual patient, depending on a clinical diagnosis and compatibility between the medicines. Checking is performed with the prototype, checking fluid (without drug) and false signals. Provides engineering data for consideration NOT recommendations for treatment. The scope of the project: The limits will be used to create a zone of doubt: the project will not make claims outside of these ranges for functions about which there is no evidence in the clinic, no regulatory assessment.

III. REVIEW OF RELATED WORK

A. Smart Pumps and Dose-Error Reduction

A combination of software controls and the traditional pumping technology is known as smart-pump technology. In a typical safety layer constructed of a drug-backing library that is owned by the hospital, you will find a care-area profile, advisories and allowed ranges. Soft limit need be confirmed to use, Hard limit can't use until it is changed/chosen. Ohashi et al. conducted one systematic review that revealed incorrect use rates, incorrect doses and setting errors, as well as potential usage risks when workarounds were employed, improper response from the library and alert burden in using smart pumps [8]. Other more recent reviews come to the same conclusion that the technology is suitable for medicine security but there are also several factors that can be experienced in the use of the technology, including implementation, ability to train, maintenance, design of work flows and layouts to process data as well as the quality of data [9].

B. Embedded and Model-Based Safety

Infusion controller is a cyber-physical system: the software decisions directly impact the physical system. FDA research programme Generic Infusion Pump suggests either the adoption of reference safety models or providing the formal specifications of safety properties to be verified as a method for infusion pumps to be adopted. This aid differentiating between operating-state events, invariants and fault responses and implementation details [10]. Those can be such as: do not energize the motor if READY, do not start the infusion if ALARM or SERVICE, when the door is open stop infusion etc. The requirements will give a better guideline than such terms as "the pump must be safe.

Table 2: Comparison of conventional, smart, and proposed prototype approaches

Feature	Conventional pump	Smart pump	Proposed academic prototype
Rate execution	Manual programming	Manual or auto-programmed	Verified manual entry with bounded control
Drug limits	Usually absent	Configurable library and DERS	Demonstration library; no clinical values supplied
Fault sensing	Device dependent	Multiple integrated sensors	Pressure, air, position, door and power inputs
Monitoring	Local display	Local plus optional server	Local deterministic control and optional isolated telemetry
Audit trail	Limited or model dependent	Event and compliance logs	Timestamped settings, states and alarms
Clinical status	Regulated product	Regulated product	Not clinically validated or approved

IV. DESIGN REQUIREMENTS

The requirements were grouped up based on delivery requirement, monitoring requirement, alarm requirement, interface requirement, power requirement, data requirement and life cycle requirement. A sensitivity measure or sensitivity analysis has to be provided for each requirement with a safety association and an action must be specified in the event that the data are either not available or are found to be inaccurate. The following is a list of features required in the baseline prototype: syringe, single channel, forward injection only, local alarms, non-volatilising event log, battery backed safe shut down. Physiological inputs can be monitored and be alerted individually – but it is expressly not allowed to change the set dose.

Based on this case, the following system architecture was decided. The proposed System block diagram is illustrated below.

V. PROPOSED SYSTEM ARCHITECTURE

A. Functional Overview

These are divided into six parts - Prescription Handling, Safety-Control, Motion-Generation, Fluid-path-Surveillance, User-Interaction and Optional-Monitoring. First a care profile is selected by the clinician; then the medication-library entry, a concentration entry, and then a dosage to be prescribed (or a volumetric rate); finally, a volume to be infused. This value(s) and the result is printed out by the firmware which calculates the derived rate. When a second confirmation notification is sent, along with a self test notification, a closed door notification, a recognized syringe profile and adequate power and reasonable sensor profile notifications are received, then the infusion can be initiated. The telemetry cannot do anything about

the switching on of the motor directly, however.

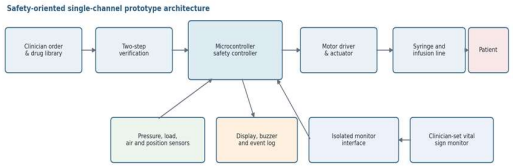

Figure 1: Proposed safety-oriented architecture for automated infusion and monitoring.

The OSEM opened up suggested AutoInfusion and Monitoring Safety Oriented Architecture is shown in Fig.1.

The different between safety critical controller and optional communication is presented in Figure 1. A verified interface and plug-in of the prescription data in the library give the rules, and hazard sensors and actuators feedback is directly plugged into the microcontroller. The display, buzzer and log are informed of the results of what the controller has determined. This was a prototype having an alarm to alert the clinician for an observation patient-monitor interface but doesn't automatically take care of the infusion rate adjustments.

B. Operating Modes

The following modes can be shown to the user: start up, self test, ready, infusing, pause, completed, alarm and service. Pause will not be recognised as pause, it will inform you how much pause is and how much volume do you still have. Service Mode is physically or crytographically limited and not available when connected to a patient. Changes to configuration are versioned, and are reviewed before they're activated. If an uncertain restart is going to take place, restart to safe stop, not silent restart.

C. Start and Continue Invariants

Prior to START, every cycle of control check if the controller has been configured, passed self-test, has a valid prescription, closed door, valid syringe, sufficient volume remaining, has a valid power margin and has plausible sensors. But as soon as any of the required conditions is falsified the motor command is cancelled – even if the user-interface task requests an explanation of the event. The alarm screen therefore, isn't a prerequisite for the safe action, rather it's a consequence of that action.

VI. HARDWARE DESIGN AND COMPONENT SELECTION

A. Microcontroller and Timing

A 32-bit Cortex-M-class microcontroller with low-power capabilities, such as communications peripherals, non-volatile memory blocks, watchdogs, and hardware timers can be used in the prototype along with space for deterministic control. No delay loop is used to generate the motor pulse train, rather a Timer Output is used. Safety inputs go to the interrupt capable pins (if applicable); polling and cross checking are performed, and if all polling and cross checking detect a fault, a fault will NOT be hidden if one interrupt occurs while the other interrupt was missed. The motor will be inhibited by Brownout detection when there is unstable supply.

Table 3: Prototype hardware blocks and selection rationale

Block	Representative implementation	Primary role	Safety consideration
Controller	32-bit MCU with timers and watchdog	State control and motor scheduling	Independent reset and motor-disable default
Actuator	Stepper motor, driver and lead screw	Controlled plunger displacement	Current limit, end stops and feedback
Pressure	Calibrated force/pressure transducer	Occlusion trend detection	Baseline drift and line compliance
Air sensing	Optical bubble detector input	Air-in-line recognition	Tubing compatibility and self-test
Position	Encoder or calibrated plunger travel	Volume and end-point estimate	Syringe profile must be identified
Interface	LCD, keypad/encoder, LEDs and buzzer	Entry, confirmation and alarms	Readable units and distinct priorities
Power	Isolated supply plus monitored battery	Continuity and controlled shutdown	Brownout inhibition and battery health
Logging	CRC-protected nonvolatile memory	Audit trail and diagnostics	Wear management and timestamp integrity

B. Optional Physiological Monitoring

An educational module connects with any heart rate, oxygen saturation, non-invasive blood pressure or temperature monitor which are separately validated by the manufacturer. Removing these data, clinician sets alert levels, plots and time-stamps data. If the sensors are not active on the computer it is NOT a physiological event. In the prototype, there will be no automatic changes, or stop events, to a

medication without a clinician validated action if there are no clinical validations.

VII. INFUSION COMPUTATION AND CONTROL MODEL

A. Prescription-to-Flow Conversion

Every quantity is stored in the controller and explicitly has units; only functions have been reviewed which convert the units. The quantity of fluid (V) which is to be prescribed and time (T) when the fluid to be given. The "Q" command is used to change the volume.

$$Q = V / T \quad (1)$$

The volumetric rate (in milligrams of mass dose per hour) is: if the amount of mass dose D (in milligrams) is to be delivered in time T (in hours) from a solution having a concentration C (milligrams/millilitres):

$$Q = D / (C\ T) \quad (2)$$

The prescriptions to be normalised by weight need a unit, k and the weight, W of the patient (which is verified elsewhere). The software does not have the ability to convert between units, and will warn you before you confirm if the rate is derived.

$$Q = (D_w\ W\ k) / C \quad (3)$$

B. Motor-Step Calculation

Once the number of cu mm per hour has been converted to the number of millilitres per hour, the number of steps per hour in the slide of the lead-screw to produce the ideal rate of f_s, can be determined, for a syringe whose internal area is A, and a step in the lead-screw motion equals delta x. A validated syringe profile correction coefficient K_s takes into account compliant and mechanical effects.

$$Delta\ V\_step = A\ delta\ x / 1000 \quad (4)$$

$$f\_s = (Q / 3600) / Delta\ V\_step \quad (5)$$

$$f\_cmd = K\_s\ f\_s \quad (6)$$

C. Delivered-Volume Estimation

This verification is done according the motor displacement, position or load in question; volume estimation is made based on this. The rate measured or inferred after taking n samples at time t (or t □ n) is:

$$V\_d(n) = Sum(i=1..n)\ Q\_i\ Delta\ t / 3600 \quad (7)$$

The value for V_rem is calculated as V_TBI - V_d. If the volume to be infused is reached then the actuator is turned off and saturation-logic does not permit a negative remaining value. Totals checks are made periodically and won't restart therapy automatically if it is powered down due to power outages.

D. Error and Feedback Control

The gravimetric or calibrated volumetric reference is used to evaluate flow performance. The percentage error, if the set value, Q_set and the measured value, Q_meas are programmed is:

$$e\_Q = 100\ (Q\_meas - Q\_set) / Q\_set \quad (8)$$

$$MAPE = (100/N)\ Sum\ |(Q\_meas,i - Q\_set,i) / Q\_set,i| \quad (9)$$

The prototype implements the bounded integral correction from position or flow feedback feature, and feed-forward step scheduling. Correction is not applied during a start transient and/or during an alarm, can only be applied in limited range of calibration values and can not be used to change a dose limit. If the desired motion doesn't occur within tolerances, controller halts operations and places a fault flag for either drive or syringe-engagement fault.

$$u(k) = sat[u\_ff + K\_p\ e(k) + K\_i\ Sum\ e(k)\ Delta\ t] \quad (10)$$

VIII. EMBEDDED SOFTWARE AND CONTROL ALGORITHM

Layered Firmware

Its software can be broken down into the following areas: Hardware abstraction, Sensor acquisition, Safety supervision, Prescription/unit logic, Motion control, User interface, Logging and Communications. Safety supervision can access all of the main inputs, and has absolute authority to stop the motor. Task Communication provides no way to directly write motor registers and bounded queue to publish data. The configuration records contain a version number, a checksum, the effective date for the configuration and the approval status. If every integrity check is all right, the previous (last) configuration accepted will be used.

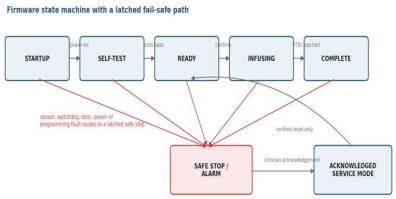

Figure 2: Deterministic firmware state machine with a latched fail-safe path.

Displays a latched deterministic firmware state machine – a fail safe path (Figure 2).

This safe behaviour is outlined in Figure 2. Sets up outputs for start-up, disables outputs. 1) Sample all sensors every control tick, 2) Range check each sensor, 3) Update filtered pressure, position, air, power and drive-current features, 4) If a critical fault occurs, then disable motor, and latch alarm, 5) If INFUSING then calculate bounded step command and update delivered volume, 6) Compare command with independent feedback and 7) Update event buffer and 8) Service the watchdog as necessary only if all required tasks finished. This is how the watchdog can not only keep track of the processor's well-being, but also of the control-loop.

IX. MONITORING, ALARMS, AND DATA MANAGEMENT

A. Infusion-Parameter Monitoring

On the primary monitor page, the name of the drug library can be viewed along with the concentration, programmed rate, derived rate, volume to be infused, delivered volume, remaining volume, elapsed time, estimated completion time, a trend of the pressure can be viewed, and the battery status and connection status can be viewed. The measurement of the units are shown after every number entry. Highlighted in a status bar are infusing, paused, complete and alarm. There are other ways of indicating priority in the interface than colour – shape, position and sound pattern support priority.

B. Physiological Inputs

If not all of the inputs for the vital sign is required then the source and freshness of the optional inputs will be shown. There are 3 states of each channel: valid, unavailable and technically suspect. If a probe is disconnected, then it should NOT display as a physiological zero. Limits are set or approved by the qualified clinicians, and do not need to be the drug-library limits. Advisory provided by the prototype will be to consider rethinking the patient and infusion, and should not be construed as having cause/effect to the change in vital-sign and infusion medication.

Table 4: Monitored variables, validation checks, and actions

Variable	Source	Validation	Displayed / logged action
Programmed rate	Confirmed prescription	Unit, range and library consistency	Show source and derived values
Delivered volume	Motor and position estimate	Monotonicity and cross-channel agreement	Total, remaining volume, mismatch alarm
Line pressure	Pressure transducer	Range, baseline, slope and persistence	Trend and occlusion alarm
Air status	Optical detector	Self-test and signal quality	Latched air-in-line alarm
Syringe position	Encoder / load feedback	Profile, direction and end-point checks	Remaining volume and disengagement alarm
Power condition	Supply and battery monitor	Voltage trend and brownout margin	Runtime estimate and staged alarms
Vital signs	External validated monitor	Freshness, quality and disconnection status	Advisory only; no automatic dose change

X. SAFETY ENGINEERING AND RISK ANALYSIS

A. Risk-Management Process

The foundation of risk management is to think about the purpose of the system, the ways in which it will likely be used and the nature of the system and the safety regions. Estimated/identified situation, sequence of events described/risk (before controls have been taken). There are three levels of control: inherent safety design; protective measures and safety information. Their controls are known to be effective, no additional risk is created by their controls and their residual risk is examined. Based on ISO 14971:2019, there is a life cycle process defined for hazard identification, risk estimation & risk evaluation, risk control as well as risk monitoring and effectiveness of risk control [4].

B. Preliminary Failure-Mode Analysis

Table 5: Preliminary failure-mode and effects analysis

Failure mode	Local cause	Potential effect	Detection / control
Motor continues unexpectedly	Driver or software fault	Over-infusion	Normally disabled enable line, watchdog, motion feedback, clamp
Motor stops or stalls	Jam, power or driver fault	Under-infusion	Position/current mismatch, staged alarm, safe stop
Pressure sensor drifts	Ageing, temperature or damage	Late/false occlusion alarm	Startup zeroing, plausibility, service calibration
Air sensor fails	Contamination or disconnection	Undetected air or nuisance alarms	Self-test, signal-quality check, line inspection

Failure mode	Local cause	Potential effect	Detection / control
Data corruption	Memory or update failure	Wrong limits or settings	CRC/signature, rollback, version approval, default safe state
User enters wrong units	Interface or transcription error	Wrong flow rate	Explicit units, derived-value review, hard limits, double check

C. Essential Performance and Standards

IEC 60601-1 [15] covers general basic safety and essential performance of medical electrical equipment and particular requirements for infusion pumps are covered by IEC 60601-2-24 [3] infusion pumps and controllers. These standards apply to a single point testing during: Accuracy testing, Alarm behaviour, Mechanical protection, Electrical isolation, Documentation and Assessment of a single point situation. Usability engineering is not only a safety process, but also processes for analysing, designing, verifying and validating aspects of usability are outlined in IEC 60601-1-6 and IEC 62366-1. These are some of the principles which a prototype can be based, but do not use the word standard as this does not imply it is following the standard.

XI. PROTOTYPE IMPLEMENTATION

A. Mechanical Assembly

The syringe cradle cannot be used for all syringes, but uses interchangeable and labeled profiles. A rigid frame ensures alignment of the barrel, plunger and lead screw & actuator. Never pull or push the plunger/interface apart. There are end stops that indicate rest positions and are positioned so that the syringe is not compressed beyond the travel allowed. The path of the tubing is located between the area of the air detector and the area of the manual/normally closed clamp. Where there are any moving parts protection is incorporated to keep the user safe.

Table 6: Proposed calibration and verification equipment

Item	Purpose	Recorded evidence	Acceptance basis
Calibrated balance	Gravimetric delivery measurement	Mass-time series and conversion factors	Predefined flow error and repeatability
Pressure reference	Pressure-channel calibration	Applied versus measured pressure	Linearity, hysteresis and alarm thresholds
Motion gauge / encoder	Lead-screw displacement	Steps, travel and backlash	Profile-specific displacement tolerance
Air-line fixture	Bubble-sensor challenge	Bubble size proxy and response	Detection and false-alarm protocol
Power analyser	Battery and brownout tests	Voltage, current and shutdown sequence	Safe transition and runtime margin
Logic analyser	Timer and watchdog verification	Pulse timing and reset evidence	Bounded jitter and correct safe state

D. Human-Machine Interface Implementation

There are 4 stages to programming: Identify, Enter, Review and Confirm. The evaluation screen shows the drug and concentration, body weight for the patient (if available), dose, and finally volumetric rate and volume which can be infused and checked for any discrepancies before being started. If you enter numbers using decimals then any zeros that appear before the first number are significant and any zeros after the last number can't exist. A physical STOP control can be found from all screens. Your critical alarms are much more noticeable than a normal alarm, and can't just be ignored like a normal alarm, due to your menubrowsing.

E. Configuration and Build Control

One release identifier applies to source code, schematic, calibration coefficient, version of the various different parts, test code & generated binaries. This build was created from a known repository. Compiler warnings are viewed as defects, static analysis results are discussed and safety requirements are correlated to tests. The release list contains the list of reviewers, date, version of the tools and open anomalies and the exact configuration installed in the prototype.

XII. EXPERIMENTAL METHODOLOGY

A. Scope of Evaluation

Change evaluation to not be a deterministic engineering simulation; not involve patients, clinical decisions, human subjects or drug administration; but with a prescription for how to do the bench testing. Sensors and actuators are simulated with

models that simulate flows, pressure, position, air, door and power signals. Results of the program are reproducible with a fixed random seed, thus avoiding random noise, latency. These key findings are: Flow accuracy, Cumulative-volume error, State transition correctness, Fault-detection latency and Motor-disable latency, Log completeness, and Restart behavior.

B. Test Matrix

Table 7: Prototype simulation and proposed bench-test matrix

Test group	Input / challenge	Replicates	Primary observation
Flow accuracy	5, 25, 50 and 100 mL/h	10 per setting	Mean rate, error, variability and delivered volume
Startup	Empty line-compliance model and normal load	10	Delay to stable delivery and overshoot
Occlusion	Step and ramp pressure disturbances	10 each	Detection, stop latency and residual pressure
Air-in-line	Simulated clear-to-air transition	20	Detection probability and false alarms
Syringe / door	Profile mismatch, disengagement, open switch	10 each	Start inhibition or safe stop
Power	Low battery, brownout and abrupt loss	10 each	Alarm sequence, disabled output and log recovery
Software	Stale data, checksum fault, watchdog timeout	10 each	Safe state, diagnostic code and restart lockout
Usability	Scripted programming and alarm tasks	Formative only	Errors, time, comprehension and recovery

C. Flow and Volume Metrics

Each programmed rate is simulated on the scale which then gives the calculated volume, using a known assumption of density. First Transient interval is not deleted (and explicit reported without explanation). The result mean, the standard deviations and root mean square (rms) errors, the maximum short window errors and the volume completion-time errors are calculated. Total results are reported as number of tries by syringe profile/load – this may hide low rate and/or high resistance behavior by just one number.

$$RMSE = sqrt[(1/N)\ Sum\ (Q\_meas,i - Q\_set,i)^2] \quad (11)$$

$$e\_V = 100\ (V\_meas - V\_target) / V\_target \quad (12)$$

D. Alarm and State Metrics

Industrially collected data – time of fault-injection (t_0), time of alarm (t_a) and time of confirmed motor-disable (t_s). The detection latency is calculated as: latency = 1/2(detection time + safe state time); safe-state latency = 1/2(safe state time + non detection time).

$$T\_detect = t\_a - t\_0 \quad (13)$$

$$T\_safe = t\_s - t\_0 \quad (14)$$

Alarm latching, alarm acknowledgement and Prohibited transitions are exactly the same as tested in an expected state sequence. Test fails if the motor is still on and the final volume doesn't equal its actual value. The independent stimulus record is used to assess whether or not the whole event-log is completed.

E. Acceptance Logic

The acceptance numbers should be determined prior to data collection and supported by a planned use and a risk analysis as well as standards and clinical engineering. Examples of engineering targets, NOT safety limits, are included in this document. Any clinical product would need to be tested over the entire range of operation, over disposable combinations, in the environment, against electromagnetic disturbances, against single failures and would have to be tested for the life of the product.

XIII. SIMULATED RESULTS AND PERFORMANCE ANALYSIS

A. Flow-Rate Results

A deterministic simulation was performed with the same controller using a profile specific calibration factor and at 4 nominal volumetric flow rates. The synthetic measured rates were 4.91, 24.82, 50.36, and 99.42 mL/h for commands of 5, 25, 50, and 100 mL/h. They are only values for a convenient verification and NOT from a certified apparatus. They aren't models to indicate what performance should be summarised - but not alongside feeling clinically similar.

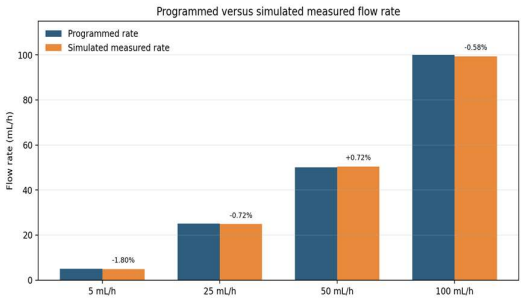

Figure 3: Programmed versus simulated measured flow across four nominal settings.

Table 8: Illustrative simulated flow performance

Programmed rate (mL/h)	Simulated measured rate (mL/h)	Rate error (%)	30 mL delivery time (min)
5	4.91	-1.80	366.6
25	24.82	-0.72	72.5
50	50.36	+0.72	35.7
100	99.42	-0.58	18.1

B. Interpretation

The M.A.P.E. average value is 0.96 per cent for the 4 points. Following a calibration bias model, quantization and bounded noise, there is no monotonic relationship between the error and the rate (for the synthetic data set). This percentage is the highest but the absolute/distance deviation of the LR point is the lowest. This demonstrates good examples of the reasons for low rate continuity, startup delay/short-window delivery and a long duration mean accuracy. In particular, the clinical consequences and an undesirable clinical outcome as a result of the lack of consistent delivery at an infill flow rate have been pointed out by FDA [17].

C. Volume and Completion Behavior

Finally, the simulated controller was stopped and the result of the Value-accumulator at the target Vol and the posited result of the independent estimate position agreed with the posited Volume-accumulator tolerance. Checks were performed periodically and records kept of the volume and also for scheduled shutdowns. After performing a simulation of a sudden power dropout, the system was able to recover the last good record, present the amount of water estimated to have been delivered and the amount of water in remain, but did not automatically restart—the operator must manually restart the system after clinical confirmation. With this safe behaviour, there will not be any unchecked infusion re-start or there will not be any infusion unchecked or will not be any infusion lost.

D. Sensor Plausibility

It was added into current vital-signs packet or external vital-signs packet was inhalated, as well as air detector disconnect was added and position and maximum-pressure were fed back. The system was coded to record in the log the type of alarm (technical, clinical and/or mechanical). Two channels in the same agreement do not necessarily mean two proper channels and with the passage of time, these two channels will have to be calibrated independently.

XIV. FAULT-INJECTION, USABILITY, AND CYBERSECURITY RESULTS

A. Alarm-Response Simulation

With 5 exemplary events, the simulation was carried out. The quickest response was found to be digital or a rapid optical input door open and an air in-line (AIR) input. Coming to the occlusion detection, it required a long-term trend of pressure as well to distinguish occlusion from the act of "handling", which resulted in the highest latency. The false alarm due to low battery, the motor turned off was manmade, and was the result of an orchestrated reaction. All critical events were latched, and no matter what, not only did the triggering signal end up being removed, but the critical events were latched.

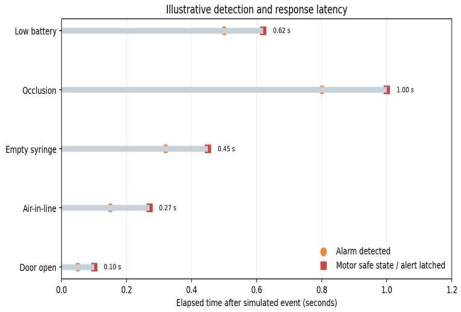

Figure 4: Illustrative detection and safe-state latency after injected faults.

Table 9: Illustrative simulated alarm outcomes

Event	Detection latency (s)	Safe-state / alert latency (s)	Observed state
Door open	0.05	0.10	Immediate motor inhibit; latched alarm
Air-in-line	0.15	0.27	Motor inhibit and high-priority alarm
Empty syringe	0.32	0.45	Complete or fault based on remaining volume
Occlusion	0.80	1.00	Pressure-qualified stop; residual pressure shown

Event	Detection latency (s)	Safe-state / alert latency (s)	Observed state
Low battery	0.50	0.62	Staged alert; controlled continuation or shutdown

B. Overall Assessment

Using a simulation, it is possible to test and validate the proposed in-silico (the control logic, the correctness and security, its accuracy in real mechanical conditions, audibility of alarms in an ICU situation, its electromagnetic compatibility, sterility, biocompatibility and long time reliability. The simplest and most crucial aspect of the findings is the traceability – each number in the results can be traced to either a reference to 'show on the model' or to a speaker's stimulus or predicted activity.

XV. DISCUSSION, LIMITATIONS, AND FUTURE SCOPE

A. Discussion

In this project, we show how a small embedded design can be utilized to validate a prescription, to control a deterministic actuator, to carry out multi-sensor surveillance, alarm management and event logging – each controlled by a microcontroller. It's not merely which Motor, which Processor, its also who is responsible for safety in the design. Dose cannot be modified locally bound energy, uncertain recovery, end sensors to close energy transport without network round trip and dose, the other hand person to follow the energy, can be modified. Such a set up retains the essential safety element idea comprehensible and tested.

While some automation will help reduce the repetition of calculations and performing functions; there are new avenues for things to go wrong. A drug library can be misaligned, the imported drug order can be mis-entered, a good drug alert can be disregarded and a very accurate pump can even dispense the wrong drug to the same accuracy as it dispenses the prescribed drug. Training and maintenance, change control/ post deployment review and ownership of content of Library in a Pharmacy with Clinical governance are other key features of the system. Safety improvements are achieved in the smart pumps's sociotechnical conditions' evidence [9].

B. Limitations

Deterministicmethod / approach: Design Study Simulations. Results presented which were not from a real patient, a real nurse, a physical prototype, a calibrated flow analyser, an ICU or an ICU biomedical Engineer and/or were not from a disposable set. Mechanical backlash, stiction and syringe to syringe variation, compliance of tubing and hydrostatic pressure, temperature and viscosity, ageing of the batteries, electromagnetic disturbance, acoustic masking, cleaning, ingress of fluids and tolerances of the component are conceptually represented. This data set (4) is not extensive enough to have operating envelope – clinically relevant. This is predicated on the external monitor having accomplished the measurement of signal quality and association with the patient. The project does not scientifically determine clinically alert limits, or whether or not a change in a parameter measured (heart rate, oxygen saturation, blood pressure or temperature) is due to the infusion. Moreover, it does not consider many interacting infusion channels (sensor and actuator), patient-controlled bolus (PTO), closed loop drug delivery and neonatal use/transport environment. These applications will add other risks, and will require their own requirements and proof.

C. Future Scope

The development is still ongoing and it features independent flow sensing, improved pressure modelling, automated syringe detection, several channel scheduling, connection of pumps with the e-record, remote inspection of pumps, prediction and maintenance, and certification of the safety state machine. Bounded and explainable would be examples of the "adaption function" – here you could adapt to think of a digital twin comparison of the expected vs. the observed pressure flow behavior, which could be meant for identifying line compliance or just partial occlusion. Cybersecurity efforts should include a strategic recovery and vulnerability management process and signed brokedowns from software installs. Design controls, quality management, a high level of verification and validation, a regulatory representation and post-marketing surveillance would be needed for clinical translation.

XVI. CONCLUSION

This automated drug infusion & monitoring system has been designed by the use of microcontroller which can incorporate the motion scheduling, continuous monitoring system to deliver the drugs in proper manner, explicit alarm logic, explicit alarm traceable records etc all within one embedded system. Single channel system architecture with verified volumetric control, air, position, door and power and faulted checked to a latched safe condition. Illustrative Simulation results do not qualify as a clinical assertion, but rather an error & timing of the alarms. Backed by rigorous evidence, the overall message is: Safety aspects of infusion demand an integrated process – from the accurate treatment prescription, to user-friendly interface design, hardware and software validation and user training, to in situ monitoring of the infusion process, to secure network connection and maintenance, through to the accurate treatment prescription. The following must be finished prior to

use of the system and is made for use as an academic prototype and NOT for patient care.

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