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PREVENTION OF IATROGENIC COMPLICATIONS AND AIR EMBOLISM IN INFUSION THERAPY IN INPATIENT AND INTENSIVE CARE SETTINGS USING THE "SMART DROP" AUTOMATED OPTICAL-SENSOR SYSTEM

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Abstract

Background. The intensive-care unit combines the highest exposure to infusion therapy with the greatest vulnerability to its failures. Among these failures, one is both serious and largely preventable: venous air embolism, a predominantly iatrogenic complication most often related to central venous access. A specific and under-addressed trigger of infusion-related harm arises at the end of an infusion, when the container empties and flow ceases, permitting blood reflux, catheter occlusion, interruption of therapy and, in high-risk conditions, air entry.

Objective. To review recent (2021–2026) evidence on infusion errors in critical care and on the pathophysiology and iatrogenic epidemiology of venous air embolism, and to present the rationale, architecture and evaluation framework of SMART DROP, a low-cost optical-sensor device that monitors infusion flow in real time and automatically closes the infusion line when flow stops.

Findings. Contemporary data confirm high medication-error rates in intensive care and a predominantly iatrogenic, frequently unrecognised and substantially fatal profile for venous air embolism, concentrated in central venous catheterisation and pressurised infusion. Existing smart-pump defences secure dose and rate but do not manage the terminal mechanical state of the line. SMART DROP is designed to act mechanically before harm develops and to alert selectively, thereby also limiting alarm fatigue.

Conclusion. SMART DROP addresses a documented, high-consequence gap in intensive-care infusion safety. Its effects are formulated as hypotheses for a two-stage technical and clinical validation programme, which constitutes the next phase of the work.

Keywords: intensive care; infusion therapy; venous air embolism; central venous catheter; iatrogenic complications; patient safety; automated shut-off; optical sensor; alarm fatigue; SMART DROP.

1. Introduction

Infusion therapy is indispensable to the care of the critically ill, in whom fluids, vasoactive drugs, sedatives and other high-alert medicines are frequently delivered through multiple simultaneous lines. This intensity of use, combined with the physiological fragility of intensive-care patients, makes the intensive-care unit (ICU) the setting in which infusion failures are both most likely and most consequential. Patient safety has become a global priority, and unsafe

medication practices — arising from systemic conditions and human factors such as fatigue and staff shortages — are a leading cause of avoidable harm, with particularly high rates reported in intensive care and emergency medicine [1].

Within this landscape, one complication commands particular concern because it is at once serious and, in principle, avoidable: venous air embolism (VAE). The recent literature is consistent in identifying VAE as predominantly iatrogenic and most often associated with central venous access, and in emphasising that its presentation ranges from clinically silent to rapidly fatal [6, 7]. A specific and under-recognised precursor of infusion-related harm — the cessation of flow when an infusion container empties — links VAE to the everyday operation of the infusion set and is not directly addressed by the smart-pump technologies that dominate current practice.

This article has two aims. First, it reviews recent (2021–2026) evidence on infusion errors in critical care and on the pathophysiology and iatrogenic epidemiology of venous air embolism, in order to define the clinical problem precisely. Second, it presents the design rationale, system architecture, operating principle and proposed evaluation framework of SMART DROP — an automated optical-sensor device that monitors infusion flow in real time and mechanically arrests the line when flow ceases — and situates it as a complement to existing defences, with its clinical value framed as a set of testable hypotheses.

2. The intensive-care setting: exposure, vulnerability and the burden of infusion errors

The ICU concentrates risk for several converging reasons. Critically ill patients receive complex, frequently changing medication regimens; many drugs are administered by continuous infusion with narrow therapeutic margins; and the patients themselves have limited physiological reserve, so that a delivery error that a stable patient might tolerate can precipitate rapid decompensation. Recent evidence quantifies the resulting error burden. A 2025 systematic review of medication errors in intensive-care settings and operating rooms reported ICU medication-error rates ranging from 1.32% to 31.7%, alongside operating-theatre rates of 7.3% to 12% [3]. An umbrella review synthesising seven systematic reviews concluded that, although numerous interventions have been evaluated, medication errors in the ICU remain incompletely controlled and continue to threaten patient safety [4].

The neonatal ICU illustrates the extreme of this vulnerability. A systematic review and meta-analysis estimated the pooled prevalence of medication administration errors in neonatal intensive care at 59% to 65%, attributing them to a combination of active failures, such as look-alike drug packaging, and latent failures, such as noisy environments and inaccurate orders [5]. Across the spectrum of critical care, therefore, the evidence describes not an occasional lapse but a systemic exposure, in which the reliability of every element of the delivery pathway — including the terminal behaviour of the infusion set — carries clinical weight. It is against this background that the specific hazard of flow cessation, and the complication of venous air embolism, must be considered.

A distinctive feature of intensive-care infusion is the reliance on continuous delivery of high-alert medications with narrow margins of safety — vasopressors, inotropes, sedatives, insulin and anticoagulants — for which uninterrupted administration is itself a therapeutic requirement. For such drugs, an unrecognised cessation of flow is not merely a mechanical inconvenience but a lapse in treatment: the abrupt loss of a vasopressor infusion can provoke haemodynamic instability within minutes, and the interruption of insulin or anticoagulation carries its own hazards. Moreover, critically ill patients commonly carry several infusions simultaneously through central and peripheral access, multiplying both the number of lines that must be watched and the number of opportunities for an end-of-infusion event to pass unnoticed. The terminal behaviour of each individual set therefore acquires a clinical significance that is disproportionate to its apparent simplicity.

3. Venous air embolism: pathophysiology, iatrogenic epidemiology and risk factors

3.1. Mechanism and determinants of severity

Venous air embolism occurs when a pressure gradient allows air to enter the venous circulation. This typically arises when venous pressure is low relative to atmospheric pressure — as in hypovolaemia, deep inspiration, or when the patient is positioned such that the access site lies above the level of the heart — and when the catheter hub or access site is exposed to ambient air [8]. Once air enters the circulation, the clinical consequence is determined by the volume of air, the rate at which it enters and the patient's position; entry that is rapid, or that occurs close to the heart, requires a smaller volume to produce cardiovascular compromise [7, 8]. Air reaching the right heart and pulmonary circulation can impair right-ventricular output and gas exchange, while paradoxical passage through a patent foramen ovale can deliver air to the systemic and cerebral circulation, producing neurological injury [7].

3.2. The iatrogenic and preventable profile of venous air embolism

The contemporary literature leaves little doubt about the origin of VAE. In a systematic review of 174 reported cases, 92% were iatrogenic, attributable in descending order to surgical interventions (50%), central venous catheter insertion or removal (36.3%), peripheral intravenous cannulae (9%) and ventilator-associated barotrauma (3.8%); overall mortality was 18.4%, only 8.6% of patients were asymptomatic, and haemodynamic instability at presentation was associated with markedly higher mortality (odds ratio 7.0) [6]. A separate review similarly concluded that most VAE is iatrogenic, with roughly half of cases arising from surgery and around 45% from the insertion or removal of central or peripheral intravenous lines [7]. Contemporary case reports reinforce the danger of the central-catheter pathway: a 2025 report describes fatal iatrogenic air embolism involving the right ventricle following internal-jugular catheterisation, despite recognition and attempted management [8], and emergency-medicine reviews stress that vascular air embolism is an iatrogenic complication that even experienced operators cannot wholly prevent and that is easily missed without a high index of suspicion [9].

The difficulty of recognition deserves emphasis, because it is the strongest argument for prevention over rescue. The clinical presentation of venous air embolism is non-specific and overlaps with many other causes of acute cardiorespiratory deterioration, so that the diagnosis depends heavily on clinical context and suspicion; a substantial proportion of cases are haemodynamically unstable by the time they are recognised, and outcomes are worse in exactly those patients [6]. Once air has entered the circulation, no management modality reliably reverses the injury, and treatment is largely supportive. This asymmetry — a complication that is easy to cause, hard to recognise and difficult to treat, yet straightforward to prevent by keeping air out of the line — is precisely the profile for which an automatic mechanical safeguard is best suited.

3.3. Implications for prevention

Two conclusions follow directly and shape the remainder of this article. First, because VAE is frequently unrecognised and may progress rapidly to a fatal outcome, prevention is a more dependable strategy than detection and rescue: the reliable course is to stop air entering the circulation in the first place [6, 7]. Second, the risk must be scoped accurately. During ordinary peripheral gravity infusion, flow simply stops when the container empties and the entry of a large air volume into the vein is unlikely; the clinically important risk of air embolism is concentrated in central venous access, pressurised or pumped infusion, and the intensive-care and paediatric settings in which such access predominates [6, 7, 8]. A device intended to prevent air embolism should therefore be designed and evaluated with these high-risk conditions explicitly in view — a principle that is built into the design and validation plan presented below.

4. The end-of-infusion failure mode and the limits of current defences

The event that links the everyday operation of an infusion set to the hazards above is the cessation of flow at the end of an infusion. In a gravity-driven set, flow is maintained by the pressure difference between the fluid column and the patient's venous pressure; when the container empties this driving pressure collapses, forward flow stops, and the system enters an unstable state in which blood may reflux into the line, promoting clot formation and catheter occlusion, and in which, under the high-risk conditions described above, air may enter the circulation. Detection of this state in conventional practice depends entirely on human observation, and is therefore tightly coupled to nursing workload, fatigue and the density of competing demands — all of which are extreme in intensive care [18, 19].

The downstream consequences of an unmanaged end-of-infusion state are themselves costly in the intensive-care context. Blood reflux and clot formation may occlude a central catheter whose placement required an invasive, risk-bearing procedure; salvaging or replacing that catheter consumes clinician time, exposes the patient to further risk, and interrupts the delivery of essential drugs. Even where no catheter is lost, the silent interruption of a continuous infusion undermines the tight titration on which critical-care pharmacotherapy depends. These considerations reframe the end-of-infusion event not as a trivial nuisance but as a recurring threat to both vascular access and therapeutic continuity in the most vulnerable patients.

Current engineered defences do not close this gap. Smart infusion pumps with dose-error-reduction software constrain the programming of dose and rate and are valuable within that scope, but their benefit depends on library maintenance and clinician compliance, which are difficult to sustain, and, more fundamentally, they do not monitor the physical progress of the infusion or respond to the emptying of the container [12, 13]. Interoperability extends smart-pump safety — a 2025 systematic review found reductions in specific administration errors of 15.4% to 54.8% and in total errors of 21.2% to 90.5% — but again addresses the accuracy of delivery rather than the terminal state of the line [11]. A parallel literature describes sensor- and Internet-of-Things–based monitors that detect the empty container and, in more advanced designs, arrest flow to prevent reflux and air entry [14, 15, 16]; clinical evaluation of such systems has begun, notably a retrospective study of an IoT infusion-monitoring system that compared matched one-year periods and examined abnormal-infusion alerts and nursing response time [14]. Yet most such work remains at the prototype stage, is seldom validated clinically, and risks adding to the alarm burden that already contributes to error in critical care [17, 18, 19]. The gap is thus specific: an integrated, low-cost, clinically validated system that combines continuous flow monitoring with active mechanical arrest, designed for the high-risk conditions of intensive care.

5. The SMART DROP system: design rationale, architecture and operating principle

5.1. Design requirements

The preceding analysis yields four design requirements specific to the intensive-care context. First, the device must monitor the physical progress of the infusion, detecting flow cessation as it occurs rather than inferring it from programming. Second, on detecting cessation it must act autonomously to arrest the line, because prevention is more reliable than detection-and-rescue for air embolism and reflux [6, 7]. Third, it must limit its contribution to alarm fatigue — a documented hazard in critical care — by acting first and alerting selectively [19]. Fourth, it must be inexpensive and simple to deploy on existing infusion sets, a requirement that the recent engineering literature shows to be achievable with low-cost components [15].

5.2. System architecture

SMART DROP comprises four functional blocks. (1) An **optical (drip) sensor** continuously observes the fluid movement in the drip chamber and measures the drip rate with

high resolution, providing a direct, real-time signal of the physical progress of the infusion. (2) A **microcontroller** of the ESP32/Arduino class receives and processes this signal and executes the decision logic, including configurable thresholds and debounce timing. (3) An **automatic shut-off mechanism** — a servo-driven or electromagnetic clamp — mechanically occludes the infusion line when flow stops, blocking blood reflux and, critically, air entry at their point of origin. (4) A **signalling and communication block** provides local indication through an LED and an audible signal and transmits a wireless notification to the nurse station and a mobile application. The device is contained in a compact enclosure, mounts directly onto the tubing of a standard infusion set, and operates on battery power for prolonged autonomous use.

5.3. Operating principle

The operating logic embodies an "act first, alert second" principle. The optical sensor tracks drip movement continuously; when the microcontroller detects cessation of flow, or a marked deviation from the expected drip rate, it first commands the shut-off mechanism to close the line and only then dispatches a notification to staff. In consequence, the mechanical safeguard against reflux and air entry is established before a complication can develop, and alerting serves to summon appropriate, unhurried human action rather than to trigger an emergency response. To prevent spurious activation, configurable debounce logic disregards transient fluctuations lasting only a few seconds — for example, drip-rate changes caused by patient movement — an approach consistent with the false-alarm-suppression strategies implemented in recent clinical monitoring systems [14]. By combining autonomous mechanical action with selective alerting, the design directly targets both the physical hazard of flow cessation and the human-factors hazard of alarm fatigue.

It is worth making explicit how this logic differs from that of a conventional monitor. A monitor that only raises an alarm transfers the entire burden of the safety response to a human who must notice the alarm, interpret it, prioritise it against competing demands and physically intervene in time — a chain that is fragile precisely under the workload conditions in which end-of-infusion events are most likely to be missed. By closing the line autonomously, SMART DROP removes the time-critical human step from the safety-critical path and reserves human involvement for the non-time-critical task of replacing or discontinuing the infusion. The alert thus changes in character from an urgent warning to a routine prompt, which is both safer and less corrosive of attention over a long shift.

6. Comparative positioning

Table 1 summarises the position of SMART DROP relative to traditional manual monitoring and to conventional smart infusion pumps. The comparison is qualitative and is intended to clarify the device's complementary role; measured superiority remains to be established through the validation programme described in Section 7.

Table 1. Qualitative positioning of SMART DROP relative to existing infusion-monitoring approaches

Attribute	Traditional manual monitoring	Smart infusion pump (DERS)	SMART DROP
Primary safety focus	Human vigilance	Dose / rate programming	End-of-infusion / flow cessation
Real-time flow monitoring	Visual, intermittent	Programmed rate, not physical drip	Optical sensor, continuous
Detection of flow cessation	Depends on attention	Limited / indirect	Automatic
Active mechanical shut-off	None	Not a primary function	Yes (automatic clamp)

Protection against air entry / reflux	None	None	Direct, at point of origin
Alarm-fatigue posture	Not applicable	Alert-driven; compliance-dependent	Act first, alert second
Principal limitation	Workload / fatigue dependent	Cost; terminal state not covered	Requires clinical validation

7. Proposed evaluation framework

Because SMART DROP exists at the prototype stage, the statements that follow are formulated as hypotheses; no clinical outcomes are claimed, and the validation programme constitutes the next phase of the work. This framing reflects the principle that the safety and effectiveness of a medical device must be demonstrated empirically rather than asserted. Three hypotheses are proposed: (H1) that continuous flow monitoring with automatic shut-off reduces end-of-infusion iatrogenic events — reflux, occlusion and, in high-risk settings, air entry; (H2) that autonomous mechanical arrest with debounced alerting reduces non-actionable alarms and nursing response burden relative to alert-only monitoring; and (H3) that prevention of silent interruptions improves adherence to the intended delivery schedule. Because air embolism is predominantly iatrogenic and largely preventable, H1 is expected to be most clearly demonstrable in high-risk settings such as central venous access and intensive care [6, 7].

7.1. Technical validation

The first stage characterises the device as an instrument. The key metrics are the sensitivity and specificity of flow-cessation detection, the false-alarm rate under simulated patient movement, the latency between cessation and mechanical closure, and the reliability and durability of the clamp across repeated actuations over the intended service life. Crucially, the behaviour of the automatic shut-off must be characterised under the conditions in which air embolism is clinically relevant — on bench models representing central venous access and pressurised infusion — rather than only under peripheral gravity conditions, so that the evidence matches the intended high-risk application.

7.2. Clinical validation

The second stage evaluates the device in use. A controlled comparative design — contrasting wards or periods with and without the system — is appropriate and is consistent with the methodology of recent studies of IoT infusion monitoring and of interventions to reduce medication errors [11, 14]. Pre-defined outcome measures, blinded adjudication of events, and control for seasonal and case-mix confounding are essential to credible inference; the recent retrospective evaluation of an IoT infusion-monitoring system, which compared matched one-year periods and independently adjudicated false alarms, provides a concrete template [14]. Proposed primary outcomes are the frequency of end-of-infusion complications per 1,000 infusions; secondary outcomes include nursing response time, the number of non-actionable alarms per infusion, the proportion of infusions completed without unplanned interruption, and staff-reported workload, complemented by an economic evaluation of cost against averted complications and staff time.

8. Implementation considerations

8.1. Local context, affordability and import substitution

The economic dimension is integral to this work rather than incidental to it. Imported infusion-safety technology is frequently expensive and poorly adapted to local workflows, whereas the recent engineering literature demonstrates that effective sensing and actuation can be achieved with inexpensive, mass-producible components [15]. A locally developed device that is validated under local clinical conditions therefore offers value both as a patient-safety

intervention and as a means of import substitution, provided that manufacturing quality and reliability meet clinical standards. Affordability is not a secondary attribute but a determinant of whether protection can be extended to the settings that need it most.

8.2. Regulatory pathway and data security

As an active device that intervenes in the infusion pathway, SMART DROP must satisfy the applicable medical-device regulatory requirements before clinical use, and the two-stage validation programme is designed to generate the technical and clinical evidence such clearance demands. Because the device communicates wirelessly and may connect to hospital systems, it also inherits the security obligations of connected medical equipment; reviews of the Internet of Medical Things document real vulnerabilities of networked infusion devices to malware and denial-of-service attacks [17]. Secure communication, authenticated updates and, above all, a fail-safe design are therefore requirements rather than options. A notable strength of the proposed architecture is that its core safety action is local and mechanical: the line can be arrested even if network connectivity is lost, which confers intrinsic resilience against both communication failure and cyber-attack.

9. Limitations and future directions

Several limitations must be acknowledged openly. The system is at the prototype stage and its clinical effectiveness is unproven; the hypotheses of Section 7 remain to be tested. Its advantage with respect to air embolism is concentrated in high-risk settings such as central venous access and pressurised infusion, and in ordinary peripheral gravity infusion its value lies chiefly in preventing reflux, occlusion and interruption rather than air embolism, which is uncommon in that context [6, 7]. Sensor reliability across the full range of clinical fluids and conditions, and the durability of the mechanical clamp over its service life, require dedicated characterisation. Connected operation raises data-security obligations that must be met [17]. Future work follows directly from these points: completion of technical validation on high-risk bench models, execution of a rigorously designed clinical study in intensive-care and central-access populations, formal reliability and security testing, and pursuit of regulatory certification, with subsequent extension to interoperability with hospital information systems and existing pumps.

10. Conclusion

Intensive-care infusion therapy carries a high and well-documented risk of iatrogenic harm, and venous air embolism — predominantly iatrogenic, frequently unrecognised and substantially fatal — is among its most serious and most preventable complications, concentrated in central venous access and pressurised infusion. The cessation of flow at the end of an infusion is a specific precursor of reflux, occlusion, interruption of therapy and, in these high-risk conditions, air entry, and it is not addressed by the smart-pump and interoperability defences that secure the accuracy of dose and rate. SMART DROP is proposed as a low-cost, optical-sensor system that monitors flow in real time and mechanically arrests the line at the moment flow ceases, acting before harm can develop and alerting staff only when human action is required, thereby also mitigating alarm fatigue. Its expected benefits are advanced as testable hypotheses, and the immediate priority is a two-stage technical and clinical validation programme, followed by regulatory certification, through which the concept can be confirmed, refined or refuted.

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