

The Patient Safety Benefits of the Plum™ Cassette

A review and assessment of infusion therapy technologies and the clinical impact of pumping mechanisms and administration set design

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Introduction

Today's infusion pumps perform essential clinical functions with increasingly advanced technology and safety features. The use of "smart pumps"—infusion pumps with drug libraries—to reduce errors during the infusion of medications and fluids has become the industry standard,^{1,2} and is recommended practice by leading safety organizations.^{3,4,5} However, smart pumps do not eliminate all types of errors.^{3,4,5} There is considerable variability in smart pump user interfaces, clinical work flows, pumping mechanisms, and administration sets.^{6,7} Device user interfaces and workflows have been an FDA focus for usability⁸ and have been the subject of bench research.⁶ The fluid pumping mechanism and administration set are also important, as they determine how fluid is delivered to a patient as well as the accuracy and consistency of the fluid delivery in various clinical settings. This review of infusion therapy technology demonstrates that the design of pumping mechanisms and administration sets have significant clinical impact.

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Patient safety issues linked to smart pumps

Risks and errors associated with smart pumps are described in surveys,² complaint investigations,⁴ literature reviews,^{5,9} and by public agencies.¹⁰ The potential types of smart pump errors are numerous,^{9,11} and certain use cases are considered higher risk than others.^{6,10} Recent publications add to the knowledge base by describing experiences and priorities of frontline clinicians and the technologies used to address smart pump errors.^{2,4}

Two recent Institute for Safe Medication Practices (ISMP) surveys, including more than 1,000 healthcare respondents, provide a glimpse into the prevalence of medication errors at the bedside and the types of challenges or obstacles that users experience with smart pumps.² The most common types of medication errors experienced in the last 12 months by respondents involved secondary infusions due to delays, omissions, or wrong rates. Users reported challenges with the use of smart pumps in categories such as Drug Library Creation, Maintenance, and Engagement; Technology Limitations; and Programming Workflow. Secondary Infusions were also described as a category of challenges, including issues such as the lack of an alert/alarm if the secondary is not running, secondary setup errors such as bag height and closed clamps, programming the primary infusion as a secondary, and forgetting to restart the primary after the secondary is complete. Challenges specific to Alarms and Sensors included difficulty managing occlusions and air-in-line alarms.

A challenge in the category of Pump Availability was described as a lack of availability of syringe pumps to deliver medications in lower volumes due to drug shortages.

Smart pump errors and the technology solutions to address them have been studied by the ECRI Institute.⁴ An investigation of 100 smart pump complaints reported to ECRI demonstrated that the leading source of errors was related to incorrect infusion concentration or parameter entries. The ECRI analysis indicates that 75% of the studied errors would be prevented by smart pump–EHR interoperability. Of the 25% of errors not addressed by interoperability, 15% were related to secondary infusion setup and require an infusion pump technology solution.

An additional set of infusion pump challenges with potential for error comes from administration sets and pumping mechanisms susceptible to variation in fluid delivery accuracy by as much as 30% with changes in administration set intake and outlet pressures.¹² Pressure variability may be brought about by clinical changes such as a high-resistance venous catheter and the height differential between the fluid container and the pump.

Ideal attributes of infusion pump technology

With an understanding of the types of infusion pump errors and a focus on the pumping mechanism and administration set, technology solutions can be envisioned to address errors related to primary and secondary infusions.

Primary infusions

Ideally, infusions from the primary fluid container should take place at the programmed rate without concern of variability during care from a changing height differential between the fluid container, pump, and patient. For example, the fluid delivery rates should be constant regardless of positioning pumps on an IV pole, transferring a patient from the operating room table to a bed, or the patient ambulating in their room.

The infusion alarm burden should be minimized, and management of common alarm types, such as air-in-line and distal occlusion, would be facilitated. Ideally, air-in-line could be managed by limiting air accumulation in the fluid path and removal of air without the need to disconnect the administration set from the patient, reducing the possibility of contamination. Transient distal occlusions due to changing conditions, such as a kinked catheter from a flexed elbow, would be managed without requiring a clinician at the bedside.

Secondary infusions

The ideal pump would deliver secondary infusions without dependence on a head height differential or the need to administer the secondary infusion as an independent primary. Delivery of the secondary infusion would not be dependent on a single back-check valve within the primary set to prevent secondary medication from flowing into the primary container rather than to the patient. The pump would alert the nurse when the secondary infusion was obstructed by a

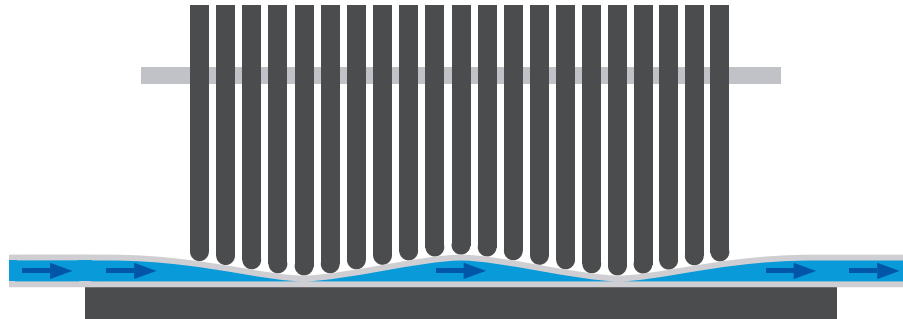
clamp or other source. The pump would deliver the exact programmed secondary volume and would then switch back to the primary infusion when indicated. In the setting of smart pump–EHR interoperability, the ideal pump would be capable of assuring that the secondary infusion is delivered and accurately documented.

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Pump technology overview

There are two large volume fluid pumping mechanisms on the market today: linear peristaltic and cassette based. Linear peristaltic pumps are available from several manufacturers while all cassette-based clinical experience comes from the Plum infusion pump platform (ICU Medical Inc., San Clemente, CA, USA). As described below, several significant clinical performance differences exist between the linear peristaltic and cassette-based system.

Deep-dive: Limitations of linear peristaltic pumping mechanisms



Linear peristaltic pumping mechanism

Most infusion pumps utilize a peristaltic pumping mechanism, which moves fluid downstream in the administration set with the assistance of the pumping mechanism and gravity. Proper filling and emptying of the pumping segment are needed for accurate fluid delivery.

Silicone pumping segment design may lead to air accumulation

The administration set pumping segment on a linear peristaltic pump is the length of tubing that interacts with the pumping mechanism to propel fluid distally to the patient. The pumping segment may be manufactured from silicone which has permeability properties that may allow air to enter the set, leading to bubble formation and air-in-line alarms. Air accumulation in the pumping segment may impact pumping accuracy as air displaces fluid from the segment, which may lead to under delivery of fluid during a pumping cycle.

Inflow pressure affects the accuracy of fluid delivery

For proper filling of the pumping segment, a height differential between the fluid container and pump is recommended by manufacturers. Fluid inflow into the pumping segment may be reduced by inadequate primary fluid container head height or falling container pressure levels with emptying, and this may reduce the volume of fluid delivery during the pumping cycle. Flow into the pumping segment may be reduced approximately 1% with each 15 mmHg of inflow pressure reduction¹² within the system. Additionally, restricted container emptying by inadequate venting or an obstructed fluid path from filters or kinked tubing may also reduce flow.

Increases in back pressure reduce pump accuracy

High back pressures may lead to reduced emptying and backfilling of the pumping chamber during the pumping cycle. The net result of an increase in back pressure is a reduction in the delivery of fluid. Increased back pressure may arise from several clinically relevant conditions such as partial tubing obstruction, high flow rates, increased fluid viscosity, small bore tubing, small bore catheters, and long catheters such as PICC lines. Outlet pressure is expected to vary over time. and infusion pumps may be programmed to deliver fluid until reaching a distal occlusion pressure threshold, which may lead

Back pressure increases may reduce flow up to 3% per PSI depending on pump design, which may translate into pump inaccuracy.

to under delivery. For example, when a distal occlusion pressure threshold is set to 11 pounds per square inch (psi), the pump will deliver fluid against a back pressure of 10 psi without alarming. Back pressure increases may reduce flow up to 3% per PSI depending on pump design, which may translate into pump inaccuracy.¹² Additive effects of intake and outlet pressures may create negative flow errors of up to 30%.¹²

Secondary infusions may be omitted or delayed

The peristaltic pump delivers fluid through the administration set without controlling whether it is from the primary or secondary container. The selection of a secondary infusion flow is determined by manual processes including the setup of the required primary–secondary head height differential, roller clamp opening, and ensuring the presence of a back-check valve in the primary line. The connection of the secondary at the primary Y-site also requires a fully opened, low-resistance needlefree connector to ensure proper fluid flow from the secondary container. In the event of a secondary setup error, such as a closed roller clamp, the pump may be programmed to deliver the secondary medication and the secondary medication may be displayed on the user interface, but due to the closed clamp on the secondary line, the medication on the primary line will be infused at the secondary rate programmed by the clinician.

Secondary infusions interrupt primary infusions

When delivered properly, secondary infusions stop the delivery of the primary infusion until fluid flow from the primary container resumes. While the clinical significance of an interrupted primary is patient specific, frequent interruptions of an ordered primary infusion may be associated with issues related to fluid balance and electrolyte homeostasis.

Administration of secondary infusions as a primary requires a dedicated flush

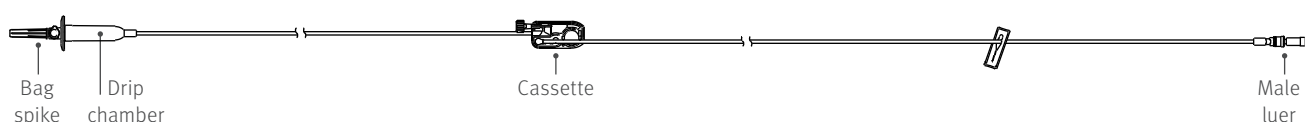
To bypass the risks associated with delays in secondary administration or interruptions of primary infusions, a secondary may itself be administered as a primary. When this strategy is followed, the clinician is then required to initiate a strategy to flush the utilized primary tubing to deliver the remainder of the secondary fluid. Delivering the secondary remaining in the tubing is critical to avoid a potential underdose as secondary infusion containers may be 50 or 100 mL while the primary set priming volume may be 20 mL or greater. Discarding the fluid remaining in the tubing may lead to a considerable portion of the prescribed dose being wasted.

Deep-dive: Advantages of the Plum cassette-based pumping mechanism

The Plum cassette-based pumping mechanism delivers primary and secondary medications differently than a peristaltic pumping mechanism. The technology is best understood with a description of the administration set and cassette, followed by a description of the pumping mechanism.

Structure of the Plum administration set with Plum cassette

The Plum administration set includes several components common to all administration sets. At its proximal end, the set includes a bag spike and a drip chamber. At its distal end, the set includes a male luer with a spin collar for secure attachment to a female luer. The differentiating feature is the cassette, which is located near the middle of the set and engages with the pumping mechanism.



Structure of the Plum cassette

A schematic description of the cassette describes the flow of fluid from container to the patient.

The Plum cassette has a U-shaped fluid path inside a rectangular housing. Fluid from the primary and/or secondary lines flows into the cassette, fills the air trap, fills the pumping chamber, and then exits the cassette through the infusion line which connects to the patient. During priming, the cassette is inverted to expel air from the air trap and fill the pumping chamber with fluid, then flipped to normal orientation for loading into the pump.

Technical capabilities of the cassette-based pumping mechanism

VOLUMETRIC DELIVERY

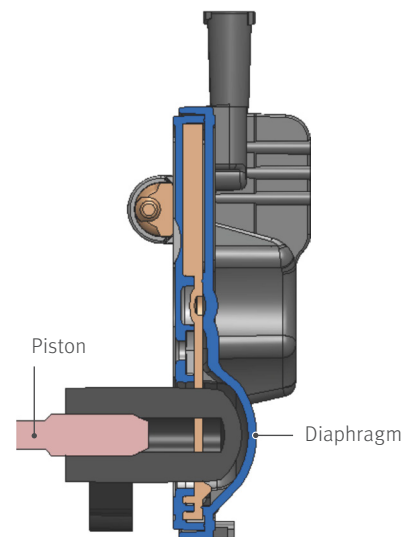
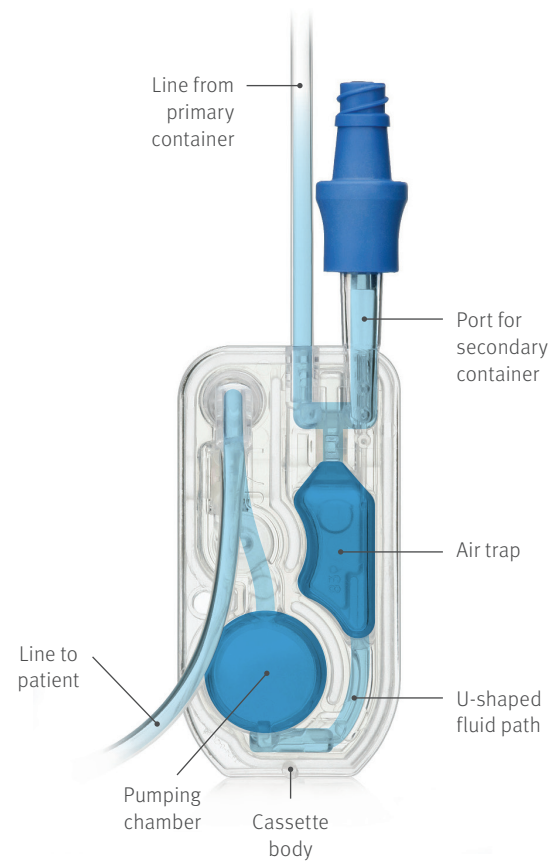
Plum infusion pumps deliver a set volume of fluid with each pumping cycle, independent of inflow pressure and back pressure. The administration set cassette incorporates a pumping chamber with a flexible silicone diaphragm that is compressed by a piston from the pump. When the chamber is full and the piston extends, a set volume of fluid is pushed from the chamber into the distal administration set. When the piston retracts, the diaphragm expands and pulls fluid from the container into the pumping chamber. The programmed rate determines the frequency of the piston extension and retraction pumping cycle and thus the volume of fluid delivery.

INDEPENDENT PUMPING CONTROL OF PRIMARY AND SECONDARY INFUSIONS

The cassette incorporates a valving mechanism that acts as the gatekeeper for fluid to flow into the cassette for primary and secondary infusions. When delivering a secondary infusion, the pumping mechanism selects fluid from the secondary port and closes the flow from the primary. When programmed for a primary infusion, the pumping mechanism selects fluid from the primary line and closes the flow from the secondary.

ALARM CAPABILITIES FOR PRIMARY AND SECONDARY INFUSIONS

Independent control of primary and secondary infusions enables infusion pump alarms to be issued for each line independently. Alarms are configured to detect proximal and distal occlusions throughout the infusion duration.



Volumetric delivery



Air trapping and elimination



Syringe or infusion set connection

AIR TRAPPING AND ELIMINATION

The cassette air trap is designed to retain up to 1 mL of air prior to generating an alarm. Once air is present and an alarm is generated, the air can be removed through an automated process of backpriming through the secondary port. Backpriming is initiated by the clinician selecting the feature through the keypad, which directs fluid from the primary container to fill the air trap and expel the air into a container attached to the secondary port, such as the secondary infusion line or a syringe.

CONCURRENT FLUID DELIVERY

In addition to the delivery of a secondary medication, the cassette valving mechanism enables concurrent fluid administration. Concurrent delivery is the infusion of primary and secondary fluids at the same time at independently determined rates. The pumping mechanism alternates drawing fluids into the cassette from primary and secondary containers to achieve the programmed administration rate of each fluid. For example, the primary infusion can be infused at 100 mL/hour while the secondary infusion can be infused simultaneously at 50 mL/hour. The rules of compatibility still apply as medications should only be infused together if they are compatible.

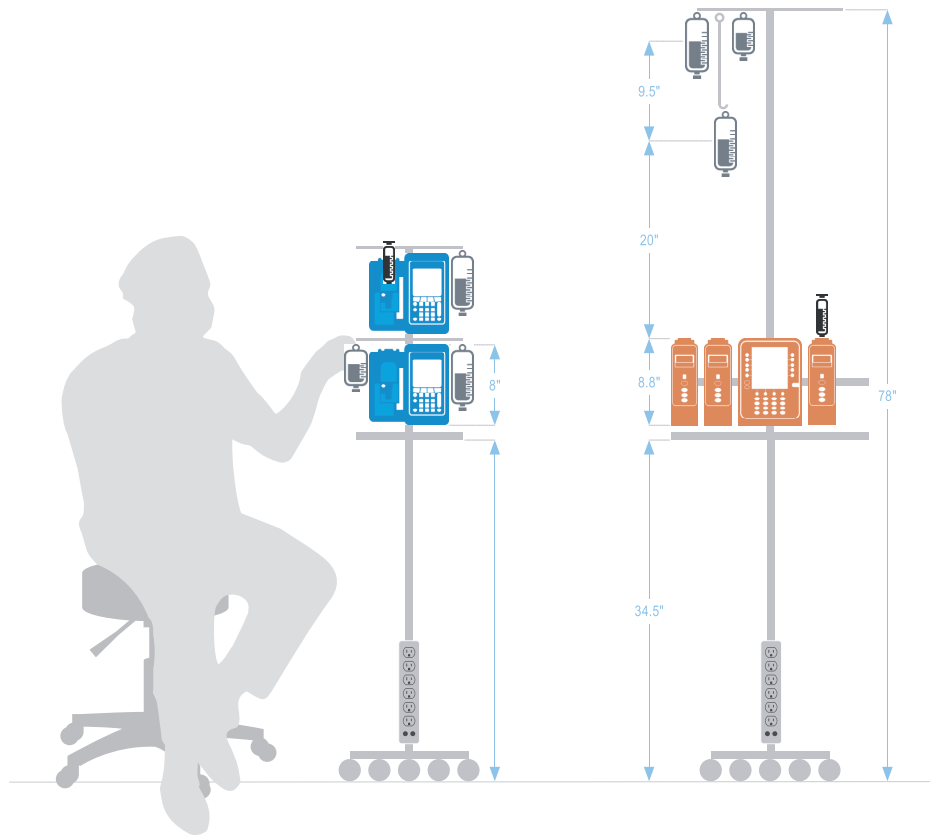
SYRINGE OR INFUSION SET CONNECTION

The Plum cassette allows for a needlefree connector or female luer to serve as the attachment point for the secondary infusion. This connection point enables attachment of administration set tubing or a syringe for container and volume flexibility in infusion delivery.

The clinical impact of the Plum infusion system

Infusion rates are stable when the clinical setting changes

Volumetric delivery infuses the primary and secondary infusions at the programmed rate regardless of bag height, system resistance, and back pressure for both secondary and primary infusions. Changes of bag heights and pump location, such as a patient transfer from a bed to a chair, are managed without the need to reconfigure the infusion system setup. An additional benefit of independence from head height requirements is the ability to configure the infusion system (pump, bags, pole, etc.) to suit the clinical setting to optimize workflows in tight spaces.



Secondary infusion delivery is simplified and sources of error eliminated

With independent control of primaries and secondaries, secondary administration no longer requires the clinician to lower the primary infusion bag with a hanger, maintain a head height differential, or be dependent on a back-check valve to safely administer the infusion. The clinician can hang the infusion bags to fit the care area and clinical scenario whether it be on the IV pole or on a pump-based hanger.

Alarms dedicated to secondary infusions recognize obstructed secondary fluid flow, for example from a closed roller clamp, and alert the clinician. In contrast, an occluded secondary line on a peristaltic pump will not generate an alarm and will lead to fluid flowing from the primary infusion container at the programmed secondary rate and a delay or omission of the secondary medication.

The 2020 ISMP Smart Pump Guidelines recommend that clinicians "use an automated secondary IV infusion management system not dependent on head height differential."

Prompt recognition of an obstructed secondary line enables the clinician to restore flow and avoid delays in therapy with medications that are frequently time-sensitive antibiotics and electrolytes. In one study, closed clamp errors occurred at a rate of 1.1%,¹³ which translates to the potential for frequent patient impact as an individual hospital may have hundreds of patients, each receiving multiple secondary infusions each day.

The 2020 ISMP Smart Pump Guidelines recommend that clinicians "use an automated secondary IV infusion management system not dependent on head height differential and can assure secondary flow."³ The Plum infusion system is the only infusion pump currently used in clinical care to meet this recommendation.

Air-in-line alarms are reduced and can be cleared without breaking the line

Air-in-line alarms interrupt infusions, can be time intensive to resolve, frequently recur, and can contribute to alarm fatigue. Furthermore, breaking the infusion line to remove air may expose the patient to injection site contamination and possible infection. The Plum cassette air trap captures up to 1 mL of air to reduce alarm burden, while backpriming enables air clearance without disconnecting the line from the patient. Air issues are further reduced as the Plum administration set's silicone diaphragm is limited to approximately the size of a dime, significantly less silicone surface area than alternative peristaltic pumping segments, which reduces the opportunity for air accumulation as bubbles.

Air management was studied in a side-by-side evaluation of the Plum 360™ and a competitive pump during a bench study of a placebo chemotherapeutic agent known for outgassing and generation of air-in-line alarms. At the study conclusion, the Plum 360 had zero air-in-line alarms while the competitor had 21.¹⁴

Documentation and Billing Claims Submissions Are Improved with Independent Primary and Secondary Infusion Control

With independent control of primary and secondary infusions, documentation with smart pump–EHR interoperability is accurate. The documentation benefits of interoperability facilitate completion of an accurate medical record and may translate to improved hospital financial performance. One community hospital found that interoperability was associated with increased infusion therapy CPT code submissions totaling an annualized \$1,147,652 (USD).¹⁵

Without this independent primary and secondary control with a peristaltic pump, when a secondary infusion is not flowing, the primary medication may be delivered and incorrectly recorded as a secondary infusion.

The primary can continue during secondary infusions

Concurrent infusion capability enables clinicians to determine whether a secondary infusion will be delivered by piggyback (secondary infuses, primary stops) or concurrently (primary and secondary infusing) and has multiple potential benefits.

Fewer primary infusion interruptions

A maintenance fluid infusion can continue at the desired rate while secondary intermittent medications are infused. This is especially valuable when intravenous access sites are limited and the primary infusion is critical to the patient's fluid balance. Repeated primary interruptions with piggybacks may impact fluid balance and complicate intake and output calculations and balance. Beta-lactam antibiotics, such as ZOSYN®, are increasingly infused over extended periods of time. ZOSYN may be administered over 4 hours, 3 times per day. When delivered by piggyback, ZOSYN may lead to an interruption of the primary infusion 12 hours per day.¹⁶ Primary infusions frequently include electrolytes, thus frequently interrupted fluid and electrolyte infusions may also affect electrolyte homeostasis.

Time-savings with multiple infusions

Infusing a secondary concurrently can also reduce therapy times. In a bench study of Plum 360 versus a competitor, the time required to complete a simulated chemotherapeutic regimen was reduced by concurrent infusion of premeds with the Plum 360.¹⁴

Potential improvement in patient comfort with irritating infusions

During the infusion of irritant medications, concurrent administration may improve patient comfort by diluting the medication with the primary infusion.¹⁷

Secondary medications can be delivered with syringes or bags

The secondary port can be used with an administration set or a syringe attached to the standard Plum cassette without specialized equipment. The flexibility to infuse medications for various container types is valuable with changing drug preparations and in times of medication shortage.²

Repeated primary interruptions with piggybacks may impact fluid balance and complicate intake and output calculations and balance.

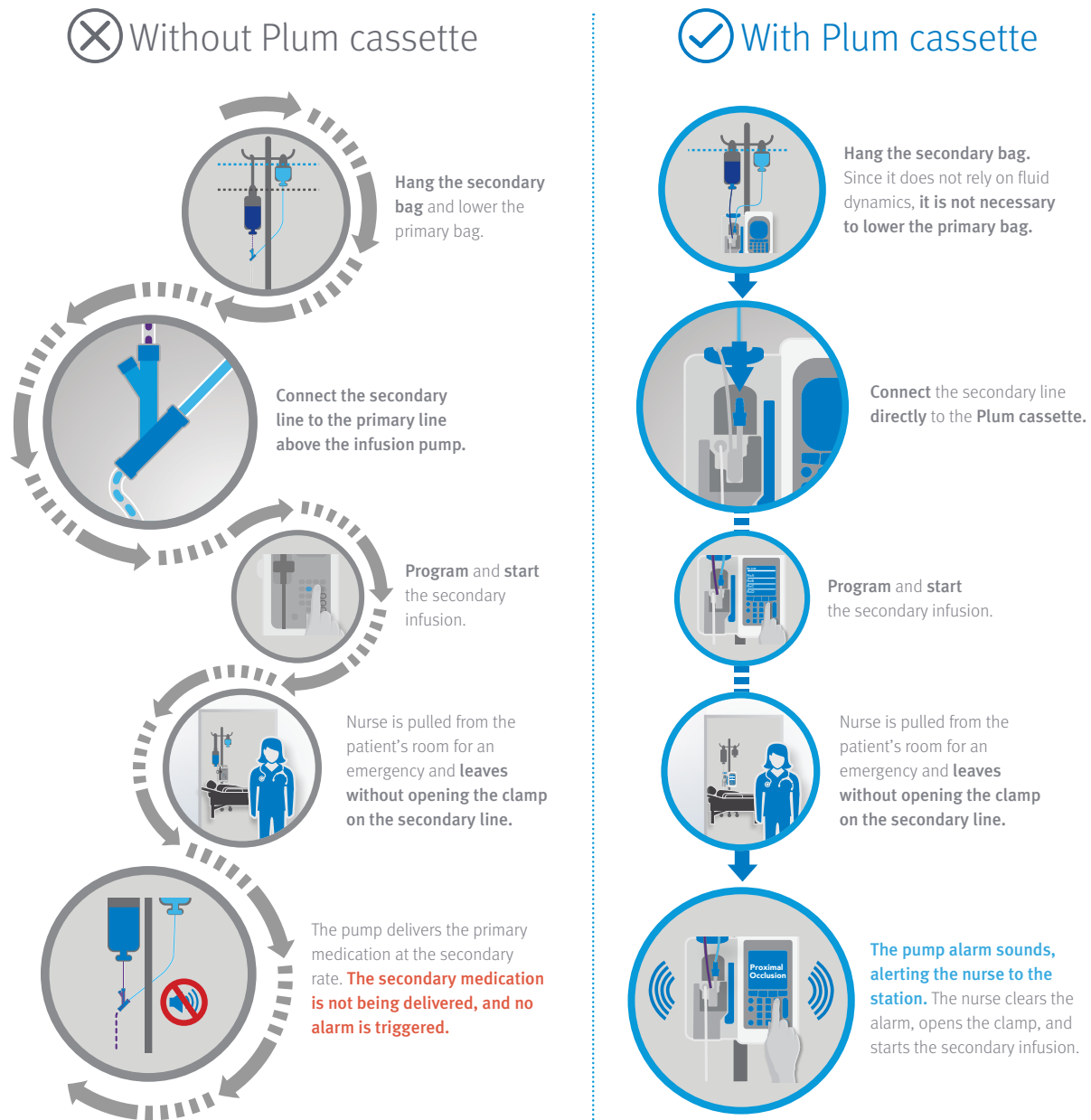
Conclusion

The use of smart pumps for the infusion of medications and fluids reduces many types of medication errors, but due to differences in design, the safety benefits vary by device. A comparison of smart pump peristaltic and cassette-based fluid pumping mechanisms demonstrates that the cassette-based infusion pumps have multiple important clinical benefits for the delivery of primary and secondary infusions. The full safety benefits of smart pumps will be realized through the effective utilization of drug library software, interoperability with the EHR, and pumping technology that delivers primary and secondary fluids accurately in complex clinical environments while also reducing the risk of human error by simplifying the administration of secondary infusions.

How a cassette-based delivery system helps streamline secondary delivery

A direct connection from the secondary line to cassette reduces risk and increases efficiency

Take a look at the infusion scenario below, both with and without the Plum cassette, to find out.



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