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Research article

Assessing the efficacy of original equipment manufacturer (OEM) intravenous infusion sets for infusion pumps: a comprehensive performance analysis

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Abstract

The study's goal was to evaluate the efficacy of OEM (Original Equipment Manufacturer) intravenous infusion sets when used in conjunction with blood tube infusion pumps. We collected data using standardized testing techniques, ensuring a 95% confidence level. We analyzed four parameters: flow rates, volume, tubing occlusion, and air bubble detection. We determined compatibility by meeting specific clinical performance standards, such as accurate flow rate, consistent volume delivery, minimal tubing occlusion, and effective air bubble detection.

The study tested four types of OEM infusion sets across three models of infusion pumps from five different companies in various hospital settings, encompassing a total of ten hospital locations. The results showed that Brand 2's infusion set met the required standards and was compatible with Brand A's Model 1A, 2A, and 3A infusion pumps. Brand 3's infusion set met the necessary criteria and was compatible with both Brand A's Model 2A and Brand C's Model 1C. Brand 4's infusion set also met the required standards and was compatible with both Brand A's Model 2A and Brand C's Model 1C. Brand 5's infusion set satisfied the requirements and was compatible with Brand B's Model 1B infusion pump.

This study provides valuable information to the medical field about the suitability and effectiveness of OEM infusion sets when used in conjunction with blood tube infusion pumps. The findings emphasize the importance of selecting compatible infusion sets and pumps to enhance patient safety and optimize healthcare practices.

Keywords

original equipment manufacturer, intravenous infusion sets, infusion Pumps

1. Introduction

In modern medical therapy, the use of contemporary medical technology is essential across various domains, including screening, rehabilitation, and treatment. Contemporary medical technology effectively integrates both non-invasive and invasive treatments within these domains [1–4]. "Invasive treatment" encompasses various complex procedures that penetrate the patient's body. For instance, we use infusion pumps to directly deliver liquids or pharmaceuticals into the bloodstream. According to the Department of Medical Sciences and the National Institute of Metrology (Thailand) [2], this medical equipment is classified as high-risk because it requires the direct introduction of solutions into the bloodstream [5–10].

Ensuring safety and precision is paramount, with a maximum permissible flow rate error of ±5% for newly purchased infusion pumps and those used in intensive care units [5–10]. For infusion pumps that have been on the market for a while, the acceptable flow rate error is within ±10% [2, 5–10]. The accuracy of the flow rate of solutions or medications administered intravenously depends on selecting the correct infusion sets that match the model and brand of the infusion pump. These sets can be either original equipment manufacturer (OEM) or non-OEM sets. Various sources, including the Department of Medical Sciences, National Institute of Metrology (Thailand) [2], ECRI [5], IEC [6], and ISO [9–10], indicate that using inappropriate infusion sets can adversely affect patient outcomes.

The clinical significance of using compatible and effective infusion sets with infusion pumps cannot be overstated. Incompatible or ineffective infusion sets can lead to incorrect dosing, potentially causing serious harm or even life-threatening conditions. This issue is especially critical in intensive care units, where precision in medication delivery is crucial for patient survival and recovery. Studies have shown that errors in infusion pump usage can lead to adverse drug events, prolonged hospital stays, and increased healthcare costs [11–14].

Most hospitals currently use infusion sets specifically designed for intravenous administration, such as the O-I-E-M type [11–14]. However, there is a concern that using non-compatible infusion sets may negatively impact patient recovery and pose health risks. It is important to test O-I-E-M infusion sets that work with intravenous administration devices to keep error margins below the levels set by the Emergency Care Research Institute (ECRI) [5, 9–10]. The Department of Medical Sciences under the Ministry of Public Health conducts this testing across a network of four hospitals.

Additional references supporting the importance of this research area highlight the potential consequences of using incompatible infusion sets. For example, studies by the World Health Organization (WHO) [15], the U.S. Food and Drug Administration (FDA) [16], and peer-reviewed journals [17–19] emphasize the need for rigorous testing and standardization to ensure patient safety.

In summary, this study aims to evaluate the efficacy of OEM intravenous infusion sets used with infusion pumps, focusing on their compatibility and clinical performance. The findings will provide valuable insights into the selection of appropriate infusion sets, ultimately enhancing patient care and safety.

Theoretical Framework: Type O-I-E-M infusion sets that are compatible with intravenous administration devices are being tested for a number of reasons. Belonging to this category is making sure the margin of error is within the parameters set by the Emergency Care Research Institute (ECRI). Furthermore, the testing is in accordance with the standards that have been established by the Department of Medical Sciences, which is part of the Ministry of Public Health, and covers a network of four hospitals.

In the realm of medicine, the process of administering fluid substances through the bloodstream can be broken down into three distinct categories, which encompass the following: (1) Peripheral Intravenous Infusion involves the administration of fluids or substances through veins close to the skin's surface. (2) Central Venous Therapy involves the administration of fluids or substances through major veins like the Subclavian Vein, Internal

& External Jugular Veins, and Right & Left Nominate Veins. This is generally used when patients are unable to consume oral nutrition. (3) Implanted Vascular Access Devices, also called Venous Ports, are placed under the skin to allow fluid delivery into large blood vessels like the Subclavian Vein and Right and Left Nominate Veins.

As described in ISO8536-4 [10], ISO1135-4 [9], the mechanism that underpins the vented infusion set is comprised of a collection of components that are depicted in Figure 1.

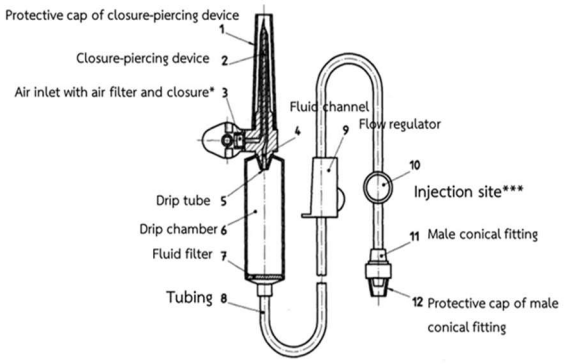

Figure 1 Displays the several components of the vented infusion set (IV set) as specified in ISO 8536-4:2015/FDA [10]

According to Figure 1, there are a total of twelve components included in the vented infusion set, which are as follows:

(1) A cap on the closure-piercing device that is designed to protect it. (2) The machine that is used to pierce the closure. (3) A closed-off air inlet with a built-in air filter. (4) A channel for fluids. (5) A tube for dripping. (6) A chamber for drip irrigation. (7) A fluid filter. (8) Engaging in the activity of tubing. (9) A regulator for the flow of fluid. (10) A place to inject drugs. (11) A male conical fitting is performed. And (12) Cover of the male conical fitting for protection.

Each of the following criteria will be used to evaluate the candidates:

1. Standard Procedures for Testing Infusion Pumps, which is a handbook distributed by the Medical Sciences Department of the Ministry of Public Health. This guide provides directions for testing infusion pumps that are utilized in intravenous medication administration settings.

2. A product standard for the industry that covers single-use infusion sets for intravenous drug delivery is known as TIS no. 1426-2546. Additionally, it details the components that make up these sets, as well as the requirements for packaging and labeling, as well as the sample techniques, acceptance criteria, and functioning testing.

3. the ISO standard no. 1135-4, which describes the material and size regulation for single-use infusion sets and single-use blood giving sets by making use of the force of gravity.

4. The FDA USA standard[10], more specifically the "Guidance for Industry and FDA Staff: Intravascular Administration Sets Premarket Notification Submissions," which offers direction on how to ensure that intravascular administration sets are properly notified prior to their release on the market.

2. Objectives

The study's goal was to evaluate the efficacy of intravenous infusion sets manufactured by OEM (Original Equipment Manufacturer) in conjunction with blood tube infusion devices.

3. Materials and methods

The project, which tested Type OEM infusion sets compatible with infusion pumps for intravenous applications, divided itself into four distinct phases.

The first phase began with the selection of materials and equipment for the project. The second phase involved acquiring the necessary apparatus, including the infusion sets intended for intravenous administration. In the third phase, the focus was on ensuring the protection and integrity of the particular infusion sets used within hospital settings. The final phase began with the testing process.

We separated the testing process into several components:

1) Selection criteria and rationale:

The selection of specific brands and models of infusion pumps and infusion sets was based on their prevalent use in various hospital settings and their reputation for reliability and performance. We included three models of infusion pumps from five different companies, each commonly used in clinical practice. The rationale for selecting these particular brands and models was to ensure a comprehensive analysis of the compatibility and performance of OEM infusion sets across a representative sample of infusion pumps.

2) Flow Rate Evaluation:

To assess the flow rate of the infusion pump, we evaluated the flow rate of original IV sets from a certain brand and compared it with the flow rate of OEM IV sets from various brands. We conducted each evaluation three times, using two sets of intravenous sets per brand. Table 3.1 displays the predetermined flow rates and durations.

Table 3.1 Flow rates and test durations.

Type IV 20 drops	
Flow Rate	Time
10 mL/h	60 min
100 mL/h	30 min
300 mL/h	10 min

3) Flow Rate and Net Volume Evaluation:

This evaluation utilized an infusion pump analyzer that adhered to the established standard testing standards described by the Department of Medical Sciences, Ministry of Public Health. Figure 2 shows a graphical depiction of the analyzer setup.

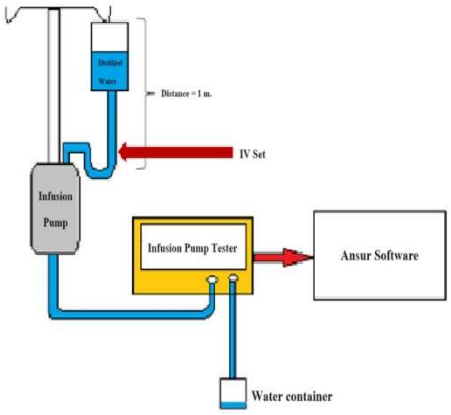

Figure 2 The analyzer setup diagram

4) Occlusion Pressure Testing:

We used an infusion pump analyzer to examine the occlusion pressure of intravenous infusion sets. We conducted the test at a flow rate of 300 mL/h, limiting the recorded pressure to less than 1,000 millimeters of mercury per instance.

5) Air-In-Line Detection Assessment:

This test determined the presence of air bubbles within infusion sets intended for intravenous use, adhering to the stipulated standard of 100 microliters. As shown in Figure 3, the test involved pulling air into

an insulin syringe to a volume of 10 units (equivalent to 100 microliters). We expected the introduction of air bubbles into the infusion pump to trigger an auditory alert.

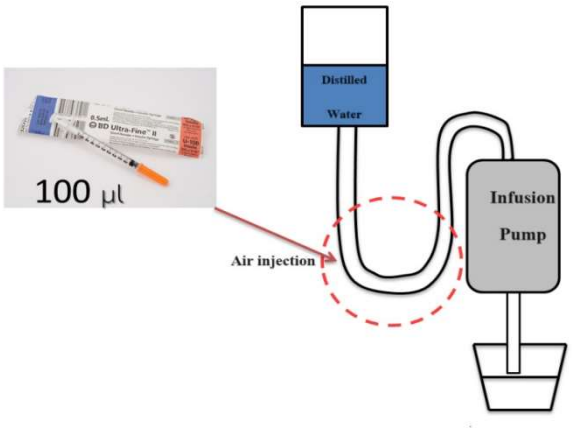

Figure 3 Infusion pump air bubble introduction section

Statistical Analysis: To ensure robust statistical analysis, we calculated the sample size based on a confidence level of 95% and an acceptable error margin of ±5%. We assumed the normal distribution of data and the homogeneity of variances. We analyzed the data using standard statistical methods, such as descriptive for categorical data.

Reliability and Reproducibility: We took measures to ensure the reliability and reproducibility of the test procedures. Standardizing all testing protocols and procedures. We are conducting multiple trials (three times for each brand and model) to ensure consistency. We calibrate all equipment before each testing session to maintain accuracy. We meticulously document all procedures and results to allow for independent verification. Following these steps ensured that the testing procedures were reliable, and the results were reproducible.

4. Results

The quality testing results for Type OEM infusion sets compatible with infusion pumps for intravenous applications were generated using testing methods aligned with standard procedures for regulating infusion pumps. Flow rate and volume at vital sites have a margin of error of ±5%, whereas the margin of error for routine areas is ±10%. We used an infusion pump analyzer to analyze the five infusion pumps we selected for testing, sourced from three different manufacturers. The following sections summarize the results based on different parameters.

4.1 Flow Rate Evaluation:

We performed the flow rate evaluation to determine the accuracy of the infusion pumps when used with different infusion sets. Table 4.1 presents the results, including average flow rates and standard deviations, while Figure 4 illustrates them.

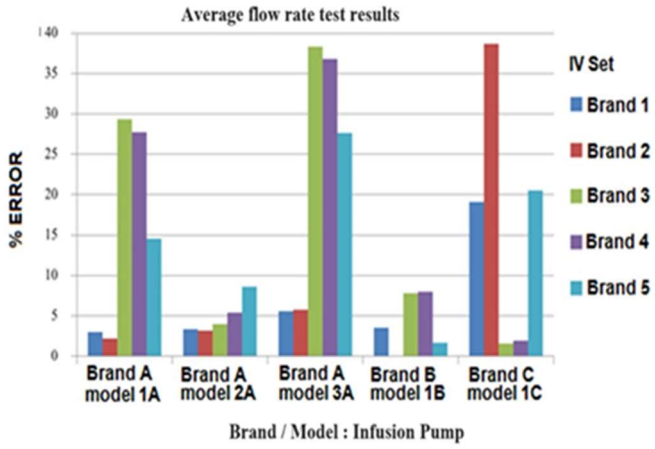

Figure 4 Results of the average flow rate test

Table 4.1 Average flow rates and standard deviations

Model	Brand	Compatible	Flow Rate (%)	Std. Dev. (%)
Model 1A	Brand 1	Yes	2.99	0.25
	Brand 2	Yes	2.17	0.30
	Brand 3	No	29.32	1.45
	Brand 4	No	27.75	1.30
	Brand 5	No	14.56	0.90
Model 2A	Brand 1	Yes	3.35	0.20
	Brand 2	Yes	3.16	0.22
	Brand 3	Yes	3.93	0.18
	Brand 4	No	5.44	0.40
	Brand 5	No	8.63	0.55
Model 3A	Brand 1	Yes	5.57	0.50
	Brand 2	Yes	5.78	0.48
	Brand 3	No	38.34	2.10
	Brand 4	No	36.79	1.90
	Brand 5	No	27.69	1.75
Model 1B	Brand 1	Yes	3.53	0.30
	Brand 5	Yes	1.50	0.12
	Brand 3	No	7.82	0.60
	Brand 4	No	7.96	0.65
Model 1C	Brand 3	Yes	2.09	0.20

4.2 Volume Distribution Evaluation:

We performed the volume distribution evaluation to assess the precision of volume delivery by the infusion pumps when used with different infusion sets. Table 4.2 summarizes the results, including average volume distributions and standard deviations, and Figure 5 illustrates them.

Table 4.2 Average volume distributions and standard deviations

Model	Brand	Compatible	Volume (%)	Std. Dev. (%)
Model 1A	Brand 1	Yes	2.27	0.15
	Brand 2	No	1.82	0.20
	Brand 3	No	28.93	1.50
	Brand 4	No	28.50	1.40
	Brand 5	No	15.14	0.80
Model 3A	Brand 1	Yes	6.02	0.40
	Brand 2	Yes	5.84	0.38
	Brand 3	No	38.65	2.20
	Brand 4	No	37.85	2.00
	Brand 5	No	28.89	1.70
Model 1B	Brand 1	Yes	3.64	0.25
	Brand 5	Yes	2.04	0.18
	Brand 3	No	8.02	0.55
	Brand 4	No	7.70	0.50
Model 1C	Brand 3	Yes	0.96	0.10
	Brand 4	Yes	2.09	0.15

4.3 Occlusion Pressure Testing:

The occlusion pressure testing evaluated the ability of infusion sets to detect occlusions. The results indicated an average occlusion pressure of 950 millimeters of mercury, with a maximum deviation of ±51 millimeters of mercury across all five machines, consistently below the 1,000 millimeters of mercury threshold.

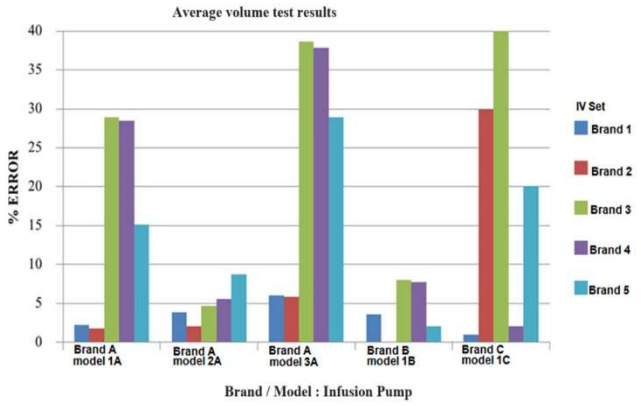

Figure 5 Volume test summary

4.4 Air-In-Line Detection Assessment:

The air-in-line detection assessment tested the sensitivity of the infusion pumps to detect air bubbles. Using a 100-microliter syringe, we introduced air bubbles into the infusion sets. All machines consistently generated "Air in Line" alerts and ceased operation upon detection, confirming the high efficacy of this testing standard.

In summary, the results demonstrate the following:

Flow Rate and Volume: Compatible infusion sets generally showed acceptable flow rates and volume distributions within the specified margins of error (±5% for vital sites and ±10% for routine areas). In contrast, incompatible sets exhibited significantly higher error rates.

Occlusion Pressure: The average pressure recorded during tubing occlusion testing was 950 millimeters of mercury, and all measurements consistently remained below or equal to the 1,000 millimeters of mercury threshold. In accordance with the specified requirements, the blood tubing sets accurately detect occlusions, as indicated by a measurement variance (max-min) of 51 millimeters of mercury.

Air-In-Line Detection: During the air bubble detection testing, we intentionally created air bubbles using a 100-microliter syringe. All machines consistently generated "Air in Line" alerts and stopped operations, confirming the high efficacy of this testing standard.

These findings provide a comprehensive evaluation of the compatibility and performance of OEM infusion sets with various infusion pumps. They highlight the importance of selecting appropriate sets to enhance patient care and safety, ensuring reliable and precise operation in clinical settings.

5. Discussion

During the assessment of tubing occlusion alarms across all five machines, we measured the pressure resulting from occlusion. The average pressure determined was 950 millimeters of mercury, with values consistently remaining at or below the 1,000 millimeters of mercury threshold (Department of Medical Sciences, National Institute of Metrology (Thailand) [2, 5–10]. This constant pressure value is critical because it ensures that the blood tubbing sets accurately identify blockages, thereby complying with stipulated safety requirements. The observed variation in recordings (±51 millimeters of mercury) further supports the reliability of these measurements.

Clinical Implications: These findings have significant clinical implications. Maintaining occlusion pressure within safe limits is essential for patient safety, as excessive pressure can lead to infusion pump malfunctions or patient harm. With error rates of 2.99% and 2.17% at 10 mL/hour, 3.35% and 3.16% at 100 mL/hour, and 5.57% and 5.78% at 300 mL/hour, our study confirms that compatible OEM

infusion sets (Brand 1 and Brand 2) were better than photodiode-infrared sensors. These low error rates suggest that compatible infusion sets provide more accurate and reliable intravenous infusions, reducing the risk of adverse events [5–10].

Patient safety and risk: Using incompatible or ineffective infusion sets can result in erroneous infusion rates, potentially leading to severe patient complications such as over-infusion or under-infusion of medication. These errors can cause adverse drug reactions, prolonged hospital stays, and increased healthcare costs. Our findings emphasize the importance of selecting appropriate infusion sets to enhance patient safety and optimize treatment outcomes. The accurate detection of occlusions and air-in-line alerts further underscores the critical role of reliable infusion systems in clinical practice [2, 5–10].

***The Study's Limitations*:** Despite the positive findings, this study has several limitations. Firstly, conducting the study in controlled settings may not fully replicate the complexities of real-world clinical environments. Secondly, we limited the sample size to five infusion pumps from three manufacturers, which may not accurately represent all available models. Additionally, we did not assess long-term wear and tear on the infusion sets, which could affect their performance over time.

Future Research Directions: Future research should focus on expanding the sample size and including a broader range of infusion pump models and manufacturers. We need long-term studies to assess the durability and reliability of infusion sets over extended periods. Moreover, investigating the impact of different clinical conditions, such as varying patient populations and infusion protocols, could provide more comprehensive insights into the performance of OEM infusion sets.

Methodological Improvements: To enhance the robustness of future studies, we suggest incorporating real-world clinical scenarios and diverse patient conditions. Furthermore, creating standardized protocols for long-term testing and including a wider range of error metrics could provide a more comprehensive understanding of infusion set performance.

6. Conclusion

We conducted this research to determine the accuracy and fundamental information needed to select blood tubing sets, specifically OEM infusion sets compatible with blood tubing machines. The study involved testing five machines from three distinct manufacturing companies, utilized across a network of four hospitals. The primary areas of focus were: 1) testing the flow rate of the blood solution with the METRON Lagu model Blood Tubing Analyzer; 2) detecting air bubbles in the tubing sets; 3) testing for occlusions in the tubing sets; and 4) calculating the error values for each brand of tubing set when tested with different brands of blood tubing machines.

These findings provide strong evidence for the compatibility and reliability of OEM infusion sets with various infusion pumps. By adhering to established protocols and maintaining accurate occlusion pressure, these infusion sets significantly contribute to patient safety. The study highlights the importance of selecting appropriate infusion sets to ensure precise and dependable intravenous infusions, ultimately improving patient outcomes and enhancing healthcare quality.

Based on the project's results discussion, the following enhancements and advancements should

be considered: (1) It is beneficial to extend the testing to a greater number of hospitals annually, including those in both the state and private sectors, to examine a variety of brands and models of medical devices. Additionally, (2) acquiring and testing new models of blood tubing sets released to the market by various companies on a regular basis can extend the test data and provide a continuous database for hospital networks. This will guarantee a safe and continued selection of blood tubing sets.

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***Institutional Review Board Statement*:** Conducted in accordance with the Declaration of Helsinki, this study was granted approval by the Institutional Review Board of Rangsit University (protocol code RSUERB2023-012, approval date: October 30, 2023).

***Author Contributions*:** The primary author undertook data collection, analysis, interpretation of findings, and manuscript composition. Both authors participated in study design and data collection. Manuscript sections were individually crafted and collectively revised. The final manuscript underwent thorough review and gained consensus among all authors.

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