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Original Research Article

Accuracy of Control of Infusion Pumps in the Post-Market: A Practical Approach Based on IEC 60601-2-24: 2012

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ABSTRACT

Background: Infusion pumps are critical medical devices widely used in clinical practice, particularly in intensive care units, where precise delivery of fluids and medications is essential for patient safety. Deviations in flow rate accuracy may lead to underinfusion or overinfusion, potentially compromising therapeutic outcomes. Post-market surveillance of infusion pump performance is therefore a key component of clinical engineering strategies, especially under real-use hospital conditions. **Objective:** This study aimed to evaluate the post-market flow rate accuracy of volumetric infusion pumps used at the University Hospital of the University of São Paulo (HU-USP), Brazil, in accordance with the requirements of the IEC 60601-2-24:2012 standard. **Material and Methods:** Three volumetric infusion pumps of the same model, allocated in the Pediatric Intensive Care Unit (PICU), were evaluated. Flow rate accuracy tests were conducted using a measurement system composed of an analytical balance and dedicated software developed for automated data acquisition and processing. The pumps were tested at a low flow rate of 1 $mL{\cdot}h^{-1}$ over 24 hours under ambient pressure conditions, and at a nominal flow rate of 25 $mL{\cdot}h^{-1}$ over 2 h under three conditions: ambient pressure, overpressure (+100 mmHg), and vacuum (−100 mmHg). The measured flow rates were compared with the accuracy limits specified by the manufacturer. **Results:** At the flow rate of 1 $mL{\cdot}h^{-1}$, two of the three infusion pumps did not comply with the manufacturer's specified accuracy limit (±5%), exhibiting underinfusion. At 25 $mL{\cdot}h^{-1}$, all evaluated pumps demonstrated deviations exceeding the expected tolerance, particularly when subjected to pressure variations. In addition, all devices exhibited a consistent delay of approximately 11 min in completing the 24 h infusion period, despite being newly acquired and previously unopened. These findings indicate performance deviations under post-market conditions that may not be identified through routine acceptance testing alone. **Conclusion:** The results highlight the importance of implementing systematic post-market performance evaluation of infusion pumps as part of clinical engineering management practices. Even newly acquired devices may present deviations that pose potential risks to patient safety, especially in pediatric intensive care environments. The study supports the expansion of this evaluation methodology to the entire infusion pump inventory of the University Hospital, currently comprising 221 devices, and to testing scenarios involving clinically relevant medications and operating conditions. Such an approach contributes to evidence-based decision-making in medical technology management and to the continuous improvement of healthcare quality and safety.

Keywords—*Infusion pump, Accuracy, Post-market, Clinical engineering.*

INTRODUCTION

Medication errors can occur throughout the medication use process, encompassing the phases of prescription, preparation, and administration.[1] Although evidence suggests that the use of infusion pumps can reduce errors in medication administration[2,3], these devices inherently exhibit measurement deviations that must be considered. The effective use of such medical equipment by healthcare professionals is therefore essential to ensure delivery of accurate medication[4]; moreover, regular verification, maintenance, and calibration are crucial to guarantee optimal device performance.[5]

Studies have demonstrated that errors in medication administration involving infusion pumps occur across different countries, with such events reported and associated with clinical impact in different scenarios, particularly in neonatology.[6] Variability in proportion of infusion during neonatal therapies poses a significant risk to patient safety, as it may lead to underinfusion or overinfusion and consequently compromise the newborn's fluid, hemodynamic, and metabolic balance.[7]

Low-risk patients can generally tolerate ±30% variability in infusion accuracy. However, in critical situations, such as in case of patients with heart failure, liver cirrhosis, or chronic kidney disease, both underinfusion and overinfusion therapy can compromise the patient. For example, post coronary artery bypass graft patients commonly receive sodium nitroprusside to manage arterial blood pressure. Hypertension associated with underinfusion places greater stress on graft sutures, increasing the risk of internal bleeding. Conversely, hypotension resulting from overinfusion may compromise cardiovascular stability.[8]

In Brazil, recent studies have examined reports of failures associated with the use of infusion pumps. The authors identified events primarily related to operational errors and misinterpretation of alarms.[9,10] Even though such investigations contribute to strengthening research on infusion pump safety in the country, it is important to emphasize that numerous issues are also related solely to the device itself, including lack of accuracy, software malfunctioning, and recurrent alarm failures.

In 2017, Bottaro et al. presented the findings of a study conducted between 2009 and 2015 across 38 hospitals in Brazil.[11] The investigation included accuracy testing of 245 infusion pumps and revealed the poorest performance indicators, with failure proportion exceeding 40%.[11]

Although the regulatory framework governing the pre-market phase of medical devices in Brazil is well established with emphasis on verifying compliance with basic safety and essential performance requirements[12], failures continue to be reported in the post-market context, when devices are already in active use in healthcare institutions.[13]

Data from Brazil's National Notification Health Surveillance System (NOTIVISA), the national health technology surveillance platform, indicate that more than 260,000 notifications related to health products were reported between December 2006 (from the time the platform was established) and October 2025.[14] Notifications refer to reports submitted to Brazilian Health Regulatory Agency (ANVISA) regarding issues associated with products and services subject to health surveillance.[13]

Despite the considerable number of formally registered notifications, it should not be interpreted as a complete representation of reality, as underreporting remains a systemic limitation acknowledged in the country.[15]

Within this context, the present study aimed to assess the flow rate accuracy of infusion pumps in clinical use at the University Hospital, based on the technical criteria prescribed by the International Electrotechnical Commission (IEC) 60601-2-24:2012 standard[16] as well as the uncertainty assessment[17] and acceptance criteria.[18]

By presenting the results and critical analysis of the performance tests, this study seeks to contribute to the strategic planning and decision-making processes of the clinical engineering sector, supporting evidence-based actions to improve safety, optimize maintenance practices, and enhance the quality of care delivered in the institution.

MATERIALS AND METHODS

Materials

To perform the experimental procedures, the infrastructure of the Biomedical Engineering Laboratory/ Laboratório de Engenharia Biomédica (LEB) was utilized. The laboratory is equipped with an analytical balance

(BP221S, Sartorius, Göttingen, Germany); needle 18G (Descarpack, Sao Paulo, Brazil); Becker (Laborglass, Sao Paulo, Brazil); vacuum gauge (63 mm, Wika, Klingenberg am Main, Germany); pressure gauge (IDP-2000, Connect JCO, Sao Paulo, Brazil); air compressor (Schulz S.A., Joinville, Brazil); vacuum pump (Schulz S.A.); environmental conditions meter (Davis Instruments, Hayward, CA, USA); and standard mass 100 g class E2 (Knwaagen, Sao Paulo, Brazil). All measurement instruments used complied with the specifications established by the IEC 60601-2-24:2012 standard and were duly calibrated and traceable to recognized metrological standards, ensuring the reliability and accuracy of the tests performed.

Method

The methodology adopted in this study was based on the technical standard IEC 60601-2-24:2012, which prescribes the criteria for evaluating the flow rate accuracy of infusion pumps. Specifically, the procedures were carried out under items 201.12.1.101 and 201.12.1.102 of the standard, entitled Accuracy of Controls and Instruments, and followed the test configuration illustrated in Figure 1.

All tests were performed using an infusion set and recommended height (h_1 in Figure 1) specified by the manufacturer to ensure compliance with operational declarations.

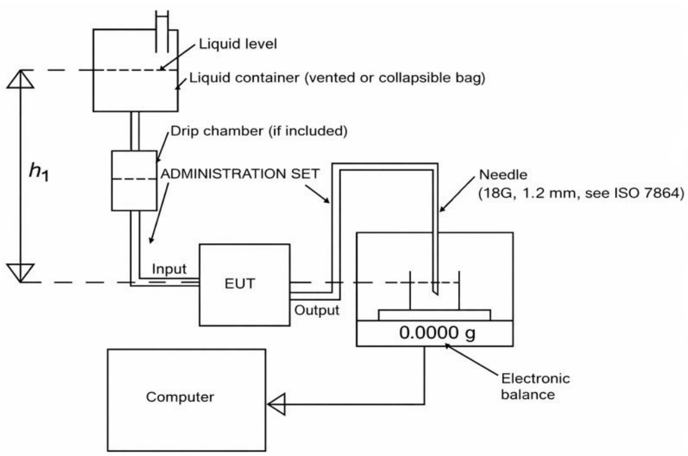

FIGURE 1. Test apparatus for volumetric infusion pumps. EUT: equipment under test.

Description

Three volumetric infusion pumps with linear peristaltic mechanisms, along with their respective dedicated infusion sets and water for medical use (test solution of ISO Class 3)[19], were supplied by the Pediatric Intensive Care Unit (PICU). All three devices under evaluation were of the same model, for which the manufacturer specified an overall mean percentage flow error of ±5% in technical documentation. For this study, the infusion pumps were anonymized and identified numerically as Infusion Pump 1, Infusion Pump 2, and Infusion Pump 3.

The experimental procedures were performed at the Biomedical Engineering Laboratory (LEB), which offered a controlled environment maintained at 23 °C ± 2 °C temperature and 65% ± 15% relative humidity (RH). The analytical balance was interfaced with a computer via RS232 communication for real-time data acquisition. The computer-operated custom software was developed in the graphical programming environment (LabVIEW, National Instruments, Austin, TX, USA), which guided the step-by-step execution of tests and performed automated data processing.

The infusion pumps were evaluated at two flow rates: 1 $mL \cdot h^{-1}$ for 24 h under ambient pressure, and 25 $mL \cdot h^{-1}$ for 2 h. At the 25 $mL \cdot h^{-1}$ flow rate, tests were initially performed under ambient pressure and subsequently repeated under controlled overpressure (+100 mmHg) and vacuum (−100 mmHg) conditions. To guarantee pressure application, an acrylic chamber of appropriate dimensions was built to enclose the analytical balance. Pressure conditions were actively monitored throughout the experiments using a pressure gauge and a vacuum gauge.

Before initiating the test, a layer of oil was carefully added to the water for medical use contained in a Becker placed on the analytical balance. This oil layer served to minimize evaporation during long-duration tests, thereby preserving the integrity and accuracy of the mass measurements over time. Furthermore, a preliminary study was conducted by the laboratory to quantify the mass loss of sodium chloride solution because of evaporation throughout the test, even with the protective oil layer in place. The measured mass loss was subsequently used to correct final measurements.

All formulas employed in this study were prescribed by the IEC 60601-2-24:2012 standard, which defines the technical criteria.

RESULTS

The results of the tests performed on the infusion pumps are presented in Table 1, which summarizes the overall mean percentage flow error corresponding to the trumpet curve analyses at time points T1 and T2, performed at 1 mL·h^{-1} for 24 h.

TABLE 1. Accuracy results based on trumpet curves at T1 and T2 for the flow rate of 1 mL·h^{-1}.

Medical Devices	T1	T2
Pump 1	−3.78%	3.46%
Pump 2	−11.36%	−1.64%
Pump 3	−8.75%	0.94%

Note: T1 is designated as the second hour of the test period, while T2 corresponds to the last hour.

Figure 2 shows T1 and T2 trumpet curves for Infusion Pump 1 operating at a flow rate of 1 mL·h^{-1}.

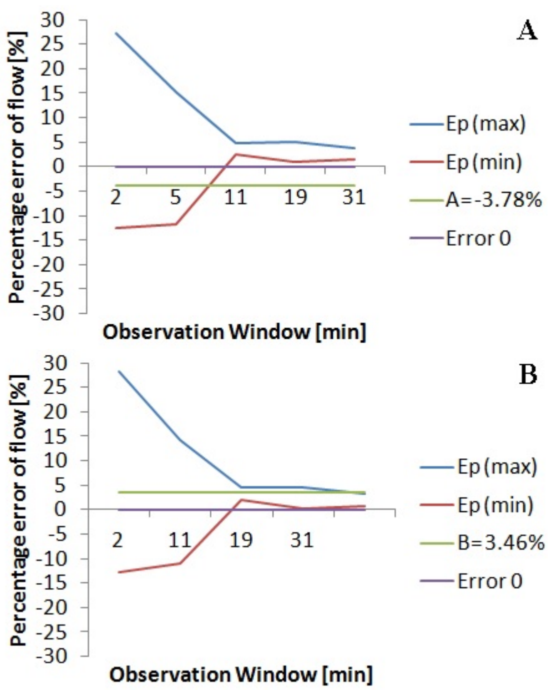

FIGURE 2. Trumpet curves of Infusion Pump 1 at a flow rate of 1 mL·h^{-1}.
Note: Ep(max): maximum measured error in observation window; Ep(min): minimum measured error in observation window; A: the overall mean percentage flow error measured over the analysis period T1; and B: the overall mean percentage flow error measured over the analysis period T2.

Table 2 shows the overall mean percentage flow error based on the T2 trumpet curve analysis for the infusion pumps operating at a flow rate of 25 mL·h^{-1} under ambient pressure as well as under overpressure and vacuum variations.

TABLE 2. Accuracy results based on trumpet curves at T2 for a flow rate of 25 mL·h^{-1}.

Medical Devices	Ambient pressure (T2)	Overpressure(T2)	Vacuum(T2)
Pump 1	−6.04%	−4.29%	−7.84%
Pump 2	−6.49%	−5.81%	−12.57%
Pump 3	−6.83%	−6.79%	−6.73%

Note: T2: the last hour of the test period.

Figure 3 shows the T2 trumpet curves of Infusion Pump 1 operating at a flow rate of 25 mL·h^{-1} under ambient pressure, overpressure (+100 mmHg), and vacuum conditions (−100 mmHg).

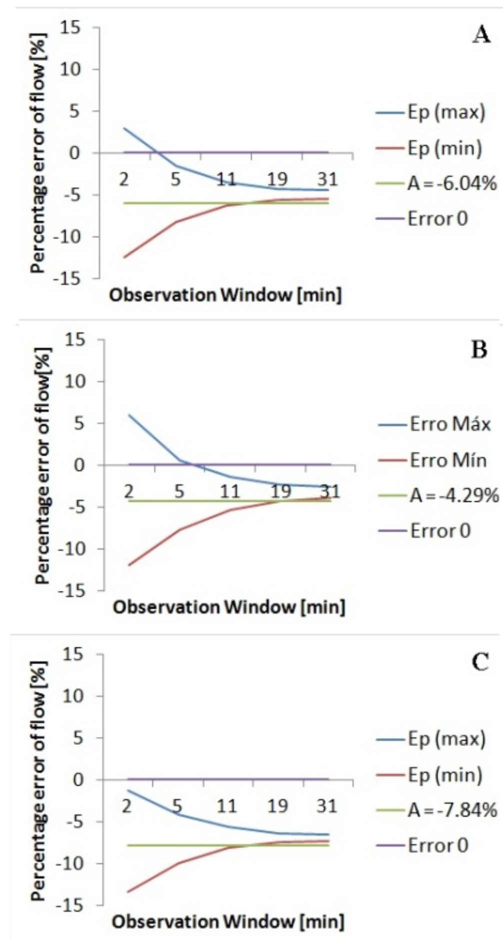

FIGURE 3. Trumpet curves of Infusion Pump 1 at 25 $mL\cdot h^{-1}$. (A) Refers to ambient pressure. (B) Corresponds to overpressure. (C) Corresponds to the vacuum condition. Notes. Ep(max): maximum measured error in observation window; Ep(min): minimum measured error in observation window; A: the overall mean percentage flow error measured over the analysis period T2.

DISCUSSION

The primary objective of this study was to assess the flow rate accuracy of infusion pumps currently in use at the University Hospital of University of São Paulo (HU-USP), Brazil, comparing their performance against the accuracy specifications declared by the manufacturer. The findings revealed that the tested equipments delivered infusion outside the acceptable tolerance limits. The infusion pumps consistently administered less than the programmed amount, and such deviations may result in underinfusion, potentially compromising the efficacy of clinical treatments.

Bottaro M et al.[11] did not disclose the involved manufacturers in their findings, as this information was anonymized, which precludes a direct comparison of specific devices. Despite this limitation, a broader comparison was established: post-market data indicate that numerous infusion pumps are currently displaying significant issues concerning infusion accuracy.

During the tests, it was observed that all three infusion pumps, when set to a flow rate of 1 $mL\cdot h^{-1}$ over 24 h, exhibited a uniform delay of 11 min in completing the programmed volume. Even with this extended duration, the total volume infused remained below the intended target. As shown in Table 1, infusion pumps 2 and 3 failed the T1 test. Furthermore, according to the data presented in Table 2, these same pumps failed under all tested conditions at a flow rate of 25 $mL\cdot h^{-1}$. In contrast, Infusion Pump 1 met the accuracy criteria in both T1 and T2 evaluations at 1 $mL\cdot h^{-1}$, and in the T2 test at 25 $mL\cdot h^{-1}$ under overpressure conditions.

Infusion Pump 1, at a flow rate of 1 $mL\cdot h^{-1}$, exhibited an overall mean percentage flow error within the tolerance limits specified by the manufacturer. However, a detailed analysis of the trumpet curves, as shown in Figure 2, reveals significant amplitude variability in flow, which may compromise its suitability for use in newborn patients, where high accuracy and stability are critical for safe and effective therapy.

Unfortunately, LEB is not authorized to conduct technical investigations aimed at determining the root causes of the device issues. The infusion pumps used at HU-USP were obtained through a leasing contract. According to this method, while the manufacturer supplies the devices, the hospital is responsible for purchasing infusion sets, maintenance, and calibration directly from the manufacturer.

Although many infusion pumps operate across a wide range of flow rates, for example, from 0.1 $mL\cdot h^{-1}$ to 999 $mL\cdot h^{-1}$, the tests conducted in this study did not encompass the device's full operating range; however, they provide an important indicator of its performance quality. The study is still in progress and follows a three-stage timeline, advancing from standardized accuracy tests prescribed by IEC 60601-2-24 to evaluations at clinically used flow rates and, ultimately, to simulations of real PICU conditions using medications of varying viscosities.

The results obtained highlight the importance of implementing systematic and standardized performance verification protocols as part of routine clinical engineering practice. Additionally, it is important to emphasize the need for continuous monitoring and quality assurance, even for new devices that are unused and sealed in original packaging. The underperformance of brand-new pumps underscores the critical role of post-market evaluations before clinical deployment.

CONCLUSION

The study supports the proposed objective and reinforces the relevance of structured accuracy evaluation for infusion pumps in clinical scenarios. The consistent deviations observed, particularly in devices that had not yet been placed into clinical service, demonstrate the importance of testing protocols that go beyond the minimum regulatory requirements.

This work, however, is part of an ongoing initiative. The initiative will be expanded to include the entire inventory of infusion pumps in the hospital, which currently comprises 221 devices. Future assessments are not limited to flow rates and fluid prescribed by the IEC 60601-2-24:2012 but incorporate input from clinical teams regarding commonly used medications and clinically relevant infusion profiles, thereby ensuring that testing protocols are aligned with real-world usage and institutional needs.

SUPPLEMENTARY MATERIALS

Not applicable.

AUTHOR CONTRIBUTIONS

Conceptualization, D.R., E.S. and H.M.; Methodology, D.R., E.S., and H.M.; Formal analysis, D.R.; Investigation, D.R., D.N, and P.Z.; Data curation, D.R.; Writing original draft, D.R. and E.S.; Writing, review and editing, D.R., E.S., M.N. and H.M.; Visualization, D.R.; Supervision, H.M.

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DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICTS OF INTEREST

The authors declare that they have no conflict of interest.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Part of the findings reported in this manuscript was previously presented at the Third Latin American Seminar on Clinical Engineering, held on May 20–21, 2025, São Paulo, Brazil.

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