

## Pump up the Volume Fluid Delivery Performance Testing Under Increased Scrutiny as Infusion Pump Market Expands

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## Introduction

Infusion pumps, a common fixture at the bedside in patient care, are essential for administering life-sustaining medications in precise doses. These devices encompass a wide range, from insulin pumps to patient-controlled analgesia and on-body self-medication systems. Given their critical role, the margin for error is incredibly slim. Even a slight discrepancy in the prescribed flow rate can lead to severe outcomes, such as hypoglycemia in diabetics.

Pump manufacturers go to great lengths to avoid harm to patients as a result of incorrect dosing. A key aspect of this is post-market surveillance, which helps to identify defects, leading to voluntary or FDA-mandated recalls. In such events, the repercussions can be significant. Impacted companies may face increased scrutiny by regulatory bodies, including more testing and audits, along with heavy logistical costs and negative publicity.

Consequently, the accuracy of fluid delivery performance testing for medical pumps is an indispensable aspect of their development and maintenance. As advanced pumps gain popularity, they are subject to even greater scrutiny. This trend is fueled by the need for precision in administering highly concentrated drugs, such as monoclonal antibodies, gene therapies, and advanced cancer treatments, which require pump doses measured in microliters, and even nanoliters, per hour. The higher accuracy is also vital for devices intended for at-home self-medication.

This article will provide an overview of the testing process for medical infusion pumps, including flow rate testing, and spotlight key lab weighing innovations that are helping manufacturers meet the demands of a stringent regulatory environment





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Medical pump manufacturers navigate a rigorous testing process that spans the entire lifecycle of the product. From the initial stages of product development and design verification to ongoing quality control and post-market failure investigations, each phase is subject to meticulous regulatory inspection.

The regulatory landscape governing infusion pumps varies by region. For example, in the US, the Food and Drug Association (FDA) enforces rigorous safety and performance standards, while the Medical Device Regulation (MDR) dictates compliance eligibility in the EU. Supplementing these regional regulations are global standards set by organizations like the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), which cover manufacturing and electrical safety of medical devices. Additionally, pharmacopeias, such as the Uniform Standards of Professional Appraisal Practice (USPAP), contribute further to these standards.

Medical pumps undergo a series of comprehensive tests to ensure their accuracy and reliability. These include:

- **Accuracy Tests:** Pumps are evaluated for their ability to deliver fluids at precise flow rates under varying conditions, ensuring patients receive the correct medication dosage.
- **Reliability Tests:** Devices are tested under extreme conditions to guarantee consistent performance, even in challenging medical environments.
- **Safety Evaluations:** Pumps are checked for potential hazards, including electrical shocks and mechanical stress, while key safety features like occlusion detection are rigorously tested.

Using the right tools is crucial, as it allows for accurate measurement of the pumps' functionality, directly impacting patient safety and compliance with stringent healthcare standards.



### The Challenges of Flow Rate Testing

Flow rate testing provides a thorough assessment, verifying that an infusion pump can deliver fluids at the rates prescribed by a healthcare practitioner. It covers a range of tests to verify the pump's performance across its entire operational spectrum, including different flow rates, pressures, and delivery modes. Dynamic weighing plays a crucial role in this process, offering real-time measurement of the fluid dispensed.

Two critical parameters that fall under this category are Bolus Dose and Basal Flow Rate assessments:

- **Bolus Dose:** A bolus dose is a rapid, single-shot medication delivery by an infusion pump, differing from continuous infusions. Testing ensures the pump correctly administers these quick, large doses, critical for immediate-response scenarios like pain management or insulin delivery.
- **Basal Flow Rate:** This assesses the pump's ability to deliver medication consistently over a long period at a set rate, crucial for maintaining steady medication levels in treatments like insulin therapy for diabetes or continuous pain management.

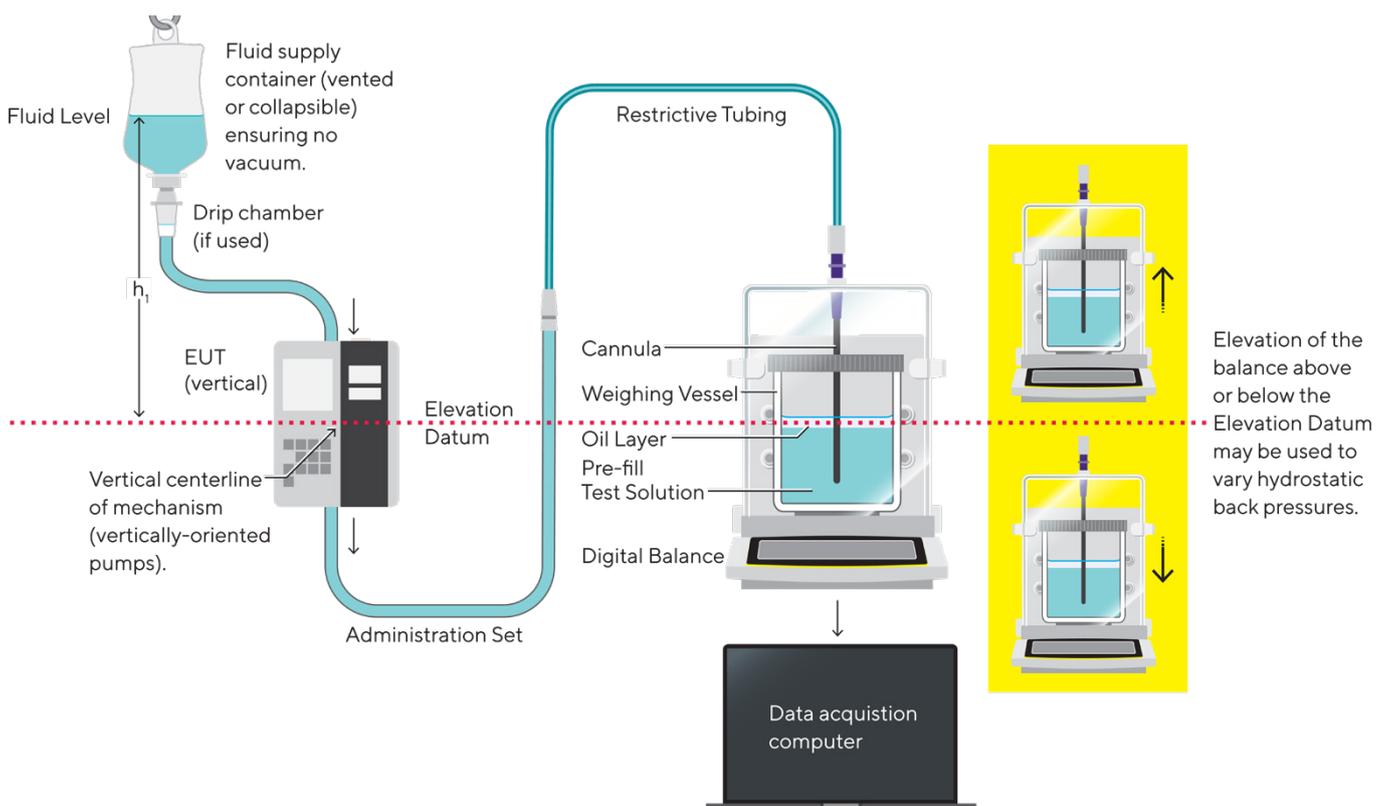
A laboratory balance is primarily used for testing the pump bolus dose or basal flow rate. The main worry with these measurements is over- or under-estimation of the dose. This can happen for a few different reasons.

Environmental instability, such as fluctuating temperature, humidity, and pressure, can affect weighing data accuracy. While the laboratory environment can be difficult to control, some lab weighing technologies are able to adapt to these influences. Additionally, issues like needle skimming, where the needle does not maintain consistent contact with the liquid, can lead to inaccurate data. Other effects, such as continuous evaporation and electrostatic charges, especially in inadequately shielded or coated equipment, can also skew the results.

### Advanced Weighing Technologies Deliver Accuracy

For precise testing of infusion and syringe pumps, selecting the right lab balance is critical, particularly to comply with standards and technical reports such as IEC 60601-2-24 and AAMI TIR 101:2021, which provide testing guidelines. There are five essential parameters to consider in a lab balance:

- **Readability:** This measures the smallest weight difference a balance can detect, crucial for precision. Readability ranges from 1 mg in Precision Balances to 0.001 mg in Micro Balances. The TIR 101 provides guidance on selecting resolution values based on flow rates for optimal precision.
- **Capacity:** This refers to the maximum weight a balance can accurately measure. For infusion and syringe pump testing, a balance with a high capacity allows high quality readings over longer, uninterrupted testing periods.
- **Linearity Deviation:** This indicates the balance's ability to maintain accuracy across various weight values. As volume increases during testing, maintaining linearity is vital for accuracy throughout the entire volume | delivery | weighing range.
- **Drift:** This is a fluctuation in weight readings not due to actual weight changes. It can be reduced by using a monolithic weighing system, a single-block aluminum design that provides better stability and less drift than traditional multi-component systems.
- **Data Integrity:** This indicated compliance with 21 CFR Part 11 and EU Annex 11, which guarantees tamper-proof, timestamped electronic records.



## Supporting Manufacturers with Expertise and Innovation

Sartorius supports medical device manufacturers with advanced weighing instruments and expertise. The Cubis® II series is an industry-recognized name in quality control applications, known for its premium balances that meet the demands of modern, regulated environments with exceptional performance, compliance support, and flexible connectivity.

When it comes to dosing accuracy verification, Cubis® II balances are engineered to address some of the common challenges discussed previously. They offer high readability, ample capacity, and minimal weighing drift, as the key drivers of reliable weighing performance. Full compliance with 21 CFR Part 11 and EU Annex 11 further supports manufacturers' needs around data quality.

## Weigh Up The Performance of Medical Infusion Devices



> 1000 mL/h	10 mL/h to 1000 mL/h	0.1 mL/h to 10 mL/h	<0.1 mL/h
<ul style="list-style-type: none"><li>■ Precision Balance</li><li>■ Resolution 1/10 mg</li><li>■ Capacity 5200/14200 g</li></ul>	<ul style="list-style-type: none"><li>■ Analytical Balance</li><li>■ Resolution 0.1 mg</li><li>■ Capacity 520 g</li></ul>	<ul style="list-style-type: none"><li>■ Semi-micro Balance</li><li>■ Resolution 0.01 mg</li><li>■ Capacity 220 g</li></ul>	<ul style="list-style-type: none"><li>■ High-Capacity Micro Balance</li><li>■ Resolution 0.001 mg</li><li>■ Capacity 61 g</li></ul>

In addition to these important features, here are a few more differentiators that make this brand suitable for dose verification testing:

- **Environmental Adaptability:** The monolithic weighing system guarantees minimal weighing drift. Additionally, an integrated ionizer effectively neutralizes electrostatic charges, while a coated draft shield further enhances the accuracy of dose estimation.
- **Reimagined Cleanability:** A combination of smart design and software-guided with guided protocols simplify routine cleanings, essential for managing accidental sample spillage.
- **Real-Lab Performance:** Testing data demonstrate full alignment between in-lab performance and the specification sheet, ensuring dependable results at the customer site.

## Conclusion

The future of drug delivery systems points toward customization, patient-centric approaches, higher concentration micro-dosing, new biotherapeutics, and the integration of digital technologies such as AI and machine learning. These trends underscore the growing need for precision in drug delivery and the importance of advanced testing and measurement solutions. Advanced weighing technologies play a pivotal role in equipping manufacturers with essential data that proves their product is safe for patients.

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