



Automatic Double Check Monitoring of Continuous Fluid Excretion and Urine Output

Nicolas Goy¹, Philippe Beuret², Alexandre Despond³, Reza Porouchani⁴ and Jean-Jacques Goy^{*5}

Abstract

Introduction: In modern clinical settings, vital signs are typically monitored electronically, except for urine output, which still relies on manual recording. This manual process is prone to human errors. In this study, we assessed, in vitro, the ability of a novel electronic device to measure real-time flow output, such as urine output, using a combination of two different methods.

Methods: Urine output was measured using a combination of gravimetry, with a dynamometer, and capacitive sensing to improve precision. Data were collected in three different flow settings: low (<20 ml/hour), medium (20 to 150 ml/hour), and high (>150 ml/hour). Additionally, two different situations were tested: with the dead space and Pasteur's chamber either full or empty.

Results: The differences between the injected and measured volumes varied between 2 to 3 ml for the low flow setting, 0 to 2 ml for the medium flow setting, and 0 to 5 ml for the high flow setting. This corresponds to a maximal error of 3%, regardless of the injected volume and flow rate in ml/hour. The capacitive sensors exhibited the expected behavior, producing a parallel curve representing the expected and measured flow.

Conclusion: Our findings demonstrate that accurate measurements of volume and flow output can be achieved by combining gravimetry and capacitive sensor. To confirm the device's usefulness in measuring urine output in real-life clinical settings, clinical trials are necessary.

Keywords: Urine output, Gravimetry, Capacitive sensors, Urine outflow measurement

Introduction

In physiologic studies and clinical situations, measuring fluid flow is critically important. Nowadays, most physiological parameters of patients in intensive care units (ICUs) are electronically monitored using highly sophisticated devices (1). These devices not only measure and display parameters but also compare them against pre-established normal values, alerting medical staff if values deviate from acceptable ranges. This automatic determination reduces workload and human error. One of the most relevant physiological parameters, urine output, is still primarily measured manually. Recent advancements have seen the development of electronic devices that measure urine output with high accuracy and precision in clinical settings (2-6).

These devices minimize interobserver variability, suggesting better

Affiliation:

¹Goyman engineering SA, Yvorne, Switzerland.

²Clinique la Prairie ; Montreux, Switzerland.

³Argamat Company, Payerne, Switzerland.

⁴Vector gestion CIE, Lausanne, Switzerland, Payerne, Switzerland.

⁵Clinique Cecil, University Hospital, Fribourg, Switzerland

*Corresponding author:

Jean-Jacques Goy, Clinique Cecil, Av. Ruchonnet 53, 1007 Lausanne, Switzerland.

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management of ICU patients and improved outcomes when urine output is electronically monitored. By reducing errors and omissions, these devices also save nursing staff time. Several different devices are available today, employing various measurement methods such as gravimetry (7), capacitance-based urimeters (8), custom-designed sensors using proprietary thermal transfer algorithms (2), and low-cost, specially designed devices (9). While precise, these devices often have disadvantages that complicate their use in clinical settings. We have designed a new device that aims to resemble existing urinary bags and be as user-friendly as possible. Our methodology employs a combination of gravimetry and capacitive analysis to measure both the total volume of liquid and the hourly rate of liquid excretion. This prototype is dedicated to improving urine output measurement.

Methods

Device

The experimental device, the Diuricheck (Diuriflux system, Noville, Switzerland), is designed to measure total volume and hourly flow of urine output (Figures 1 and 2). This device integrates both dynamometric and capacitive sensing technologies to ensure accurate and reliable measurements.

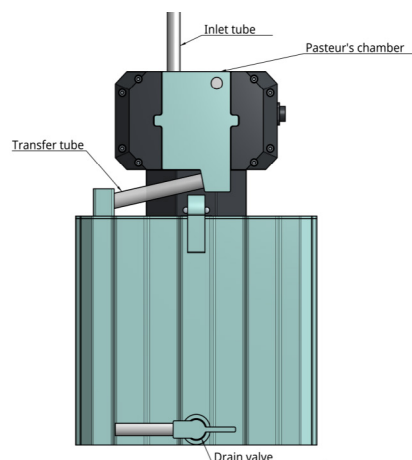


Figure 1: This figure shows the device from its back.

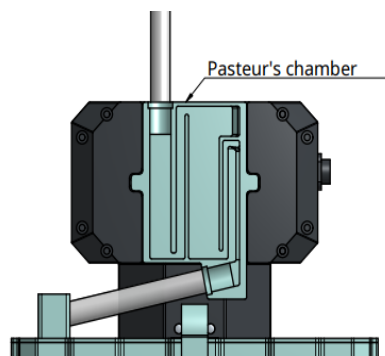


Figure 2: Details of the Pasteur's chamber.

Dynamometric System

The urimeter weighs the urinary bag at regular intervals using a dynamometer. The core of the device is a strain gauge load cell, which converts force into an electrical output signal proportional to the applied force. This technique, detailed previously by Keil et al. (2017), utilizes the Flintec Tension Load Cell Type UXT-50kg-C3 (Flintec Inc., Hudson, MA, USA), known for its high accuracy based on the modified Wheatstone bridge (10) (Figure 3). To ensure accurate measurements, accelerometers are mounted on both sides of the dynamometer to detect and compensate for vibrations and tilt. This setup mitigates the impact of external factors, such as a chair leaning on the bag.

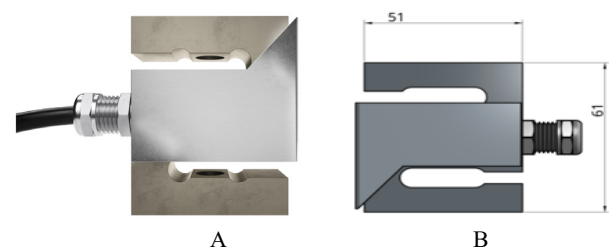


Figure 3: Details of the used dynamometer in A. Dimensions of the system in B in millimeter.

Capacitive Sensing System

Capacitive sensing technology is employed to control and verify the values provided by the dynamometer (Figure 4 and 5). This technology is based on coupling, which detects and measures anything conductive or with a dielectric constant different from air. The device uses 28-bit capacitive-to-digital converters and level-sensing techniques, enabling high-performance capacitive sensing of liquid levels (12). The capacitive sensors serve as a control mechanism to ensure the accuracy of the dynamometric values. The curves obtained from the capacitive sensors must align with those from the dynamometric measures. Any discrepancies or interruptions in flow are detected by the capacitive sensors and reported on the screen. This dual approach enhances the reliability of the measurements, providing a double-check system for the values recorded by the dynamometer.

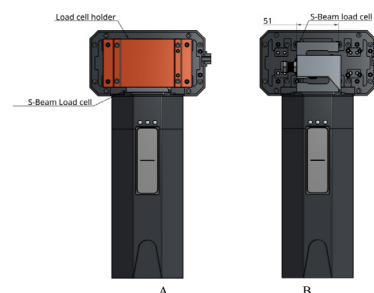


Figure 4: Details of the electronics located behind the Pasteur's chamber. Device (orange color) that ensures the rigidity of the system in A. Dynamometer in its final position in B after removing the orange device in B.

Pasteur Drip Chamber

The dry Pasteur drip chamber is equipped with an anti-reflux tube system to prevent retrograde migration of bacteria and venting air inlet filters for pressure balance. The chamber consists of multiple sub-chambers that fill up based on liquid pressure, which is proportional to flow. This configuration allows for early detection of flow variations, such as catheter disconnection. Two capacitive sensors are incorporated within the Pasteur drip chamber. The first sensor detects the presence of liquid when the patient is connected to the system. The second sensor measures the height of the liquid within a sub-chamber that contains an auto-siphon system. The fill/empty cycle of this sub-chamber is indicative of the flow rate.

Data Transmission and Monitoring:

The device employs a wireless connection to transmit data to a central monitoring system. The measurements of volume and flow per minute are displayed on a screen for continuous monitoring. Additionally, capacitive sensors behind the Pasteur drip chamber and behind the urine bag are used to check the correct mounting of the chamber and the bag, providing an added layer of reliability.

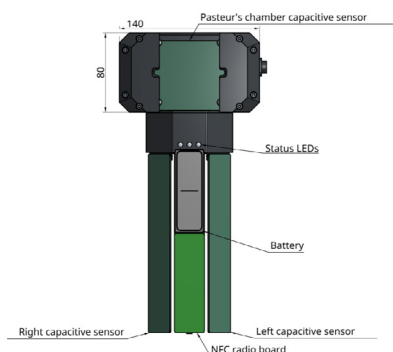


Figure 5: Section showing the location of the capacitive sensors behind the urinary bag.

Advantages: The combination of capacitive sensing and dynamometric measures offers significant advantages, including enhanced accuracy and a robust verification system. The wireless data transmission facilitates seamless integration into existing central monitoring systems, reducing workload and minimizing human error. The operating flow chart of the system is illustrated in Figure 6, detailing the integration and operation of these components within the Diuriflux 2023.

Experimental set-up

The experimental setup is depicted in Figure 7. The configuration is designed to simulate clinical conditions for urine measurement. Here's a detailed description of the setup. A funnel is positioned above the measuring device to act as a bladder. This simulates the natural flow of urine from a patient's bladder. The distal tip of the urinary catheter, with

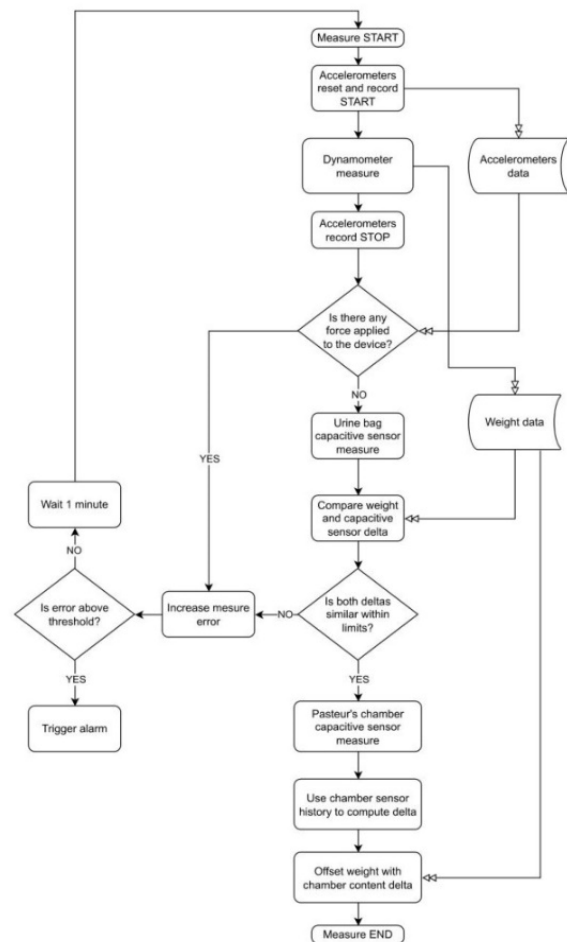


Figure 6: Operating flow chart of the system.

the balloon inflated, is placed in the funnel. This setup mimics the bladder-catheter interface commonly seen in patients. The catheter is connected to drainage tubing similar to what is used clinically. This tubing runs through the measuring system, ensuring that the experimental conditions closely resemble those in a clinical setting. The drainage tubing passes through the measuring device, which includes both the dynamometer and capacitive sensing systems. This setup allows continuous monitoring and measurement of urine output. The tubing connects to a rigid urinary bag, which serves as the collection reservoir. This bag is positioned below the Pasteur's chamber, ensuring a continuous column of fluid from the funnel (bladder simulator) to the collection reservoir. Positioned at the entrance of the rigid bag, the Pasteur's chamber plays a critical role in early flow detection and pressure regulation. The chamber helps maintain a continuous flow of fluid and provides early detection of flow variations. This setup ensures that urine output can be accurately measured and monitored, simulating real clinical conditions. The combination of a funnel, urinary catheter, drainage tubing, measuring system, and rigid urinary bag provides a comprehensive system to evaluate the performance of the experimental device under controlled experimental conditions.

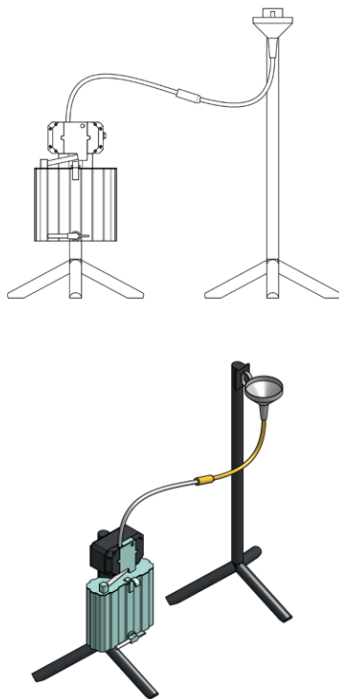


Figure 7: Experimental set-up showing the funnel functioning like a bladder, connected to the inlet of the device at the top of the Pasteur's chamber. Set-up assembly diagram in A and photograph in B.

Data acquisition:

The weight of saline is detected in the urinary bag. This represents the volume of saline injected in the system minus the volume remaining in the tubing, called dead space and that of the Pasteur's room. It should be noted that the curves of capacitive sensors do not give the volume of liquid. They indicate the kinetics of the flow and ensure that there have been no external events disturbing the measurement. These curves should parallel to the curve of flow and weight.

In-vitro testing:

The experimental setup described above was subjected to rigorous in-vitro testing to assess the performance and accuracy of the Diuriflux 2023 system under various conditions.

Flow Rates: Low Flow: Less than 20 ml/hour, Medium Flow: Between 20 to 150 ml/hour, High Flow: Over 150 ml/hour

Volumes: The system was tested with a wide range of total volumes, from as low as 67 ml to as high as 920 ml.

Dead Space Consideration: The dead space, which includes the volume of liquid remaining in the tubing and the Pasteur's chamber, was a critical factor in the testing. Two distinct scenarios were tested:

1. With Emptying of Dead Space and Pasteur's Chamber: This scenario ensured that all liquid, including

what was in the dead space, was accounted for in the weight measurements.

2. Without Emptying of Dead Space: This scenario left the liquid in the dead space, simulating a condition where not all liquid is transferred to the urinary bag.

Measurement Parameters:

- **Weight Measurement:** The weight of the saline in the urinary bag was continuously measured. This weight represented the total volume of saline injected into the system minus the volume remaining in the dead space.
- **Capacitive Sensors:** These sensors did not measure the volume directly but provided information on the kinetics of the flow. The curves generated by these sensors were expected to parallel the flow and weight curves, indicating no external disturbances.

Results Interpretation.

- The weight measurements gave a direct correlation to the volume of saline injected into the system.
- The capacitive sensor curves served as a validation tool to ensure the accuracy of the weight measurements by detecting any anomalies or disturbances in the flow.
- For each flow rate and volume scenario, the measurements from both the dynamometer and capacitive sensors were compared. The alignment of the capacitive sensor curves with the weight and flow curves indicated successful measurement without external disturbances.

This comprehensive in-vitro testing verified that the system could accurately measure urine output under varying conditions, ensuring reliability and precision in clinical settings.

Results

The data are summarized in Table 1 and in Figures 8 to 10.

Low flow results:

In the low flow setting, the system was tested with flow rates of 16 and 18 ml/hour and total volumes of 67 and 296 ml. The precision of the device was calculated as the difference between the injected and measured volumes. For the 16 ml/hour setup, the difference was 1% and for the 18 ml/hour setup, the difference was 3%. A specific observation is presented in figure 8. The device measured a flow rate of 17 ml/hour. The total injected volume was 67 ml, and the total measured volume 65 ml (differences: 2 ml (3%)). At the beginning of the perfusion, the Pasteur's chamber was full. The superimposition of the displayed and measured curves was almost perfect. The capacitive curve (violet curve) followed the measured and displayed curves closely. This

Table 1: this table report the values measured in the 3 different situations tested low flow < 20 ml/hour, medium flow > 20 ml /hour and < 150 ml/hour and high flow > 150 ml/hour.

Test number	Injected volume (ml)	Value displayed on the screen	Volume in the urinary bag	Volume in the dead space + Pasteur's chamber	Difference between real and measured values
Low flow (16 ml/hour)	296	299	209	90	3 (1%)
Low flow (18 ml/hour)	67	65	65	0	2 (3%)
Medium flow (108 ml/hour)	300	300	260	40	0
Medium flow (128 ml/hour)	665	663	633	30	2 (1%)
Medium flow (45 ml/hour)	438	438	438	0	0
High flow (2700 ml/hour)	225	225	220	5	5 (2%)
High flow (1834 ml/hour)	214	214	211	3	3 (1.5%)
High flow (1215 ml/hour)	405	403	353	50	2 (1%)
High flow (1971 ml/hour)	920	923	923	0	0

curve is situated both under and over the other curves because it is normalized between 0 and 1, as shown on the secondary Y-axis on the right. The weight of the saline in the urinary bag was continuously measured, representing the total volume of saline injected into the system minus the volume remaining in the dead space. These capacitive sensors did not measure the volume directly but provided information on the kinetics of the flow. The curves generated by these sensors were expected to parallel the flow and weight curves, indicating no external disturbances. The weight measurements provided a direct correlation to the volume of saline injected into the system. The capacitive sensor curves served as validation figures to ensure the accuracy of the weight measurements by detecting any anomalies or disturbances in the flow. The alignment of the capacitive sensor curves with the weight and flow curves indicated successful measurement without external disturbances

Medium flow results:

In the medium flow setting the system was evaluated with flow rates ranging from 45 and 128 ml/hour and total injected volumes between 300 and 665 ml. The precision of the system was calculated based on the difference between the injected and measured volumes and ranges from 0 and 2 %. These results are presented in Figure 9. Initially, the measured curve did not align perfectly with the displayed curve due to the presence of dead space and an empty Pasteur's chamber. Once the dead space and Pasteur's chamber were filled, the measured and displayed curves became strictly parallel. After accounting for the volume of the dead space and the Pasteur's chamber, the total measured volume equaled the total injected volume. The capacitive curve (violet) accurately followed the measured and displayed curves. The curve was normalized between 0 and 1, and it fluctuated above and below the other curves, as shown on the secondary Y-axis on the right (Figure 9). The initial discrepancy between the measured and

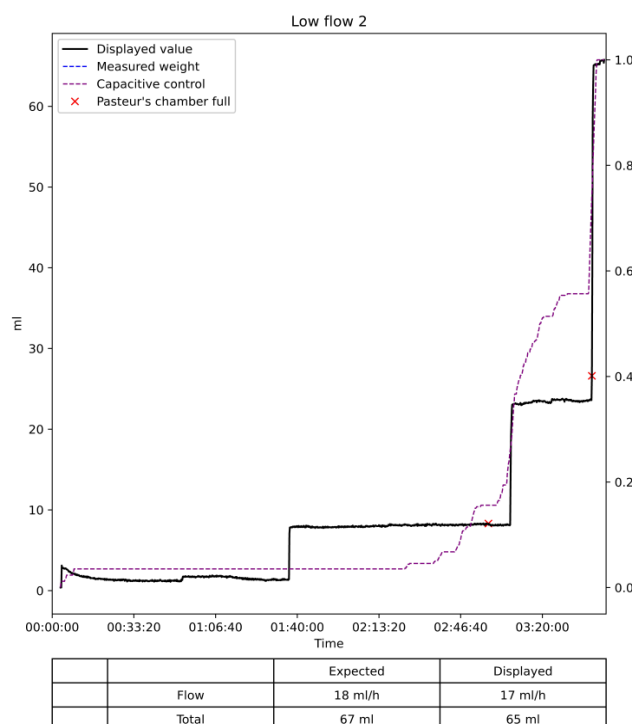


Figure 8: This figure shows the low situation with a flow of 18 ml/hour of injected saline.

displayed curves was attributed to the unfilled dead space and Pasteur's chamber. Once these spaces were accounted for, the curves aligned closely, demonstrating the system's accuracy. The capacitive sensors provided additional validation by ensuring that the flow measurements remained consistent and identifying any anomalies.

High flow results:

In the high flow setting, the system was evaluated with flow rates ranging from 1215 to 2700 ml/hour and total

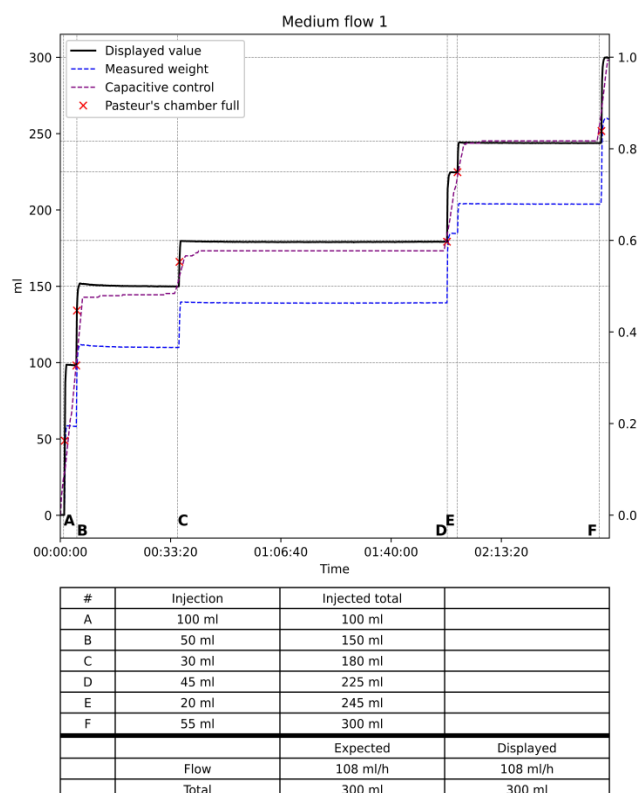


Figure 9: Medium flow measurement at 108 ml/hour.

injected volumes between 225 and 920 ml. The precision of the system was assessed based on the difference between the injected and measured volumes. For this setting, the precision was high, with differences ranging from 1% to 2%. At the start of the measurements, both the dead space and the Pasteur's chamber were filled. The results demonstrated a perfect correlation between the expected and measured curves with a minimal difference of 3 ml (1.5%). The capacitive curve (violet) accurately followed the measured and displayed curves, and was normalized between 0 and 1, fluctuating above and below the other curves, as shown on the secondary Y-axis on the right (Figure 10). The high flow rate did not influence the measurement accuracy. The device maintained high precision across varying flow rates. Both scenarios (empty or full dead space and Pasteur's chamber) did not affect the measurements significantly. When starting tests with a full dead space and Pasteur's chamber, the expected and displayed curves were almost superimposed with differences less than 5 ml. When starting with an empty dead space and an empty Pasteur's chamber, these spaces needed to be filled before measurements began. Once filled, the curves became perfectly parallel. The capacitive sensor located behind the Pasteur's chamber detects the presence of liquid in the tubing connected to the patient. When triggered, it indicates that liquid is present in the Pasteur's chamber. The dynamometer's initial weight measurement signifies that liquid has reached the container. An offset is added to the

displayed value to account for the volume of the tube and Pasteur's chamber. The time between liquid detection in the Pasteur's chamber and the container provides an initial flow indication, which is checked against the flow after a few seconds to ensure correct operation. The capacitive sensors' curves followed the dynamometer's curves closely. For very low flow rates, the capacitive curves remained flat until Pasteur's chamber was filled. These curves then remained parallel to the expected and displayed curves.

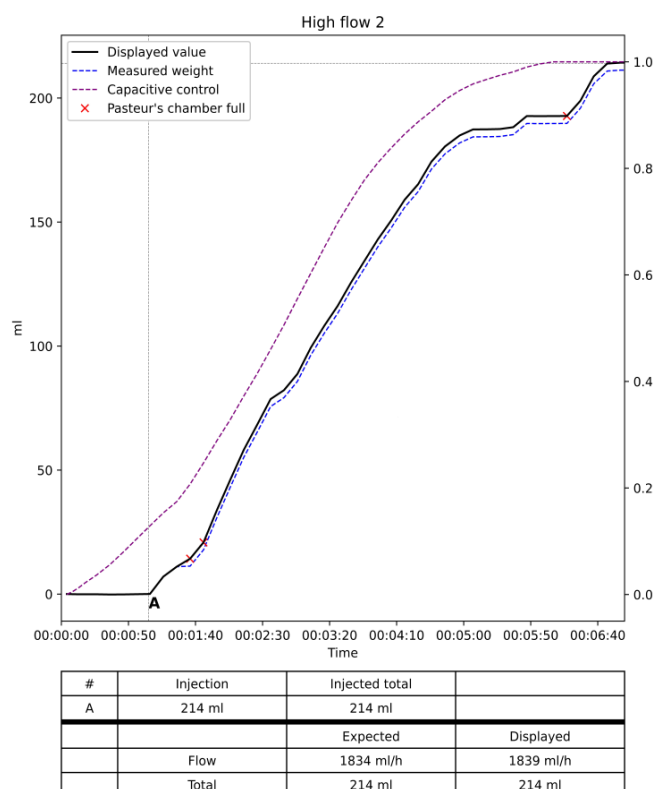


Figure 10: High flow measurement with a full dead space and Pasteur's chamber at the beginning of the measures.

Comparison of common existing method of flow measurement:

There are over ten different urinometers currently available, each employing various principles such as weight measurement, flow detection, photoelectric detection, infrared barriers, or capacitive measurement (13). Despite the diversity in sensor technologies, none of these models has fully met all the criteria for clinical use, and many have been discontinued (7-9,13,15,16). Gravimetry is known for its precision in measuring urine output. However, it is susceptible to external factors such as bed height changes and external contact, which can alter measurements significantly. These challenges include susceptibility to environmental changes and movements that can impact measurement accuracy. Recent work (17) supports the accuracy of gravimetric devices, with errors reported to be less than 5%.

Nonetheless, real-life testing is necessary to fully understand these limitations. Capacitive sensors are used to measure liquid height since a very long time (18,19). However, it but can drift over time and may not be as accurate as gravimetry (7,16). Capacitive measurements can also suffer from saturation issues when used in systems with high flow rates. Thermal transfer methods, which measure flow based on temperature gradients, offer another approach but come with disadvantages, such as being disposable and higher costs per patient (4).

Advantages of Combined Measurement Approaches:

Our device integrates gravimetry with capacitive sensing to capitalize on the high accuracy of gravimetric measurements while using capacitive sensors to detect anomalies and disturbances such as vibrations or obstructions. Our system achieves an error margin of approximately 3%, which is competitive with other devices. For instance, (9) report an error margin of less than 2%, while the Sippi system (20) shows error margins around 5%, and some systems using infrared barriers accept errors of up to 15%. The current array of urinometers demonstrates the difficulty in finding a device that balances precision, simplicity, and ease of use in clinical settings. Many existing devices either do not meet precision standards or are not practical for daily use by nursing staff. By merging gravimetric and capacitive measurement technologies, our device addresses the limitations of each individual method. Gravimetry provides high accuracy, while capacitive sensing helps in detecting and compensating for potential disruptions. Our goal was to create a device that is not only accurate but also user-friendly for nursing staff. The combination of these technologies aims to enhance reliability and facilitate integration into routine clinical practice.

Discussion

In intensive care units (ICUs), the precision and reliability of physiological measurements are critical for patient management. Studies indicate that automated urine output measurement is superior to manual methods, offering better correlation and reducing the risk of missing oliguria, which can lead to severe complications such as acute kidney injury and increased mortality (2, 28,21,22). Automated systems are designed to provide continuous, real-time data, significantly improving the accuracy of urine output monitoring and allowing for timely interventions. For example the RenalSense Clarity RMS Sensor Kit utilizes thermal sensors to measure urine flow based on thermal transfer principles (2). It provides accurate flow measurements by detecting temperature changes in the urine but has a high cost, which limits its widespread adoption in clinical settings. This high price point may contribute to its limited use in routine practice. Other devices like the Accuryn Monitoring System (25), (26) or the Sensica Urine Output System (17) are other commercially available continuous urine monitoring device.

Currently, there is limited publicly available information on the Accuryn system's performance and adoption. The device's effectiveness and acceptance in clinical practice remain unclear. The Sensica was recalled in 2022 due to reported inaccuracies, as noted by the (27). The recall indicates significant concerns regarding its reliability, which has impacted its availability and clinical use. Some urine output measurement devices, including those from various manufacturers, are approved for use in certain countries but not universally. For instance, devices may receive approval in regions such as Israel but face regulatory hurdles or lack approval in other major markets like the USA, as highlighted by Lee et al. (2023). This discrepancy can affect the widespread adoption and utilization of these devices globally.

The urine output measurement system proposed by (9) utilized capacitive sensors to measure urine levels within a rigid container. The device also employed read switches activated by a magnetic float to measure the volume of urine collected in a series of cascade containers. The system used capacitive sensors to measure the amount of urine within a rigid container. Capacitive sensors detect changes in the dielectric constant when urine fills the container, providing an accurate measurement of the liquid volume. Read switches, activated by a magnetic float, measured the amount of urine collected in two containers arranged in a cascade system. The float rises with the urine level, triggering the read switches to signal when each container is full. Once one of the containers filled up, it was automatically emptied using a siphon mechanism, allowing urine to begin collecting in the next container. This ensured continuous measurement without manual intervention. The system required multiple components, including rigid containers, capacitive sensors, read switches, and a siphon mechanism. This complexity could make it difficult to use and maintain in a clinical setting. The arrangement of two containers in a cascade system, along with the associated hardware, required a significant amount of space, making it impractical for crowded hospital environments. The system included an electronic unit that sent the collected data via Bluetooth to a PC, where the urine output was calculated and monitored in real-time.

While this system demonstrated an interesting combination of capacitive sensing and mechanical measurement techniques, its practical limitations in terms of user-friendliness and space requirements hindered its further development and commercialization. This highlights the importance of balancing technical innovation with practical usability when designing medical devices for clinical use. The gravimetric method of measuring urine output, which was presented many years ago, offered a simple, inexpensive, and dynamic approach to monitoring urine flow (7). Despite its potential, it faced technical challenges that prevented its widespread adoption in clinical practice. However, gravimetry is straightforward, relying on the measurement

of weight to determine urine volume. It allows for the measurement of urine flow over very short time intervals (less than 1 to 5 seconds) and can detect minor changes in flow as small as 2-3 ml. Gravimetry is also inexpensive compared to more complex technological solutions, but it can be affected by external factors such as bed height changes or movements that can alter weight measurements. Initial attempts to implement gravimetric methods faced technical problems that hindered their development for clinical use. Specific details on these issues were not widely documented but likely included sensitivity to environmental factors and difficulties in maintaining consistent calibration.

The Sippi device is a digital device using the capacitive technology. It is an automated urine meter that incorporates biofilm control and wireless connectivity (8). It offers the potential benefit of reducing urinary tract infections by actively combating biofilm formation. As of now, there are no clinical data available to substantiate its efficacy and reliability in a real-world setting. More recently a new low-cost, already mentioned before, system has been proposed, the IoT Urine Scale. This low-cost device utilizes gravimetry and transmits data via Bluetooth to a cellular phone. It employs a strain gauge load cell, an integrated circuit with an amplifier, an analog-to-digital converter, and a WiFi-enabled microcontroller (15). The IoT Urine Scale is cost-effective and leverages modern technology for real-time data transmission and monitoring. However, the authors did not address the potential inaccuracies that could arise from shocks or movements impacting the measurement system. This could be a significant drawback in clinical environments where stability cannot always be guaranteed.

The developed Diuriflux 2023 system has demonstrated success in capturing simulated urine output with high accuracy. Specifically, the system showed only a 1 to 5 mL mean difference between the actual volume and the Uriflux 2023 measurements, which corresponds to a 1-3% error range. In clinical medicine, such a percentage error is negligible and does not significantly impact patient management even if careful and frequent urine output monitoring is very important, especially in patients with heart failure or shock. Urine output is essential to manage fluid intake and removal. Sometimes minute-to-minute changes in urine output are of critical importance (23). Moreover, the rate of urine output (mL/min) is difficult to measure for nurses due to practical reasons, and the bag graduations make precise evaluation challenging. As a result, detecting any rapid changes in urinary flow can be difficult and inaccurate. Electronic assessment of the urine output flow could be of great importance in clinical practice.

Our device has several advantages. It uses gravimetry as the measurement system combined with capacitive sensors. This dual approach provides a double-check mechanism, ensuring high accuracy and reliability as demonstrated

by our in-vitro results. Measurement problems detected by the gravimetry sensor are immediately identified by the capacitors, which then signal any issues to the staff. Our device has other additional advantages that enhance its functionality and usability in clinical settings. The integrated accelerometers automatically detect and correct for excessive movements, ensuring that the measurements remain accurate even in dynamic environments. This feature helps to minimize errors caused by patient movements or other external factors. The system can also analyze changes in urinary output on a minute-by-minute basis, providing immediate feedback on any significant fluctuations. This capability is crucial for early detection and response to acute changes in patient condition. Designed to resemble existing bedside monitors, the device is easy to use with almost no learning curve for healthcare professionals. This familiarity helps to facilitate quick adoption and integration into routine clinical practice.

Summary:

The Diuriflux system, integrating gravimetric and capacitive sensor technologies, demonstrates high accuracy and adaptability in in-vitro testing. It effectively measures urine output and flow with an error margin of approximately 3%, aligning well with current clinical standards. The system's design emphasizes ease of use and is like existing clinical devices, making it a practical option for hospital settings. Given its precision and user-friendly nature, the Diuriflux system may have significant clinical potential and could be widely adopted in hospital practices globally.

Limitations: The overall results obtained with the Diuriflux system indicate promising accuracy and adaptability for urine output measurement in vitro. However, these results cannot be directly extrapolated to in-vivo situations. To ensure the system's reliability and effectiveness in real-world clinical settings, further validation is required. The next step involves conducting in-vivo tests within an intensive care unit to assess the device's performance under actual patient conditions.

Author Contributions: Conceptualization, N.G, methodology, P.B., J.J.G, N.G, supervision, R.P, J.J.G, writing, J.J.G; N.G, software, N.G, resources, A.D, original draft preparation, J.J.G, project administration, A.D, funding acquisition, R.P, A.D, P.B.

Contributions: N.G. is the engineer who developed the concept and realize the technical part of the project. P.B. had the idea and partially developed the concept of using both techniques. J.J.G wrote the manuscript and analyzed the data in collaboration with A.D. R.P. was the engineer who supervised the electronic part of the project.

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