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From manual to digital: prospective ICU evaluation of the FIZE kUO[®] for continuous urine output measurement

Olivier Zerbib¹, Tawfik Mahamid¹, Noa Ben-Noon¹ and Shaul Lev^{1,2*}

Abstract

Background ICU nurses manage complex, time-sensitive care while also performing frequent manual tasks. Manual urine output (UO) measurement is one such task that remains labor-intensive, interruptive to workflow, and prone to delays - despite the need for timely and accurate recording. Automation may reduce this burden and improve consistency of monitoring. The FIZE kUO[®] is an electronic urinometer designed to provide continuous, real-time UO data without requiring manual handling.

Methods We conducted a prospective, single-center pilot study to evaluate the usability, workflow impact, and safety of the FIZE kUO[®] device in 10 critically ill patients. Nurses completed staged questionnaires before, during, and after use to assess perceptions of manual monitoring versus automated monitoring. Device performance and adverse events were documented throughout monitoring.

Results Nursing staff reported positive perceptions regarding ease of setup (84–87%), time saving (74%), and improved recognition of changes in UO (87%). At treatment completion, 88.9% of nurses indicated the system prevented missing data, and 78% reported it facilitated earlier identification of situations requiring intervention. The device provided continuous monitoring for a total of 1,263 patient-hours, with no device-related adverse events or serious adverse events observed.

Conclusion Automating urine output monitoring was perceived by nurses as beneficial for workflow efficiency, data reliability, and clinical awareness. Nurses perceived the FIZE kUO[®] to reduce repetitive manual tasks and support timely decision-making. These findings support the potential of automated UO monitoring to alleviate components of ICU nursing workload.

Keywords Electronic urine monitoring, Urine output, Critical care monitoring, Fluid management, Acute kidney injury, Medical device

*Correspondence:

Shaul Lev
shaul4687@gmail.com

¹Department of General Intensive Care, Hasharon Hospital, Rabin Medical Center, Petah Tikva, Israel

²Gray Faculty of Medical and Health Sciences, Tel Aviv University, Tel Aviv, Israel



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Introduction

Nurses are the backbone of intensive care, providing continuous monitoring and complex care under high-pressure conditions. Yet the nursing profession is facing a global workforce crisis characterized by chronic understaffing, burnout, and overwhelming administrative workloads [1, 2]. These pressures reduce time available for direct patient care, increase the risk of errors, and contribute to job dissatisfaction and turnover.

Patient to nurse ratios vary widely across countries, and many ICU staff work hours exceed measured demand, as assessed by the Nursing Activities Score (NAS) [3]. On average, ICU nurses spend approximately two-thirds of their shift on direct care tasks [4]. Manual handling of bodily fluids further adds to workload and exposes staff to occupational risks, particularly when protective equipment or infection-control practices are inconsistent [5, 6].

Such high-acuity, high-intensity demand underscores the potential value of automation: By automating repetitive tasks such as manual urine output recording, digital systems reduce workflow interruptions and give nurses more time for direct patient care. When performed in alignment with human-centered design, automation technologies hold promise for better patient care while complementing nursing practice [7].

A prime example of a task suitable for automation is urine output (UO) monitoring. UO is a fundamental physiological parameter and a sensitive indicator of renal function and hemodynamic status, particularly in critically ill patients [8]. Yet, despite its clinical importance, UO measurement remains largely manual. Nurses must interrupt other care activities every hour to inspect and record urine volumes at scheduled intervals, which may disrupt workflow and delay documentation. Intermittent measurement may also reduce the temporal resolution available for detecting changes in UO [9, 10].

Automated electronic urinometers have emerged to address these limitations. By providing continuous urine-output data, these systems may reduce repetitive manual tasks and improve consistency of recording. Prior evaluations suggest that electronic systems may improve accuracy and reliability relative to manual measurement [9, 10]. The FIZE kUO[®] is an electronic urinometer designed for continuous UO monitoring and integration into ICU workflow.

This study evaluates the FIZE kUO[®] system in a prospective, single-center pilot trial in critically ill adults requiring indwelling Foley catheters, with a focus on nursing usability, workflow impact, and patient safety. By centering on nursing experience, we examine how automated urine output monitoring can streamline routine tasks, support timely clinical decisions, and enhance overall ICU care.

Methods

Study design and ethical approval

This prospective, open-label, single-center, single-arm feasibility pilot study was conducted in the General ICU at Rabin Medical Center. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki (2013 revision) and with current Good Clinical Practice (GCP) and International Council for Harmonization (ICH) guidelines. Ethical approval was granted by the Institutional Review Board (Helsinki Committee) of Rabin Medical Center, Petah Tikva, Israel (approval number 0736-21-RMC). Informed consent was obtained from all patients or their legally authorized representatives before any study-related procedure.

As a feasibility pilot, the sample size was pragmatic (convenience-based) rather than powered for a specific endpoint. Ten consecutive eligible patients were enrolled to assess usability, perceived workflow impact, and safety and to inform the design of future controlled studies.

Study population

Adult ICU patients (≥ 18 years) requiring an indwelling Foley catheter for ≥ 24 h were eligible. Exclusion criteria included pregnancy, pelvic/genital surgical disruption, or permanent urinary catheterization. Ten eligible patients were enrolled between June 2023 and January 2024 and monitored throughout their ICU stay using the FIZE kUO[®] automated urine output system. There were no withdrawals.

Investigational device

The FIZE kUO[®] (Developed by FIZE Medical Ltd., Israel) is an electronic urine output monitor that measures urine output continuously, with minute-by-minute resolution. The system comprises a bedside console and a disposable kit which connects to any standard Foley catheter.

Data collection and endpoints

The primary outcome was usability and perceived impact on nursing workflow, confidence in measurement reliability, and clinical decision-making. The pre-, during-, and post-use questionnaires were developed by the study team specifically for this study, based on the study objectives and on domains relevant to ICU urine-output monitoring: measurement burden, timeliness, reliability, ease of use, and clinical decision-making. The instruments were not formally validated. The full questionnaires are provided in Supplementary File 1.

Questionnaires were distributed per care shift rather than once per individual nurse; the same nurse could therefore contribute more than one response over the monitoring period. A total of 98 responses were obtained (pre-use $n = 15$, during-use $n = 74$, post-use $n = 9$) from nurses who cared for the study patients (approximately

15 nurses overall). Because responses were not linked to individual respondents, they cannot be treated as fully independent. The secondary outcome was device safety, assessed by the frequency and severity of device-related adverse events.

Statistical analysis

Questionnaire items were summarized using response distributions and percentages. For 5-point agreement items, a positive response was defined as a score of 4–5 (“Agree” or “Strongly agree”). For 7-point items, a positive response was defined as a score of 6–7. Safety was summarized descriptively. Given the small sample and feasibility design, no inferential analyses were performed.

Results

Study population characteristics

Ten ICU patients (4 female, 6 male; mean age 69.1 ± 12.2 years) were enrolled. The cohort reflected a clinically complex population, with most patients presenting multiple comorbidities, including renal and metabolic disorders, infections, and respiratory or vascular complications, representing a typical high-acuity ICU environment, where manual urine output monitoring is labor-intensive and prone to interruptions.

Usability evaluation by nursing staff

Nursing staff perceptions regarding the usability of the electronic urine output monitoring device were positive, as assessed through three-stage questionnaires (Figs. 1, 2 and 3).

Nursing perceptions before automation (baseline burden)

Prior to the use of the FIZE kUO, a questionnaire was distributed to assess staff perceptions of the challenges of manual urine output monitoring (Fig. 1). Although 60% of staff reported urine output was easy to accurately measure manually, 53.3% of staff said it can be difficult to know if the measurement is reliable. 66.7% of staff reported measuring urine output on time is difficult due to the workload in the ICU. Even when the measurement is done on time, 60% of the nurses said the data isn't immediately recorded into the medical records. Furthermore, 60% believed different staff members can measure differently, indicating a lack of standardization and inherent variability.

Nursing experience during use

A second questionnaire was distributed during the course of treatment to understand nursing staff perceptions of the FIZE kUO[®] device (Fig. 2). During active use, 83.8% and 86.5% found the device and disposable kit were comfortable to connect to the catheter and to hang on the patient's bed, respectively. 77% reported the device was easy to relocate to a new patient, and 74.3% said the device saved time. Importantly, 86.5% found the graphic display of information helped identify urine output changes on time and better understand patient condition, and 73% reported the device facilitated faster clinical decisions.

Post-use reflections and comparison to manual monitoring

The third questionnaire was distributed at the end of treatment, after the use of the device was complete and offered a comparison to manual urine output monitoring (Fig. 3).

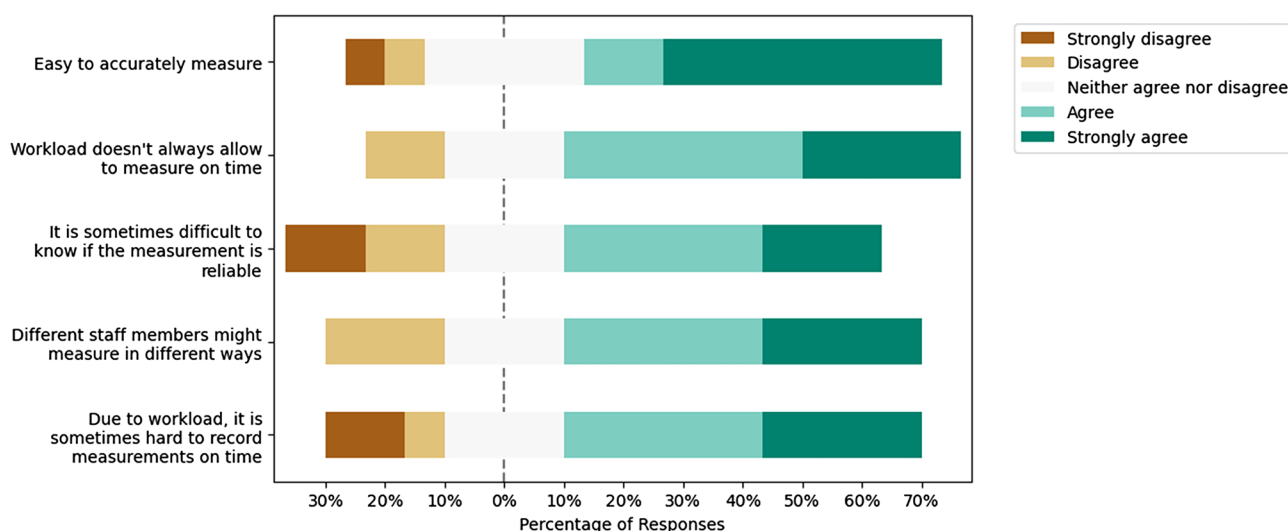


Fig. 1 Reported challenges with manual urine output monitoring. Pre-treatment nurse questionnaire responses ($n = 15$), shown as stacked bars, illustrate the frequency of agreement versus disagreement with each statement

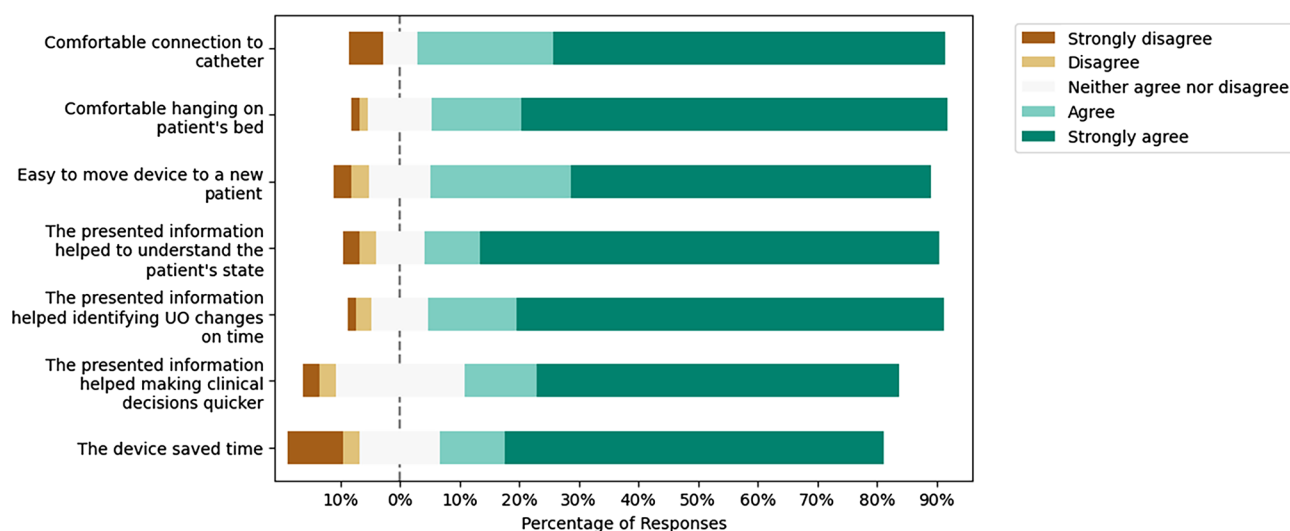


Fig. 2 Reported experiences with the FIZE kUO® device. Mid-treatment nurse questionnaire responses ($n = 74$), displayed as stacked bars, show the distribution of agreement versus disagreement with each statement

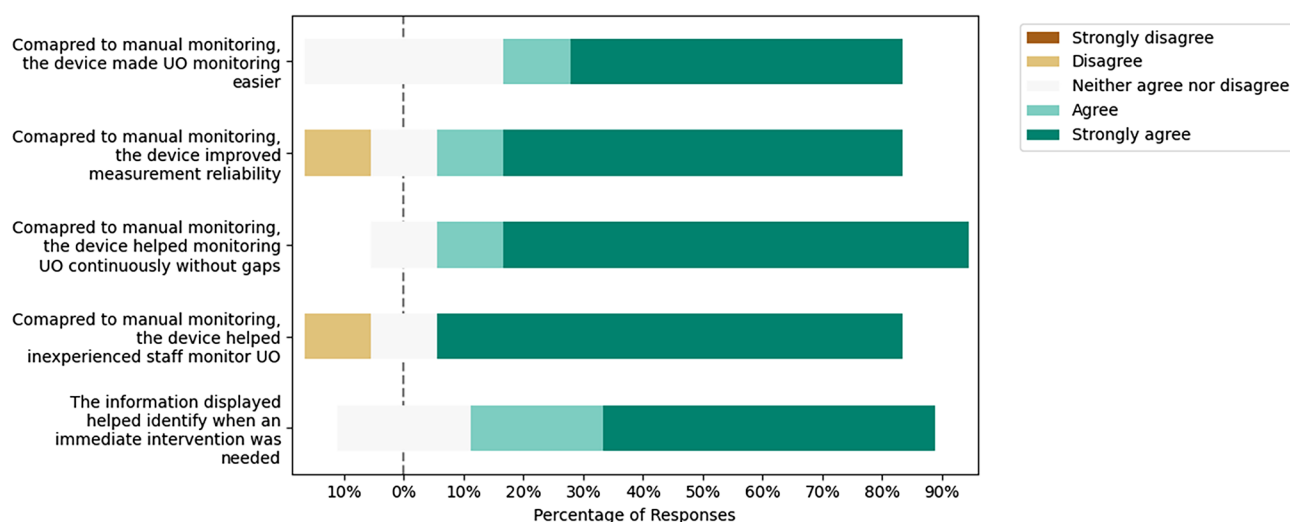


Fig. 3 Reported advantages of automatic over manual urine output monitoring. Post-treatment nurse questionnaire responses ($n = 9$), displayed as stacked bars, show the distribution of agreement versus disagreement with each statement

66.7% and 77.8% of staff found that the device made monitoring urine output easier and more reliable compared to manual monitoring. 77.8% thought the device helped inexperienced staff monitor urine output. 88.9% of staff said the device helped urine output monitoring without missing data. Importantly, 77.8% of the staff reported that the device supported the identification of situations requiring immediate intervention.

Device performance and safety

The FIZE kUO® device monitored urine output for an average of 126.3 (SD = 111.7, min = 17.8, max = 337.1) hours per patient with a total of 1263.3 monitoring hours. Two malfunctions occurred. One involved a disposable kit and was resolved by replacing the disposable; the

second involved a connection cable, was detected during device connection, and was resolved by replacing the cable. In both cases, monitoring was restored promptly without impact on patient treatment. No device pauses were reported across 168 recorded shifts.

Ten adverse events occurred in 3 of 10 patients (30%). Eight were severe and two were moderate; none met criteria for a serious adverse event. No event was attributed to the investigational device or study procedures, and no event required discontinuation of device use. Patient-level details are provided in Supplementary File 2.

Discussion

The findings of this feasibility pilot support the usability and practical feasibility of automated urine output monitoring in the ICU. Nurses generally reported that the FIZE kUO[®] was easy to use, saved time, and helped them recognize changes in urine output and identify situations requiring attention. These findings reflect staff perceptions and should not be read as objective evidence of reduced workload, earlier intervention, or improved clinical outcomes.

Urine output remains one of the few vital parameters still measured manually in the ICU, and its manual measurement requires repetitive nursing tasks and intermittent documentation. In critical care environments where nurses manage multiple unstable patients, staff perceived that reducing this repetitive, low-value task freed attention for direct patient care. Automated systems may reduce task fragmentation and provide more continuous data capture, although no time-motion analysis or documentation audit was performed here to confirm this.

In addition, the use of automated systems has the potential to lower exposure to bodily fluids and improve the psychological comfort of nursing personnel - a benefit often overlooked in device evaluations. As ICUs continue to face nurse-to-patient ratios below recommended levels, nurse-centered technologies of this kind were perceived as fitting into existing workflows without adding complexity.

Previous studies have reported improved accuracy of automated urine monitoring systems compared with manual methods [9–12]; accuracy was not formally evaluated in the current study. The present findings therefore address feasibility, usability, nursing perceptions, and safety rather than superiority over conventional monitoring. The device was used for 1,263.3 patient-hours with only two promptly corrected malfunctions and no device-related adverse events, supporting the feasibility of prolonged use in this small cohort.

This study has several limitations. It was a small, single-center, single-arm feasibility pilot and was not powered for clinical endpoints or designed to evaluate superiority over conventional urine monitoring. The questionnaires were developed for this study and were not formally validated; content and face validity were assessed only informally. Responses were collected per shift and were not linked to individual nurses, so repeated responses from the same staff may have introduced clustering and non-independence. Findings are self-reported and may be subject to response and social-desirability bias. No objective comparison with manual monitoring was performed for accuracy, documentation timeliness, workload, or clinical outcomes. The results should therefore be interpreted as exploratory perceptions. Larger controlled

multicenter studies are needed to evaluate objective workflow measures and patient-centered outcomes.

In this single-arm feasibility pilot, the FIZE kUO[®] was found to be usable, safe and technically reliable, and nurses perceived it to reduce repetitive manual tasks and support timely awareness of changes in urine output. The study did not assess superiority over conventional monitoring or effects on accuracy, workload, AKI detection, fluid balance, or length of stay. These findings support further controlled evaluation of automated urine output monitoring using objective workflow and clinical endpoints.

Abbreviations

UO	Urine output
ICU	Intensive care unit
AKI	Acute kidney injury
NAS	Nursing Activities Score
AE	Adverse event
SAE	Serious adverse event
GCP	Good clinical practice
IRB	Institutional review board

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12912-026-05421-1>.

Supplementary Material 1

Supplementary Material 2

Acknowledgements

Not applicable.

Author contributions

All authors contributed to the preparation, review, and approval of the manuscript and take responsibility for the content.

Funding

This clinical study was sponsored by FIZE Medical Ltd. The authors declare no specific grant from any funding agency for the preparation of this paper.

Data availability

The datasets generated and analyzed during this study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The clinical study was conducted in accordance with the ethical principles of the Declaration of Helsinki (2013 revision) and with current Good Clinical Practice (GCP) and International Council for Harmonization (ICH) guidelines. Ethical approval was granted by the Institutional Review Board (Helsinki Committee) of Rabin Medical Center, Petah Tikva, Israel (approval number 0736-21-RMC). Informed consent was obtained from all patients or their legally authorized representatives prior to any study-related procedure.

Consent for publication

Not applicable.

Competing interests

This study was sponsored by FIZE Medical Ltd., the manufacturer of the FIZE kUO[®]. The authors declare no personal financial relationships or employment with FIZE Medical Ltd.

Received: 7 May 2026 / Accepted: 22 September 2026

Published online: 30 September 2026

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