Integrating Human Factor Engineering in Point-of-Care Diagnostics: Proflo-U® Platform for CKD Monitoring

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ABSTRACT

Background: Human Factors Engineering plays a critical role in ensuring the safety, usability, and effectiveness of point-of-care diagnostic devices, particularly in resource-limited settings and self-monitoring environments. This study evaluates the integration of human-centered design principles into Proflo-U®, a PoC diagnostic platform developed for chronic kidney disease monitoring through quantitative measurement of the urine albumin-to-creatinine ratio.

Methods: The study incorporated user feedback, System Usability Scale-based assessments, risk analysis, and usability testing to optimize the platform, comprising a test kit, analyzer, and smartphone application. Risk assessment was conducted in accordance with ISO 14971:2019 and evaluation followed ISO 9241:2018 principles. A multidisciplinary team identified potential hazards, assessed associated risks, and implemented control measures. Usability testing involved 15 participants aged 30–50 years, including expert and non-expert users. Task completion time, operational challenges, and user feedback were evaluated, with analysis of variance (ANOVA) used to compare responses across user groups.

Results: A total of 51 potential risks were identified and assessed. Following the implementation of risk control measures, the mean risk score decreased significantly from 5.7 ± 2.2 to 1.5 ± 0.6 ($p < 0.001$), with a large effect size (Cohen's $d = 1.98$). Of the 24 user-identified feature requirements, 22 were incorporated into the platform, addressing all basic and performance needs and 67% of exciting needs. Usability testing demonstrated that participants from different professional backgrounds could complete the testing workflow following a brief demonstration. No statistically significant differences in usability feedback were observed among the three user groups ($p = 0.06532$). Cartridge orientation and sample handling were identified as areas requiring further improvement.

Conclusion: Integrating HFE into Proflo-U® development significantly improved risk management and supported usability across diverse user groups. This approach provides a systematic framework for developing safer, accessible, and user-centered PoC diagnostic platforms for CKD monitoring in clinical and self-monitoring settings.

Keywords: Human Factor Engineering, Point-of-Care Diagnostics, Chronic Kidney Disease, System Usability Scale, Risk Analysis.

INTRODUCTION

Chronic Kidney Disease (CKD) is a prevalent and increasingly significant global health issue, with profound implications for both individual well-being and healthcare infrastructure worldwide. As evidenced by the Global Burden of Disease study, the prevalence of kidney dysfunction continues to rise, with more than 3.1 million deaths attributed to CKD in 2019 alone, ranking it as the seventh leading risk factor for mortality globally (Francis et al., 2024). This burgeoning epidemic is further compounded by its substantial economic burden, encompassing not only the costs associated with dialysis and transplantation but also the management of associated comorbidities and complications as the disease progresses.

Efforts to mitigate the burden of CKD necessitate multifaceted approaches encompassing lifestyle interventions, risk factor management, and structural healthcare reforms. While the long-term benefits of these measures are undeniable, their full impact may only be realized over generations. In the interim, early detection and risk stratification assume paramount importance, affording opportunities for the implementation of therapeutic interventions aimed at slowing, halting, or even reversing the progression of CKD. The consensus guidelines established by organizations such as KDIGO and professional societies advocate for the routine screening of albuminuria, particularly in high-risk cohorts such as individuals with diabetes mellitus. Notably, among diabetic patients, albuminuria serves as a robust predictor of progression to End-Stage Renal Disease (ESRD), underscoring its clinical utility in risk stratification and therapeutic decision-making (Hemmelgarn et al., 2010) (Thakur et al., 2022) (Stevens et al., 2024) (Levey et al., 2005) (Buse et al., 2020) ("Chronic Kidney Disease and Risk Management: Standards of Medical Care in Diabetes—2022," 2022)

Furthermore, heightened vigilance through regular albuminuria monitoring is recommended for individuals with hypertension, cardiovascular disease, or evidence of deteriorating renal function. Albuminuria, categorized into distinct stages based on urinary excretion levels, facilitates risk assessment and informs tailored management strategies. However, conventional laboratory-based techniques for albuminuria assessment are often constrained by logistical challenges, leading to delays in result delivery and hindering timely intervention. In response to the imperative for accessible and expedient diagnostics, recent advancements have witnessed the emergence of point-of-care (PoC) solutions for albuminuria screening. These technologies offer the promise of rapid and decentralized testing, thereby overcoming the limitations of centralized laboratory-based assays (Mathaweesansurn et al., 2017; White et al., 2011). Conventional urine albumin analysis of 24hrs collected urine is cumbersome, inconvenient and a time taking process.

Of late, spot urine test with Urine Albumin and Creatinine Ratio (UACR) is being adopted as an efficient alternate to the routine 24hr urine collection (Teo et al., 2015)**,** where both albumin and creatinine is measured individually from freshly collected urine sample and the ratio is calculated. For values of UACR <30mg/g it is classified as A1 or normo-albuminuria, microalbuminuria (A2) if UACR is between 30-300mg/g and albuminuria (A3) for UACR > 300mg/g.

For a PoC device, usability is a primary factor of consideration, besides the accuracy and sensitivity. This is because, such technology is often used in settings with minimum infrastructure and minimally trained (or un-trained) operators. The human factors in such resource limited environments are often under-accounted in the design of such PoC technologies that unfortunately affects their field level performance. This leads to "human factor design" becoming of critical value in the development of PoC and self-health monitoring medical devices. Such an approach ensures accuracy, usability, efficiency, and safety. By keeping its target users (individuals with varying levels of health literacy and technological proficiency) at the centre of the design process, it becomes possible to improve the reliability of POCT to approach clinical level accuracy.

The incorporation of principles of human factors engineering, such as user-centric design and ergonomic considerations, developers can create devices that accommodate diverse user needs and preferences. Intuitive interfaces, clear instructions, and ergonomic form factors enhance user acceptance and engagement, promoting adherence to monitoring protocols and facilitating timely intervention. Moreover, human factor design minimizes the risk of user errors and improves device reliability, thereby enhancing the overall effectiveness of PoC and self-health monitoring solutions in empowering individuals to actively manage their health.

Recently, we have developed a PoC platform device Proflo-U® that has been evaluated for its diagnostic accuracy and ability to PoC deploy in a separate study. (Satyanarayana et al., 2024) In this paper we present our implementation of human factor design engineering in the product development, and quantitative framework that (leads to statistical analysis of the output) has helped in the design of the Proflo-U platform that ensure functionality, safety and usability of the platform at PoC and self-health monitoring environments.

MATERIAL AND METHODS

Platform description

Test kit- The cartridge on which the test shall be performed for the quantitative analysis of the albumin (’Mishra and ’Mishra, 2023) and creatinine.

Analyzer- The device that will read the fluorescence and absorbance generated in response to the test.

App- An alternate to the analyzer display unit that shall convert the fluorescence/absorbance output from the analyzer into meaningful and understandable value by treating them with the pre-installed calibration curve.

Human Centered Design:

Study design and participant recruitment

Volunteers were identified from different backgrounds to obtain input on the design of the platform. The volunteer profiles have been chosen considering the platform to be developed should be used at Point of Care or as self-health monitoring.

The study has been conducted by adopting System Usability Scale (SUS). Volunteers have been provided with a questionnaire has ten items for each component of the platform and their responses have been recorded on a 5-point Likert scale, where 5 for features at top priority and 1 least priority for the user (“SUS: A ‘Quick and Dirty’ Usability Scale,” 1996). The design of the questionnaire is based on the in-vitro diagnostic device requirements.

Risk analysis team constitution and risk analysis matrix

A risk analysis team has been constituted as per the requirement of ISO 14971:2019. The team has been represented by experts in clinical practice, engineering design, quality assurance, regulatory affairs, and potentially a safety expert, ensuring a comprehensive evaluation of potential risks associated with a medical device across its lifecycle. Risk, risk scenario and risk impact have been analyzed using Risk Matrix Tool based on severity and probability scoring as prescribed under ISO 14971:2019 (“ISO 14971:2019 - Medical devices — Application of risk management to medical devices,” 2019).

Usability testing:

Usability testing has been conducted on the guidelines of ISO 9241:2018 to access and get feedback on the Proflo-U® platform effectiveness, efficacy and satisfaction using KANO model (Machin, 2016). As the product is an in vitro diagnostic product, FDA requirement has also been given priority wherever needed (“ISO 9241-11:2018 - Ergonomics of human-system interaction — Part 11: Usability: Definitions and concepts,” 2018). For example, the volunteers and testing environment have been chosen to ensure minimum five representations from each use environment and user type. The assessment has been done on measurable attributes like task completion time, error rate, user satisfaction ratings, and the ability to navigate through the system effectively. Beta testing has been conducted with the user groups for time to complete the task and ANOVA analysis of the feedback obtained (*Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff Preface Public Comment*, 2000).

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RESULTS

SUS analysis with volunteers for Proflo-U® platform

A critical component in the development of new products is the inclusion of input from potential users. This input is invaluable in defining and understanding the technical/functional needs that the product must fulfil. This input also serves as a guide to less tangible, but often as important, attributes such as satisfaction, acceptability or aesthetics. Along with the functional needs, these play an important role in the ultimate success of a product. However, to obtain these inputs in a more controlled and informed manner, we have defined the various components of the Proflo-U® platform in Section 2.1. Another important aspect in the Human-centric design is to define the user of the product and hence the needs, capabilities, and limitations of such a user could be efficiently captured in the study. The Proflo-U® platform is expected to cater to multiple user types, such as, in self-health monitoring segment: patient and their care givers, doctor's clinic segment: clinicians and compounder, in diagnostic lab segment: lab technicians, in hospital: nurses. Thus, volunteers were chosen accordingly.

The SUS methodology was adopted to evaluate each component of platform. As each component has features that are independent and unique on its own way, therefore, each component has been treated as a separate system. The volunteers were provided with a questionnaire list of 10 features for each component of the platform and were assigned a score on the 5-point Likert scale. The volunteer's scoring has been analysed with SUS analogy for each feature and scoring has been obtained. The minimum and maximum SUS score obtained for test kit were70 and 90, while for analyzer 72.5 and 97.5 whereas the app obtained 72.5 and 95 respectively.

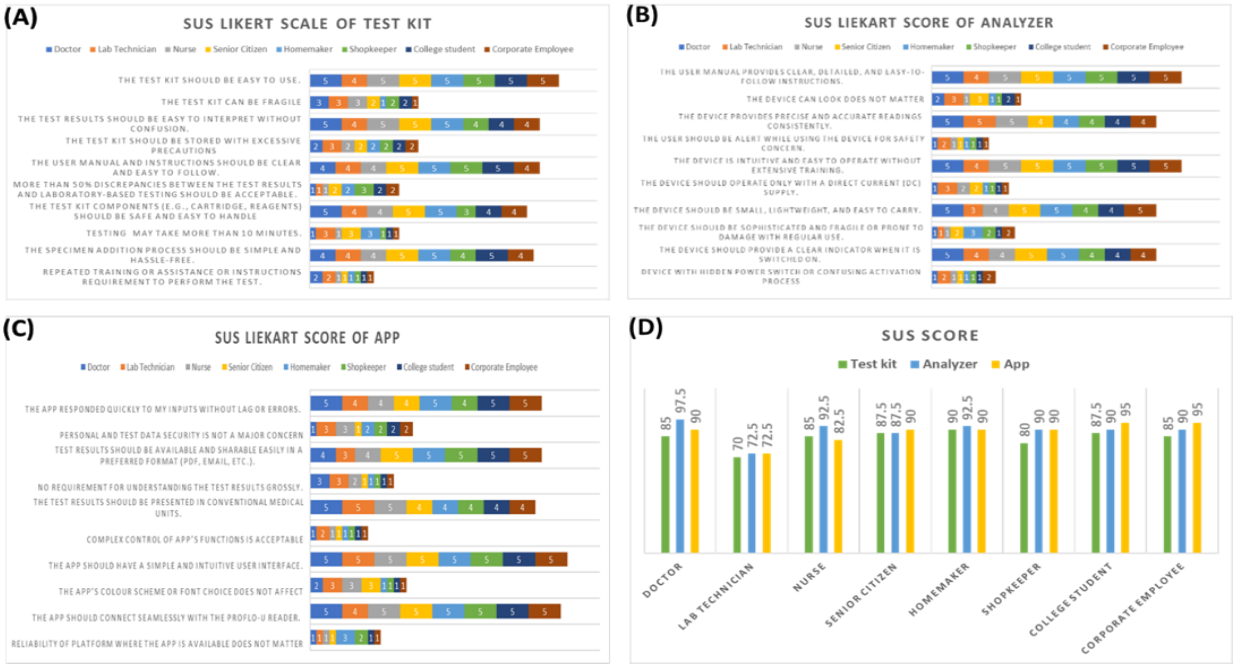


Figure 1: SUS analysis with volunteers to ascertain design input for components of Proflo-U® platform. Likert Scale for all 10 SUS questionnaire of test kit (A), Analyzer (B) and App (C). Calculated SUS score for each system from all the eight categories of volunteers (D).

Risk analysis of the Proflo-U® platform

Based on the design inputs provided by the participants about the functional requirement of the product, a preliminary list of features was created. Based on this information, the risk management team initiated the risk analysis in accordance with the guidelines of ISO 14971:2019. The team had expertise in clinical practice, engineering design, quality assurance, regulatory affairs, and risk management to comprehensively evaluate potential hazards and mitigate risks associated with the device throughout its lifecycle. The team evaluated each

component of the platform and constructed scenario where the risk could be anticipated and what risk possible throughout the entire lifecycle of the product. These risks are then analyzed for the probability of occurrence and severity to assign a risk score based on the ISO 14971:2019 scoring system. The control measures that were already in place or could be taken in future were then determined for each risk and mitigation/ minimization of the risk is suggested. The acceptability criteria were fixed for the risk score of ≤ 3. In total n=51 risks were identified and analyzed in test kit, analyzer, app and product insert (Distribution of risk: Figure 2A) As previously described, the product is an in-vitro diagnostic platform for the early diagnosis of a chronic non-communicable disease and hence the severity of risk is generally 'Low' but the probability of risk to occur is 'High'. Therefore, the primary control measures were to reduce the probability of risk to occur in future. (Rout and Sikdar, 2017) No extreme risks were identified due to the nature of the product, 13 were identified as high risk ($5 <$ Risk score ≥ 10) and one low risk (Risk score ≤ 3). A large majority of the points appeared under moderate risk n=37 with risk score (3< Risk Score >6). After control measures were, taken all the risk were found to be in low-risk category (Figure 2B and 2C). Next, we performed statistical analysis of the risk score, prior to and after control, with paired sample t-test (with 95% Confidence of Interval with the hypothesis mean of after control ≠ before control mean). Results of the paired-t test indicated that there was a significant difference between **Before Control** ($M = 5.7$, $SD = 2.2$) and **After Control** ($M = 1.5$, $SD = 0.6$), $t(50) = 14.1$, $p < .001$. On average, risk reduction was about 3.2 points lower after taking control measures while Cohen's D was 1.98 (>0.8). (Figure 2D).

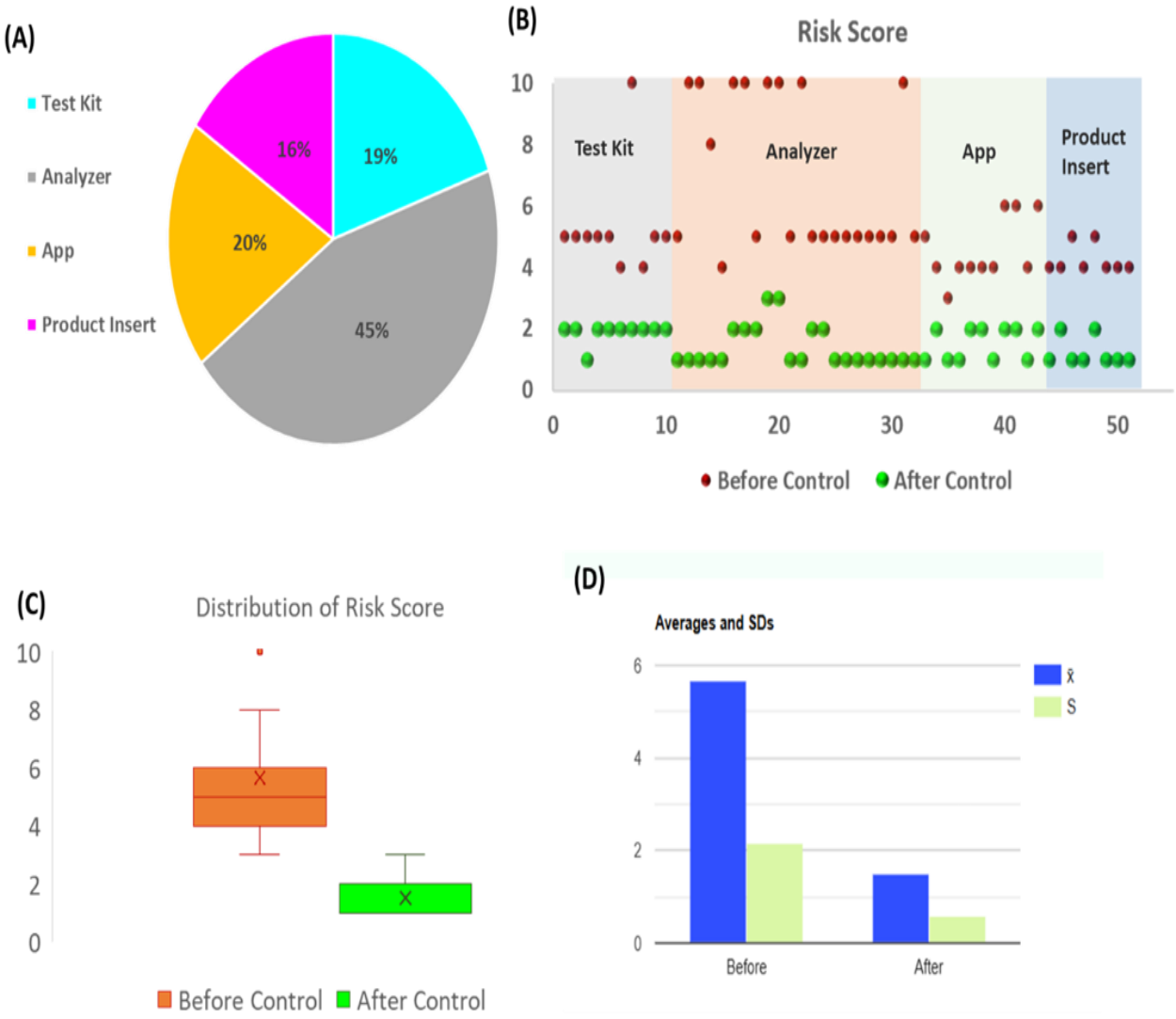


Figure 2: Statistical analysis of risk reduction after control measures. A. Percentage distribution of identified risk for various components of the platform with n=51. B. Mapping of risk score before and after the control measures. C. Distribution and spread of risk score before and after control measures with Box-Whisker plot. D. Average and Standard deviation obtained before and after with two tailed t-test analysis of the risk scores.

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Based on the input obtained from the stakeholders and risk analysis team, 24 major features have been identified which based on the overall inputs were classified into basic needs (6 features), functional needs (12 features) and exciting needs (6 features) with the KANO model (Figure 3A). This has been further analysed regarding the quantitative value for the customer satisfaction scale and the implementation level. Out of 24 feature requirements, 22 have been addressed, which includes all 100% features of Basic needs and 100% features of performance needs while 67% of the exciting needs were addressed, and the rest 33% were marked for the next developmental cycle (Figure 3B). The two primary unaddressed needs were Additional Information (Blogs, Diet) and Different Language Option, that would make the product user- friendly but were not immediate requirements as the user segment was well versed with English as a language of communication. Therefore, these features were provisioned for implementation during later stage of the product life cycle.

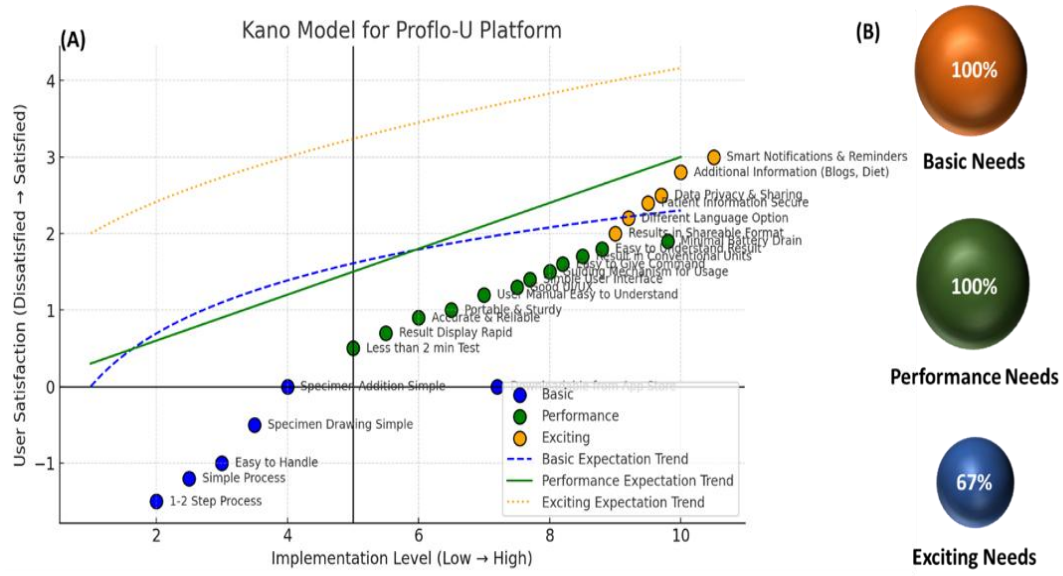
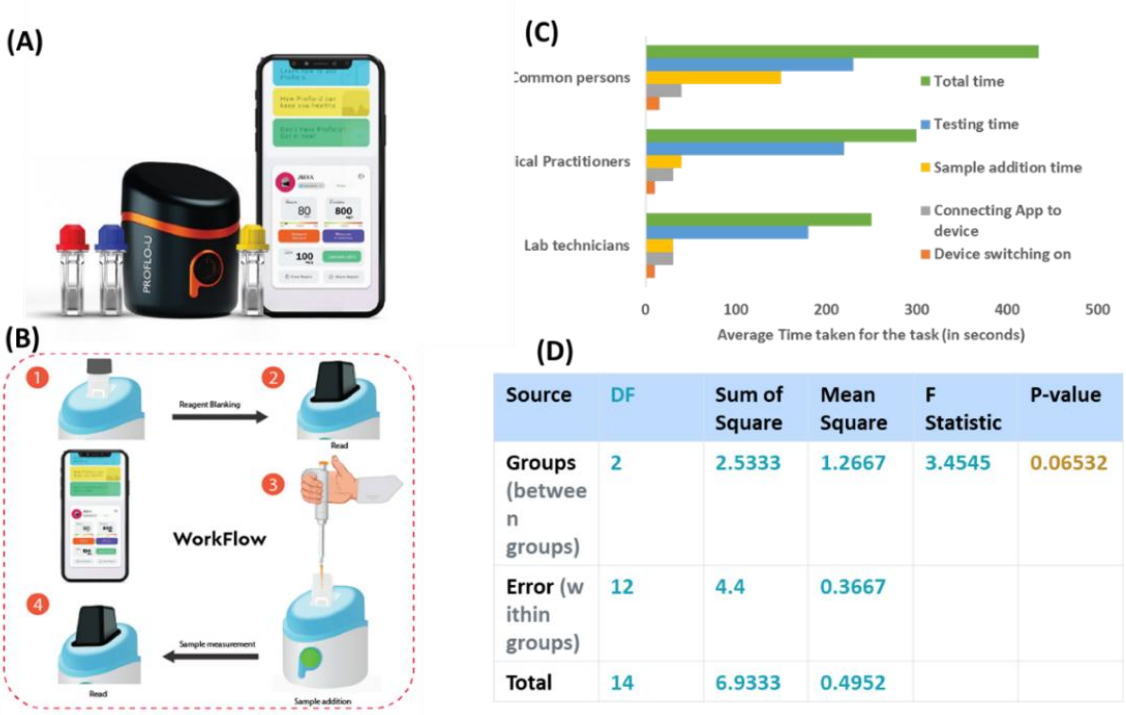


Figure 3: Proflo-U® platform features input and output analysis. (A) KANO Model analysis of the feature inputs for Proflo-U® platform with x axis representing implementation level and y axis the user satisfaction. (B) Proflo-U® platform has incorporated features in the output from each need category in percentage.

Usability test

The beta testing was initiated with the Proflo-U platform (Figure 4A), where the test locations chosen for the study were based on its intended use environment (which include diagnostic laboratory, Doctor's clinic, hospital OPD and home). A total of 15 volunteers (within the age group of 30-50 years, with near equal representation from both gender) were chosen who could be further classified equally into Medical Practitioners, Laboratory Technicians and common people/non-experts. More than 80% of the participants were considered technologically adept (defined as using a smartphone and downloading at least 1 application in the past 6 months and using apps at least 1 time per week). Each of them was given brief introduction and product usage demonstration (or through a video tutorial) just once (Figure 4B). The volunteers were requested to perform the task, where the Proflo-U® test kit, analyzer, mobile phone with an installed app, product insert, and a sample have been provided. Volunteers have been observed for 3 important parameters; (1) Whether the environment has impact on the usage of the platform, (2) Whether the user is able to conduct tests end-to-end without error and without seeking help from the instructor and (3) How much time does the user take to complete the task. At the end of the study, feedback was requested from the volunteers with the set of questionnaires. It was observed that; the work environment has minimum impact on the product use as the professional users (like medical practitioners and lab technicians) are used to them. Moreover, the non-experts were also able to use Proflo-U® efficiently. This might be attributed to the fact that in the last couple of years there has been substantial exposure to smartphones, mobile apps and working with smartphone connected devices or accessories. We have observed, in most cases the user did not require to reference to the product insert as the instruction on the app was intuitive and the target user could navigate with considerable ease. Further, as expected the lab-technicians were able to complete the task in less than 4 minutes (the benchmark created for the test time) and the average time taken by the medical practitioners were between 4-6 minutes, while the non-expert took anywhere between 4-10 minutes.

The maximum time taken by the non-expert was to add the sample to the cartridge and put the cartridge in the specific orientation, this probable reason could be attributed to lack of prior experience of sample testing/operating such products (Figure 4). The assumption is derived from the fact that one of the volunteers who was diabetic and had experience of testing blood sugar with glucometer, could perform the test in less than 5 minutes time. Placing the cartridge in the specified orientation in the analyser was identified as a significant challenge, as the marking made on the cartridge was transparent embossing of small star and user found it difficult to identify properly. Challenge with this step was observed with all the volunteers. Another significant difficulty with common person as a user, especially, was that they were unsure whether the sample volume that was aspirated (with the pipette and tip provided) was correct. As the analyzer has minimalistic user interaction, none of the target users reported any problem. Similarly, they could effortlessly use the app for the task from end to end. The final aspect of usability test was feedback from the user with a set of questionnaires and last, analysis of variance (ANOVA) was used to determine if there was any significant difference in response. Interestingly, the null hypothesis is accepted, there is no significant difference in the response of the three group on the Proflo-U® platform though each group belongs to different work environment especially the group representing non-expert where p-value obtained 0.06532.



(D)

Source	DF	Sum of Square	Mean Square	F Statistic	P-value
Groups (between groups)	2	2.5333	1.2667	3.4545	0.06532
Error (within groups)	12	4.4	0.3667		
Total	14	6.9333	0.4952		

Figure 4: Usability test of Proflo-U platform. (A) The Proflo-U platform and its components, (B) the workflow of the platform describing each step of operation, (C) the time taken for different activity of the task by different group of users and (D) the ANOVA analysis of the user feedback from the three different groups.

DISCUSSION

The results of this study underscore the critical role of Human Factor Engineering (HFE) in designing an efficient and user-friendly Proflo-U® point-of-care (PoC) diagnostic platform for Chronic Kidney Disease (CKD) monitoring. Through System Usability Scale (SUS) assessment, risk analysis (ISO 14971:2019), and usability testing (ISO 9241:2018), this study successfully identified and mitigated potential usability challenges while ensuring that the platform remains accessible to both trained healthcare professionals and non-expert users.

The SUS analysis provided valuable insights into the usability constraints and strengths of the Proflo-U® platform. Volunteers evaluated the test kit, analyzer, and mobile application, and their responses revealed a high degree of usability and acceptability. While healthcare professionals and trained lab technicians found the test kit easy to use, non-expert users encountered minor difficulties in sample handling and cartridge orientation. The analyzer received high usability scores across all groups, reflecting its intuitive operation and minimal user interaction requirements. Similarly, the mobile application was well received, with users appreciating its clear

instructions and easy navigation, highlighting the importance of a well-designed graphical user interface (GUI) for PoC devices. The analysis also revealed that while lab technicians and clinicians completed tasks in under four minutes, non-professional users took between four and ten minutes, primarily due to unfamiliarity with sample handling and proper cartridge placement. Interestingly, a volunteer with diabetes who was accustomed to home-based glucose testing completed the test within five minutes, demonstrating that prior exposure to PoC diagnostics reduces the learning curve and increases confidence in device usage.

The risk analysis, conducted in accordance with ISO 14971:2019, identified 51 potential risks categorized by probability and severity. The initial risk assessment classified 13 scenarios as high-risk ($5 <$ risk score < 10), 37 as moderate-risk ($3 <$ risk score < 6), and 1 as low-risk (risk score < 3). Following the implementation of risk control measures, all risks were effectively reduced to the low-risk category, with the average risk score decreasing from 5.7 to 1.5 ($p < 0.001$). The Cohen's D effect size (1.98) confirmed a large impact of risk mitigation measures, ensuring that safety and reliability were significantly enhanced. This reduction in risk was attributed to key improvements, including better labelling, optimized device ergonomics, and refined software instructions, which collectively minimized the probability of user errors.

The usability testing, conducted in clinical settings, diagnostic laboratories, and self-testing environments, further validated the effectiveness of the platform. The study confirmed that environmental factors had minimal impact on device usability, ensuring that Proflo-U® could be reliably used in a wide range of real-world conditions. Participants successfully completed testing tasks with minimal errors, with non-expert users requiring slightly longer durations to perform the tests. The primary usability challenge was related to cartridge orientation and sample handling, particularly for non-professional users, suggesting that clearer physical design markers and instructional aids could further improve the testing process. Importantly, the ANOVA analysis ($p = 0.06532$) indicated no significant usability differences between healthcare professionals and non-experts, implying that despite initial challenges, the learning curve for first-time users was manageable. This reinforces the effectiveness of the human-centered design approach in ensuring accessibility for a broad user base. The major design limitation observed in the usability test was putting the cartridge in the same orientation as demanded by the test procedure. Immediate effective solution has been proposed a visually distinctive marking on the face of the cartridge to guide the orientation of cartridge in the analyzer. However, a more robust and error-proof design shall be introduced in the later phase of product cycle on the chassis of the analyzer that shall allow guided cartridge insertion in a particular orientation only. There are certain desirable features demanded by the users like single cartridge for both urine albumin and creatinine test, however, there is incompatibility between the test reagents has not been included in the design under present technical unfeasibility but has been listed in one of the features to be investigated during the later stages of product life cycle.

These findings align with existing research on PoC diagnostics (Gerth-Guyette et al., 2021; Mori et al., 2011), which emphasize that usability and ergonomic design play a crucial role in device adoption, accuracy, and long-term adherence to testing protocols. Studies on PoC glucose monitoring have demonstrated that user-friendly interfaces significantly improve compliance and accuracy, findings that parallel the usability trends observed in this study (Harvey et al., 2016). Likewise, research on PoC albuminuria testing suggests that sample handling remains a common challenge for non-expert users, supporting the observed need for clearer cartridge orientation markers and improved sample volume guidance in Proflo-U®. Furthermore, recent literature on home-based PoC CKD management highlights the growing importance of patient-friendly diagnostic tools, reinforcing the necessity of integrating human factors principles into device development to facilitate self-monitoring and personalized disease management.

The findings of this study highlight key areas for further design enhancements in Proflo-U®. Future iterations of the platform should incorporate more prominent cartridge orientation markers, as difficulties in aligning the test kit were observed among first-time users. Additionally, a guided sample handling mechanism or visual indicators could improve user confidence in pipette usage and accurate sample placement. The integration of multi-language support and educational resources, such as in-app blogs and dietary recommendations, could further improve accessibility and engagement, particularly for self-monitoring users in diverse populations.

Thus, the integration of Human Factor Engineering in the development of Proflo-U® has significantly improved usability, safety, and effectiveness, demonstrating the value of a human-centered design approach in PoC

diagnostics. The study successfully validated the usability and risk management framework, ensuring that the platform meets the needs of both clinical professionals and non-expert users. The findings contribute to the

broader field of PoC diagnostic development, reinforcing the need for ergonomic considerations, intuitive interfaces, and comprehensive risk assessment in medical device innovation. Future iterations of Proflo-U® will incorporate additional user-driven refinements, further enhancing its role as a reliable and accessible CKD monitoring solution in diverse healthcare settings.

CONCLUSION

The integration of Human Factor Engineering (HFE) in the design and development of Proflo-U®, a point-of-care (PoC) diagnostic platform for CKD monitoring, has demonstrated significant improvements in usability, safety, and operational efficiency. By employing a user-centered design approach, the platform was optimized to accommodate diverse user groups, including healthcare professionals and non-expert users, ensuring ease of use in both clinical and self-monitoring settings.

Comprehensive System Usability Scale (SUS) analysis and ISO 14971:2019-compliant risk assessment enabled the identification and mitigation of potential usability barriers and risks, significantly reducing the average risk score and enhancing device reliability. The usability evaluation, conducted in real-world environments, confirmed that the platform facilitates rapid and accurate testing with minimal user errors. Notably, beta testing and ANOVA analysis revealed no statistically significant usability differences across user demographics, underscoring the effectiveness of the intuitive design.

These findings reinforce the critical role of HFE in PoC diagnostic development, emphasizing the need for ergonomic considerations, clear user guidance, and risk-based design refinements. Future iterations of the Proflo-U® platform will incorporate additional user-driven enhancements, such as improved cartridge orientation markers and sample volume indicators, to further optimize usability. The study establishes a robust framework for integrating human-centered design principles into medical device development, ultimately contributing to the broader goal of accessible, reliable, and efficient diagnostic solutions for early disease detection and management.

Conflict of Interest

All authors declare that they have no conflicts of interest

Declaration

The authors declare that the written consent has been obtained from the voluntary study participants. No Institutional Ethical committee clearance taken for the study.

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