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Ultrasound-Assisted Continence Care Support in an Inpatient Care Setting: A Mixed-Method Pilot Study

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ABSTRACT

This non-randomised exploratory intervention and feasibility study examines the impact of digital assistive technology (DAT), comprising a DFree Professional ultrasound sensor, on nursing care for continence support. Additionally, it evaluates nurses' willingness to incorporate DAT into the planning and practical implementation of care processes. The extent to which DFree Professional supports clinical care delivery and assists nurses in managing activities of daily living related to micturition remains unclear. It is anticipated that DFree will contribute to a reduction in nurses' workload in continence care settings. The device was designed with the objective of ensuring high usability for the nursing staff and of increasing user acceptance over the course of the study. This mixed-methods pilot study included 31 nurses from neurology and geriatrics wards over 3 months. Quantitative data were collected using the technology usage inventory (TUI) at three time points and System Usability Scale (SUS) assessments at one (final) point. Qualitative data were gathered through focus group interviews. Ethical approval and informed consent were obtained. The study revealed a decline in the intention to use (ITU) of the DFree Professional sensor. Usability ratings reported the SUS benchmark of the study, yielding a mean SUS score of 50.9, which is below the commonly referenced benchmark of 68 for acceptable usability. Nurses reported the device has potential reductions in workload and improved management of continence care, if further infrastructural and problems with interfaces are solved. Qualitative findings highlighted user-friendly features and identified barriers to implementation, such as technical integration into existing systems. The DFree Professional sensor shows promise in enhancing nursing efficiency and reducing the burden of continence care. Future research should explore long-term effects on defined patient groups and broader applicability across diverse clinical settings.

Trial Registration: German Register of Clinical Studies: DRKS00031483

Abbreviations: ACC, accessibility; ANX, anxiety; CUR, curiosity; DAT, digital assistive technologies; DFree Professional, diaper-free ultrasound sensor; EAS, ease of using a technology; INT, interest; ITU, intention to use; SKE, scepticism; STC, structured text condensation; SUS, system usability scale; TREND, transparent reporting of evaluations with non-randomised designs; TUI, technology using inventory; USE, usefulness; VAS, visual analogue scale.

Sebastian Hofstetter and Madeleine Ritter-Herschbach contributed equally to this work.

Summary

- What is currently known?
  - Digital assistive technologies (DAT) for continence care have been explored primarily in home-based and outpatient settings.
  - A substantial body of research has demonstrated the potential of such technologies focusing on supporting self-management in patients with urinary incontinence, enhancing their independence and reducing incontinence burden.
  - The DFree Personal ultrasound sensor has demonstrated potential in predicting urination needs and optimising care routines in non-clinical environments.
  - Nevertheless, the evidence regarding the feasibility, acceptance and utility of DAT in inpatient clinical care remains limited.
- What does this article add?
  - This study offers the inaugural empirical evaluation of the DFree Professional ultrasound sensor within a hospital-based nursing context.
  - The study appraised nurses‘ intention to utilise the device, its perceived usability and barriers to implementation.
  - While the sensor shows promise in reducing workload and enhancing continence care, technical and organisational challenges hinder its effectiveness in clinical practice.
  - The findings underscore the significance of infrastructure adaptation and staff training to enhance DAT integration in inpatient care.

1 | Introduction

Bladder dysfunction represents a significant and expanding public health concern, affecting approximately 50 million individuals globally [1]. These conditions encompass a wide range of disorders, from urinary incontinence (UI) to bladder emptying disorders with acute post-renal kidney failure [2, 3]. From the perspective of inpatient urological care, these dysfunctions present significant challenges for healthcare systems, in terms of both the allocation of resources and the direct impact on patients' quality of life. The management of bladder dysfunction is of paramount importance in reducing the associated physical and psychological burdens. From a physical perspective, bladder dysfunction can give rise to secondary complications, including skin irritation, urinary tract infections and an increased risk of falls due to urgency-related instability [4]. From a psychological perspective, the loss of continence frequently results in social withdrawal, diminished self-esteem and elevated levels of distress [5–7]. Older, multi-morbid people, in particular, suffer from the negative effects on their quality of life. In geriatric patients, the prevalence of UI is up to 80% [8]. From a healthcare perspective, inpatient settings frequently rely on absorbent products or basic sensor technologies for the monitoring and management of bladder dysfunction [9]. These conventional solutions, while addressing immediate needs, have little impact on the long-term care burden on nursing staff or on the achievement of comprehensive, patient-centred outcomes (e.g., quality of life) [10]. It has been demonstrated that patients with bladder dysfunction are more prone to prolonged hospitalisation and repeated admissions [11], which in turn increases the workload of healthcare providers and nurses [5, 12]. The advent of new technologies, such as digital assistive technologies (DATs), offers a promising avenue for addressing these limitations in the field of urological medical and nursing care [3, 13–15].

The ‘diaper free’ ultrasound sensor (DFree Professional) represents a novel approach to the prediction of urination needs and the enabling of timely interventions. DFree Professional has been developed for utilisation in medical facilities, such as hospitals and nursing homes, as well as in-home care agencies. The device, when used in conjunction with a base station, facilitates the remote monitoring of patients' urination status via cloud-based technology. This enables physicians, nurses and other professional care providers to remotely monitor patients' urination patterns, facilitating more efficient and comprehensive healthcare management [16, 17]. The device has the potential to reduce the risk of adverse events, such as incontinence-related bedwetting, while simultaneously alleviating the strain on caregivers as well as nurses in inpatient care settings [18–20]. The preliminary evidence indicates that DAT has the potential to enhance outcomes of continence care by facilitating greater independence and encouraging involvement in care processes for individuals with urological conditions. Continence care is defined as the comprehensive nursing practices aimed at supporting and managing an individual's bladder and urinary control. A fundamental aspect of professional nursing practice entails the assessment, diagnosis and intervention to address fundamental human needs [21–23]. This encompasses the provision of essential care, including elimination and continence support, which constitutes a crucial component of the fundamental principles of caring [21]. The programme incorporates evidence-based interventions, including bladder training, scheduled toileting and prompted voiding, which are tailored to patients' physiological and cognitive needs to minimise UI and preserve dignity [24]. UI—the involuntary leakage of urine [25], is a prevalent condition that significantly impacts quality of life and is a key focus of continence care. Within the domain of nursing practice, the management of incontinence entails a systematic evaluation of the individual patient's bladder function, the formulation of bespoke care plans and the utilisation of non-invasive assistive devices or technological solutions to promote continence and maintain independence. IJUN-published literature highlights the pivotal function of nurses in implementing patient-centred and standardised continence care protocols, such as prompted toileting and scheduled voiding. This is particularly salient in the context of older or rehabilitative patient groups, with the objective of enhancing the effectiveness of nursing care and optimising patient outcomes [3, 23, 25].

This study examines the incorporation of the DFree Professional ultrasound sensor into inpatient urological and micturition nursing care, with a focus on its usability, nurses' intention to use (ITU) and possible impact on nursing care workflows. These endeavours seek to address significant deficiencies in current care strategies by leveraging technology to improve both patient and provider experiences.

2 | Aim

The aim of this study is to evaluate the impact of the DFree Professional ultrasound sensor on professional continence care practices within inpatient settings [17].

This study seeks to investigate how DFree Professional facilitates nursing workflows, identifies changes and barriers related to nurses' ITU the technology and explores nurses' reception of sensor integration and associated software into inpatient nursing care processes. Furthermore, the study examines the co-creation and participation of implementation strategies to ensure high acceptance and usability in clinical practice. Specifically, the study aims to measure whether the use of DFree supports and improves anticipatory continence care coordination and reduces nursing workload. These clinical aspects are operationalised through validated usability and acceptance instruments (SUS, TUI) and explored in depth via qualitative interviews.

3 | Methods

3.1 | Study Design

This study was designed as a monocentric, exploratory, mixed-methods pilot study, conducted in an inpatient care setting [17]. The aim was to assess the usability, acceptability and impact of the DFree Professional ultrasound sensor on inpatient care to support continence care. The methodology is reported in accordance with the guideline for transparent reporting of evaluations with non-randomised designs (TREND) [26]. The study employed a mixed-methods approach integrating both qualitative and quantitative data collection methods to ensure comprehensive analysis [27, 28]. The so-called sequential explanatory design [27] enables the identification of quantitative results that require further elucidation. The sequential explanatory design with mixed methods comprises two distinct phases: a quantitative phase and a qualitative phase. The researcher initiates the study with a quantitative phase, which is followed by a second qualitative phase. The objective of this second phase is to provide a more in-depth explanation of the initial quantitative results.

Part 1 included using the technology using inventory (TUI) [29]. Three measurement points were established: pre-implementation (T1), mid-intervention (T2) and post-intervention (T3) to assess ITU. Therapy satisfaction was assessed using the German version of the system usability scale (SUS) [18–20, 30–31] at T3. The SUS developed by Brooke [18] has been extensively validated across a broad range of applications and technologies. Its robustness, high internal consistency (Cronbach's α typically >0.85) and sensitivity to usability differences have been confirmed in multiple studies, including in healthcare and clinical contexts [19, 30]. The technology usage inventory (TUI) is a psychometrically validated German-language instrument developed by Kothgassner et al. for assessing individual attitudes towards technology. As stated in the TUI manual [29], the inventory demonstrates satisfactory construct validity, criterion validity and internal consistency (Cronbach's α ranging from 0.70 to 0.89 across subscales). The TUI is specifically designed to evaluate technology-related dimensions such as curiosity, anxiety, perceived usefulness and ITU, making it suitable for studies assessing digital tools in healthcare settings.

Part 2 included a focus group interview that analysed participating nurses' subjective experiences regarding the user-friendliness, potential hurdles and support achieved through the use of the DFree Professional ultrasonic sensor (Triple W Japan K.K., Tokyo, Japan). The evaluation was carried out using Malterud's content-analytical and topic-generating method of structured text condensation (STC) [32, 33], with the data processing being carried out by ChatGPT 4.0.

Both parts were then related to each other using triangulation; that is, merging the data through a combination of qualitative and quantitative research (Figure 1).

3.2 | Setting and Participants

At the time of the study, a total of 52 specialist nurses were employed in the two internal departments of the hospital—27 in the neurology department and 25 in the geriatric department. Initially, 31 nurses consented to participate in the introductory and feasibility study. The final sample size of approximately 30 participants was in line with established recommendations for pilot studies, which aim to assess the feasibility, usability and acceptance of interventions in real-world clinical settings. As the objective of this study was not to test hypotheses but to generate preliminary data and inform future research, no formal power calculation was conducted. Conversely, the sample size was determined in accordance with the recommendation that 24–30 participants is adequate for pilot studies of this nature [34, 35]. The participant flow throughout the study is detailed in the corresponding diagram (Figure 2).

The sample size was determined based on the feasibility and the availability of nursing staff in the setting under investigation. For a feasibility study with an exploratory character, a minimum number of 30 participants was deemed sufficient to gain initial insights into the acceptance and usability of the device. Following consultation with the respective clinic and nursing management, as well as approval by the staff council, the nurses were recruited through internal communication channels and by their team leaders, with participation being voluntary. Inclusion criteria required nurses to be directly involved in continence care processes and willing to participate in both the training and evaluation phases.

3.3 | Intervention

The DFree Professional ultrasound sensor was integrated into the routine activities of daily living of participating wards. The device is capable of predicting bladder filling and signalling the need for urination through a connected app [3, 36–38], thereby aiding both patients and caregivers in the management of continence care. Prior to implementation,

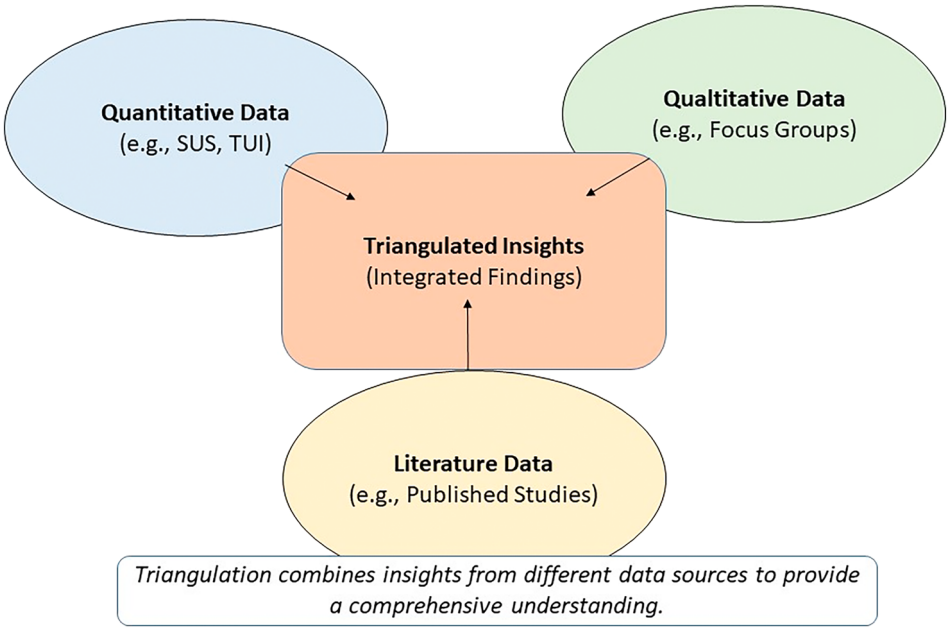

FIGURE 1 | Triangulation of result.

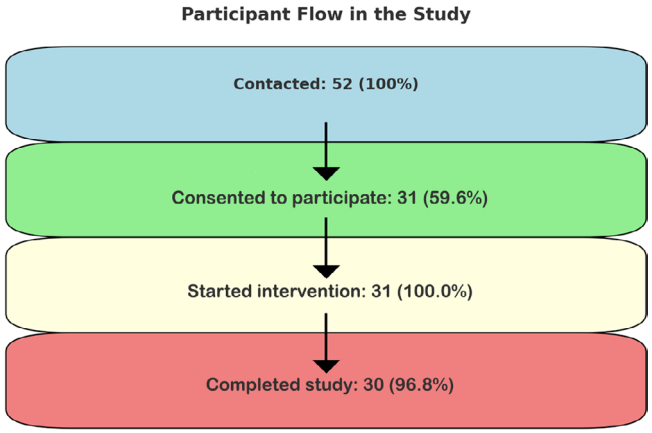

FIGURE 2 | Participant flow in the study.

nurses received structured training on the utilisation and functionalities of the sensor, following the SEQI framework [39], which emphasises sensitisation, evaluative introduction, qualification and implementation in digital care technologies. The training programme encompassed practical sessions on the utilisation of the DFree device, the interpretation of sensor output and its incorporation into clinical continence care protocols. The format promoted active user participation, contextual learning and reflection. Ongoing on-site support was provided throughout the study to facilitate implementation. As no patient-related data were collected, formal written patient consent was not required. However, all patients receiving continence care supported by the DFree device were informed verbally about the project during their hospital stay. Patients were granted the opportunity to consent or withhold consent from the use of the device, with no repercussions for their clinical care. In all cases where patients or relatives expressed objections, the device was not used.

3.4 | Data Collection

3.4.1 | Quantitative Measures

3.4.1.1 | **TUI.** The quantitative data collection was carried out using two established instruments: the TUI and the SUS. The TUI was employed to assess nurses' ITU the DFree Professional technology at three distinct time points: pre-implementation (T1), mid-intervention (T2) and post-intervention (T3). The TUI offered insights into various dimensions, including curiosity, anxiety, user-friendliness, usefulness, scepticism and accessibility [29]. The TUI contains a total of 30 items divided into 8 scales. In addition, the TUI includes the ITU scale. All scales consist of four items, except for the scales Accessibility, User-Friendliness and ITU, which only have three items. Similarly, a theory-based parallel form of the TUI was created, which also contains 30 items and 8 scales and can be used for progress analysis (multiple measurements). Items with the wording 'this technology' refer to the technology to be evaluated in the study. The wording 'this technology' can be replaced by the name of a specific technology if this is desired to make the items easier to understand. These items are the items of the scales immersion, curiosity, accessibility, user-friendliness, usefulness, scepticism and ITU (Table 1).

The ITU visual analogue scale (VAS) is a 10-centimetre tool that is used to assess the degree of agreement or disagreement with a given statement. The scale's endpoints, defined as 'applies' and 'does not apply', respectively, serve as reference points for quantifying the intensity of agreement. The distance from the right endpoint, which represents full disagreement, is measured to the response cross on the line. The distance determined in this way (in millimetres) is determined for all three items (A–C) and summed up, resulting in a maximum scale sum of 300 and a minimum of 0 for the ITU scale. Item A is defined as 'Would you want to use this technology?' Item B is defined as 'Would you purchase this technology?' Item C is defined as 'Would you want to have access to this technology?' [29].

TABLE 1 | Description of the technology usage inventory scales [17, 29].

Scale	Description
Curiosity (CUR)	Curiosity and unpreparedness of a person regarding a specific technology.
Ease of using a technology (EAS)	Perceived user-friendliness, like the ease of handling and willingness to obtain information independently.
Interest (INT)	Perceived specific technology interest.
Usefulness (USE)	Perceived usefulness for the user (TAM)* of a specific technology. Refers to support or assistance.
Scepticism (SKE)	A person's scepticism and distrust about the use of a specific technology. Assessment of risks, dangers, disadvantages.
Accessibility (ACC)	Perceived considerations for the extent of availability being perceived of a specific technology.
Anxiety (ANX)	Refers to emotional anxiety aspects and concerns.
Intention to use (ITU)	Intention to actually use a specific technology.

Note: * TAM = Technology Acceptance Model as introduced by Davis (1989) [40], which identifies perceived usefulness and perceived ease of use as fundamental determinants of user acceptance of technology.

Descriptive and inferential statistics were employed to analyse the TUI scores, thereby capturing the participants' attitudes towards the technology at each stage of its implementation. Concurrently, the SUS [18, 20] was administered to evaluate the nurses' perceptions of the DFree Professional device's usability. The SUS was implemented at the final measurement point (T3) and participants responded to a 10-item Likert scale. The results were then subjected to analysis and interpretation, with the interpretation framework informed by established benchmarks for acceptability. A score of 68 or higher was considered indicative of the system's fit for use [18, 20]. The SUS offers a focused evaluation of the user experience, including the ease of use and the perceived complexity of the device. The SUS and the TUI complemented each other by offering both broader and more specific perspectives on the usability and acceptance of the DFree Professional technology among the participating nurses. TUI scores were analysed by means of descriptive and inferential statistics [17]. The quantitative analysis was carried out using IBM SPSS Statistics V.25. The data were described using mean values and standard deviations (MW, SD). Frequencies were presented in absolute terms and as a percentage (%).

3.5 | Qualitative Measures

The initial study protocol proposed the utilisation of semi-structured expert interviews with a sample size of 6–10 participating nurses, with the objective of gathering qualitative insights pertaining to the usability, acceptance and integration of the DFree Professional ultrasound sensor into clinical workflows [17]. However, during the recruitment phase, only three nurses expressed a willingness to participate. This response rate was insufficient to achieve the anticipated sample size for individual interviews, necessitating a reassessment of the methodological approach. To address this limitation, a focus group methodology [41] was adopted as an alternative to the planned expert interviews. Focus groups represent a well-established qualitative method that allows for the exploration of shared experiences and collective insights within a group setting. The advantages of this approach include the generation of dynamic discussions and the ability to elicit a wider range of perspectives through interactive dialogue [41].

The decision to transition to a focus group format was informed by a number of considerations:

1. Due to the *limited number of participants*, the research was constrained in terms of the depth and breadth of insights that could be obtained through individual interviews. The limited number of available participants would have considerably restricted the depth and breadth of insights that could be obtained through individual interviews.
2. The objective is to achieve the *greatest possible data richness*. The focus group setting facilitated group interactions, enabling participants to build on each other's responses and thereby uncover nuanced experiences and shared challenges that may not have emerged in isolated interviews [41].
3. The question of *feasibility and ethical responsibility* is of paramount importance. The focus group format was designed to optimise the use of resources while respecting the time constraints and availability of the nursing staff. This approach aligns with ethical considerations to minimise participant burden.

Although focus groups are conducted in a manner that differs from that of individual interviews, they remain consistent with the study's original term of exploratory design and user-centred approach [17]. The data collected through this format provided valuable insights into the practical implementation of DFree Professional and the experiences of nursing staff in adopting this technology. This flexibility in methodology highlights the importance of adapting research designs to real-world conditions in order to generate evidence while maintaining rigour and relevance in achieving the study objectives.

The transition from expert interviews to focus groups was documented transparently and aligned with established qualitative research standards in order to ensure the validity and reliability of the findings.

4 | Results

4.1 | Sample Characteristics

The study sample comprised 31 participants, with valid data provided for the majority of variables. The majority of participants (45.2%) were between the ages of 21 and 30 years,

TABLE 2 | Mean and standard deviation (SD) of the subscales of the TUI at all three measurement times.

	Results $n = 31$											
	T1				T2				T3			
Scales	*N*	Range	Mean score	SD	*N*	Range	Mean score	SD	*N*	Range	Mean score	SD
Curiosity	29	5.00–26.00	14.38	4.44	28	4.00–22.00	14.10	5.17	30	4.00	12.70	5.64
Fear of using a technology	29	4.00–24.00	11.41	5.49	29	4.00–24.00	10.86	5.26	30	3.00–18.00	11.13	2.71
Interest	.	.	.	.	29	4.00–27.00	16.93	5.77	30	4.00–26.00	17.50	6.10
User friendliness	.	.	.	.	29	3.00–17.00	10.51	2.91	30	3.00–17.00	9.83	2.86
Usefulness	.		.	.	29	4.00–27.00	18.89	5.53	30	4.00–24.00	14.76	5.18
Scepticism	.	.	.	.	29	4.00–21.00	15.75	2.97	29	4.00–20.00	16.44	3.41
Accessibility	.	.	.	.	29	3.00–17.00	10.96	2.71	30	3.00–18.00	11.13	2.71
Intention to use (ITU)	30	26.00–94.00	64.57	17.58	29	0–94.00	63.48	28.39	30	0–92.00	47.83	25.42
Purchase suggestion	30	23.00–93.00	64.90	20.36	28	0.-94.00	62.25	28.83	30	0.-89.00	48.80	24.67
Utilisability	30	8.00–96.00	63.67	22.01	28	0.-100.00	63.71	30.25	30	0.-91.00	48.50	25.28

Note: One participant completed only the demographic section but did not participate in the main quantitative survey. Therefore, demographic data are based on $n = 31$, while quantitative analyses were conducted with $n = 30$.

followed by 19.4% aged 31–40 years and 16.1% in the 51–60 years age range. A mere 3.2% of participants were above the age of 60. The sample was predominantly female (67.7%), with 29.0% male participants. One participant did not provide data regarding gender. With regard to the period since qualification, 32.3% of the sample had completed their training within the previous 5 years, while 19.4% had between 5 and 10 years of experience. Smaller proportions of respondents indicated that they had been qualified for between 11 and 20 years (22.6%) or over 25 years (9.7%), respectively. With regard to professional qualifications, the majority of participants (80.6%) had completed a 3-year nursing training programme, while 9.7% held a nursing degree and one participant (3.2%) reported a 2-year training programme. Overall, the sample comprised a predominantly young, female nursing workforce with varying levels of experience, the majority having completed standard 3-year nursing training.

4.2 | Quantitative Results

The results of the TUI were assessed at three time points: baseline (T1), after the introduction of the technology (T2) and following practical implementation (T3). The SUS was employed to assess the perceived usability of the system at the final measurement point.

At T1, the baseline measurements indicated an initial level of curiosity and technology-related anxiety among participants regarding the utilisation of the DFree Professional technology. Following the intervention at T2, interest showed an increase, while curiosity remained relatively stable. Accessibility was rated at a moderate level and user-friendliness received a slightly lower evaluation. Perceived usefulness was rated positively, while scepticism was also present at a measurable level. Technology-related anxiety remained relatively unchanged. The ITU the technology showed a high mean score at T1. At T3, interest remained stable, while curiosity exhibited a slight decline. A minor increase was observed in accessibility ratings, whereas both user-friendliness and perceived usefulness showed a decrease. Scepticism demonstrated a slight increase, while technology-related anxiety remained relatively stable. The technology's ITU saw a decline compared to the previous measurement point, particularly, in the subscale of 'purchase suggestion' and 'utilizability'.

For a detailed overview of the numerical values, please refer to Table 2.

The individual questions of the ITU scale were employed for the purpose of recording the specific intention to utilise a particular technological innovation. It can be seen, therefore, that ITU is a prerequisite, in that it predicts the subsequent use of the device. The transition in the ITU from T1 to T3 is demonstrated in Figure 3.

The SUS was administered at the conclusion of the study. The mean SUS score was 50.86 (SD = 14.47), with values ranging between 15.00 and 82.50. These findings provide a comprehensive overview of participants' attitudes and perceptions of the DFree Professional technology, including interest, curiosity, accessibility, user-friendliness and perceived usefulness, over the three measurement points. The SUS results provide an overall usability evaluation of the system at the conclusion of the study. Specifically, the questions about 'ease of use' ($n = 31$)

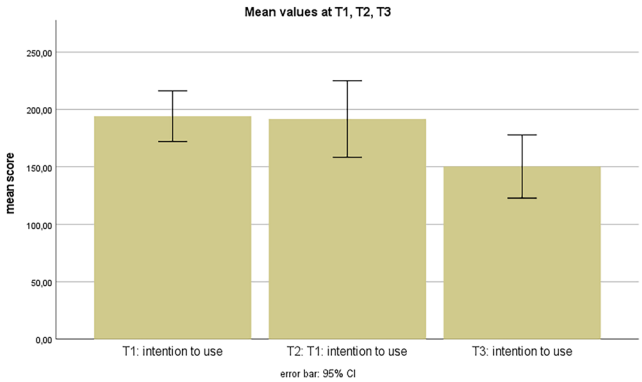

FIGURE 3 | Error bar chart of the mean values at the measurement times T1, T2 and T3.

and 'confident using' ($n = 31$) were answered positively by the majority of participants, whereas the question regarding 'frequently system use' ($n = 31$) was answered negatively in some cases. Participants who tended to be more satisfied according to the feedback provided on the SUS questionnaire also reported a better ITU on the TUI. According to the SUS manual, a system is considered usable if it attains a score of 68, which was not reached in our study except for three participants. A subsequent Pearson correlation analysis yielded a positive yet non-significant correlation ($r = 0.190$, $p = 0.322$) between the overall SUS score and ITU at T3.

4.3 | Qualitative Results

The focus group offers a comprehensive insight into the subjective assessments and experiences of nursing staff with the DFree Professional ultrasound sensor. The interviews conducted following the test phase permitted the acquisition of general insight into the extent of support with regard to continence care and the perceived usefulness of the device. It identifies the principal challenges and opportunities that arise from the utilisation of the device. The nurses discussed the applicability, acceptability and practicality of the device from the nurses' and patients' points of view. Issues such as hygiene concerns, technical and infrastructural difficulties, as well as time requirements are weighed against a positive perception of the device as a potential aid in promoting and maintaining continence. The overall impression is that nurses consider the DFree Professional sensor to be potentially helpful, especially for partially independent and oriented patients. Challenges arise from technical, hygienic and organisational problems that affect ITU, acceptance and usability in inpatient care in a gerontological setting. In the area of neurological care, the device's efficacy depends on the level of orientation and neurological impairment. The qualitative data were subjected to analysis using the method of STC as proposed by Malterud [32, 33]. This approach facilitated the generation of insights pertaining to the experiences and perceptions of nursing staff with regard to the utilisation of the DFree Professional in clinical practice. The method demonstrated its suitability for the transition from conducting individual interviews to conducting focus group interviews. The analysis identified four key themes that encapsulate both the potential benefits and the challenges associated with the device. The overall impression was that the DFree Professional sensor was perceived as potentially beneficial, particularly, in supporting patients who are oriented and self-sufficient, where it could facilitate greater independence and improve continence care supported by nurses. However, significant challenges emerged in relation to technical issues, concerns regarding hygiene and the additional workload required for implementation.

1. Usability and Acceptance: The DFree Professional sensor was perceived as a useful tool for patients who were oriented and self-sufficient, as it could assist in the improvement of continence care and foster independence. However, in cases where patients exhibited cognitive impairments, such as those associated with dementia, the device was frequently rejected or removed by the patients themselves. Furthermore, some family members expressed discomfort, perceiving the sensor as invasive or unnecessary.
2. Technical Barriers: The participants identified a number of technical challenges that affected the functionality of the sensor. However, these issues were not exclusive to the device itself but rather reflected the necessity to establish the requisite digital infrastructure, both within and beyond the organisation, in order to facilitate the practical deployment of such digital assistance technologies at a low threshold. The technical issues identified included frequent Wi-Fi disconnections, limited battery life and inaccuracies in measurements, especially for overweight patients. Furthermore, concerns were raised about hygiene and cleaning the sensor after incontinence incidents. It was noted that the current cleaning procedures are unsuitable and insufficient for routine care.
3. Organisational Barriers: The incorporation of the device into existing work routines presented considerable difficulties. The nursing staff reported that the time required to adjust the sensor for each patient resulted in an increased workload. Moreover, the absence of real-time notifications or integration with existing documentation systems constrained the device's practical utility. It was proposed by the participants that the implementation of individualised devices or automated alerts could enhance the usability of the device in practice.
4. Training and Education Needs: Insufficient training in the use of the DFree Professional sensor led to uncertainty and inconsistent use among nursing staff. Participants emphasised the need for comprehensive training, including hands-on demonstrations and step-by-step instructions. They also highlighted that repeated training opportunities and access to educational materials, such as video tutorials, would help improve confidence and competence in using the device.

5 | Discussion

The objective of this study was to evaluate the ITU, usability, acceptance and integration of the DFree Professional ultrasound sensor into clinical workflows [17] using a sequential explanatory mixed-methods design [27]. The quantitative findings from the TUI [29] and the SUS [18–20] were augmented by qualitative insights gleaned from focus group discussions analysed as

suggested by Malterud [32, 33], thereby providing a comprehensive understanding of the technology's implementation in inpatient care settings to support continence care.

5.1 | Discussion of the Quantitative Results

The TUI results demonstrated that the initial interest in the DFree Professional sensor remained relatively stable over time, with a mean score of 16.93 at T2 and 17.50 at T3. There was a slight decline in curiosity between these time points, from 14.11 to 12.70, which may indicate a waning enthusiasm following practical experience with the device. The perception of accessibility and user-friendliness remained consistent but at moderate levels, with a slight decline in the latter over time. A notable decline was observed in the perceived usefulness of the device, from T2 (18.90) to T3 (14.77), suggesting that participating nurses encountered practical challenges during implementation. A critical factor contributing to this decline was the restrictive nature of the existing 'Internet network infrastructure', which is not yet optimised to support such devices. The frequent disconnection between the ultrasound sensor and the monitoring tablet led to impaired functionality, thereby diminishing the perceived usefulness of the device. This observation underscores the notion that the observed decline in the 'ITU' was not attributable to the device itself but rather to the connectivity issues stemming from the suboptimal digital infrastructure prevalent in German healthcare facilities. These challenges impede the implementation of innovative technologies, which in turn affects nurses' willingness to adopt the device due to its diminished functionality in practice. There was a slight increase in scepticism towards the technology, while technology-related anxiety remained low and stable throughout the study period. The ITU the DFree Professional sensor exhibited a decline from 191.64 at T2 to 145.13 at T3, indicative of a diminished proclivity to integrate the device into established routines of care.

The SUS results provided further support for these findings, with an overall mean score of 50.86 (SD = 14.47), which fell below the benchmark score of 68 for acceptable usability. The SUS item analysis revealed that participants perceived the app as somewhat secure and learnable (with mean scores of 2.23 and 2.63, respectively). However, they also reported the need to invest effort to learn its use (with a mean score of 2.68) and rated the app as unnecessarily complex (with a mean score of 1.65).

5.2 | Discussion of the Qualitative Results

The qualitative focus group discussions yielded four major themes that contextualised the quantitative findings. These were usability and acceptance, technical challenges, organisational barriers and training needs.

1. *Usability and acceptance*: Participants noted that the DFree Professional sensor was particularly useful for cognitively intact and self-sufficient patients, where it supported independence and improved continence care. However, it was deemed unsuitable for patients with dementia, who often rejected the device.
2. *Technical challenges*: Issues such as frequent Wi-Fi disconnections, limited battery life and inaccurate measurements, particularly, for overweight patients, were identified as significant barriers. It is important to clarify that the Wi-Fi disconnections were not caused by deficiencies in the DFree Professional device itself but rather by the restrictive network infrastructure within the clinical setting. Specifically, the hospital's security protocols mandated that devices be disconnected from the network every 12–24 h, requiring manual reconnection by the users. This process significantly increased the workload for staff and contributed to reduced acceptance of the device. Additionally, concerns about hygiene when cleaning the sensor after incontinence incidents further diminished its overall usability.
3. *Organisational barriers*: Participants described the additional workload required to adapt the device for each patient as a major limitation. The lack of integration into existing documentation systems and real-time notifications further hindered its practical use.
4. *Training and education needs*: Insufficient initial training resulted in uncertainty and inconsistent application. Participants emphasised the need for comprehensive and repeated training sessions, including practical demonstrations and instructional materials [42].

6 | Integration of Quantitative and Qualitative Results

The quantitative results clearly showed that there was moderate interest and initial curiosity about the DFree Professional sensor. This was evident from the stable interest scores from the TUI, which were 16.93 at T2 and 17.50 at T3. However, there was a slight decline in curiosity from 14.11 at T2 to 12.70 at T3, a trend that was corroborated by the qualitative findings. During focus group discussions, participants were unequivocal in their optimism about the sensor's potential for supporting independent and cognitively intact patients, particularly in neurological or rehabilitative settings. It is clear from statements such as 'I find it good for patients who are independent and oriented, they will benefit from it' that this is a positive perception. However, enthusiasm quickly dissipated as practical challenges emerged during routine use. Participants were frustrated by technical issues, such as frequent Wi-Fi disconnections and battery life constraints, which led to a reduction in motivation to continue using the device. This feedback provides a clear and definitive explanation for the quantitative drop in perceived usefulness (TUI_T2: 18.90 to TUI_T3: 14.77) and the significant decline in ITU (TUI_T2: 191.64 to TUI_T3: 145.13).

The SUS results irrefutably reflect this dynamic. The overall SUS score of 50.86 (SD = 14.47) is below the 68 benchmark, clearly indicating that the device's usability is suboptimal. The SUS scores can be attributed to multiple practical challenges, including the complexity of use and the need for frequent manual

interventions when contextualised with the qualitative results. The focus group participants were unequivocal in their assessment of the sensor, describing it as 'cumbersome' and noting that it often required substantial effort to operate effectively. One participant stated, 'When too many problems arise, motivation to use the device drops quickly because the time investment is much higher than simply checking on patients regularly'. These accounts align closely with the quantitative ratings on SUS items, such as 'I had to learn quite a bit to use the app' (mean = 2.68) and 'The app seems unnecessarily complicated' (mean = 1.65). The user-friendliness ratings remained low, despite showing no change (TUI_T2: 10.52, TUI_T3: 9.83). This was reflected in the qualitative feedback about integrating the sensor into daily workflows. Participants stated that the lack of real-time notifications and the reliance on centralised devices, such as tablets, are significant barriers to smooth operation. It is clear that the device does not work if there is only one tablet. Individual devices or notifications linked to our documentation systems are essential to ensure seamless integration and optimal usability. These insights clearly show that the sensor's limited integration into existing nursing systems had a negative impact on both its perceived accessibility and ITU over time. It is notable that technology-related anxiety remained consistently low (TUI_T2: 10.86, TUI_T3: 10.68), a finding that was reinforced by the qualitative data. Participants were confident in their ability to learn and operate the sensor, particularly with appropriate training. This is reflected in SUS items like 'I believe most people can learn to use the app quickly' (mean = 2.63), which shows that while the device was perceived as challenging to integrate, participants were confident in its use. However, the focus groups made it clear that more training is needed to explain why there have been inconsistencies in how the device has been used. Participants demanded comprehensive, repeated instruction to ensure greater confidence and competence, noting insufficient initial training. 'We needed more structured and larger-scale training sessions with examples or videos'. This finding demands investment in staff training to improve the sensor's usability and acceptance.

6.1 | Connecting Usability, Organisational Barriers and Target Populations

The integration of quantitative and qualitative data also permits an investigation of the relationship between usability and target patient groups. Although quantitative ratings for usability and user-friendliness decreased over time, qualitative findings indicate that these perceptions were significantly influenced by the specific patient population. The participants consistently identified patients who were oriented, younger and cognitively intact as the ideal users of the DFree Professional sensor. Statements such as 'In neurology or rehabilitation settings, with patients who are able to utilise the device independently, it is a logical choice' illustrate its potential for targeted use. In contrast, the device was deemed unsuitable for geriatric or dementia patients, where rejection of the sensor and removal of the device were common issues. 'Dementia patients simply remove it because it is perceived as a foreign object on their body'. These insights provide a potential explanation for the moderate SUS score and the decline in quantitative measures such as ITU. Although the device demonstrated potential in specific patient groups, its universal implementation across all patient populations resulted in inefficiencies and frustration among staff, ultimately reducing overall acceptance. At this juncture, modifications to the device, akin to those employed in the development of diabetes-specific aids such as continuous glucose monitoring systems or insulin pumps [43], could prove instrumental in preventing the improper removal of the ultrasound sensor when worn by individuals with dementia. It should be noted, however, that even if the sensor is removed, the risk of injury appears to be significantly reduced, as with the removal of an obstructed permanent bladder catheter. Aligning the sensor's use with appropriate patient populations may lead to improvements in both perceived usefulness and usability outcomes.

6.2 | Technical and Organisational Barriers

The findings consistently highlighted technical barriers as a significant issue in both the quantitative and qualitative data. Participants expressed frustration with Wi-Fi disconnects, inaccurate readings and limited sensor battery life, all of which directly impacted their perceptions of usability. This is consistent with the lower SUS scores and TUI evaluation results regarding usability and accessibility. A key factor contributing to these challenges was the restrictive network infrastructure in clinical settings, which hindered the seamless integration of external devices such as the sensor. In particular, the lack of simple and secure connectivity options—driven by strict institutional policies—exacerbated these technical issues. To improve usability and accessibility, healthcare providers, including hospital and long-term care facility operators, must prioritise infrastructure upgrades that support the integration of external devices and DATs. In this context, a 'constructive' rather than a 'defensive' approach to data protection, emphasising that regulation should enable rather than hinder innovation, is of maximum importance [44]. The current 'defensive' approach to privacy in healthcare in our study results in restrictive network protocols, such as mandatory device disconnections every 12–24 h, which require manual reconnection and place an additional burden on using nurses. A 'constructive' approach would balance security with usability, fostering environments where external devices can be more easily and securely integrated. Organisational challenges, such as the lack of real-time notifications and seamless integration with existing documentation systems, were also significant barriers to successful implementation. Participants repeatedly emphasised that improved integration is a prerequisite for making the sensor a practical part of routine procedures: 'If the alerts were integrated into our systems, it would be much easier to use'. Overcoming these organisational and technical barriers requires not only device-specific improvements, but also institutional efforts to create adaptable digital infrastructures. This shift will depend on stakeholders adopting a more progressive, enabling attitude towards digital transformation in healthcare.

7 | Synthesis of Findings

The sequential explanatory design enabled a more profound comprehension of the quantitative outcomes through qualitative insights. While the quantitative data indicated a decline in scores for usefulness and ITU, the qualitative findings revealed

that these trends were driven by a combination of technical limitations, increased workload and inappropriate patient targeting. Positive aspects, such as low technology-related anxiety and high confidence in learning, suggest that with targeted improvements in training, technical performance and organisational integration, the sensor could achieve greater usability and acceptance.

8 | Conclusion

The combination of quantitative and qualitative data offers a comprehensive insight into the usability and acceptance of the DFree Professional sensor in inpatient care settings. Although initial interest and curiosity were encouraging, practical challenges, technical issues and organisational barriers had a significant impact on the perceived usefulness and ITU the device. It is imperative that these obstacles be overcome through enhanced training, enhanced technical reliability and more seamless integration into existing workflows. Doing so will facilitate greater acceptance of the DFree Professional sensor and enable the realisation of its full potential, particularly, in the context of targeted patient populations. Further research should concentrate on optimising implementation strategies and investigating the technology's suitability for use in settings with cognitively intact patients. This study demonstrates the intricate relationship between usability, technical performance and organisational factors in the deployment of the DFree Professional sensor. The quantitative results indicated moderate levels of usability and a decline in the ITU the device. These findings were further elucidated by the qualitative data, which highlighted technical challenges, training needs and patient suitability as key factors. To optimise the sensor's potential, future implementation efforts should priorities the resolution of technical issues, the enhancement of staff training and the integration of the device into existing workflows. Furthermore, the targeting of specific patient populations, such as those with intact cognition and those undergoing rehabilitation, may enhance the device's acceptance and outcomes.

8.1 | Strengths and Weaknesses of the Study

This study has several strengths that contribute to its value in evaluating the implementation of the DFree Professional ultrasound sensor in inpatient urological care. First, the utilisation of a sequential explanatory mixed-methods design permitted a comprehensive investigation of the research question. The quantitative results obtained from the TUI and the SUS provided measurable insights into usability, acceptance and ITU. In addition, the qualitative focus groups offered a deeper contextual understanding of the aforementioned findings. This integration enabled a more detailed and sophisticated interpretation of the findings, thereby enhancing the reliability of the results. Second, the study was conducted in a real-world setting within the context of inpatient care, thereby ensuring both ecological validity and relevance to clinical practice. By engaging nursing staff as key stakeholders, the study was able to gain insight into the practical challenges and opportunities of implementing DATs in demanding care environments. Furthermore, the identification of specific patient populations where the device may be most beneficial (e.g., cognitively intact or rehabilitative patients) highlights potential avenues for future implementation. It is important to note that studying is not without limitations. A primary limitation of the study is the relatively small sample size, particularly, for the qualitative focus groups, where only three participants were included, rather than the planned 6–10. This may have resulted in a restricted diversity of perspectives being captured in the qualitative analysis. Nevertheless, the STC method ensured that meaningful themes could still be derived. Another limitation is the technical challenges encountered with the DFree Professional sensor, including issues with connectivity, constraints on battery life and measurement inaccuracies. While these challenges provided valuable insights into the potential barriers to implementation, they may have negatively influenced participants' overall evaluations, particularly, in the TUI and SUS scores. Moreover, the study was conducted at a single clinical site, which may limit the generalizability of the findings to other healthcare settings. It should be noted that organisational workflows, infrastructure and patient populations can vary significantly across different institutions and therefore the results may not be fully reflective of experiences in other contexts. Additionally, the study employed self-reported measures for the TUI and SUS, which are susceptible to response biases, including social desirability and recall bias. The combination of these measures with objective data, such as usage logs or patient outcomes, has the potential to further strengthen the findings in future research. In conclusion, while this study offers valuable insights into the usability and acceptance of the DFree Professional sensor, its limitations regarding sample size, technical challenges and generalizability must be considered. Addressing these limitations in future research will help validate and extend the findings, ultimately supporting the successful implementation of DATs in clinical practice.

Author Contributions

All authors contributed to the conception and design, data acquisition, analysis and manuscript preparation. All authors agreed to the final version and met at least one of the following criteria (recommended by the ICMJE [http://www.icmje.org/recommendations/]): Substantial contributions to the conception and design, acquisition of data, or analysis and interpretation of data. Drafting the article or revising it critically for important intellectual content.

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Ethics Statement

The Ethics Committee of the Martin-Luther-University Halle-Wittenberg approved this study with approval number 2023-031, dated 11.05.2023. The study was done in agreement with the guidelines of the Helsinki Declaration as revised in 1975.

Consent

Informed consent was obtained from all the participants.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **File A. File B. File C.**