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How Artificial Intelligence Challenges Tailorable Technology Design

Insights from a Design Study on Individualized Bladder Monitoring

Pascal Fechner · Fabian König · Jannik Lockl · Maximilian Röglinger

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Abstract Artificial intelligence (AI) has significantly advanced healthcare and created unprecedented opportunities to enhance patient-centeredness and empowerment. This progress promotes individualized medicine, where treatment and care are tailored to each patient's unique needs and characteristics. The Theory of Tailorable Technology Design has considerable potential to contribute to individualized medicine as it focuses on information systems (IS) that users can modify and redesign in the context of use. While the theory accounts for both the designer and user perspectives in the lifecycle of an IS, it does not reflect the inductive learning and autonomy of AI throughout the

tailoring process. Therefore, this study posits the conjecture that current knowledge about tailorable technology design does not effectively account for IS that incorporate AI. To investigate this conjecture and challenge the Theory of Tailorable Technology Design, a revelatory design study of an AI-enabled individual IS in the domain of bladder monitoring is conducted. Based on the empirical evidence from the design study, the primary contribution of this work lies in three propositions for the design of tailorable technology, culminating in a Revised Theory of Tailorable Technology Design. As the outcome of the design study, the secondary contribution of this work is concrete design knowledge for AI-enabled individualized bladder monitoring systems that empower patients with neurogenic lower urinary tract dysfunction (NLUTD). Overall, this study highlights the value of AI for patient-centeredness in IS design.

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1 Introduction

Individualized medicine, also referred to as personalized medicine, seeks to improve disease treatment by tailoring medical interventions to the unique and nuanced characteristics and contextual factors of a single patient (Goetz and Schork 2018). As wearable technologies, such as wristwatches and miniaturized wearable sensors, enable the collection of person-specific physiological and biochemical health parameters, they contribute to the advancement of individualized medicine (Chan et al. 2012; Ho et al. 2020;

Patel et al. 2012). Smart wearables, in particular, combine data collection and intelligent data analysis to prevent and detect various types of diseases at an early stage (Andreu-Perez et al. 2015; Baig et al. 2017), extending patient touchpoints far beyond the regular medical check-ups of today's healthcare system (Patel et al. 2012; Wu et al. 2008).

From an IS perspective, smart wearables play an increasingly crucial role in the development of individual IS, which empower individuals to produce informational products or services according to their own needs and preferences (Baskerville 2011; Benbunan-Fich 2019). In the IS field, well-established generic design guidelines exist, as exemplified by the design science research (DSR) paradigm (Gregor and Hevner 2013) or traditional and agile software development methods (Aitken and Ilango 2013). However, despite the potential of incorporating the user's role in the IS design process (Kujala 2003; Tait and Vessey 1988), IS theory has long underrepresented the circumstance that individual users can continuously and flexibly adapt IS to better align with specific goals in the context of use (Baskerville 2011; Germonprez et al. 2011). Against this backdrop, Germonprez et al. (2007; 2011) introduced the Theory of Tailorable Technology Design, which considers both the initial developers (i.e., primary design process) and the users (i.e., secondary design process) as designers during the lifecycle of an IS.

Since the inception of the Theory of Tailorable Technology Design, AI and related technological advances have driven significant improvements in various business applications (Baird and Maruping 2021). Technological advances have also led to the emergence of AI-driven IS that can learn inductively from data and address complex decision-making problems autonomously (Baird and Maruping 2021; Berente et al. 2021). Baird and Maruping (2021: 319) argue that rather than serving as a passive tool, the proactive and autonomous behavior inherent in AI-enabled IS “fundamentally changes how we should theorize around such artifacts.”

Considering the trend toward individualized medicine and other forms of individualization in IS, it is crucial to explore the design of AI-enabled IS that provide users with the ability to actively participate in the design process through adaptation according to their individual goals. However, IS theories such as structuration theory (Orlikowski 1992) or adaptive structuration theory (DeSanctis and Poole 1994) do not comprehensively describe and explain the design of AI-enabled IS. Also, theory on the design and analysis of AI-enabled systems does not account for the interplay among the designer, user, and AI-enabled system. In recent years, there have been efforts to theorize the design of such systems. For example, Herm

et al. (2022) discussed explainable AI, and Kane et al. (2021) explored emancipatory assistants. As these efforts mainly address the AI components of IS, they do not contribute to the interplay between the designer, user, and AI-enabled system. By contrast, the Theory of Tailorable Technology Design offers a more holistic view on the initial design and the role of the user, making it a suitable lens for future theory building. However, as the theory was introduced before the prevalence of AI-enabled IS, it focuses exclusively on the human role in tailoring IS. Therefore, to challenge and advance the Theory of Tailorable Technology Design, this study articulates the conjecture that the knowledge about tailorable technology design does not effectively account for AI-enabled IS.

To investigate our conjecture, we conducted a design study in the form of an advanced DSR project (Peppers et al. 2007), which involved the exploitation of state-of-the-art AI technology in a strategic public–private partnership with inContAlert GmbH. Given the conceptual synergies of tailorable technology design and individualized medicine, the goal of the design study was to develop an AI-enabled individual IS that serves as a revelatory example to exploratively challenge the explanatory power of the Theory of Tailorable Technology Design with regard to AI-enabled IS (Tsang 2014). Building on a smart wearable, the AI-enabled individual IS aimed to tailor to and improve the treatment process for patients who have lost bladder sensation. To address the socio-technical nature of tailorable technology design, we engaged with multiple stakeholders during the creation and evaluation of the proposed DSR artifact (Venable et al. 2016).

Our contributions to the field of IS are twofold. Based on the observations and insights from the revelatory design study, the primary contribution consists of three propositions for secondary design mechanisms that culminate in a Revised Theory of Tailorable Technology Design. Our work is the first to disclose interaction patterns between users and AI-enabled IS, laying the foundation for future theory building. The secondary contribution of our work, specifically the result of the design study, is an innovative DSR artifact that provides concrete design knowledge for an AI-enabled individual IS, showcasing how smart wearables can empower patients in chronic disease management. The design study further demonstrates how algorithmic individualization techniques can enhance predictive performance for bladder monitoring (i.e., the continuous monitoring of the urinary bladder volume), outperforming the predictive performance of previous studies on a real-world dataset of 22 subjects.

The structure of our work is as follows. Section 2 provides the theoretical background on individual IS and smart wearables as well as the Theory of Tailorable Technology Design. While Sect. 3 outlines the research design, Sect. 4

presents the design study, following the DSR reference process of Peffers et al. (2007). Drawing on the presented DSR artifact and the observations from our design study, Sect. 5 discusses the theoretical and practical implications of our work. Section 6 concludes our study considering limitations and potential avenues for future research.

2 Theoretical Background

2.1 Individual Information Systems and Smart Wearables

In the design study at hand, we focus on individual IS as the core of our research. In contrast to enterprise IS (e.g., enterprise resource planning, customer relationship management, or supply chain management) that support the execution of organizational processes (Seddon et al. 2010), individual IS are designed for being used by individuals beyond the work context (Alter 2008; Baskerville 2011; Benbunan-Fich 2020). Baskerville (2011: 1) defines an individual IS as “an activity system in which individual persons, according to idiosyncratic needs and preferences, perform processes and activities using information, technology, and other resources to produce informational products and/or services for themselves or others.” Enabled by the evolution of the Internet of Things and the miniaturization of electronics, individual IS are becoming increasingly prevalent in diverse domains (Baskerville 2011; Niknejad et al. 2020; Yetisen et al. 2018).

Wearable technology is a key factor in the evolution of individual IS, since it is primarily intended for personal use (Benbunan-Fich 2019). It represents a prosthetic, extending the user’s mind and body (Benbunan-Fich 2019; Oberländer et al. 2018). Wearable technology is characterized by its light weight and ability to be worn on the body to measure motion and/or vital signs (Abouzahra and Ghasemaghaei 2022). This allows for the detection of activities, positions, and body conditions without requiring active human intervention (Bardhan et al. 2020; Jiang and Cameron 2020). The size constraints of wearable technology lead to minimalist designs, often without screens or buttons, creating a clear separation between physical and digital interfaces (Benbunan-Fich 2020). The fragmented component architectures therefore typically consist of physical sensors that collect user data at high resolution and frequency (Yetisen et al. 2018; Zhu et al. 2020), and software applications that display the results of data aggregation and analysis (Benbunan-Fich 2020; Yang et al. 2021; Zadeh et al. 2021).

Advancements in machine learning (ML) and deep learning (DL) enable wearable technology to take over decision-making processes that were previously performed

by humans. Wearables that possess self-x capabilities (e.g., self-monitoring, self-configuration, and self-optimization) are considered as ‘smart’ (Alraho et al. 2022; Huber et al. 2019; Shi et al. 2020). They can assume responsibility and rely on their own perceptions instead of acting on prior knowledge instilled by their designers (Baird and Maruping 2021). Smart wearables can also connect with applications, such as smartphone apps, to allow for monitoring and user feedback (Abouzahra and Ghasemaghaei 2022; Chatterjee et al. 2018). In sum, wearable technology and AI-driven individual IS in general can exhibit new levels of autonomy by taking over active decision-making based on inductive learning from data (Baird and Maruping 2021; Berente et al. 2021), resulting in increased proactivity by initiating actions autonomously (Wenninger et al. 2022).

In the healthcare domain, examples of smart wearables include devices that support diabetes patients with individualized recommendations on activity and dietary behavior (Chatterjee et al. 2018), motion sensors to monitor the self-care ability of the elderly (Zhu et al. 2020), and fall detection through a combination of wearable sensors and neural networks (Yu et al. 2021). To maximize treatment effect, smart wearables in healthcare can incorporate multi-faceted tailoring capabilities for the individual patient based on collected data (Yang et al. 2021). However, despite the availability of patient-specific real-time data, a one-size-fits-all paradigm still prevails (e.g., Sabry et al. 2022; Site et al. 2021). Specifically, potential solutions train ML models that minimize predictions errors for a broad test population and use these general models to infer the state of all users (Chen et al. 2020). Consequently, there is a critical need for smart wearables that can proactively and autonomously tailor to the individual patient, rather than relying on static, predetermined processing functionality (Wu et al. 2008). In addition, smart wearables must take into account further contextual factors to increase individualization and predictive performance (Andreu-Perez et al. 2015). Users should be able to adjust relevant information on their current clinical picture and to update changes in anatomical characteristics (e.g., weight) that are not monitored by a wearable sensor (Wang et al. 2022). Furthermore, user involvement is essential to ensure that more accurate predictions ultimately lead to treatments and recommendations that are actionable for the individual patient (Baig et al. 2017). For this reason, smart wearables in healthcare should provide the possibility to set key medical thresholds (Goetz and Schork 2018) and to alter personal preferences (Mountain et al. 2010).

2.2 Theory of Tailorable Technology Design

The Theory of Tailorable Technology Design characterizes tailorable technologies as “a class of information systems

designed with the intention that users modify and redesign the technology in the context of use” (Germonprez et al. 2007: 351). Four characteristics define tailorable technology: a dual design perspective, user engagement, recognizable environments, and component architectures (Germonprez et al. 2007). As shown in Fig. 1, the design process of tailorable technology consists of two subprocesses, which rely on nine design principles (i.e., task setting, recognizable components, recognizable conventions, outward representation, metaphor, tools, methods, functional characteristics, and user representation) and which are carried out by the designer and the user.

The designer provides the initial state of the IS in the primary design process (Germonprez et al. 2007). In the secondary design process, which follows the primary design process, users engage as co-designers of the IS through active use and modification (Germonprez et al. 2007; 2011). The concept of secondary design comprises a functional and a content layer (Germonprez et al. 2011). While the functional layer entails new or changing combinations of functions that emerge through the secondary design process, the content layer covers the creation and presentation of information. Although several studies by IS scholars have built on the Theory of Tailorable Technology Design and provided valuable insights, none have specifically addressed the design of AI-enabled IS. Pries-Heje and Hansen (2017), for example, define deep secondary design, which allows users to change not only the functional and content layers but also the level of technological complexity of an artifact (e.g., by transitioning from basic web-apps to full-fledged IT applications). Hansen and Pries-Heje (2018) propose the concept of unbounded secondary design, which involves exporting the primary design into new contexts and domains. Miah et al. (2019), on the other hand, present a meta-design theory for tailorable decision support systems.

Beyond the Theory of Tailorable Technology Design, selected aspects of AI-enabled IS that can be tailored during use have been implemented or have been theorized upon. For instance, Yang et al. (2023) utilize transfer learning in an IS artifact designed for text-based personality detection, while Ampel et al. (2024) employ transfer

learning to prevent cyber breaches. Nevertheless, previous research lacks a holistic perspective on how to design AI-enabled IS that account for modification during use.

Focusing on the initial design of IS, autonomous design describes the independent design decisions of autonomous software tools (e.g., in the form of initial drafts of virtual worlds in game design) (Seidel et al. 2018, 2020). However, autonomous design applies to AI-driven design before use and does not cover design during use (either human-driven or AI-driven). Similarly, the co-design of AI-enabled systems involves users in the design process of an IS (e.g., Panigutti et al. (2023) and Stawarz et al. (2023)), but does not account for their active participation during use (Noorbergen et al. 2021). In the broader field of human-AI interaction, tendencies toward user tailoring are present but primarily concentrate on the initial design of AI-enabled system (Amershi et al. 2019). Design theory for explainable intelligent IS partially considers the user perspective (Herm et al. 2022; Langer et al. 2021). Yet, it falls short in accounting for the active role of the user in tailoring the IS. Additional perspectives on AI in the initial design process include the design theory for emancipatory assistants (Kane et al. 2021) and interactive ML (Dudley and Kristensson 2018). The former addresses the handling of oppressive AI, while the latter supports optimizing ML outcomes for users but lacks concrete IS design knowledge.

Considering the modification of IS during use, structuration theory and adaptive structuration theory can be distinguished (Gaß et al. 2015). Structuration theory differentiates between the “design mode and the use mode” (Orlikowski 1992: 412) of technology and acknowledges “the ongoing potential for users to change [the technology] (physically and socially) throughout their interaction with it” (Orlikowski 1992: 412). Adaptive structuration theory, on the other hand, provides a model describing the interplay between information technology, social structures, and human interaction (DeSanctis and Poole 1994). Structures built into technology “may be modified, enhanced, or combined with manual procedures, thus creating new structures within the technology” (DeSanctis and Poole 1994). However, neither structuration theory nor adaptive structuration theory elaborate further on the design of IS for the purpose of individualization for a specific user. While the structuration theory of Orlikowski (1992) builds a new theoretical model to investigate the interaction between technology and organizations, the adaptive structuration theory of DeSanctis and Poole (1994) studies information technologies in the context of organizational change. Although the notion of IS individualization during use has been a part of several IS theories, the underlying design processes – especially during productive use – remain poorly researched (Noorbergen et al. 2021).

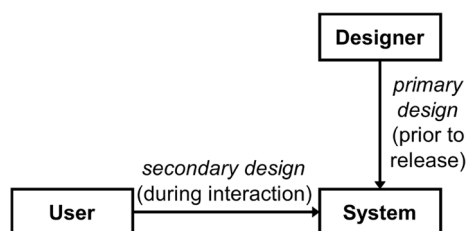


Fig. 1 Design process of the Theory of Tailorable Technology Design (Germonprez et al. 2007; 2011)

3 Research Design

We posit the conjecture that the knowledge about tailorable technology design does not effectively account for AI-enabled IS. To investigate this conjecture, we conducted a revelatory design study. The goal of the design study was to develop an AI-enabled individual IS to generate insights into how the Theory of Tailorable Technology Design may need to be extended in the light of AI-enabled IS.

The design study was realized with an advanced DSR project in the healthcare domain and is grounded in the Theory of Tailorable Technology Design as justificatory knowledge (Gregor and Hevner 2013; Hevner 2007). The developed DSR artifact includes a smart wearable to enable bladder monitoring in real-world scenarios by tailoring and adapting to the individual patient. As the design study provided a situational context for collecting extensive qualitative and quantitative evidence similar to a single-case study (Eisenhardt 1989), it served as a revelatory example to critically challenge the Theory of Tailorable Technology Design (Tsang 2014; Yin 2009). In contrast to the largely observational perspective inherent in case study research (Yin 2009), the design study required active researcher involvement in building and evaluating the targeted DSR artifact.

To generalize the empirical evidence gained throughout the design study, we drew on the generalizability framework proposed by Lee and Baskerville (2003). Following the example of Kratsch et al. (2021), we employed a two-stage generalization approach that allowed us to generalize from empirical (E) to theoretical statements (T). The initial data-to-description strategy (EE) involved generalizing the comprehensive empirical evidence from the case study (E) into higher-level descriptive empirical statements (E) in the form of observations related to tailorable technology design (see Sect. 4.5) (Lee and Baskerville 2003). The subsequent description-to-theory strategy (ET) used these observations (E) as the basis for identifying relationships and inferring propositions that account for the impact of AI-enabled IS for the Theory of Tailorable Technology Design (T) (see Sect. 5.1) (Lee and Baskerville 2003). As our primary contribution, these propositions culminate in a Revised Theory of Tailorable Technology Design, adding to the descriptive sense-making knowledge about tailorable technology design (Gregor and Hevner 2013) and therefore contributing to future theory building (Tsang 2014).

Figure 2 depicts the DSR reference process proposed by Peffers et al. (2007), which we adopted for executing the exploratory design study. The developed artifact – the model for individualized bladder monitoring systems – demonstrates how an AI-enabled individual IS building on a smart wearable can be tailored to individual users for bladder monitoring.

In Step 1, *Problem Identification & Motivation*, we observed that despite a large and diverse target group living with NLUTD, there is no solution to accurately predict bladder volume in real-world scenarios. Therefore, in Step 2, *Definition of Design Objectives*, we used relevant literature to define design objectives (DOs) that novel and tailorable solutions must meet to adequately address this gap. In Step 3, *Design*, we conceptualized on how to individualize bladder monitoring. In Step 4, *Demonstration*, we instantiated the artifact in the form of a prototypical implementation consisting of a wearable sensor module and a smartphone app. As part of Step 5, *Evaluation*, we ensured the rigor of our research and collected further evidence for theory challenging. Considering the socio-technical nature of the DSR artifact (Gregor and Hevner 2013), we chose the Human Risk & Effectiveness strategy of the Framework for Evaluation in Design Science as a blueprint (Venable et al. 2016) and followed an evaluation strategy with five evaluation episodes. In Step 6, *Communication*, we share our research through this publication. While our primary contribution lies in the propositions culminating in a Revised Theory of Tailorable Technology Design, our secondary contribution is the concrete design knowledge gained from the developed DSR artifact.

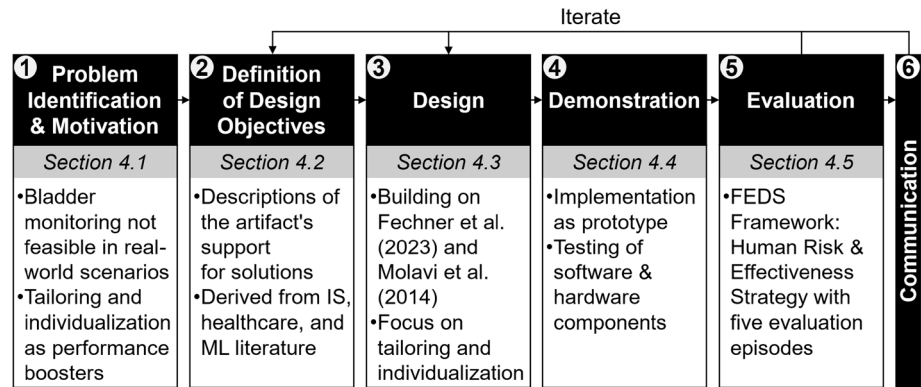
4 Design Study in the Bladder Monitoring Domain

The design study is structured according to the DSR reference process described in Sect. 3. While the design and evaluation of the artifact would allow for an extensive elaboration on the technical and algorithmic details, we here focus on the content relevant to challenging the Theory of Tailorable Technology Design as the basis for our primary contribution below. Additional material relevant for our secondary contribution is provided in the appendix (available online via <http://link.springer.de>) and referenced throughout the design study. To ensure transparency in the generalization of our findings, we highlight the observations (i.e., Observations O1–O5) we made analyzing our qualitative and quantitative empirical data.

4.1 Problem Identification and Motivation

In our design study, we tackle current medical issues in bladder monitoring. Bladder monitoring is a promising use case for chronic disease management (Bardhan et al. 2020). It holds significant untapped potential for individualization and tailoring in healthcare through smart wearables that record and leverage new patient-related data. An improved solution for bladder monitoring targets individuals affected by NLUTD (Ginsberg et al. 2021). NLUTD involves a

Fig. 2 DSR process based on Peffers et al. (2007) and Venable et al. (2016)



significant number of people living with spinal cord injuries, multiple sclerosis, parkinsonism, and spina bifida (Böthig et al. 2020). Since patients can lose bladder sensation and the ability to void voluntarily (Tudor et al. 2016), they typically need to self-catheterize, which is time-consuming and uncomfortable (Averbeck et al. 2018; Böthig et al. 2020).

The gold standard treatment for NLUTD involves emptying the bladder every three to four hours to prevent the negative consequences of bladder over-distension (i.e., exceeding the normal bladder capacity of 400–600 ml by more than 20%, i.e., 80–120 ml) (Dorsher and McIntosh 2012; Madersbacher et al. 2012; Norton and Brubaker 2006; Verpoorten and Buyse 2008). Since a time-driven treatment does not account for actual bladder volume and the individual's anatomical characteristics, it cannot reliably protect against over-distension of the bladder and its negative consequences (e.g., spontaneous voiding or damage to health from concomitant kidney disease (Dik et al. 2006)). More accurate information on bladder volume could enable volume-dependent catheterization, thereby preventing secondary disease (Flack and Powell 2015), improving the health-related quality of life (Lockl et al. 2022), and reducing the total cost of bladder management by nearly half (Polliack et al. 2005).

Today, however, continuous bladder monitoring is not yet feasible due to the medical expertise and stationary equipment required (Dicuio et al. 2005; Palese et al. 2010). As an initial step to individualize the treatment of NLUTD and shift the focus from scheduled voiding toward a volume-responsive treatment, preliminary research has proposed several non-invasive techniques that use biomedical sensor data for bladder monitoring (Jonas et al. 2023; Nasrabadi et al. 2021; Semproni et al. 2022). Among these technologies, near-infrared spectroscopy (NIRS) offers the advantages of safety and ease of use (Molavi et al. 2014). Despite promising results in laboratory settings (Fong et al.

2018; Kristiansen et al. 2004; Reichmuth et al. 2020), previous studies on bladder monitoring report reliability and validity issues that restrict applicability in real-world scenarios (Kamei et al. 2019; Molavi et al. 2014). Given that the performance of previous solutions is likely to degrade under real-world conditions (Argent et al. 2021), there is a significant need for a solution to improve bladder monitoring for individual patients in real-world scenarios; especially considering that previous work collects data at a personalized level but employs a one-size-fits-all approach to data analysis and user interaction.

4.2 Definition of Design Objectives

As outlined in Table 1, we derived six DOs from relevant literature that specify how the “artifact is expected to support solutions” (Peffers et al. 2007: 55) for the chosen application context to improve and individualize bladder monitoring in real-world scenarios. As a starting point for determining a set of DOs that is well-suited to purposefully guide the design of the artifact, we reviewed the seven generic DOs for non-invasive bladder monitoring proposed by Fechner et al. (2023). Due to their relevance for bladder monitoring, we adopted the three DOs ‘accurate bladder measurement’ (DO1), ‘continuous monitoring’ (DO2), and ‘unobtrusiveness’ (DO3) without modification. In contrast, we assessed the two DOs that concentrated on the communication of a predicted bladder volume to the user (i.e., ‘active notification’ and ‘transparent reporting’) as well as the DO that focused on the interplay of hardware and software (i.e., ‘interoperability’) to be outside the imperative scope of our design study. We also did not include the DO ‘personalization’ since it was insufficiently specific for this study. To capture the multiple facets of individualization more comprehensively, we instead built on the relevant literature presented in Sect. 2 and derived three

Table 1 DOs for the artifact

DO	Description	Central References
DO1	<i>Accurate bladder measurement</i> To restore patients' ability to manage their bladder, the artifact must enable the monitoring of bladder volume with acceptable accuracy. To avoid over-distension, bladder volume should not exceed regular capacity by more than 20% (i.e., 80 – 120 ml)	Kim et al. (2019), Madersbacher et al. (2012)
DO2	<i>Continuous monitoring</i> To effectively help patients who have lost bladder sensation, the artifact must be able to continuously measure the bladder volume. Thus, patients can obtain knowledge of their bladder volume regardless of their current activity	Darwish and Hassanien (2011), Ashworth and Hagan (1993)
DO3	<i>Unobtrusiveness</i> To not restrict patients' activities, the artifact must unobtrusively integrate into their daily routine	Chatterjee et al. (2018), Darwish and Hassanien (2011)
DO4	<i>Consideration of context</i> To integrate contextual changes that cannot be detected by sensors into bladder monitoring, the artifact must provide means for patients to update their clinical picture and anatomical characteristics (e.g., weight)	Andreu-Perez et al. (2015), Wang et al. (2022)
DO5	<i>Autonomous adaptation</i> To ensure a consistently high level of predictive performance for each individual patient, the artifact must proactively and autonomously adapt to recorded sensor data and contextual information of the individual, which may change over time	Chen et al. (2020), Wu et al. (2008)
DO6	<i>User-centric interaction</i> To enable individual treatments and recommendations, the artifact must foster user engagement and allow to set and adjust personal preferences (e.g., when to send an alert), and user feedback (e.g., on prediction quality)	Germonprez et al. (2011), Goetz and Schork (2018), Mountain et al. (2010), Baig et al. (2017)

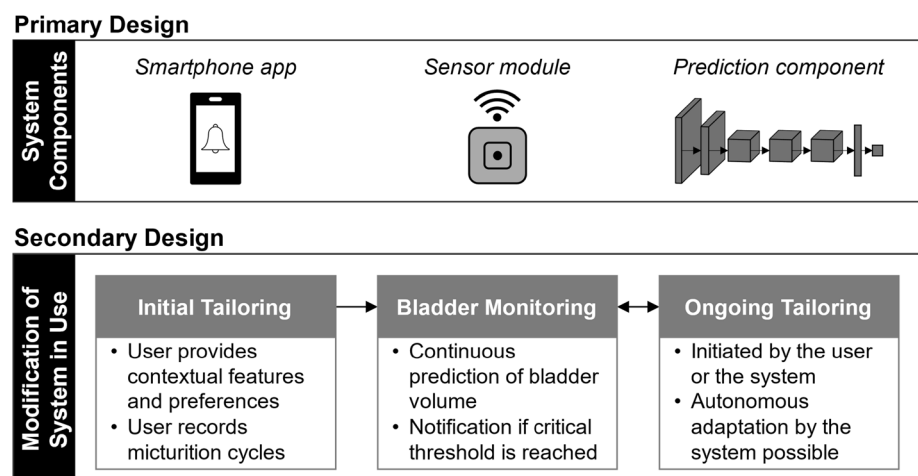
new DOs: 'consideration of context' (DO4), 'autonomous adaptation' (DO5), and 'user-centric interaction' (DO6).

4.3 Design Specification

Figure 3 presents the final version of the model for individualized bladder monitoring systems, reflecting all adjustments that resulted from the feedback and insights

obtained throughout the five evaluation episodes of our DSR process. The model for individualized bladder monitoring systems serves as a suitable example for challenging the Theory of Tailorable Technology Design. The artifact adhered to the theory's design principles and conforms to its four definitional characteristics (Germonprez et al. 2007). It explicitly distinguishes between an initial design and subsequent user tailoring, in accordance with

Fig. 3 Model for individualized bladder monitoring systems



the characteristic dual design perspective. With respect to the user engagement characteristic, the artifact provides functional components for user modification in accordance with the purpose of bladder monitoring. The artifact has three functionally complete system components (i.e., characteristic component architectures), which have clearly defined characteristics to support user tailoring (i.e., recognizable environment characteristic).

From a **Primary Design** perspective, the artifact consists of a *smartphone app* that allows users to provide micturition volumes, contextual features (i.e., sex, age, body mass index, and skin tone) (DO4), and preferences (i.e., the alarm threshold in *ml*, when to send a notification, and the type of notification) (DO6). A non-invasive *sensor module* can be attached to the users' lower abdomen with a custom-made belt without restricting movement or negatively impacting daily routines and activities (DO3). The sensor module continuously records key data points for bladder monitoring (i.e., acceleration and NIRS data at wavelengths of 775, 855, 970, and 1,020 nm following Molavi et al. (2014)) and pre-processing (i.e., temperature for verifying sensor attachment) (DO2). The *prediction component* builds on transfer learning to individualize bladder monitoring for a single user (DO5). Transfer learning is a technique that can improve the speed and effectiveness in training ML models (Lu et al. 2015). The central assumption of transfer learning is that knowledge gained from learning a specific task (i.e., source task) can be generalized and repurposed, thereby augmenting a related learning task (i.e., target task) (Pan and Yang 2010). This transfer of knowledge can be done via shared model parameters, reuse and reweighting of data instances, identification of relationships, and learning appropriate feature representations (i.e., feature-representation-transfer) (Pan and Yang 2010). Since DL models automatically learn feature representations across multiple successive information processing layers in an end-to-end manner (Deng and Yu 2014), transfer learning for DL (i.e., deep transfer learning) generally follows a feature-representation-transfer approach. Thus, deep transfer learning is particularly useful to address generalization problems of DL models fitted on small datasets (Weiss et al. 2016; Yim et al. 2017). Such small datasets also prevail in the case of bladder monitoring, as human biology limits the number of micturitions per day and, thus, the amount of training data for each individual patient. *Feature extraction* and *fine-tuning* are two common strategies for deep transfer learning. Both strategies use a DL model already trained for the source task (i.e., base model) as a basis to train a model for the target task (Chollet 2018; Lu et al. 2015). To preserve the typically more generic representations contained in the first layers of the base model (Lu et al. 2015), weight changes can be disabled for specific layers during the transfer

learning process (i.e., freezing a layer) (Iman et al. 2023). It is further possible to remove existing layers or add new ones in both strategies (Chollet 2018; Iman et al. 2023). In the feature extraction strategy, a randomly initialized output layer (i.e., regressor) replaces the pre-trained output layer of the base model. The model is then trained for the target task using the feature representation capabilities of the otherwise frozen base model (Chollet 2018; Morales and Roggen 2016). The fine-tuning strategy focuses more on slightly adapting the original feature representation capabilities by unfreezing and re-training a predefined number of base model layers for the target task (Chollet 2018; Iman et al. 2023; Lu et al. 2015). Since fine-tuning proved to be the most effective in a benchmarking of different ML techniques on a real-world micturition dataset (see fourth evaluation episode in Sect. 4.5), the prediction component uses fine-tuning.

With respect to the **Secondary Design** process, the artifact includes three phases (i.e., Initial Tailoring, Bladder Monitoring, and Ongoing Tailoring) that explicitly consider that users modify and tailor the artifact in the context of use (Germonprez et al. 2007; 2011). To enable a consistently high level of predictive performance (DO1), individualization is achieved by initial tailoring before productive use and subsequent demand-driven and autonomous re-tailoring interwoven with productive use.

The mandatory *Initial Tailoring* phase aims to calibrate the artifact to the individual user by fine-tuning the prediction component while also taking user characteristics into account. To begin, users provide their contextual features and preferences described above. To calibrate the prediction component to their individual physique, users must record at least ten micturition cycles while wearing the sensor module. The recorded micturition cycles are used to gradually fine-tune the prediction component, which is first trained on a generic multi-user dataset to learn meaningful feature representations for bladder monitoring as a basis for deep transfer learning. The patient interviews in the second evaluation episode of the artifact suggested ten micturition cycles as a reasonable number for initial tailoring. Nevertheless, it is also possible to extend the Initial Tailoring phase until the data points no longer improve the predictive performance or the predictive performance reaches an acceptable level from the user's perspective.

The *Bladder Monitoring* phase starts after the Initial Tailoring phase and supports management of the bladder. Users wear the sensor module continuously, which allows them to access predicted bladder volume information via the smartphone app. Once the bladder volume reaches the critical threshold, the app sends a notification as defined by the individual user.

The *Ongoing Tailoring* phase accounts for changes of users' anatomical characteristics and preferences over time. Since it partially overlaps with the Bladder Monitoring phase, there may be frequent iterations between ongoing tailoring and monitoring. The first scenario for ongoing tailoring is analogous to the Initial Tailoring phase. Users can record additional micturition cycles and thereby initiate further refinement of the predictive performance (user-driven). The artifact can also trigger re-tailoring (artifact-driven) if it detects changes in the characteristics of the sensor measurements or if user preferences, such as too-late notifications, could be improved. Additionally, the second scenario in the Ongoing Tailoring phase involves completely autonomous adaptive capabilities of the artifact that do not require active feedback from the user (DO5). As shown in the third evaluation episode, the artifact can determine the time of voiding based on the sensor data. It can use this knowledge to generate corresponding micturition volume estimates that serve as surrogate truth labels for autonomous individualization of algorithmic operations. The prediction component can utilize these surrogate truth labels in the same way as user-generated truth labels, as demonstrated in the fifth evaluation episode.

4.4 Demonstration

The prototypical implementation of the model for individualized bladder monitoring systems consisted of the smartphone app, the wearable sensor module, and the prediction component. As described in Sect. 4.3, the smartphone app allows users to enter their characteristics and preferences. It also supports the tailoring between the user and the artifact through interactive recording of micturition cycles (see Fig. A.1.1 in Appendix A; available via <http://link.springer.com>). We adopted the hardware design for the NIRS sensor module proposed by Fechner et al. (2023) due to its proven efficacy in previous applications, and used a contoured housing structure that seamlessly conforms to the user's abdominal topography (Fong et al. 2018; Saffarpour and Ghiasi 2018). To reduce the potential risks associated with exposure to near-infrared radiation, such as thermal damage to the skin, the sensor module has been developed in accordance with the International Commission on Non-Ionizing Radiation Protection (International Commission on Non-Ionizing Radiation Protection 2013), and the guidelines IEC 60601-2-57 and IEC 62471 of the International Electrotechnical Commission (International Electrotechnical Commission 2015; 2023). We also implemented a strict average power limit of 2 mW to ensure safe usage (Molavi et al. 2014). The prediction component is implemented in Python 3 (Python Software Foundation 2023) and utilizes open-source libraries including Pandas (Pandas Development Team 2020),

scikit-learn (Pedregosa et al. 2011), and XGBoost (XGB) (Chen and Guestrin 2016) for the data augmentation, pre-processing, and analysis functions. Furthermore, the TensorFlow 2 library (Abadi et al. 2015) was used for deep transfer learning. To detect abnormal conditions, such as mispositioning of the sensor module, we have implemented an analysis unit that can detect deviations from the regular distribution of sensor readings.

4.5 Evaluation

Our evaluation strategy comprised five episodes that addressed the socio-technical nature of a potential solution for bladder monitoring. The series of episodes included workshops with ML experts (first episode), patient interviews (second episode), laboratory sensor experiments (third episode), benchmarking of various state-of-the-art ML models and techniques (fourth episode), and a case analysis of a patient living with spina bifida (fifth episode). Although the primarily technical first and third evaluation episodes were essential to the real-world fidelity and reliability of the artifact (March and Smith 1995), their implications for theory testing are less direct. Therefore, we provide only a brief summary of the first and third evaluation episodes below and refer to Appendix B for further details.

Summary of the 1st and 3rd Evaluation Episodes. The first evaluation episode was a series of workshops with three ML and DL experts (see Appendix B.1). The experts' recommendations enabled us to critically examine our preliminary design hypotheses and refine the artifact by exploring the implementation of individualization through deep transfer learning from a technical perspective. All experts agreed that deep transfer learning is an effective approach to optimize predictive performance for new users in real-world contexts. Based on the experts' feedback, we were able to include additional user-specific characteristics for individualization (e.g., weight, height, and skin tone) and revise the data pre-processing and analysis functionality of the artifact. In the third evaluation episode, we tested the quality of the developed sensor module under controlled conditions (see Appendix B.3). The results of our experiments suggest a negative correlation between the NIRS data and bladder volume, supporting the theory that a full bladder absorbs more photons than an empty bladder (Molavi et al. 2014). We found that sensor data peaks followed by decreasing sensor values can help determine the time of bladder emptying. This allowed the artifact's functionality to predict surrogate bladder volumes, which serves as the basis for autonomous tailoring. As summarized in Observation O1, both evaluation episodes

contributed to the quality of the artifact from a primary design perspective.

Observation O1: *A careful primary design process is essential to lay the foundation for AI-enabled tailorable technology design.* The design specification in Section 4.3 highlights the importance for IS designers to anticipate potential tailoring mechanisms that users may employ during a secondary design process. As the first and third evaluation episodes demonstrate, designers must be aware of the design challenges and requirements that may arise from AI-enabled individual IS. While the importance of a careful primary design aligns with the work of Germonprez et al. (2007; 2011), they do not provide explicit guidance for AI-enabled systems.

2nd Evaluation Episode: Patient Interviews. To assess the value of our artifact for its target group, we conducted 15 semi-structured interviews with potential users living with NLUTD. As presented in Appendix B.2, our interviews included individuals composed of different age groups both long-standing and those more recently living with NLUTD. The initial set of shorter interviews with participants P01–P04 focused on users' basic attitudes toward tailoring in general, to address concerns that increased user involvement might have a negative impact on the willingness to adopt a potential solution. While participant P02 stated that the daily routine of a user might change over time, necessitating the artifact to calibrate to changing usage patterns, he said that tailoring would not impact his inclination toward usage. By contrast, the other three participants expressed that an individualization phase would have a positive (P04) or a highly positive (P01, P03) influence on their willingness to use the artifact.

The feedback prompted us to conduct a more comprehensive examination of user expectations and requirements for individualizing bladder monitoring as part of a smart wearable's secondary design process. Therefore, the subsequent eleven interviews with participants P05–P15 explored potential user feedback on the design of interactions with the artifact during the individualization process. These interviews lasted between 34 and 78 min. We excluded the interview with participant P13 from further analysis, as the interview revealed that this person was not affected by NLUTD, although the medical indication and preliminary information on the medical disease led to an initial inclusion as interviewee. While two participants communicated that the tailoring capabilities did not exert an influence on their willingness to adoption (P08, P10), all other participants articulated either a minor positive influence (P14), a positive influence (P06), or a decidedly positive influence (P05, P07, P09, P11, P12, P15). The participants also highlighted potential complications for

tailoring, such as excessive movement (P10, P12), improper positioning of the artifact (P05), and integrating tailoring into the daily routine (P14). When asked about the maximum length of time acceptable for the Initial Tailoring phase, most interviewees stated timespans between one (P05, P10, P14) and two weeks (P06, P07, P09) as acceptable. While some patients opted for longer durations (P08, P11), others implicitly indicated their acceptance for longer tailoring durations due to the positive effects of a reliable solution for their quality of life (P12, P15). Based on the participants' responses, we considered ten micturition cycles to be an appropriate minimum amount for the initial tailoring stage, as these can be recorded conveniently within one week. Observation O2 provides a concise overview of the feedback on tailoring an artifact before its productive use.

Observation O2: *Users are willing to invest time in an Initial Tailoring phase if it increases the usefulness of the artifact.* This feedback from the patient interviews is essential because tailoring an IS that leverages deep transfer learning requires active user involvement and data input during the secondary design process. While Germonprez et al. (2007; 2011) point out the active involvement of the user, all user actions are unconstrained (i.e., user can engage with the system without restrictions). However, an Initial Tailoring phase is crucial for the proper functioning of our artifact and thus precedes full-featured interaction.

When asked about the Ongoing Tailoring phase, all ten participants showed their support (P05, P06, P07, P08, P09, P10, P11, P12, P14, P15). When asked about their attitude toward ongoing tailoring, participant P10 replied: "Yeah, sure. So, if that's possible and I notice that [the artifact] is wrong more often, then I have no problem at all feeding back this to the system. I think that would be a good thing because sometimes a medication doesn't work [...]. So, this is an ongoing change, this bladder. [...] I think it's even a mandatory requirement that the system should tailor itself." Participant P15, on the other hand, conditioned willingness on the level of effort required. P15 further expressed a desire for autonomous adaptation as follows: "So I think that the AI must draw on my interventions. Otherwise, how should it be able to have a positive learning curve. And I think that there is something like mutual feedback: I learn something for myself in dealing with the AI and the AI learns something from me through the feedback. And I can imagine that this is, let's say, an inverse process. In the beginning, I get more involved, and then the AI gets more involved." Across interviews, the proposed interaction between users and the artifact was considered as important, including some degree of

automated adaptation by the AI. Participant P11 highlighted the importance of autonomous adaptation capabilities. Taking his experience of rapid bladder filling after transitioning from prolonged wheelchair use to a reclined position as an example, he emphasized that automated adaptation capabilities would ensure that the artifact remains effective in its operation by proactively taking into account the context of body position and movement patterns. Observation O3 summarizes feedback on tailoring during productive use and reflects the role of the IS.

Observation O3: *Users advocate an Ongoing Tailoring phase in which the user and the IS are active participants.* The user feedback indicates interest in interactive IS adaptations that ensure proper functioning and can be initiated from both sides. Additionally, some users expected autonomous tailoring capabilities of the artifact. Germonprez et al. (2011: 663) highlight the role of the user in the Theory of Tailorable Technology Design by stating that “people are active, aware, and intentional participants in an ongoing process of embodied interactions involving technological and social dualities.” The active tailoring involvement of the system, however, is not foreseen by the Theory of Tailorable Technology Design.

4th Evaluation Episode: Benchmarking of Different ML Approaches on a Real-World Dataset. To test whether algorithmic individualization can achieve superior predictive performance compared to user-agnostic bladder monitoring approaches, we conducted a comprehensive comparison of different ML techniques and models on a real-world micturition dataset. The main aspects of the benchmarking are presented below. More detailed information on the implementation of the benchmarking can be found in Appendix B.4.

The dataset was recorded over a 12-month period by a heterogeneous group of 22 test subjects without any restrictions on data recording to ensure real-world fidelity. After pre-processing, 762 micturition cycles were used as a basis for benchmarking. To ensure comparability with previous results, we drew on established ML and DL models that also applied in other NIRS-related bladder monitoring research (Fechner et al. 2023). These are random forest (RF), deep neural network (DNN), convolutional neural network (CNN), and long short-term memory network (LSTM). Due to the limited ability to process large amounts of data, we did not include a support vector machine and instead incorporated an XGB. We also used a simple multiple linear regression (MLR) model to test if the more computationally intensive models could improve accuracy. We combined the ML and DL models with four ML techniques (i.e., multi-task and single-task learning as

well as feature extraction and fine-tuning). The multi-task technique followed the traditional one-size fits all paradigm by training a single model for all test subjects (Caruana 1997). In the single-task technique, a single model was trained for each test subject using only the data for the specific test subject (Caruana 1997). As the feature extraction and the fine-tuning techniques leverage deep transfer learning, they were only applicable to the three DL models (i.e., DNN, CNN, and LSTM).

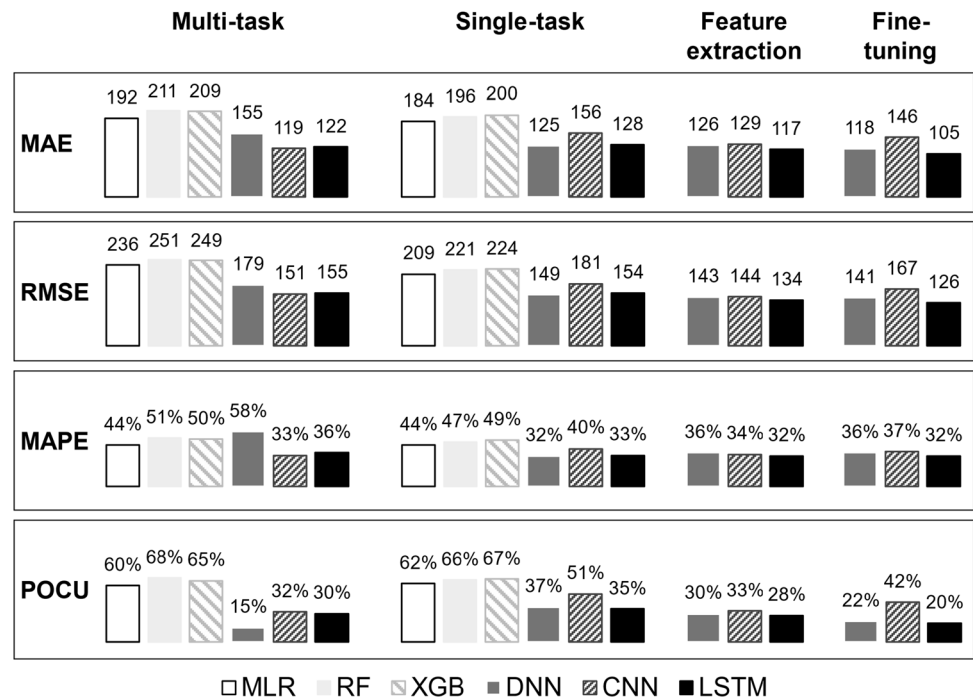
Figure 4 presents the prediction results for the different possible ML and DL combinations based on sensor data and contextual user features. The performance metrics employed were mean absolute error (MAE), root mean squared error (RMSE), mean absolute percentage error (MAPE), and the percentage of critical underestimations (POCU) (i.e., predictions that underestimate bladder volume by more than 120 ml, see DO1). As it was not possible to perform the evaluation for subjects with less than ten valid micturition cycles, only the test data of the twelve subjects for whom all individualization techniques could be trained were included in the results to ensure comparability.

As shown in Fig. 4, the single-task technique did not significantly improve the performance of the models compared to the multi-task setting, which could be attributed to the limited amount of data. Also, the ML models (i.e., RF and XGB) did not achieve results comparable to those of the DL models using either the multi-task or single-task techniques. Therefore, the prediction task at hand can be considered ill-suited for these two model architectures, which performed even worse than the simple MLR. While both deep transfer learning approaches yielded better results for all metrics with the LSTM model, the results worsened slightly with the CNN. The top-performing combination was an LSTM model trained with a fine-tuning approach. It achieved a MAE of 104.96 ml, demonstrating the potential of deep transfer learning captured in Observation O4.

Observation O4: *Deep transfer learning can improve predictive performance through algorithmic tailoring to the individual user.* As shown in Fig. 4, our comparative analysis on a real-world bladder monitoring dataset revealed that deep transfer learning via fine-tuning can outperform other ML techniques by drawing on feature representation patterns learned from other users. AI components are not anticipated by the Theory of Tailorable Technology Design, yet they present another way to achieve tailoring to the user on the functional level.

The benchmarking results also provide valuable insights for bladder monitoring when compared to previous research. Fechner et al. (2023) who also used NIRS and

Fig. 4 Performance metrics for the test data from twelve subjects. *Note* ML and DL models were trained only on sensor data and user-related features



acceleration sensor data found that models with a time component performed better than models without a time component. Notably, our analysis of a significantly larger dataset showed that the top-performing LSTM fine-tuning model can outperform models trained using a multi-task technique (i.e., the traditional one-size-fits-all paradigm), even when the latter models have access to time and sensor features (refer to Table B.4.3 in Appendix B.4). As shown in Appendix B.4, our application of the SHAP (SHapley Additive exPlanations) library (Lundberg and Lee 2017) on the best performing LSTM fine-tuning model also revealed that the NIRS features were the most important for predicting bladder volume. Since the time between micturitions can vary significantly depending on hydration levels, fluid intake and other factors, the ability to predict bladder volume using sensor data alone is an important step toward real-world bladder monitoring.

5th Case Analysis of a Patient Living with Spina Bifida
Adhering to the guidelines of the Human Risk and Effectiveness evaluation strategy (Venable et al. 2016), our final evaluation episode embodied a high degree of naturalistic and summative qualities. Accordingly, we conducted a comprehensive two-week case analysis with a participant affected by NLUTD. The participant reported a dependency on catheterization since birth due to spina bifida and an inability to void naturally. The case analysis involved regular interaction with the participant, providing us with multi-layered insights into his interaction with the artifact. We conducted semi-structured interviews before (i.e., P06 as part of the interviews in the second evaluation episode),

during, and after the case analysis. All three interviews were recorded, transcribed, and lasted between 23 and 39 min. To ensure continuous feedback, the participant stayed in touch with the research team via instant messaging and phone calls.

During the case analysis, the participant wore the sensor during everyday activities such as walking, cycling, and working. He recorded a total of 117 h of sensor data and 29 micturition cycles in the smartphone app. For eleven micturition cycles, the participant also measured micturition volume and entered it into the smartphone app. The participant provided feedback on the usability of the belt for positioning the sensor module and on the sensor module itself. Despite initial difficulties with correct positioning and a tendency to slip toward the navel during movement, he rated the usability of both components as good (2) on a seven-point Likert scale ranging from very bad (− 3) to very good (3). He also voiced his preference for a slimmer case for the sensor module. Regarding the smartphone app, the participant appreciated the ease and simplicity of entering micturition volumes and mentioned occasional latency. He concluded that he had established a routine with the artifact and was pleasantly surprised by its overall usability. The participant also performed the Initial Tailoring phase and indicated a sense of being able to influence the functionality of the artifact. He also expressed satisfaction with the tailoring experience. When asked about the effect of the tailoring capabilities on his intent to use the artifact, the participant expressed that it had enhanced his positive disposition beyond his original

expectation prior to use. While the participant had considered a two-week period appropriate for the Initial Tailoring phase during the first interview, he later expressed that he would prefer a shorter period of one week.

As we already assessed the predictive performance of our artifact in the fourth evaluation episode, we evaluated the artifact in a hypothetical scenario. The participant had to imagine a typical routine of a day at work and at home. The participant was then asked to decide whether he would empty his bladder based on a prediction of his bladder volume. The prediction was made for a micturition cycle recorded by the patient, with the best performing LSTM prediction component pre-trained on the other recorded micturition cycles. Based on the predicted volume of 346 ml, the participant decided to postpone the catheterization. Additionally, the participant stated that, based on the prediction, he would have catheterized if he had a longer meeting ahead of him. After the true volume of 280 ml was revealed, the participant concluded that the artifact served its purpose despite the discrepancy, as his ideal volume for bladder emptying was between 400 and 450 ml.

Observation O5: *The tailoring process of an individual IS can be integrated into a user's daily routine under real-world conditions.* The case analysis confirmed that the tailoring capabilities of our artifact are positively perceived by a potential user. In line with the real-world use cases presented by Germonprez et al. (2007; 2011), the real-world applicability of our AI-enabled artifact was demonstrated.

The Theory of Tailorable Technology Design provided valuable guidance in the design process of our artifact. However, our observations revealed that several AI-related aspects of our artifact could not be adequately described by the theory. While Germonprez et al. (2007; 2011) highlight the active involvement of the user in the secondary design process, the Theory of Tailorable Technology Design lacks explanatory power regarding the inclusion of AI components in the design (Observations O1, O4, and O5) and the role of AI in the tailoring process (Observations O2 and O3).

5 Discussion

5.1 Theoretical Implications

The Theory of Tailorable Technology Design distinguishes between primary and secondary design processes (see Fig. 1). As discussed below, the design study and the evaluation of the artifact confirmed the general usefulness and validity of the theory's dual design perspective on

tailorable technology. Moreover, the comprehensive empirical evidence gathered during the design study supported our conjecture that the current knowledge about tailorable technology design does not effectively account for AI-enabled IS.

Therefore, as a primary contribution of this work, we infer three propositions for advanced secondary design mechanisms which explicitly consider AI-enabled IS. The propositions are based on the observations from our design study and are elaborated in the following. Figure 5 shows how these propositions culminate in a Revised Theory of Tailorable Technology Design.

Implications of the Design Study for the Primary Design Process. The primary design process of the Theory of Tailorable Technology Design involves the designers of IS to build and implement features prior to release (Germonprez et al. 2007; 2011). While the focus of our work is on the interaction between users and AI-enabled IS as part of the secondary design process, our design study also provided insights into the primary design process. As stated in **Observation O1**, a careful primary design process forms the basis for the interaction between an AI-enabled IS and its user in the secondary design process. Consequently, initial IS designers have to consider the inscrutable nature of AI (Berente et al. 2021) and ensure the proper functioning of AI-enabled components. As illustrated by our application of the SHAP library (Lundberg and Lee 2017), plausibility checks beyond traditional software testing may need to be considered in the primary design process.

Implications and Propositions of the Design Study for the Secondary Design Process. In the secondary design process of the Theory of Tailorable Technology Design, users actively modify the IS and become co-designers (Germonprez et al. 2007; 2011). While the Theory of Tailorable Technology Design discloses the effects of users shaping a system, our design study indicates that the mutual shaping

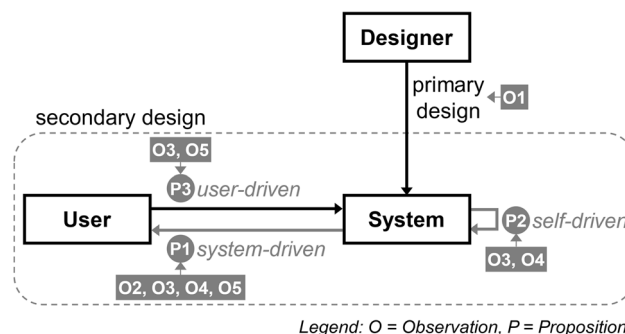


Fig. 5 Revised Theory of Tailorable Technology Design based on Propositions P1-P3 for secondary design mechanisms. *Note* The color black represents elements from the original theory, while the color gray represents adaptations

of the IS by the users and the IS per se has not yet been accounted for. The design, demonstration, and comprehensive evaluation of our DSR artifact enabled us to make three propositions for secondary design mechanisms that refine the Theory of Tailorable Technology Design.

Proposition P1 *The secondary design process can include system-driven interactions, in which the IS prompts the user for tailoring.*

The Theory of Tailorable Technology Design states that users “are simultaneously acting with and being acted upon by system functions and content” in the secondary design process (Germonprez et al. 2011: 669). While the theory provides rich conceptualizations of the users’ role in the secondary design process, it does not elaborate on the role of the IS. As introduced in Sect. 4.3, the DSR artifact created in our design study (i.e., the model for individualized bladder monitoring systems) comprises AI functionality that allowed us to investigate the impact of an AI-enabled individual IS on the secondary design process.

The artifact leverages deep transfer learning, which was viewed as an effective individualization technique in several workshops with ML experts. The artifact’s implementation of deep transfer learning involves an Initial Tailoring phase prior to productive use, during which users provide contextual features (i.e., sex, age, body mass index, and skin tone). In addition, users must record at least ten micturition cycles while wearing the sensor module to initiate the deep transfer learning process for the artifact’s prediction component. The Initial Tailoring phase has been corroborated repeatedly throughout the evaluation of the artifact. Most of the interviewed patients expressed a positive attitude toward the Initial Tailoring phase if it would lead to higher predictive performance (**Observation O2**), while benchmarking different ML techniques on a real-world dataset showed that the predictive performance increases (**Observation O4**). Furthermore, a case analysis with a potential user provided additional support for the applicability of the Initial Tailoring phase under real-world conditions (**Observation O5**). Based on these findings, we conclude that tailoring an IS does not necessarily occur as a byproduct of system use or tinkering by the user. Instead, the secondary design process can require tailoring that is mandatory and initiated by the IS. We argue that this tailoring is particularly relevant for AI-enabled individual IS as these systems have inductive learning capabilities that allow them to adapt to an individual user. This type of system-driven tailoring is also highly related to the primary design process of tailorable technology design, since the initial developers of the IS must decide whether and how to incorporate mandatory system-driven tailoring.

Our design study also revealed a second type of system-driven tailoring, which we identified in the Ongoing

Tailoring phase considered for the DSR artifact. During the Ongoing Tailoring phase, users or the artifact may trigger re-tailoring of the artifact’s prediction component, which requires recording additional micturition cycles. Besides the continued ability to tailor system components that are unrelated to AI, users can thus influence the performance of the prediction component by providing additional training data. Furthermore, the artifact is designed to initiate a recalibration request to the user if, for example, the sensor readings change due to external factors such as fast changes in body weight. The active triggering role of the artifact was also approved in the patient interviews (**Observation O3**). Therefore, we conclude that AI-enabled IS can leverage their data-driven decision-making capabilities to initiate system-driven interaction with the user, leading to re-tailoring. The IS exceeds its previously assumed passive role and acts as a distinct actor alongside the user in the secondary design process.

Proposition P2 *The secondary design process can include self-driven tailoring by the IS.*

System-driven interactions as those considered in Proposition P1 require explicit user input. However, it may not always be feasible or desirable for users to constantly fulfill IS requests for additional input. Taking the bladder monitoring application scenario from our design study as an example, recording additional micturition cycles asks users to measure voided urine with a measuring cup and enter the volume into the smartphone app. Given the effort involved, it is not surprising that the interviewed patients considered the ability of our AI-enabled individual IS to self-tailor to be an essential feature (**Observation O3**). The self-tailoring feature of the artifact is based on the possibility to autonomously determine the time of a micturition based on the sensor data, which is feasible as shown in the third evaluation episode presented in Sect. 4.5. The artifact can then generate surrogate truth labels for the voided volume using the recorded pre-micturition sensor data. The surrogate truth labels serve as impulse for the deep transfer learning prediction component (**Observation O4**), enabling a continuous cycle of learning and autonomous tailoring of the AI-enabled individual IS.

The design study exemplifies a secondary design mechanism for tailorable technology that involves an AI-enabled individual IS acting autonomously. While the design study implements only one of many potential paths for autonomous self-tailoring, it demonstrates that IS can act without human intervention or even (user-sided) human knowledge (Berente et al. 2021). This highlights the importance of considering the autonomous decision-making capabilities of AI-enabled IS in the Theory of Tailorable Technology Design.

Proposition P3 *The secondary design process evolves from being completely user-driven to incorporating both active and passive forms of user engagement.*

Germonprez et al. (2011) postulate that users actively participate in the adaptation and modification of IS during the secondary design process. Our design study indicates that users are willing to actively engage in tailoring an AI-enabled individual IS (**Observation O3**), which was also confirmed in a real-world case analysis (**Observation O5**). Therefore, although the Theory of Tailorable Technology Design does not preconceive the capabilities of AI, it already covers the active role of users in redesigning an AI-enabled IS during the secondary design process. Furthermore, its implications for tailoring non-AI components remain valid.

The original conceptualization of the secondary design process regarded the user as the sole initiator and actor (Germonprez et al. 2007; 2011). However, due to the emergence of AI and IS-sided tailoring requirements, the user is no longer the only actor capable of initiating tailoring in the secondary design process. Therefore, we perceived a need to expand the secondary design process. We posit that the secondary design process must reflect the AI-enabled IS as a distinct actor that can initiate tailoring toward the user (Proposition P1) and autonomously perform tailoring-related activities (Proposition P2). Moreover, the secondary design process needs to address the mechanisms that result from the enhanced autonomy and proactivity of AI-enabled IS.

Synthesizing Propositions P1–P3 into a Revised Theory of Tailorable Technology Design

We argue for three propositions (i.e., Propositions P1–P3) for secondary design mechanisms that enable a more comprehensive understanding of the tailoring process for AI-enabled IS. The propositions are based on insights and observations from our design study in the bladder monitoring domain and culminate in a Revised Theory of Tailorable Technology Design. It represents an important first step toward an updated Theory of Tailorable Technology Design. As shown in Fig. 5, the revised theory considers the user and the system as separate actors that perform tailoring in the secondary design process. The system-driven mechanism discloses that the IS calls the user for tailoring (Proposition P1). The self-driven mechanism reflects the IS as an autonomous actor in tailoring (Proposition P2). The user-driven mechanism describes the user's role in tailoring both AI-related and AI-unrelated system components (Proposition P3).

Our first and second propositions (i.e., system-driven tailoring and self-driven tailoring) advance the work of Pries-Heje and Hansen (2017) by providing additional

mechanisms to consider in the deep secondary design process. Since both system-driven tailoring and self-driven tailoring require the system designer to align the IS with its intended domain, domain shifting as presented in unbounded secondary design (Hansen and Pries-Heje 2018) depends on cross-domain transferability. Taking our findings into a broader context, our work contributes to design knowledge on human-AI interaction (Amershi et al. 2019). It also exemplifies how the performance of AI-enabled IS can be optimized through interactive ML (Dudley and Kristensson 2018). Finally, we advance research on the co-design of AI-enabled IS (Panigutti et al. 2023; Stawarz et al. 2023) by responding to the call for more research on post-design (Noorbergen et al. 2021) and by showcasing AI as an active co-designer in the secondary design process.

5.2 Practical Implications

The design study addresses a pressing medical issue for patients with NLUTD. Hence, as the secondary contribution of this work, the presented model for individualized bladder monitoring systems provides concrete design knowledge for an AI-enabled individual IS. Specifically, the artifact shows how AI-enabled individual IS that build on smart wearables and deep transfer learning can improve predictive performance in the bladder monitoring domain. The real-world fidelity differentiates the artifact from previous studies, most of which were conducted in laboratory settings with strict data collection protocols (Fong et al. 2018; Kristiansen et al. 2004; Reichmuth et al. 2020). An evaluation episode on a real-world dataset of 22 heterogeneous test subjects lead to a MAE of 104.96 ml, surpassing prior benchmarking results (e.g., Fechner et al. (2023)). Overall, the artifact can offer valuable guidance for the development of healthcare solutions that can adapt to the unique biological and physiological characteristics of an individual user.

6 Conclusion

Healthcare can highly benefit from advances in individualized medicine by focusing on the individual patient. Advances in AI and related technologies have notably stimulated the design of AI-enabled IS, providing unprecedented opportunities for patient-centeredness and empowerment. In tailorable technologies, users of an IS are actively involved in its design process. As current theorizing solely accounts for human actors, we posit the conjecture that the knowledge about tailorable technology design does not effectively account for AI-enabled IS. In response, we conducted a revelatory design study to investigate the Theory of Tailorable Technology Design

(Germonprez et al. 2007; 2011) by designing, demonstrating, and evaluating an AI-enabled individual IS to improve bladder monitoring for NLUTD patients. Our results provide a better understanding of the roles of designers, users, and AI-enabled IS for tailorable technology. Based on the observations during our design study, as our primary contribution, we inferred three propositions for secondary design mechanisms in tailorable technology design. Besides the traditional user-driven secondary design, we found that the IS per se is a distinct actor in the secondary design process through self-driven and system-driven secondary design. We consequently confirm the conjecture that the Theory of Tailorable Technology Design does not effectively account for AI-enabled IS. These findings lead us to a Revised Theory of Tailorable Technology Design. As our secondary contribution, we provide guidance on how an AI-enabled individual IS can be designed and implemented using the specific case of a smart wearable for NLUTD patients. Our findings emphasize the importance of patient-centeredness in healthcare IS design, suggesting the new paradigm that AI not only complements but also enhances individualized healthcare.

Our work is subject to limitations that open up promising avenues for future research, both for IS research and the medical field of NLUTD. Referring to Lee and Baskerville (2003: 224), we suggest that our generalizations should be “taken as well-founded but as-yet untested hypotheses”. While our design study was a well-suited first step to challenge existing knowledge about tailorable technology design, we focused on only one very advanced AI-enabled individual IS. Consequently, our propositions and the Revised Theory of Tailorable Technology Design require validation and confirmation, for example, via more general theory building approaches like multiple-case study research (Eisenhardt and Graebner 2007). In doing so, IS beyond the individual level should be incorporated to move research toward a Unified Theory of Tailorable Technology Design. Over and above the conceptual level, confirmatory studies could also explore selected aspects of the Theory of Tailorable Technology Design in more detail, for example by testing the validity of the design principles proposed by Germonprez et al. (2007). Furthermore, we focused on the functional mechanisms of the secondary design process exploring the impact of AI on the design of tailorable technologies. While secondary design includes a content layer in addition to the functional layer (Germonprez et al. 2011), we apply our propositions just to the functional layer of secondary design. Thus, future research could investigate how the tailoring of content influences AI-enabled tailorable technology design. Germonprez et al. (2011: 667) state, that “language serves as an important component of secondary design at the content

layer [...]”. Analyzing generative AI technologies, for example, could provide fertile ground for scientific inquiry (Feuerriegel et al. 2023), as AI can dynamically create or modify content and thereby influence the design of IS.

Considering the medical context of NLUTD, the design study presents several limitations that can be addressed in future research to enhance the usefulness of bladder monitoring. Due to the rather exploratory nature of our design study, it is necessary to conduct long-term medical studies to further evaluate the usability and long-term effectiveness of the proposed sensor device. In addition, the applicability of our individualization approach (i.e., fine-tuning) to different demographic groups remains to be explored. Finally, a viable solution must ensure privacy and data security. For instance, federated learning could provide an avenue for individualization by harnessing collective user data while maintaining individual privacy (Liu et al. 2022). In addition, the implementation of edge computing could be beneficial to safeguard patients’ data against potential security vulnerabilities in smartphones or server systems (Becker 2018; Gopinath et al. 2022).

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