Wearable Miniaturised Smart Device For Children With Nocturnal Enuresis

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Abstract

This research was designed to evaluate if it is viable to awaken children with urinary incontinence at the pre-void phase using a smart wearable device and enable them to control incontinence with fine-tuned individual parameters determined by the device intelligently. To address this research question, a miniaturised wearable smart device was built in this multidisciplinary research to monitor the non-linear behaviours of the bladder during its expansion with urine intake. The device, with its customisable abilities, sets an individual alarm point to awaken the child with incontinence before voiding. Safety parameters, aesthetics and ergonomic use of the device were investigated through hospital trials with children and the device was improved based on the obtained feedback from these trials.

Clinical Relevance: The device will help children learn how to control their incontinence over time.

Introduction

This study was designed to assess if it is feasible to: i) awaken children with Nocturnal Enuresis (NE) at the pre-void phase using a smart wearable device and ii) enable them to control incontinence with fine-tuned individual parameters determined by the device intelligently using ultrasound (US) technologies. A miniaturised smart medical instrument -- the so-called MyPAD -- was built to treat NE by involving the public and patients. Readers are referred to our earlier published patents and papers [1], [2], [3], [4], [5], [6], [7] to discover the elaborated phases of this multidisciplinary research. In this particular study, efficiency, safety parameters, aesthetics and ergonomic use of the device were investigated through hospital trials with children under the observations of physicians and nurses.

Methodology

The first miniaturised device built in this research is shown in Fig. 2 (top). The primary components of the Artificial Intelligence (AI) interface instilled into the device are delineated in Fig. 1.. A merge of Bidirectional Long Short-Term Memory Recurrent Neural Networks (Bi-LSTM-RNN) and Reinforcement Learning (RL) is utilised. The main elements of the device (Fig. 2 (bottom).) are i) one US transducer for emitting single element US signals, ii) four US transducers for receiving A-mode echoed pulses within a depth up to 15 cm, iii) a US electronics unit for tuning signals, iv) a printed circuit board (PCB) for processing the acquired echoed pulses and establishing a bridge between the US electronics, and v) an AI unit for determining and setting individual alarm points.

Trials, Observations and Advancement

The validation of the system was conducted both on the tissue-mimicking phantom developed in this research and on volunteers. 8,876 data samples (both from the phantom and volunteers) were used to establish the trained model and 980 reserved data samples were used to test the model, resulting in a sensitivity (Se) (i.e., ``Alarm'' signals correctly classified as ``Alarm'') value of 97.1% and a specificity (Sp) (i.e.,``No-Alarm'' signals correctly classified as ``No-Alarm'') value of 99.2% with an overall accuracy rate of 98.2%. Physicians and nurses from the Royal Preston Hospital evaluated the performance, efficiency, safety parameters, aesthetics and usability of the prototype MyPAD instrument (Fig. 2) on children at the Lancashire Research Facility. During these trials, data samples were recorded from different stages of the bladder while the bladder was filling up with urine to power the decision-making capabilities of the AI interface. The observations perceived by the physicians and nurses and their recommendations to empower the device are provided in Tables 1 and 2. The advancements on the device considering these observations and recommendations are presented in Table 3.

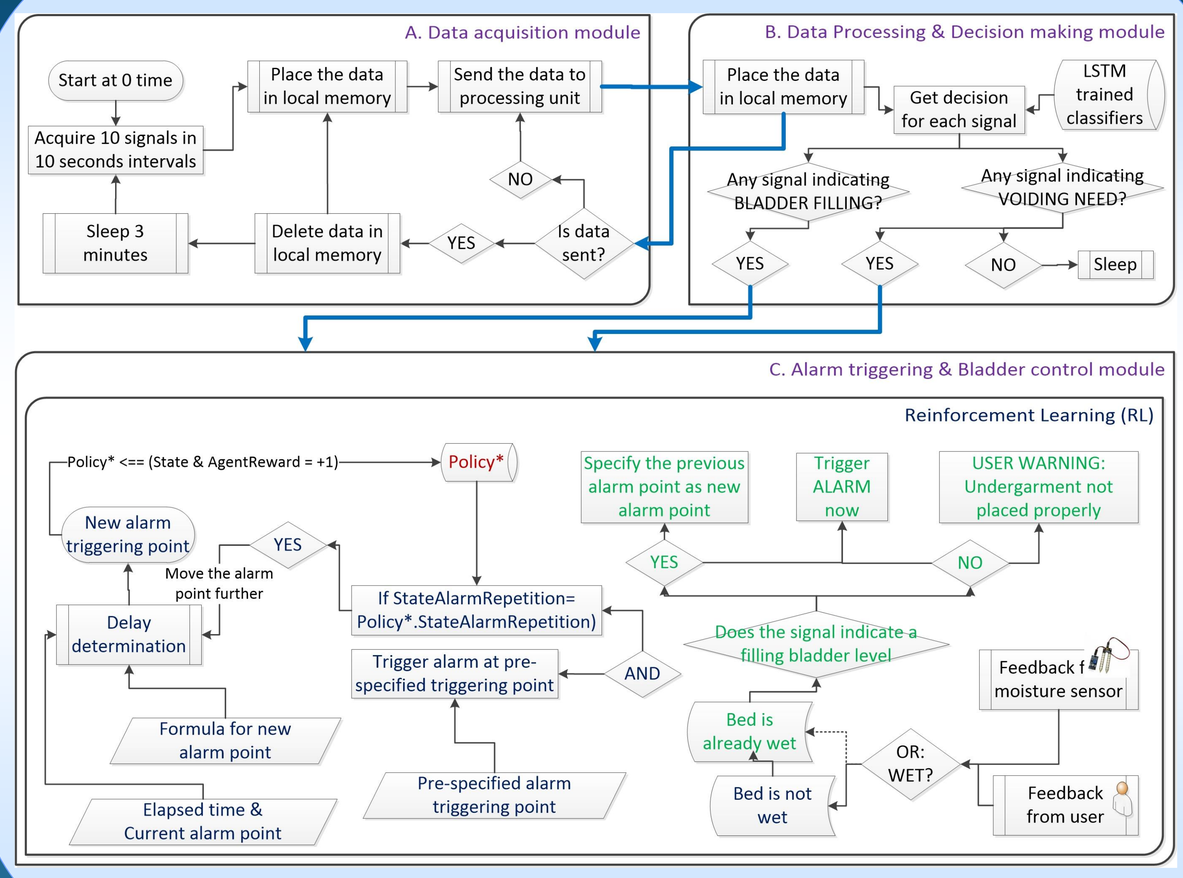

Figure 1. The primary components of the AI interface instilled into the device.

Figure 2. The advanced MyPAD device: i) US transmitter, ii) US receivers, iii) US electronics, iv) PCB, and v) AI unit. Top first version; Bottom last version.

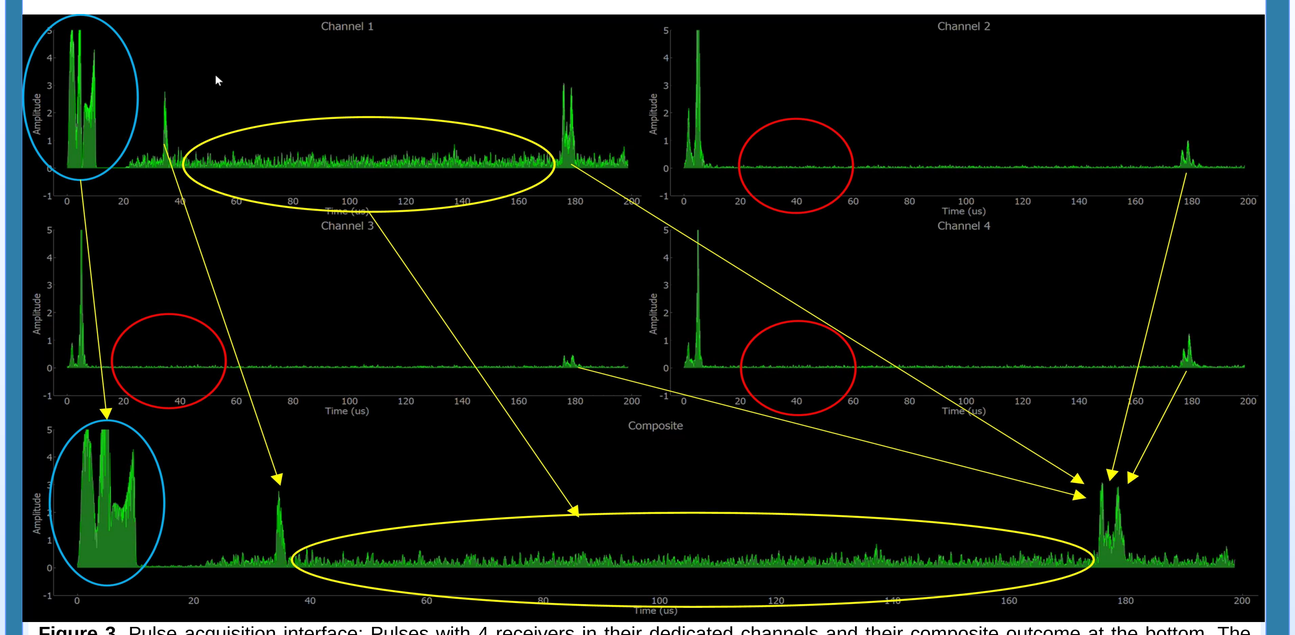

Figure 3. Pulse acquisition interface: Pulses with 4 receivers in their dedicated channels and their composite outcome at the bottom. The first amplitudes in the frames correspond to the echoed pulse coming from the anterior wall whereas the second amplitudes correspond to the pulses from the posterior wall of the bladder. The red circles indicate the places where no echoed pulses are detected from the anterior wall because of the reflection and refraction angles of the emitted US beams from the transmitter. The amplitudes in the yellow ovals indicate the noise caused by the high signal-to-noise ratio.

Table 1. Observations of the medical professionals.

1	Overall it seems alright to wear. When not moving you can't feel it is there unless you touch it.
2	It didn't move, but the child was in the bed most of the time. Also, the tight clothes helped keep it in place.
3	Even when going to the toilet, it stayed in place.
4	The device can be uncomfortable when moving around.
5	The garment does look weird, but once you wear it, it looks alright.
6	Garment did not have a hole for the probe wires.
7	Waterproof connectors were quite bulky.
8	Battery wires and probe wires were not adequately restrained.
9	The circuit box got noticeably warm after 4 hours of use, which is slightly worrying when children will wear it for up to 10 hours in bed under the blankets.

Table 2. Recommendations from the facility.

1	Less breakable (the connection of the battery charger came out. The device looks delicate).
2	Fewer parts: a device in one piece, rather than the 3 components connected with wires. There was no way to attach the battery case to the probe case.
3	Sealant around the electronics case made the device look too much like a prototype.
4	All parts needed labelling to improve ease of use.
5	The child felt the size of the US box. It would be better with no wires attached.
6	The garment looks alright, but it needs to fit the child.
7	Some stickers would make it look more attractive for younger children.

Table 2. Recommendations from the facility.

1	Extra heatshrink was added to the battery and probe wires to prevent tangling.
2	Garments were adjusted to allow for probe wires.
3	All components were labelled to improve ease of use.
4	Velcro loop was used to attach the battery to the electronics case.
5	The electronics case was resealed with clear silicon to improve waterproofing and aesthetics.
6	Decision-making ability of AI was improved by incorporating the collected data instances into the training process.

Discussion

The results suggest that the Bi-LSTM-RNN-based approach substantially outperforms the feature-based ML techniques (see our previous study [2]) based on the A-mode US signals and the datasets acquired from the human body, primarily from the bladder. Furthermore, with the help of the RL technique built in the study, the system does not need to train itself for each child for customisation. From a technical standpoint, essential sensitive customisation and adjustments per child can be carried out intelligently in an autonomous manner by considering the particular characteristics of the child during the use of the device. More explicitly, the system, with RL, is turned into an intelligent system built upon Bi-LSTM-RNN with pre-trained classifiers. It becomes a perpetual intelligent learning system using RL.

Conclusion

The device, developed in this research to treat urinary incontinence, was improved based on the obtained feedback from parents, children, physicians, and nurses during hospital trials. The outcome of the clinical trials provides robust empirical support for the efficacy of the MyPAD device, both in setting appropriate alarm points at the pre-void phase as delineated in Fig.3 and in helping the child control his/her incontinence with fine-tuned individual parameters determined by the device with successive uses. The smart machine will be improved and miniaturised further to ensure its efficacy.

Future work

International standards such as CE mark, comfort (e.g., more ergonomic geometry, aesthetics, and further miniaturised casing with further miniaturised electronics and sensors), and safety concerns (e.g., waterproofing, cables, heating of the electronics) will be ensured before long-term use of the device with more volunteers. The developed techniques are aimed to be validated on this device with 10 children that have NE after these standards have been certified. Then, the device is aimed to be inspected with larger groups before mass production for commercialisation using Federated Learning (FL) [8].

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The methods, patient and public involvement in this research were approved ethically by NHS Health Research Authority: North West - Greater Manchester Central Research Ethics Committee (ID:247101).

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