A vest for treating jaundice in low-resource settings

1st Davide Piaggio
School of Engineering
University of Warwick
Coventry, UK
d.piaggio@warwick.ac.uk

2nd Martina Andellini
School of Engineering
University of Warwick
Coventry, UK
martina.andellini@warwick.ac.uk

3rd Mahir Taher
School of Engineering
University of Warwick
Coventry, UK
mahir.taher@warwick.ac.uk

4th Leandro Pecchia
School of Engineering
University of Warwick
Coventry, UK
l.pecchia@warwick.ac.uk

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***Abstract*—Neonatal Jaundice (NJ) is a worldwide and commonly known issue with known treatment and preventions. However, in low-resource settings (LRSs), the solution to treatment is far from trivial. This paper aims to address the issues and causes for insufficient NJ phototherapy on a global scale, presenting the design, test and development of a first prototype of a vest, with embedded fibre optics and sensors for autonomous phototherapy treatment of new born jaundice in LRSs. Specifically, this paper evaluates and reports on the feasibility of such a device to be a means of delivering complete and effective phototherapy treatment to jaundiced neonates in LRSs. Among the main innovations included in our design, are garmented jaundice treatment, accessibility in LRSs, and integrated diagnostics for a closed loop control. The scope will hopefully facilitate at-home treatment in an effort to fulfil the global unmet need for phototherapy, typically occurring in rural and LRSs. In particular, this paper focuses on how the results of the needs assessment were cascaded into an innovative product design specification.**

***Index Terms*—jaundice, low-resource settings, medical device, phototherapy**

I. Introduction

Neonatal Jaundice (NJ) is one of the most common conditions in newborns [1]. It is present in 60% of all births (and up to 80% of preterm births) worldwide, and the 10.5% of all neonates require prophylactic phototherapy treatment [2], [3]. NJ is usually due to the incapacity of neonatal livers to metabolize unconjugated bilirubin as they are still organically developing [4]. It results in yellow coloration of the skin and sclera because of the accumulation of conjugated or unconjugated bilirubin. The former being very rare (approximately 1 in every 2500 infants) and pathological and the latter being most common (with over 75% of cases being physiological) [5], [6]. NJ is indeed the 7th most common cause of neonatal mortality up to the age of 6 days worldwide [7]. A systematic literature review and meta-analysis of studies related to the global prevalence of NJ concluded that NJ rates are associated with a significant health burden in low- and middle-income countries (LMICs), further positing that the annual global morbidity and mortality rate due to NJ (114000 and 63000 per annum, respectively) described by Bhutani et al. is likely to be significantly underestimated [8], [9]. Several studies underlined how, in LMICs, NJ is not always accurately diagnosed, and treatment is not always effective [7], [10]–[14]. If left untreated, NJ may lead to an array of kernicterus spectrum disorders (e.g., mild permanent brain damage, brain diseases, hearing loss, celebral palsy and death) [1], [15]. Improving the healthcare of NJ is of international relevance. As outlined in the National Health Service (NHS) Long Term Plan, there are the relevant ambitions to provide extra support to premature births, expand support for perinatal mental health conditions and reduce child deaths during birth by 50% [16]. Additionally, there needs to be a greater push towards 'out-of-hospital' care, proliferating access to treatment for a greater share of the population. To this regard, this project aims at a shift from a hospital-based phototherapy to a home-based one, which has already been proven to be an effective solution to mitigate hospital patient load [17], [18]. In light of global health initiatives, should the concept of the project be fully realizable, it will aim to contribute towards the United Nations' Sustainable Development Goal 3, Global health and wellbeing, specifically in terms of target number 2, i.e., lowering the global neonatal and under-five mortality rate [19].

In literature, there are selective studies from low-resource settings (LRSs) commonly identifying the need for more effective phototherapy by means of delivery [8], [10]–[14], [20]. In particular, the two field studies conducted in Nigeria and in India highlighted the most common issues with treatment to be:

1) insufficient light irradiance (when compared to the American Association of Paediatrics [21] standards);
2) poor maintenance of burnt out/dysfunctional light sources;
3) poor operation and management of NJ with phototherapy;
4) and inconsistent and unreliable electrical supply.

Although the devices currently used in LRSs for phototherapy have the capacity to deliver effective treatment, their real utility is limited due to poor management strategies. Furthermore, the need for "out of hospital" care emerged as international relevance across the socio-economic spectrum. As it has been stated by the NHS [16], it is widely accepted that accessible 'out-of-hospital' care has the potential to be more cost-effective, reasoning as to why it is manifested in popular literature [22]. There are selective studies from LRSs

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highlighting that NJ is often inconsistently (and hence ineffectively) managed, identifying common failure modes such as insufficient training, poor setups with insufficient irradiance, poor maintenance and the idleness of the 70% of the donated medical devices [2], [11], [12], [23]–[26]. However, with locally sourced manufacturing (e.g., 3d printing), increasing interest in resilient medical device design, donations (although there are major concerns as to its long term benefit), and remanufacturing, there are causes for optimism in improving global healthcare in an attempt to accommodate and improve medical device management in LRSs [26], [27]. Although the developing phototherapy devices used in LRSs have proved to be effective, [28], [29], they are not able to totally meet the needs highlighted above. Contemporary phototherapy devices show a push towards using LEDs or surface mount LEDs (SMLEDs) with their advantageous high-irradiance-to-temperature output. However, although they are designed with portable power unit suitable for at-home therapy, not all the systems are independent from constant power supply, that is generally deemed to not be a commodity by definition of LRSs [30]. Moreover, the devices are designed as structures to wrap around the neonate for proximal emission while published research into garmented phototherapy is limited. One paper describes the design development of an 'automatic and portable phototherapy garment', featuring a transcutaneous blood bilirubin measurement device [31]. However, the main limits that emerged are related to the position of LEDs, directly on the garment itself, which affects the comfort and distribution of the light on the screen surface. Another current paper, implementing the plastic optical fibres (POF) in textiles to control light-output in NJ phototherapy context [32], concluded a real viability in using garmented treatment with sufficient irradiance [33]. For these reasons, domestic LRSs solutions for NJ has been of growing World Health Organisation (WHO) interest, as an increasing number of device proposals in this domain have been published into the 'WHO compendium of innovative health technologies for LRSs' [34].

Overall, this project aims to address the issues and causes for insufficient NJ phototherapy on a global scale by presenting the results of a needs assessment cascading into an innovative product design specification. This paper presents the envisioned ideal requirements of a vest embedded with POF and trans-cutaneous bilirubin (TcB) diagnostics integrated with the device for autonomous phototherapy treatment of newborn jaundice in LRSs. Moreover, it also presents the results of a feasibility study for some of the requirements conceived for our product, in particular those related to the use and efficacy of LED-powered fibre-optics in a newborn-sized vest.

II. Methods

A. Needs assessment and product design specification

The system V-model (see Figure 1), was holistically adopted throughout the project: from researching the clinical problem, defining the user requirements, formalizing the functional requirements, setting the design specifications and then continuing through with the design plan and implementation. Verification was then attempted at each stage and, beyond this project, prospective complete validation would occur through more iterations. The clinical problem was defined throughout a need assessment process focusing on intended patient population and setting of use. More specifically, seven field studies have been performed in Sub-Saharan Africa: one in South Africa (2016), three in Benin (2017, 2018 and 2019), one in Ethiopia (2018), and one in Uganda (2019). During some of these field studies, medical locations were inspected and assessed and local biomedical engineers and technicians were interviewed and shadowed withing their workplaces, in order to evaluate the major challenges and opportunities [26], [35]. The review of the field notes and of the related publications, as well as the focus groups with relevant experts, and the literature review were essential to understand the intended population and setting of use as well as the requirements needed for our prototype. A literature review was then carried out in order to encompass the aspects of the clinical need that inform on the design criteria specification for the phototherapy vest and the solution scope, including the exploration of the viability of integrating transcutaneous bilirubin (TcB) diagnostics with the device. Results from literature review were compared and integrated with the relevant standards and regulations (e.g., the European medical device regulation 2017/745). Once the general design requirements were defined, a list of detailed user and functional requirements was set up. The way to measure them and their punctual definition were outlined throughout the integration between evidence from literature, and international experts' and stakeholders' opinions.

B. Feasibility study

The feasibility of some of the aforementioned requirements was evaluated during the prototyping and validation phases, in collaboration with a UK-based smart textiles company, Footfalls&Heartbeats[1]. The extent of Footfalls&Heartbeats' input into the project was in the practical design and implementation of the textile vest with optical fibres. In fact, the project's design specifications were taken by Footfalls&Heartbeats to produce the first iterations of the vest, which thereon have been subject to verification and validation testing.

C. Validation

Several tests were performed to evaluate:

1) the modelled absorption at an interpolated or extrapolated skin thickness, to assess the level of light penetration;
2) safe phototherapy emission bandwidth verification;
3) LED performance and efficacy comparison;
4) fibre-optic loss prediction and required number of LEDs to achieve effective phototherapy.

The tests (see Figure 2) were performed taking into account the light power spectra specifications for efficient phototherapy, presented by the American Academy of Pediatrics (AAP)

[1]https://www.footfallsandheartbeats.com/

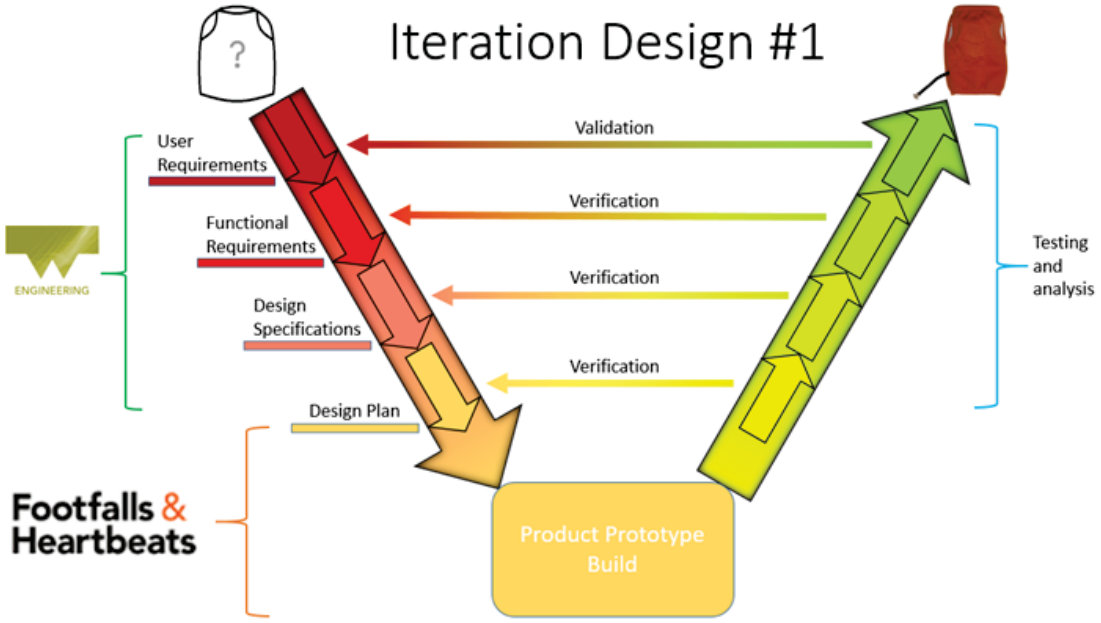

Fig. 1. Diagram of the systematic design approach for the project, highlighting the different roles.

[21]. The tests were performed using a spectroradiometer (EKO Spectroradiometer LS-100), different LEDs, the vest prototype, and 2mm-thick synthetic skin samples. Moreover, a power source with a voltage and current readout (VOLTCRAFT Power supply LSP-1403) was used, as well as a multimeter to verify current readout on power supply and take LED voltage (VOLTCRAFT Multimeter VC265), a laptop for data measurement and storage, a ruler for apparatus distance setting, and a thermometer and hygrometer (Anymeter Thermometer and Hygrometer TH101E).

III. Results

A. Needs assessment and product design specification

The results from the needs assessment are summarised in the requirements shown in Figure 3. These have been taken from American and UK NJ management standards as well as modern NJ therapy devices, and have most significantly highlighted our prototype's need to increase its radiated intensity at skin surface.

The requirements were grouped into 7 domains, presented in decreasing order of importance:

1) Neonate Safety, comprising all the requirements related to the risks to which the newborn is exposed, linked to UV light and possible healthcare-acquired infections (HAIs)
2) Vest Fibre-optics and LEDs, comprising all the requirements related to the intensity and characteristics of the blue light for optimal skin radiation levels
3) Bilirubin Diagnostics, comprising all the requirements related to the bilirubin sensor for the closed-loop therapy
4) Operating Temperature, comprising all the requirements related to the monitoring of the room temperature and the temperature reached by the skin of the newborn
5) Electronics and Data Relay and User Interface, comprising all the requirements related to the power supply, the communication protocols, storage, and the ease of use
6) Cost, comprising all the requirements related to the costs of production and maintenance
7) Military standards, comprising all the requirements related to the resilience of the device to harsh environmental conditions (e.g., high temperatures).

B. Evolution of the concept

The initial prototype design for the vest included light emission at the end of the fibre-optic tips directly onto the skin. Textile samples of end-emitting fibres had already been produced by the company and so were already feasible. However, as prototype development went on, there were discussions with Footfalls&Heartbeats on using side illuminating fibres instead, as the end tips embedded in the fabric were relatively sharp and would give physical discomfort unsuitable for a neonate. The current prototype relies on side-illuminating POFs inserted non-uniformly and set into the vest using thermosetting plastic (see Figures 4, 5 and is 8.5x13.5 cm in size (complying with clothing sizes by Noppies), and weighs 100 g. The vest itself is stretchable, washable, foldable, and lightweight and has an inner layer of spun polyester, providing comfort to the neonate as they move around through treatment.

Furthermore, a prospective detachable light link means the neonate may also be taken out of phototherapy temporarily for post maternal care and bonding without a big hassle of deconstructing the setup for phototherapy. The current design concept also includes a battery to make the device less reliant on possibly unreliable power sources, a temperature sensor to ensure that the newborn is never exposed to harmful temperatures, and a trans-cutaneous bilirubin diagnostics unit

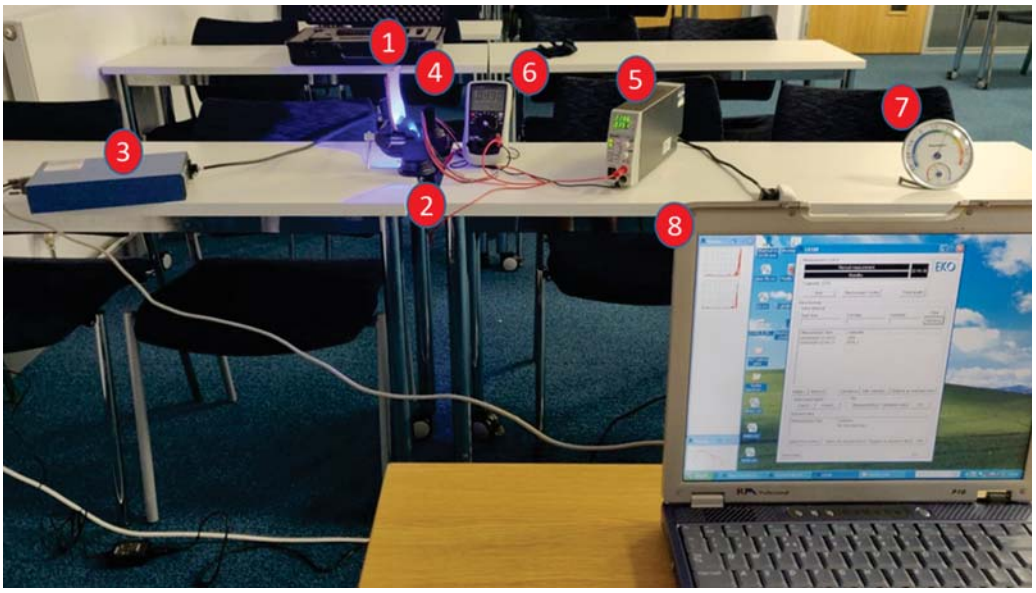

Fig. 2. Experimental setup example for testing with synthetic skin: skin sample (1), bench clamp (2), calibrated absolute spectroradiometer (3), monochromatic light source (LED) (4), Power supply (5), multimeter (6), laptop (7), thermometer and hygrometer (8).

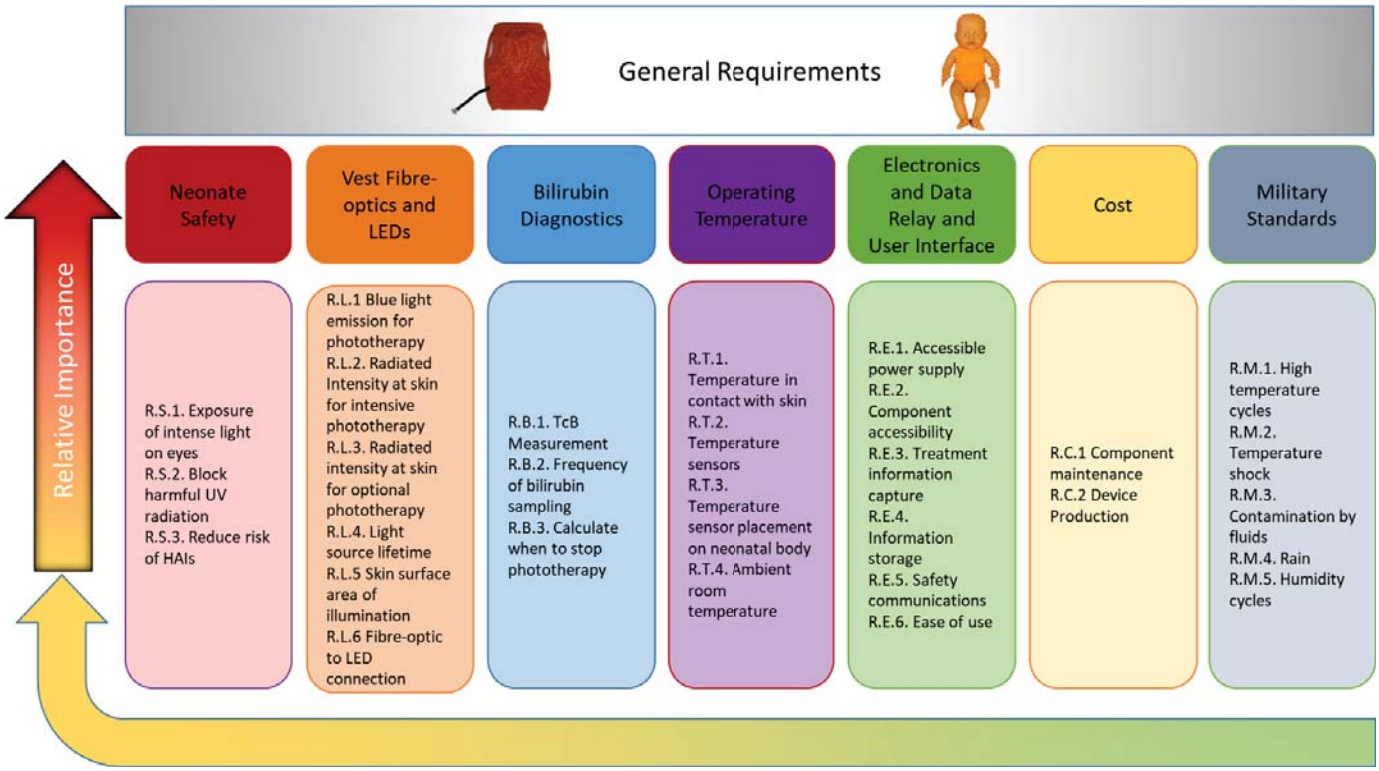

Fig. 3. Conceptual device requirements, laid out first in terms of category and secondly in terms of importance. The relative importance (going right to left, upwards) between categories and then sub-category requirements is illustrated.

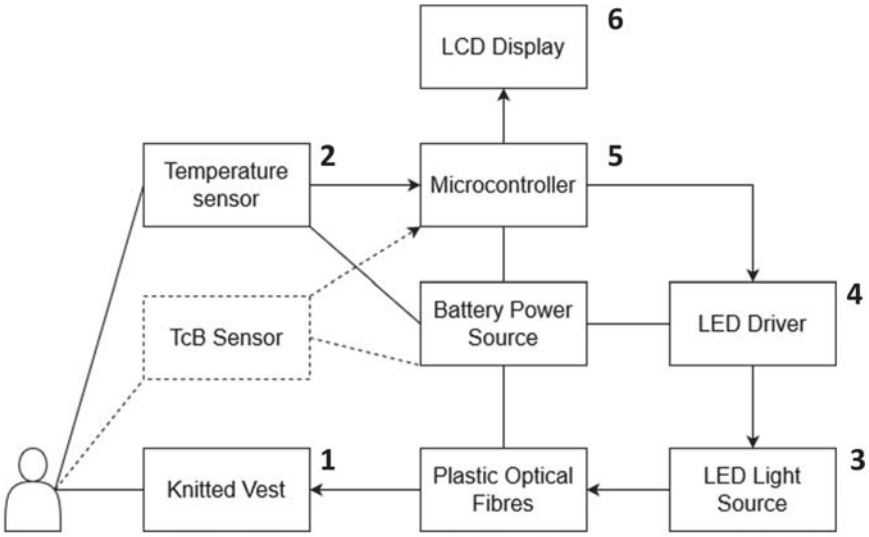

Fig. 4. The block diagram of the newborn vest. The dashed box represents possible future developments of the enhancements of the prototype. The annotations refer to Figure 5

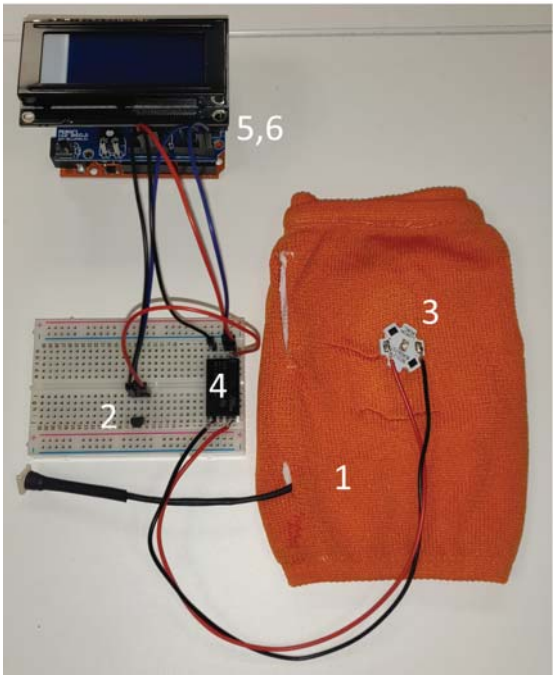

Fig. 5. Prototype components layout with annotations referring to Figure 4

to automatically evaluate the need for phototherapy and adjust the treatment settings, without the intervention of a doctor. In this way, the complete prototype would be easy to use for lay-users and could be a potential solution for at-home therapies.

C. Feasibility study

As of now, with the current prototype we were able to fulfil the following requirements, either by light testing or by observation and analysis: R.L.1. (via observing the emission spectrum to have dominant wavelengths suitable for phototherapy), R.L.4. (via LED manufacturer stating average 50'000 operational hours), R.L.6. (via a 3D printed pigtail), R.S.2. (via observing negligible UV emission in spectra), R.T.1. (via comparison with other phototherapy devices), R.S.1.(via vest design with opaque outer layer), R.S.3. (via washable vest), R.C.1. (via modular design), R.C.2 (via components and vest manufacturing price). The primary focus now is the prototype's radiated intensity, which reaches around 1 mW/cm^2, inadequate for effective phototherapy (R.L.2, R.L.3).

IV. Discussions and Conclusions

Results shows promise in the ability to emit an appropriate spectrum for NJ phototherapy, but is yet to achieve sufficient skin irradiance through the means. It mainly provides testament to the potential of wearable health care, specifically under phototherapy treatment, as the vest is designed to be suitable for the dimensions of a neonate and can illuminate enough surface area for standard phototherapy. By design, this vest would be simple enough for lay users whilst improving ease of maintenance through being modular and leaving little leeway for delivering insufficient irradiance, given the light source is at skin surface level (provided the output irradiance improves to meet NJ phototherapy standards). As of yet, there is no conceptual implementation for a TcB unit, but there is practical accommodation for it with the presence of a microcontroller and a light source control. Further into development, this device can expect to engage with a range of pressing stakeholders, as is typical of medical devices. Because the prototype textiles manufacturing for this device uses a practically state-of-the-art machine (further details being trade secrets of Footfalls&Heartbeats), assessing the feasibility of regional textiles manufacturing in LRSs of this device will require further research. It is worth noting that the fabrics

materials and POFs for manufacturing the prototype vest alone (i.e., not including LEDs and electronics) can be priced at less than $3 per vest, as stated by Footfalls&Heartbeats, which raises optimism for the prospect.

V. Limitations

The project presented in this paper is that undertaken by one of the authors in fulfillment of a BEng in Biomedical Engineering. The project was thus subject to time and resource constraints, and could be further extended with additional resources and workforce, in addition to further smart fabric industry collaboration.

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