Leading the way in human-centric healthcare

Thiru Kanagasabapathi, PhD, and Ashok Sridhar, PhD, from TNO@Holst Centre (Eindhoven, The Netherlands) showcase their new wearable health patch for Io(M)T applications

Digital health technologies are changing the way the healthcare is delivered. Advancement in digital health technologies are helping to shift the focus away from 'treating patients' towards 'ensuring the well-being of a person', and in taking preventive measures for vulnerable group of people. Impact of the current COVID-19 pandemic has only accelerated the adaption of digital health technologies in daily clinical practice (1). Patient care is transitioning to de-centralised care settings with real-time monitoring, where in-person consulting is preferred only as a second line in the treatment. This facilitates healthcare practitioners (HCP) to provide intervention along the care continuum and deliver care outside of traditional hospital environment. This also has a positive impact on the patient experience and well-being, resulting in greater human-centricity in healthcare.

Wearable devices play a key role in facilitating this transition in care delivery, and this is expected to gain momentum with increasing access to 5G technology (2). These devices are well on their way to forming the backbone of internet of medical things (IoMT), offering the possibility to continuously monitor and wirelessly communicate the physiological parameters of the wearer at any location, without interfering with his/her daily activities.

Wearable health patches for human-centric healthcare

Wearable devices for health applications come in various form factors. Wrist-worn devices, smart clothing, health patch devices and EEG headsets are some of the main embodiments of such devices. Of these, wearable health patches are probably the most versatile, offering the possibility to include a variety of sensors for collecting various electrophysiological and optical signals. A wearable health patch can be considered as a "smart band-aid" that can be directly applied on the skin. Apart from sensors, a typical wearable health patch consists of an energy source and a data processing module with storage and (wireless) communication capabilities. The device can be used to make contact measurements on various parts of the body, depending on the application needs. Contact area of a patch on the human body consists of suitable skin adhesive for short/long-term adhesion and electrodes for signal acquisition.

Figure 1 shows the exploded view of different layers of an example health patch device developed based on TNO@Holst Centre's proprietary system architecture. In this particular design, the readout electronics houses the data processing and communication module as well as a rechargeable battery. The readout electronics is reusable while the rest of the patch needs to be replaced typically after a week's use.

Parameters that can be measured by wearable health patch devices include, but are not limited to, heart rate, heart rate variation (HRV), respiration rate, respiration depth, temperature, oxygen saturation and blood pressure. Wearable health patch devices yielding clinical-grade data that can be used for patients with (or persons vulnerable to) chronic obstructive pulmonary disease (COPD), cardiac disease, COVID-19, bladder monitoring, sleep disorder, etc., have been developed by different companies, and are at various stages of commercial implementation. Figure 2 shows a healthy volunteer wearing a health patch device to monitor heart rate and respiration rate.

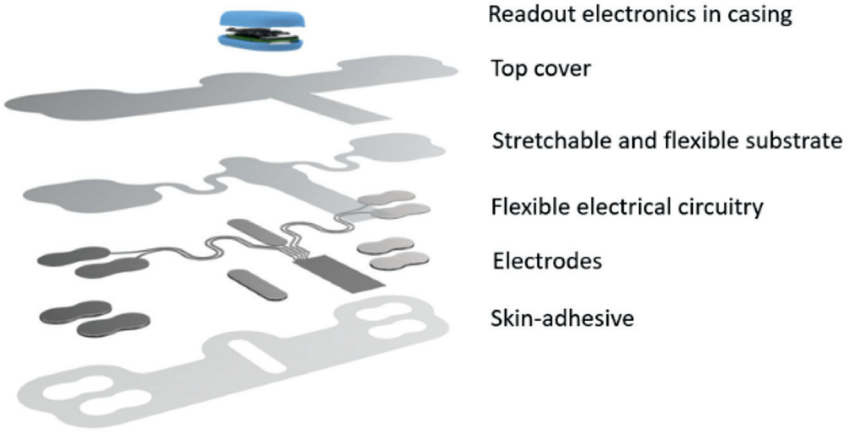

Fig 1: Cross-sectional view of various layers of a health patch device

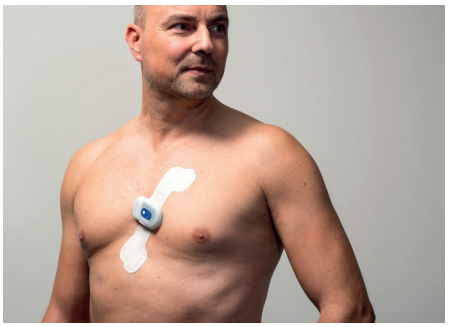

Fig 2: A healthy volunteer wearing a health patch device across his chest to monitor heart rate and respiration rate

With the advancement of sensing technologies and miniaturisation of sensors, even more parameters can be measured, giving a holistic picture of the wearer's physiological status. For instance, biochemical sensors that can analyse sweat, saliva, blood, tears, etc., can be used to probe biomarkers, thereby giving the HCP a detailed insight into a person's health. These so-called digital resilience biomarkers allow for the measurement of personal biological dynamics of an individual, thereby giving a highly personalised feedback to improve health. (3)

Key challenges in wearable health patch development

There are certain key challenges that need to be addressed while developing a wearable health patch device. To start with, there is no 'one-type-fits-all' wearable device that can fulfil the application needs of different target groups. A wide range of factors influence the configuration, applicability and the accuracy of a health patch device, a selection of which is listed below:

- Physiological parameter that needs to be measured;
- Location on the human body where it will be applied;
- Target group of people (elderly, patients, high-risk groups, infants, etc.);
- Setting in which it is used (clinical, home, anywhere, etc.);
- Required duration of wear;
- The primary objective: Is the device intended for prescribing course of treatment or an intervention, or is it solely meant for monitoring purposes?

The interaction between various layers of a wearable health patch is key in delivering an optimised device suitable for real world applications. It is critically important to select suitable materials for the patch development. Skin contact layers of the patch such as the electrodes for good quality signal acquisition, adhesives to ensure long-term reliable adhesion and the substrates that can provide sufficient stretchability, conformability and breathability, are crucial elements of the patch, both individually, and in combination with other layers. The selection of these materials needs to take into account the various influencing factors listed above. This complex interaction requires innovative materials, the selection of which requires a highly specialised knowledge. An example of this is the knowledge of printed electronics. Traditional electronics can yield flexible circuitry (e.g., polyimide-copper flex PCB), but not a stretchable circuitry, especially for a multi-layered circuit structure. In the case of a health patch device worn across, e.g., the chest, as shown in Figure 2, it is essential that the device is stretchable. Printed electronics offers the possibility to additively print the circuit structures using special stretchable inks/pastes on stretchable substrates, resulting in a device that can reversibly expand by 20% or more, over hundreds of thousands of cycles.

In terms of signal and data quality, traditional gel-based electrodes and skin adhesives used in the conventional patient monitoring applications are the gold standard for benchmarking wearable health patch devices. That said, wearable devices also need to comply for long-term continuous wear and comfort. The traditional gel-based electrodes are not suitable for long-term continuous wear, as they can cause dryness and itchiness of the skin. Dry electrodes are much more suitable than gel-based electrodes for many use cases. The know-how to implement dry electrodes effectively in a wearable health patch device is not yet widely available, and vests with a few R&D centres and companies.

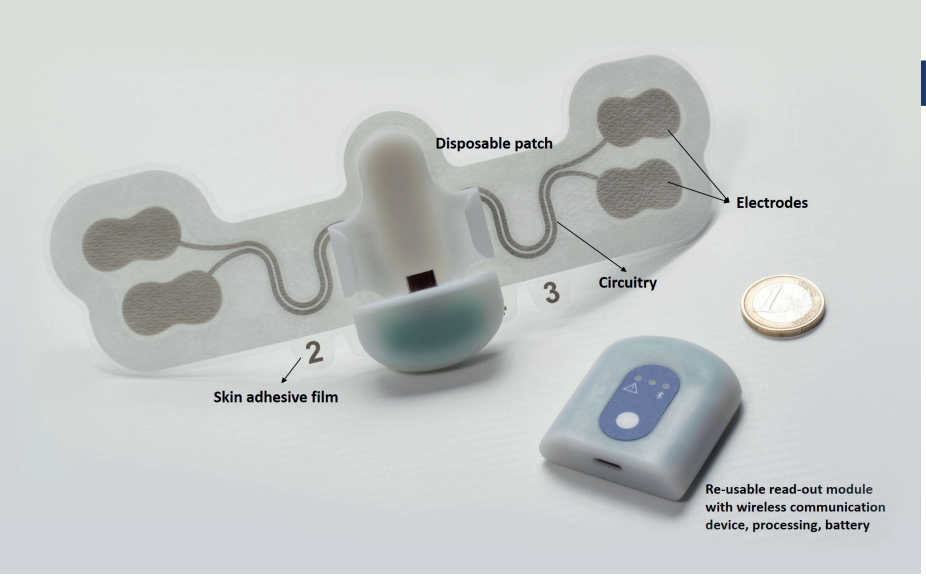

Fig 3: Wearable health patch platform with a disposable patch and a re-usable readout from TNO@Holst Centre

Shaping the next generation of wearable health patch devices

TNO@Holst Centre specialises in developing electronic devices that are flexible, stretchable, wearable, washable and conformable. These building blocks enable the next generation of wearable devices that can facilitate the transition towards IoMT. A key development from TNO@Holst Centre is the "wearable health patch platform", which was developed together with 2M Engineering (Valkenswaard, The Netherlands). This platform, shown in Figure 3, addresses some of the key challenges highlighted in the previous section, and offers the possibility to customise the health patch device based on the application needs.

The salient features of the wearable health patch platform from TNO@Holst Centre are as follows:

- By using the appropriate types of sensors, this platform can be adapted to monitor patients with COPD, cardiac diseases, COVID-19, irritable bowel disease (IBD), elderly people or pre- and post-operative monitoring;
- Dry electrodes are used to extract ECG and bioimpedance. They offer the possibility of long-term wear of up to one week, with investigations currently ongoing to extend this up to 14 days;
- The material stack, including the electrical circuitry and the carrier substrate, are stretchable. This allows for expansion and contraction of the torso due to breathing, as well as shape changes due to localised movements, without compromising the measurement accuracy;
- Re-usable electronics;
- Water-proof device;
- Algorithms to translate raw data into actionable information for the HCPs.

As an independent R&D innovation centre, TNO@Holst Centre aims to support companies that want to develop and commercialise wearable devices for IoMT applications, based on its wearable health patch platform. To this end, TNO@Holst Centre is performing clinical trials to validate the health patch platform for different use cases including COPD, IBD and sleep monitoring. This will help both companies that might want to co-develop a wearable health patch with TNO@Holst Centre by considerably shortening the development and validation process, as well as hospitals and pharmaceutical companies that might want to use this health patch platform for their own clinical studies.

Image sources: TNO@Holst Centre

(1) https://www.euro.who.int/en/health-topics/Health-systems/digital-health/news/news/2020/9/digital-health-transforming-and-extending-the-delivery-of-health-services

(2) Lee, S.M., Lee, D. Healthcare wearable devices: an analysis of key factors for continuous use intention. Serv Bus 14, 503–531 (2020). https://doi.org/10.1007/s11628-020-00428-3

(3) van den Brink W, Bloem R, Ananth A, Kanagasabapathi T, Amelink A, Bouwman J, Gelinck G, van Veen S, Boorsma A and Wopereis S (2021) Digital Resilience Biomarkers for Personalized Health Maintenance and Disease Prevention. Front. Digit. Health 2:614670. doi: 10.3389/fdgth.2020.614670