A Human Centred Design Approach for System Integration of Wearables

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Together with the company Kenzen AG, CSEM is developing sensor patches for the analysis of unique biomarkers in sweat (including electrolyte imbalance, e.g. sodium, potassium) as well as monitoring sweat rate noninvasively on the skin, indicative of relevant health conditions. Integrating these electro-chemical sensors with advanced vital sensing technologies is key to the next generation of wearable patch devices to provide actionable insights on critical physiological indicators that directly influence one's health and well-being.

Determining the form factor design on wearable patch devices under the Usability IEC 62366 & Risk management ISO 14971 approach, provides valuable insights for the industrial partner when selecting the best matching technologies. This approach applies to medical device manufacturers in order to be compliant with the Medical Device Directive MDD 93/427EWG.

Engineering requirements are performed on the entire system to define the user's requirement specifications with the industrial partner. The specification list based on field of use (FOU) and intent of use (IOU), for example, ensures that the goals are understood prior to the start of the project.

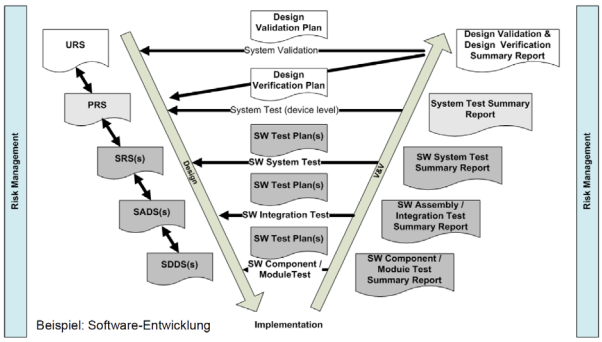

Figure 1: V-model of the product life cycle.

The modular system design approach to electronics and all interphases enables multiple nodes of communication and the accommodation of other sensor combinations due to its modular toolbox design approach (see Figure 2 below).

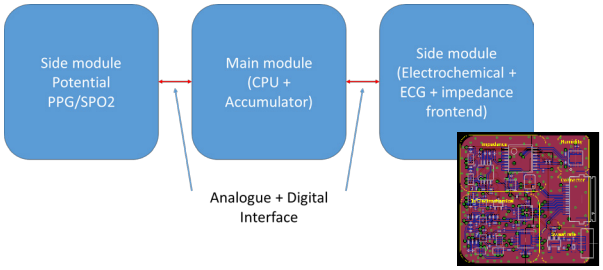

Figure 2: Modular architecture of a multi-purpose central node connected to function-specific side modules.

Early on, functional mock-ups of all components (transparent adhesive patch, electronics, housing, sensors) are tested and further developed in multiple iteration loops following the V-model of the product life cycle.

Regarding the disposable side of the system (Figure 3), screen printed electrodes are functionalized to measure e.g. Na, K, pH, or skin impedance providing information to determine dehydration status.

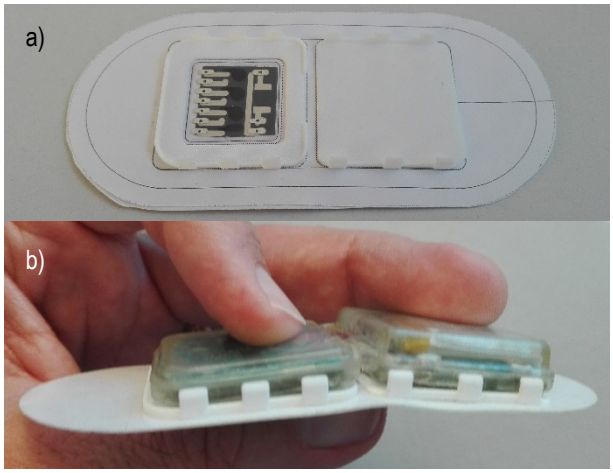

Figure 3: (a) Single use patch mock-up with electrochemical sensor and (b) clip mechanism with transparent flexible housing on adhesive patch.

The first results obtained by the Kenzen wearable patches for pH monitoring in sweat are displayed in Figure 4 below. Monitoring pH for several hours was demonstrated with the following specifications: pH range pH 8 – pH 3, rapid response (<1min) with a resolution of 0.1 pH unit.

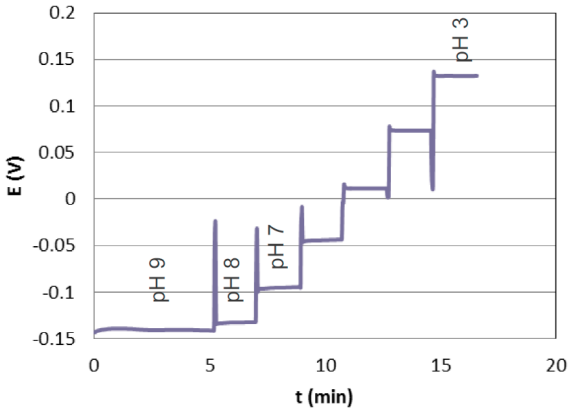

Figure 4: pH sweat monitoring using patch and sensor in Figure 3.

• Kenzen AG