TNO innovation for life

TNO is an independent research organisation that connects people and knowledge to create innovations. For a healthier, safer, and more sustainable life.

> *V3 helps to define the clinical validation strategy and unite scientists and engineers from multiple disciplines, which is crucial for the successful clinical evaluation of a novel digital biomarker.*
>
> **—Willem van den Brink,** Scientist, Netherlands Organisation for Applied Scientific Research (TNO)

The Opportunity

- TNO is developing a **multiparameter vital-signs patch** research platform featuring novel self-adhesive dry electrodes technology to deliver high-quality medical grade data over a long term (14+ days) while maintaining skin comfort.
- The platform **integrates sensors** for ECG, respiration rate, multiwavelength SpO2, skin and body temperature, accelerometer, & more.
- With this platform TNO performs and enables the development of **diverse novel clinical-grade digital biomarkers.**

The Resource

- TNO used the V3 Framework to:
  1. Ensure multidisciplinary team, including those with clinical, physiological, pharmacological, and engineering backgrounds, speaks the **same language**
  2. Confirm diverse novel digital biomarkers are **clinically validated**
  3. Establish a **fit-for-purpose** validation strategy for its vital-sign patch, targeting the clinical evaluation of diverse digital biomarkers in multiple domains.

The Impact

- TNO performed **technical verification** of the vital-sign patch at 3 levels: (i) at a level of material; (ii) at the level of functions (e.g., ECG electrodes); and (iii) at the level of the patch (e.g., ECG and other vital signs acquisition in time).
- TNO **analytically validated** its multiparameter vital-signs patch against gold standards.
- As of December 2022, there are **several clinical studies** to identify digital biomarkers for cardiovascular, chronic inflammatory, and respiratory diseases using the patch.
- Clinical insights drive innovations in wearable patches, continuously optimizing technical configuration for optimal utility and usability.