ICARUS – a Wearable Platform for Voice-as-a-Digital-Biomarker Applications

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Vocal biomarker research has a huge potential of scalability: today almost all personal devices are equipped with microphones, and they are available to the majority of the public. Clinical validation is an indispensable step before diagnostic technologies appear in our daily lives. ICARUS device aims at providing a complete solution to run large-scale clinical studies: an easy-to-use, modular system capable of acquiring relevant physiological signals, as well as voice, at a quality equivalent to the gold standard references readily used in the clinic for diagnostic purposes.

Digital biomarkers extracted from human voice hold a potential to significantly improve public and individual health. Voice can be acquired by personal devices and the same devices can be used to provide rapid diagnostics or report the progression of a disease to the clinicians. Today, however, the lack of clinical validation remains as a major challenge impeding the deployment of such technologies. Clinical validation requires collecting voice along with clinically relevant measurements (e.g., electrocardiogram, breathing patterns, etc.) on large patient cohorts – and thus requires easy-to-use and -deploy solutions. To address this need, CSEM, in collaboration with IDIAP, developed the integrated sensing platform, ICARUS, which synchronously measures multiple physiological signals and records speech.

ICARUS can measure (i) 1-lead electrocardiogram (ECG), (ii) transthoracic impedance (IMP), (iii) phonocardiogram (PHG), (iv) activity parameters (ACC) based on a 3-axis accelerometer, and (v) record speech. ICARUS device was envisioned and developed with maximum tunability options to allow fast deployment in clinical studies addressing different use cases. More explicitly, the device supports multiple sampling frequencies and resolutions for each signal. Keeping the demand of edge computing in mind, ICARUS device was equipped with an ARM Cortex-M4 processor.

Figure 1: ICARUS device resting on its docking station.

ICARUS device (Figure 1) comprises a measurement unit, a reference sensor, and a 1-wire connection between these two sensors. Thanks to CSEM's proprietary technology (EP2101408), the 1-wire connection does not have to be shielded nor insulated to acquire medical grade ECG. This feature simplifies the assembly and reduces production costs. The sensors can be recharged via the docking station which also allows downloading the recorded sessions to a PC via USB. The sensors can be clipped onto a generic chest belt or a sport bra using the flaps equipped with magnets. The magnets also serve to self-align the sensors to the docking station to ensure a reliable electrical contact during recharging and downloading.

All parts of ICARUS device in contact with the skin are manufactured using appropriate biocompatible materials. The electrodes are fabricated with medical grade 316L stainless steel and are then over-molded in the housing part (medical ABS) touching the skin. The sensing contact for the phonocardiogram acquisition (electronic stethoscope) is produced with medical grade silicone. The cable connecting the two sensors has a medical PVC outer jacket. Finally, a medical grade epoxy resin is used to glue the top and bottom parts of the housings.

Acquired signals (Figure 2) are recorded on an on-board memory and a down-sampled version of them is transmitted to the tablet (or any other portable device) by means of Bluetooth Low Energy (BLE) communication. An FCC/RED certified BLE module (ANNA B-112, u-blox, Switzerland) is used to ensure compliance with electromagnetic compatibility requirements. On the portable device side, an application was developed (running on Android v11 or newer) to display the signals (ECG, IMP, ACC, PHG, Speech) real-time. Moreover, the application provides additional information such as connectivity status of devices, sampling rate of signals, and battery/memory autonomy. Real-time clock on the ICARUS device is automatically set via the Android application. This feature allows timestamping the signals with a universal internet clock, thus providing a means to synchronize the signals with other devices used in the clinical data collection.

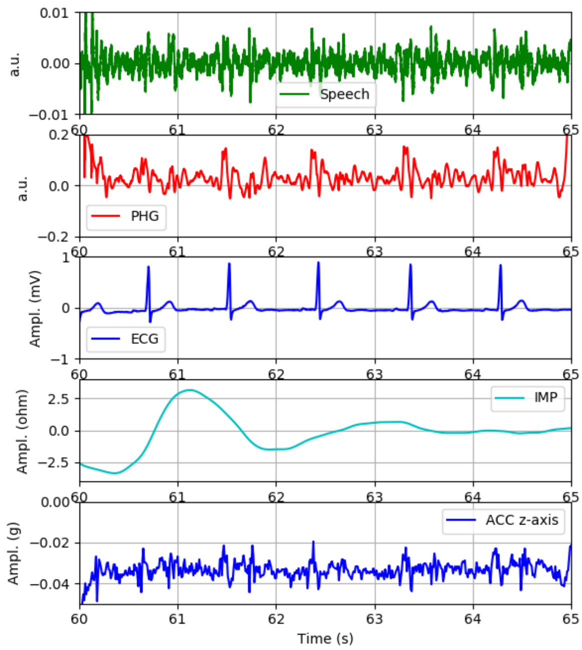

Figure 2: Signals acquired by ICARUS device (position: sitting; a deep breathing at the beginning and then tidal breathing).

ICARUS device is currently used in two studies for validation: stress evaluation and estimation of hypoglycemia. This work was partly funded by Canton of Bern. CSEM is thankful for their support.

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