MiniNOB—Miniaturized Wearable System for NOBP Measurement

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MiniNOB is a three-year MIP (2015–2017) targeting the development of a TRL-5 miniaturized wearable medical device for the continuous measurement of non-occlusive mean blood pressure (NOBP) and multi-lead electrocardiogram (ECG). The device consists of four low-cost low-power highly-integrated cooperative sensors clipped in and connected by a conductive fitting chest garment (e.g., a bra or a vest). The intended use of the product is the continuous monitoring of blood pressure and ECG of outpatients. The project is executed under ISO13485 in order to maximize its value for future customers active in the medical market.

As shown in Figure 1 (upper left corner), state-of-the-art products use an inflatable cuff to measure NIBP (non-invasive blood pressure) and adhesive gel electrodes to measure multi-lead ECG. CSEM's current technology (upper right corner) does not use an inflatable cuff (except for a short calibration) to measure blood pressure but instead relies on a continuous surrogate of non-occlusive mean blood pressure (NOBP) computed from ECG, impedance cardiography (acquired with the same electrodes as ECG), and chest photoplethysmography for pulse arrival time (PAT). It has been shown [1] during clinical trials that this CSEM's patented approach has performances compliant with the British Society of Hypertension (grade A) for more than two weeks after a single calibration manoeuver.

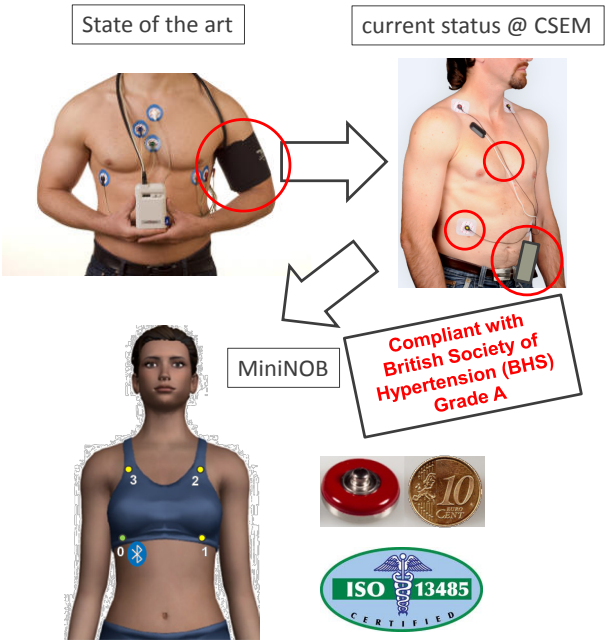

Figure 1: State of the art (product), current development status at CSEM, and project MiniNOB that targets the development of a medical device consisting of only four button sensors embedded in a vest or bra to simultaneously and continuously measure NOBP (cuffless blood pressure) and ECG. The red circles show the progressive simplification and increase of wearability of the device.

MiniNOB (as shown in the bottom of Figure 1) targets to measure NOBP and multi-ECG with the same approach but from only four dry-electrode miniaturized cooperative sensors embedded in a bra or vest (no cables, no explicit electronics box, no adhesive gel electrodes).

The cooperative sensor approach [2] is also a CSEM's patented technology that allows one to drastically simplify cabling and connectors while keeping the best signal quality. In MiniNOB, the four cooperative sensors will have each only one contact with the skin and one with the garment. The latter will embed a single electrical connection that will be unshielded and only weakly insulated so as to significantly reduce the integration challenges and thereby costs and risks of unreliable measurements.

The sensors are miniaturized thanks to a dedicated ASIC developed in the project. The ASIC will be able to allow digital communication between the sensors so that all sensors work in perfect synchronisms [3] and so that all measured signals are concentrated to a single sensor. The latter will be equipped with Bluetooth for communications with the external world. The ASIC will also contain the ECG and impedance frontends, as well as circuits for efficient power management and support for photoplethysmography measurement.

The MiniNOB device is developed according to our quality system for the development of medical devices certified compliant with ISO13485. The fulfilment of such high-quality standard will significantly increase the demonstrator value for customers active in the medical market and reduce the time to market of their product based on this technology.

In addition to NOBP and multi-lead ECG developed in full compliance with ISO13485, the device can easily be extended with other signals, such as heart rate, respiration rate, chest SpO2, core body and skin temperatures, activity, etc. as in the LTMS-S development [4], but in a more integrated version.

In conclusion, MiniNOB is offering a medical device able to improve the diagnostic and treatment of outpatients suffering from heart and cardiovascular diseases with a smart garment featuring exceptional level of ease-of-use and comfort for the measurement of high-quality ECG and NOBP.

[1] J. Solà, *et al.*, "Wearable PWV technologies to measure Blood Pressure: eliminating brachial cuffs" Engineering in Medicine and Biology Society (EMBC), 2013 35th Annual International Conference of the IEEE, pp. 4098–4101

[2] M. Rapin, *et al.*, "Cooperative dry-electrode sensors for multi-lead biopotential and bioimpedance monitoring" Physiol Meas. 2015 Apr, 36(4):767-83

[3] O. Chételat, *et al.*, "Synchronization and communication of cooperative sensors", 37th Annual International Conference of the IEEE Engineering in Medicine and Biology Society—EMBC2015, Milan (IT), 25–29 August 2015

[4] O. Chételat, *et al.*, "Clinical validation of LTMS-S: a wearable system for vital signs monitoring", 37th Annual International Conference of the IEEE Engineering in Medicine and Biology Society—EMBC2015, Milan (IT), 25–29 August 2015