A Medical Compliant Wearable Monitoring System for 12-Lead ECG

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CSEM is developing a medical compliant multi-sensor monitoring device which specifically addresses the diagnostic of multiple health diseases related to metabolic syndrome conditions. By combining the monitoring of the cardiac activity (12-lead ECG), respiratory activity (thorax and abdominal impedance measurements) and physical activity (3D accelerometer), this innovative medical device aims at improving ambulatory long-term monitoring of patients in terms of diagnostic accuracy and, consequently, reducing medical outpatient follow-up costs. The entire product development is compliant to ISO 13485 and all the appropriate standards.

Metabolic syndrome is a disorder of body energy utilization and storage that increases the risk of developing cardiovascular disease and diabetes. The Nano-Tera project called ObeSense aims at developing low-power wearable multi-sensor monitoring systems permitting to better manage the therapies of this population group (estimated to be in the US one third of the adult population). The ObeSense solution will allow physicians to continuously monitor the most important medical parameters of patients suffering from metabolic syndrome and thus reduce medical follow-up costs of outpatients in ambulatory conditions.

The Wearable Electronic System (WES12) is a class IIa medical device dedicated to cardiac long-term clinical monitoring and integrating a 12-lead electrocardiogram, 3D accelerometers, and bio-impedance measurements. The device can be interfaced with fourteen standard male clips (*e.g.* gel or textile electrodes) and offers the possibility to store raw data and to automatically analyze synchronized long-term ECG, respiratory and body motion signals in terms of heart rate, rhythm and waveforms, ECG quality index, respiratory rate, and energy expenditure (see Figure 1).

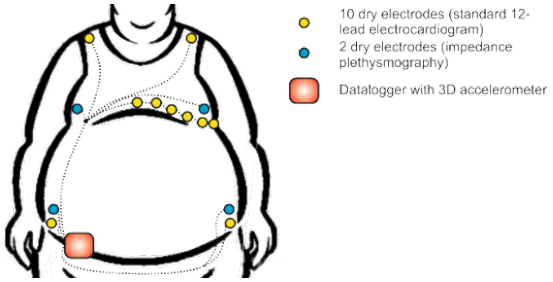

Figure 1: WES12 medical device setup.

The main functionalities of the WES12 includes: automatic recording, streaming, automatic transfer and low power warning. The internal recording is controlled via a push button or automatically trigger by the presence of ECG signals. All raw data are recorded internally without any compression. The medical staff (user) has access to the SD card with raw data. It is possible to stream and visually inspect the ECG signals via a dedicated mobile application. When placed on the docking station, an automatic data transfer and internal data management application is launched. Below a certain battery level, a LED is switched on to warn the user. The final firmware and software design is based on the user specific needs and requests. The development of the product follows CSEM procedures compliant with *ISO 13485* standard [1]. The Planning phase has been completed and has already provided the planning, the initial risk assessment, the risk management plan, the clinical use case, the user requirement specifications, the project management plan, the literature review, the software development plan, and the product quality plan documents. The feasibility phase is on-going and a prototype which respects both user requirements and essential requirements (standards *IEC60601-1* [2], *IEC60601-2-25* [3] and *IEC60601-2-27 ed. 2.0b:2005* [4]) is being developed. The following list of documents is being finalized: risk analysis, usability- software- hardware-requirement specifications, feasibility analysis, verification and validation matrix documents.

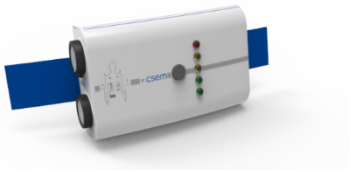

Figure 2: WES12 medical device demonstrator.

The clinical investigation of the approach—which shall be approved by SwissMedic and CHUV's Ethics committee—will be supervised by the cardiology institute at CHUV and validated on patients after an ischemic event or after an atrial fibrillation ablation procedure in long-term follow-up conditions. On the product aspect, this clinical investigation shall validate the user and patient acceptance. On the research aspect, it shall investigate on statistical relationship between cardiovascular and physiologic markers (including heart rate, heart rate variability, presence and recurrence of arrhythmias, beat-to-beat blood pressure variability, presence and recurrence of hypotensive periods, presence and recurrence of sleep apnea periods, physical activity patterns, and energy expenditure profiles) and symptoms as reported by the patient (including symptomatic fatigue and shortness of breath).

By offering such large scale of markers, WES12 aims at improving the actual management of metabolic syndrome medical issues.

[1] ISO 13485:2003, “Medical devices – Quality management systems – requirements for regulatory purposes”, ISO standards, ed. 2.0, ICS 03.120.10, pp. 1–57, 2003

[2] IEC 60601-1 ED.3.0:2005-12, “Medical electrical equipment – Part I: General requirements for basic safety and essential performance”, International Electrotechnical Commission standards, ed. 3.0, ICS 11.040, pp. 1–408, 2005

[3] IEC 60601-2-25:2011, “Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs”, International Electrotechnical Commission standards, ed. 2.0, ICS 11.040.55/99, pp. 1–196, 2016

[4] IEC 60601-2-27:2011, “Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment”, International Electrotechnical Commission standards, ed. 3.0, ICS 11.040.55, pp. 1–146, 2015