Validation Results of the Long-term Medical Survey System (LTMS-S) for Antarctica

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Since 2002, CSEM has been working for the European Space Agency (ESA) to develop and manufacture a system to study the adaptation of crewmembers in space analogues (like Concordia in Antarctica) in order to prepare future long-term manned missions. The latest project LTMS-S had the objective of extending the monitoring capabilities of CSEM's cooperative sensors with pulse oximetry and core body temperature (CBT), and to clinically validate the accuracy of the monitored signals.

LTMS-S is a new wearable system for the monitoring of several physiological signals – including a two-lead electrocardiogram (ECG) – and parameters, such as heart rate, breathing rate, peripheral oxygen saturation (SpO_2), core body temperature (CBT), and physical activity. As illustrated in Figure 1, all signals are measured using only three sensors embedded in a vest. The sensors are standalone with their own rechargeable battery, memory, wireless communication and with an autonomy exceeding 24 hours.

Figure 1: Overview of LTMS-S monitoring capabilities.

An important part of the project was devoted to the verification and clinical validation of the system. The LTMS-S electronics successfully passed the safety tests as well as the ECG performance tests of the international medical standards 60601-1 and 60601-2-47.

After approval of the ethics committee of the canton of Vaud (ref. CER-VD protocol 268/13), two protocols were performed at the HNE (Neuchâtel hospital) to evaluate the accuracy of the LTMS-S sensor against gold standard devices. The first one addressed the circadian rhythm that was evaluated by monitoring twenty healthy subjects in a closed environment during 24 hours. In the second protocol, 15 healthy subjects performed several activities while normobaric hypoxia was induced.

The statistics of the resulting performances are presented in Table 1. A more detailed version of the results was presented at EMBC 2015 [1].

No significant difference was found between heart rate and activity class estimated by LTMS-S and the corresponding references, respectively the Polar RS800CX and a manual segmentation. The results obtained for breathing rate are slightly below the 95% that would consider the systems as equivalent. However, the comfort brought by the LTMS-S in comparison with the reference device (MetaMax), which requires the subject to wear a mask, is undeniable and should in most applications compensate the slight loss of accuracy.

Table 1: Summary of LTMS-S performances (mean ± std. dev.).

Parameter	Evaluation criteria	Performance
Heart rate	Time percentage in ±5 bpm	96±7.2%
Breathing rate	Time percentage in ±3 rpm	92.5±4.6%
Activity class	Time percent. of correct class	98±0.3%
SpO_2	Root mean square error on all data points	3.7±0.9%
	Root mean square error after automatic rejection of unreliable signal	2.7±0.8%
CBT	Correlation	r=0.7, p=0
	Root mean square error	0.22 °C

The accuracy obtained with the SpO_2 sensor is within the requirements of ISO 80601-2-61 (<4%). Moreover, an unsupervised quality index algorithm was implemented increasing SpO_2 sensor performances from 3.7% to 2.7%, while rejecting 37% of the data automatically recognized as unreliable. Finally, the analysis showed a good agreement (r=0.7) between LTMS-S CBT and the ingestible temperature-sensor pill indicating that for the implemented conditions, the LTMS-S sensor was able to track circadian CBT variations.

This validation shows that the LTMS-S system can accurately monitor a large number of physiological parameters. Combined with the comfort of a vest, this system offers new opportunities for the monitoring of patients and athletes.

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[1] 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