DELIVERABLE REPORT

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Project acronym: **LUCA**

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Deliverable reported: **D3.5 Fully functional LUCA system - Demonstrator**

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Name, title and organisation of partner:

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Project website address: **www.luca-project.eu**

1) Scope of the document

This is a report describing the fully functional LUCA demonstrator. Here we provide a summary with the description of the demonstrator and of the *in vivo* tests that have been performed to demonstrate the functionalities and usability of the demonstrator. We provide a brief summary of the results and a full report is available upon request. The planned tasks within this deliverable were completed and all goals were achieved as planned.

2) LUCA system demonstrator

Significant updates of LUCA hardware and software (SW updates see D2.8) were implemented in order to provide a LUCA system to be operated in a clinical study environment by medical doctors. This has been confirmed in a practical demo session (Figure 1, right[1,2,3,4]) at ICFO acquiring combined US-optical data. The LUCA Main Module (MM) controls the overall device (Figure 1, left, present SW version V1.1) managing the communication with an Ultra Sound Module (USM) implemented LUCA application being the primary user interface for medical doctors and the Nirfast Evaluation Module NEM (postprocessing).

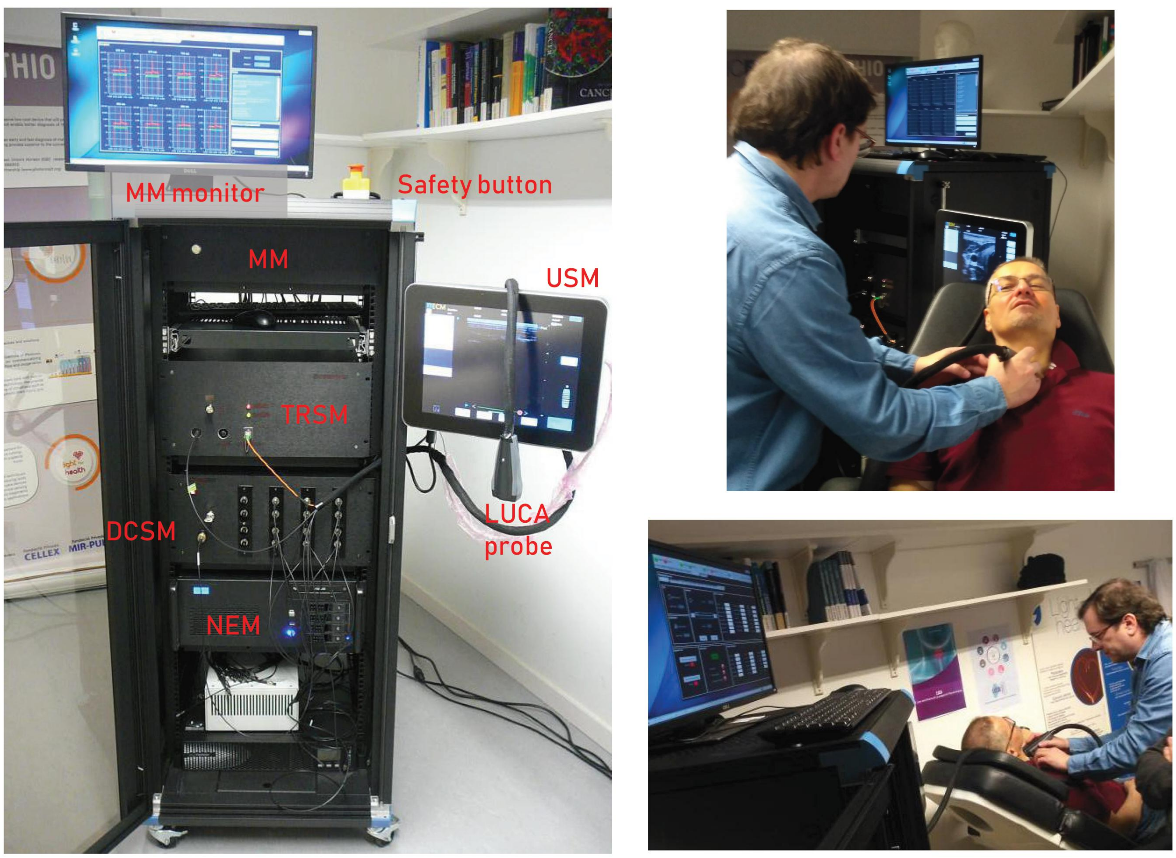

Figure 1 Overall LUCA system (left side) and pictures taken during US-optical data acquisition at the practical demo session (right side)

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1 https://twitter.com/EIBIR_biomed/status/1088031227788120064
2 https://twitter.com/ICFOnians/status/1088030399928958978
3 https://twitter.com/ICFOnians/status/1088110900622561284
4 https://twitter.com/EIBIR_biomed/status/1088028792126402560

Major recent hardware implementations are:
a) optical safety circuitry, supervising the interlocks (keys, laser fibre connection, probe safety button/ touch sensor), in order to provide a software-independent clearance for enable signals of laser emission
b) electrical safety circuitry, breaking the current to the isolation transformer and after the UPS with an emergency shutdown button. Corresponding circuitry and connection updates have been implemented as well in the Diffuse Correlation Spectroscopy Module (DCSM) and Time Resolve Spectroscopy Module (TRSM).

3) Demonstration tests

Here we provide the description and the results of the tests performed to demonstrate the functionalities of the LUCA system.

The tests consisted in (i) an *in vivo* thyroid exam following the LUCA measurement protocol (5 subjects), (ii) *in vivo* measurements on arm muscle to check the variability of the measured parameters due to probe replacement (5 subjects), and, (iii) an arterial arm cuff test to check the capability of LUCA to detect externally induced variations of the optical and dynamic properties of the tissue (1 subject). The tests have been performed on volunteer subjects by researchers of ICFO, Politecnico di Milano, HemoPhotonics and by doctors of IDIBAPS/Hospital Clínic.

(i)- The LUCA thyroid exam consisted of an ultrasound (US) exam of the thyroid combined with the diffuse optical measurements. Once the LUCA multimodal probe was placed in the right position on the thyroid (guided by US images), the optical acquisition was activated by the doctor directly through the US module interface and by pressing the probe safety button. The data acquisition lasted two minutes. Once the exam was completed, the data have been stored for post-processing. The blood flow index of the 5 subjects measured was retrieved with an average variability of 22% which is comparable with the literature [1]. The average absorption spectrum of the 5 subjects shows shape and values comparable with the literature [2] but with an extremely lower inter-subjects variability over all the spectral range. While the reduced scattering spectrum showed higher values with respect to the literature [2], probably due also to the analysis model employed.

(ii)- These tests had the aim of measuring the variability on the measured optical parameters after replacing the LUCA probe in the same position (on the subject's arm) several times, i.e. test/re-test variability. We have measured an average inter repetition variability of 17% (with an intra-repetition variability of 11%) in blood flow. The average inter repetition variability has been 7% for absorption coefficient (from a minimum of 1% up to a maximum variability of 47% for the 5 subjects over all the 8 wavelengths) and 5% for the reduced scattering coefficient (from a minimum of 1% up to a maximum variability of 17% for the 5 subjects over the 8 wavelengths). The large range of test/retest variability for the absorption coefficient is due to a measurement on a single wavelength in 2 subjects.

(iii)- The arm cuff test was performed by positioning the LUCA probe on the subject's arm, acquiring 2 minutes of baseline signal, then blocking the venous and arterial blood flow by applying a cuff pressure of 250mmHg for two minutes, and lastly releasing the cuff and acquiring for additional two minutes. LUCA system was able to measure the externally induced variations of the blood flow index and optical properties in agreement with the literature [3,4].

The tests that were performed demonstrated that the LUCA system is well usable by medical doctors that, under the supervision of the developers, are able to measure the optical properties of the thyroid by only handling the US user interface and the LUCA multi-modal probe. The retrieved optical and dynamic parameters are consistent with previous literature. In addition, the LUCA device performances in terms of measurement repeatability and variability on the retrieved parameters have been characterized.

A detailed report of results and tests performed is available upon request.

4) Conclusions

The fully functional LUCA demonstrator was presented and tested *in vivo* with the aim of demonstrating its usability in terms of US and optical performances. The functionality tests that were performed demonstrated that LUCA system is suitable to acquire US images of the thyroid together with simultaneous optical acquisitions. The values retrieved are consistent with previous literature.

All the planned tasks within this deliverable were completed and all goals were achieved as planned.

5) References

[1] C. Lindner et al., "*Diffuse optical characterization of the healthy human thyroid tissue and two pathological case studies*". PloS one, 2016, 11.1: e0147851

[2] S. Sekar, et al., "*Broadband (600-1100 nm) Diffuse Optical Characterization of Thyroid Tissue Constituents and Application to in vivo Thyroid Studies*" in Biophotonics Congress: Biomedical Optics Congress 2018 (Microscopy/Translational/Brain/OTS), OSA Technical Digest (Optical Society of America, 2018), paper CF2B.3.

[3] D. Contini et al., "*Multi-channel time-resolved system for functional near infrared spectroscopy*" (2006) Optics Express, 14 (12), pp. 5418-5432.

[4] G. Yu et al., "*Time-dependent blood flow and oxygenation in human skeletal muscles measured with noninvasive near-infrared diffuse optical spectroscopies*" Journal of Biomedical Optics 10(2), 024027 (2005)