DELIVERABLE REPORT

Grant Agreement number: 688303

Project acronym: LUCA

Project title: Laser and Ultrasound Co-Analyzer for thyroid nodules

Funding Scheme: H2020-ICT-28-2015

Deliverable reported: D5.7 Preliminary report on clinical validation.

Due date: 31.10.2019

Name, title and organization of partner:

Gloria Aranda, Mireia Mora – IDIBAPS (Deliverable Leader)

Partners: HEMO, ECM, UOB, ICFO, POLIMI, VERMON

Duration: M36 - 48

Project website address: www.luca-project.eu

This project has received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 688303.

1) **Scope of the document:** This is the report to describe the preliminary evaluation of the proposed LUCA system from a clinical view-point. We describe the measurements in healthy subjects and subjects with thyroid nodules, and we also describe the positive and negative points of the measurements with LUCA device. **Measurements in healthy subjects:** We have performed measurements on 10 healthy subjects, 5 women and 5 men, with ages between 27 and 47 years. In all the volunteers a blood test has been performed to confirm normal thyroid function and negative thyroid antibodies, as well as a conventional ultrasound to confirm the absence of thyroid nodules. The results related to the optical parameters are shown in deliverable 5.5.

2) **Measurements in subjects with thyroid nodules:** We have performed measurements on twelve subjects with thyroid nodules (6 benign nodules, 3 multinodular goiter and 3 papillary thyroid carcinoma), most women, aged between 39 and 66 years. Benign nodules were predominantly observed in women (5/6 of the subjects) and FNA cytology results corresponded to Bethesda II (benign). Regarding patients with thyroid cancer, all were women, and the diagnosis of thyroid nodule was due to an imaging test for other reason. The 3 nodules studied were approximately 1 cm in diameter. The results related to the optical parameters are shown in deliverable 5.6.

3) **LUCA usability:** In relation to the usability of the LUCA device, we have not had negative experiences with patients. We must take into account that each patient is different and the tolerability required for the hyperextension position of the neck and the compression of the probe during the minutes necessary to obtain the optical data was variable. The hyperextension of the neck and the compression of the probe were evaluated individually according to the characteristics of the neck of each patient in order to improve the quality of the measurements. We also have to consider that swallowing may difficult the measurements and alter the results.

4) **Conclusions:** At this point, while with these preliminary measurements we cannot assess the clinical validation, the device and the probe were well tolerated. More measurements are underway as planned by the project.

This project has received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 688303.
www.luca-project.eu www.photonics21.org