



COSTRUZIONE STRUMENTI OFTALMICI



EUROPEAN COMMISSION - HORIZON 2020

# SD-OCT "MS-39"



The main objective of CSO business project is to introduce into the market the innovative MD-SD-OCT, a new ophthalmology instrument, which is able to detect, with a single tool, a range of optical pathologies wider than the state of the art technologies are capable to support, with higher performances and significant reduction of manufacturing cost. This target has been reached through the integration of traditional topography approach (Placido's disk) and innovative patented Spectral Domain Optical Coherence Tomography (ref. WO 2014/155286 A1), into a single, compact and flexible diagnosis device, real breakthrough for the market at the state of art. As a results of the technology innovation proposed and due to the usage of a less expensive technology invented by CSO (new SD-OCT management system, covered by international patent), the overall cost of the device is significantly lower than the existing applicable technology (about 40% less). CSO - with higher performance, significantly lower cost and new double technology MD-SD-OCT - will be able to improve its competitiveness in the market of ophthalmology diagnosis devices. "MS-39" is a device that can capture high-definition images of the ocular anterior segment and accurately measure various clinically interesting ocular structures - anterior and posterior corneal surface, anterior chamber, irido-cornea

angles, pupil diameter... The device integrates in one machine one of the most advanced current technologies in ophthalmology, the optical coherence tomography in the spectral domain (SD-OCT, Spectral Domain - Optical Coherence Tomography) with two proven technologies, which are Placido disc and infrared pupillometry. Placido disc technology is based on optical laws of reflection and allows accurate and reliable measurements of the sole anterior corneal surface. The SD-OCT system is based on interferometry in the spectral domain and instead allows for the acquisition of high-definition tomographic images of sections of the anterior segment and, through subsequent processing, the measurement of the anterior and posterior corneal surfaces, the anterior chamber, the irido-corneal angles (and thickness (pachymetry)). The pupillometer is a lighting and capturing system in the infrared spectrum and allows measurement of the size of the pupil and decentralization in various light conditions (scotopic vision, mesopic, photopic) and the dynamic measurement in the transition from a bright photopic to scotopic condition. A device with these characteristics has several applications in ophthalmology for:

- o Diagnosis of diseases of the eye anterior segment
- o Screening of Keratoconus, a corneal disease (progressive non-inflammatory corneal dystrophy) which usually affects both eyes (96% of cases)
- o Refractive Surgery and Cataract Surgery
- o Screening glaucoma angle-closure
- o Follow-up for corneal transplants and Follow-up to trauma
- o Design and monitoring of specialized contact lenses.

## 1.2 Work Performed so far

During the first year of the project, all the technical issues related to the existing prototype have been solved and TRL #7 has been reached while EC type-examination activities are running in order to get to #8.

Five prototype's evolutions have been realized and tested with excellent results.

The small-scale production of the first 15 items to be validated in operational environment is started.

Communication and dissemination activities have been undertaken, mainly through the presentation of the new OCT in several national and international fairs and conferences, where many ophthalmologists have experienced the equipment with great enthusiasm for its performances (imaging quality and speed).

## 1.3 Progress beyond the state of the art and expected potential impact (including the socio-economic impact and the wider societal implications of the project so far)

The most important feature of MD-SD-OCT will probably be its final cost for the end user. The price will be about 40% less of best performing OCT currently on the market, with better performances. This will enable a wider diffusion of such an important equipment, needed for diagnosis of several serious diseases of the eye and for post-surgery analysis. The final cost is not the only benefit deriving from the investment for the end user. The factors that may be beneficial in terms of cost effectiveness, if compared with the state of the art technology, can be summarized as follow:

- TECHNOLOGY IMPROVEMENT: represent a benefit in terms of competitiveness for the end user. The technology at the state of the art, is not able to provide the integration of two different diagnosis systems.
- PRICE: significantly lower price. The customer will pay less, for an higher performance device.
- PERFORMANCE IMPROVEMENT, in terms of image resolution, measurability of all the are covered by the diagnostic device and in terms of accuracy of the output, thanks to the new patented SD-OCT technology.
- RELIABILITY of the medical result: it will allow detecting pathologies in an early state and, at the same time, avoiding false detection.

All of these elements will potentially determine a positive socio-economic impact in early diagnosis of corneal pathologies. The high resolution of the images of the sections of the anterior segment allows evaluating with reliability the presence and extent of corneal pathologies of the anterior segment: Cataract is the process of progressive loss of the lens transparency. This process, linked to phenomena of oxidation of the proteins that form the lens, is the result of a biochemical phenomenon that occurs with increasing age. The increase in life expectancy has already led to an increase in the number of cases, so that today the intervention of cataract removal is one of the most performed in hospitals all over the world. It consists of the removal of the opaque crystalline and the implementation of an artificial lens. MS-39 can be useful to evaluate opacification of the lens and above all to calculate the power of an artificial lens best suited to the patient according to his needs and to the shape of the structures of his eye. Glaucoma is an important disease because it can cause irreversible damage if not detected in time, and, if not treated properly, can cause serious damage to the eye or even low vision and blindness. Among the risk factors of glaucoma are anterior chamber narrow angle. The device can capture and measure the irido-corneal angles and assess this risk. Corneal transplant is an operation aimed at all diseases of the cornea that reduce visual acuity or opacity of the tissue (post-infectious or post-traumatic scars, corneal dystrophies or degeneration) or its distortion (keratoconus, trauma). The operation involves replacing the damaged tissue with a donor cornea. The new corneal flap, which restores the transparency of the cornea, allows the patient to recover vision. The high resolution of the images of the anterior segment sections allows to assess with a certain facility the outcome of a corneal transplant and to carry out measures for the evaluation of the optical quality after surgery. The ability to measure very accurately the anterior corneal surface makes it an important instrument for planning refractive surgery, to correct defects of myopia, hyperopia and astigmatism.



## Disclaimer

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 673447.

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