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**WHITE PAPER**

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**Completed clinical investigation of safety and tolerability during 24-hour SENSIMED Triggerfish® wear: Continuous IOP monitoring with a contact lens integrating a Telemetry chip.*****Introduction***

Continuous IOP monitoring is an unmet medical need in the field of glaucoma. Dr. Matteo Leonardi has developed the SENSIMED Triggerfish®, a contact lens enabling the recording of qualitative diurnal IOP profiles during sleep and normal activities. A strain gauge embedded in a soft contact lens detects changes in the corneal curvature that are transmitted through a telemetry microprocessor, also embedded in the contact lens, to an external recorder for storage. Changes in the corneal radius of curvature have been reported to correlate to IOP changes.

***Concept***

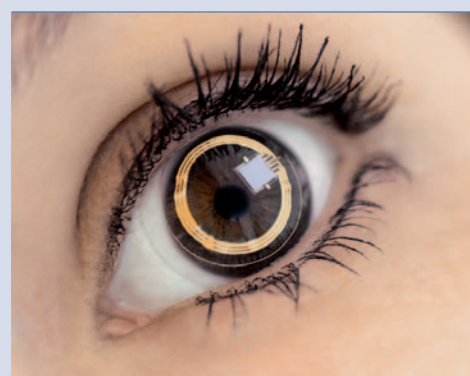
Compared to classic IOP curves established through repeated tonometer readings, the SENSIMED Triggerfish® offers several advantages and opens up yet unexplored possibilities in the area of IOP monitoring. The classical setting with repeated tonometer measurements requires patient hospitalisation while SENSIMED Triggerfish® allows patients to be monitored in ambulatory mode and to keep on with normal activities. Furthermore, IOP monitoring is possible during the sleep period and in the habitual position while Gold standard tonometry using the Goldmann applanation technique necessitates seating the patient. Finally, the device acquires data every ten minutes throughout the monitoring period, extending to 24 hours, a feature that is not realistically feasible with tonometers.

***Method***

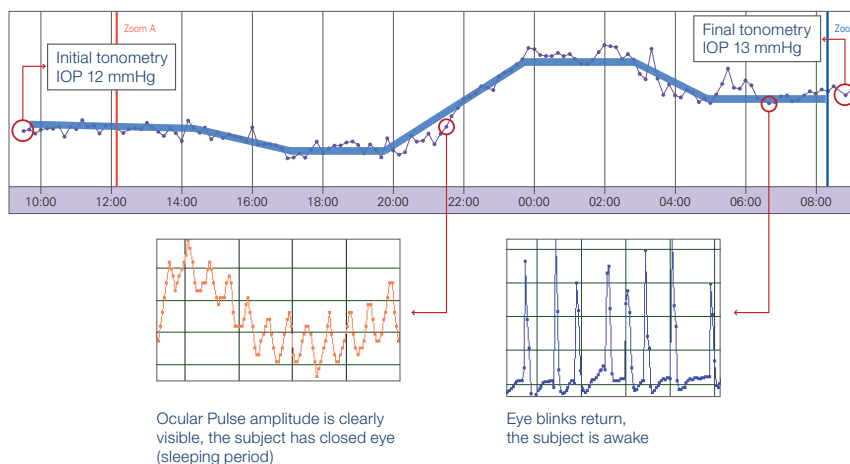
Safety and tolerability of a Sensor were recently investigated in collaboration with Prof. Mermoud during 24-hour continuous IOP monitoring in healthy volunteers. Technical and clinical aspects of the device were studied and provided encouraging indications for the continued development. In particular, the ambulatory monitoring was proven feasible with maintenance of normal daily activities such as office work as indicated in the provided log books. The sleeve provided to maintain the Recorder strapped around the waist allowed moving and sleeping without physical hindering. Sensors with a base curve of 8.7 mm were used on all subjects.

***Findings***

The Sensor generally adapted well to subject's eyes. In one subject with steep corneal radii Sensor installation was more difficult. This observation strengthens the rationale to produce Sensors with different base curves in



*SENSIMED Triggerfish® Sensor in the eye*



Example of 24hour IOP recording curve

order to propose alternatives for subjects with smaller or greater than normal corneal radii.

The recordings obtained showed varying fluctuation patterns over 24 hours. In some subjects a rather flat profile was obtained, while in others a characteristic output signal increase was observed during late evening with a subsequent return to original level during early morning. These profiles were similar to other reported previously in healthy individuals.

An ocular pulsation was observed in all subjects, indicating that the adaptation of the Sensor on the eye and its sensitivity enable the detection of the small oscillations in IOP resulting from the perfusion of the eye. The frequency of these pulsations was in the range of normal heart rhythm when subjects were at rest. Eye blinks were seen as a characteristic output signal peak over a fraction of a second during wake periods. Sleeping periods were characterised by the absence of eye blinks and the stably oscillating signal corresponding to the ocular pulsation.

### Summary

Continuous IOP Monitoring in ambulatory mode was proven feasible. We obtained encouraging indication for continued development. In this investigation subjects had healthy eyes. The SENSIMED Triggerfish<sup>®</sup> is mainly intended for glaucoma patients, patients at risk of glaucoma or patients with suspicion of high intraocular pressure. Continued work in this target population is ongoing and will be presented in the coming months.

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**The SENSIMED Triggerfish<sup>®</sup> Sensor is a soft, hydrophilic silicone disposable contact lens embedding a MEMS sensor and a telemetry microprocessor.**

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