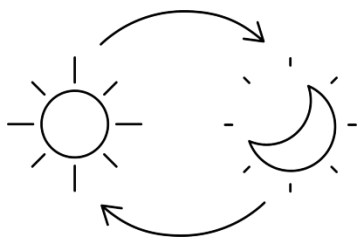


SENSIMED Triggerfish[®] provides a 24-hour continuous recording of ocular dimensional changes related to IOP in habitual body position

The dynamic nature of intraocular pressure

Intraocular pressure (IOP) is one of the major risk factors for glaucoma onset and progression and remains the sole proven modifiable factor for disease treatment, despite development of glaucomatous optic neuropathy in patients with presumably normal-ranged IOP, and progression of the disease in patients with supposed low IOP. But IOP is known to vary during the 24-hour period of the day and to be affected by many physiological parameters such as body position.



Over the last decades, several studies have suggested that capturing the dynamic nature of IOP through its physiological-induced fluctuations could be key to assess glaucoma stability.^{1,2} The currently accepted method to estimate IOP fluctuations relies on diurnal or 24-hour IOP curves with repeated tonometry measurements every single hour at best. Such procedures, however, are cumbersome (consumes scarce resources), expensive (usually requires hospitalization), inconvenient (disturbed sleep cycle as patient is awoken for nocturnal measurements) and may not adequately reflect the IOP fluctuations occurring in real-life activities.

Posture-induced IOP changes have been investigated using tonometry³⁻⁶, most of the studies evidencing higher IOP values in recumbent compared to upright positions. Furthermore, changes from supine to the lateral body position (side sleep) or prone positions during sleep were found to further increase the IOP in the lower eye (the side eye). Such IOP elevation is believed to partially explain glaucomatous damage, leading to disease progression. Therefore, some patients have been advised to sleep with their head elevated.⁷

A single monitoring session with SENSIMED Triggerfish[®] provides individual continuous and qualitative information on patient circadian ocular dimensional profile related to IOP with respect to the habitual body position.

A state-of-the-art device for enhanced glaucoma patient management



The SENSIMED Triggerfish[®] (TF) developed by Sensimed SA (Lausanne, Switzerland) is a contact lens-based device capable of recording ocular dimensional changes over the full 24-hour period in ambulatory setting, under physiological conditions.⁸ With a strain gauge embedded in a soft contact lens (Sensor), TF captures spontaneous circumferential changes at the corneo-scleral junction that occur due to ocular pressure and volume changes. TF output signals are in electronic units of millivolt equivalents (mVeq) whose mean 24-hour pattern have been shown to correlate with the mean 24-hour tonometric curve.⁹

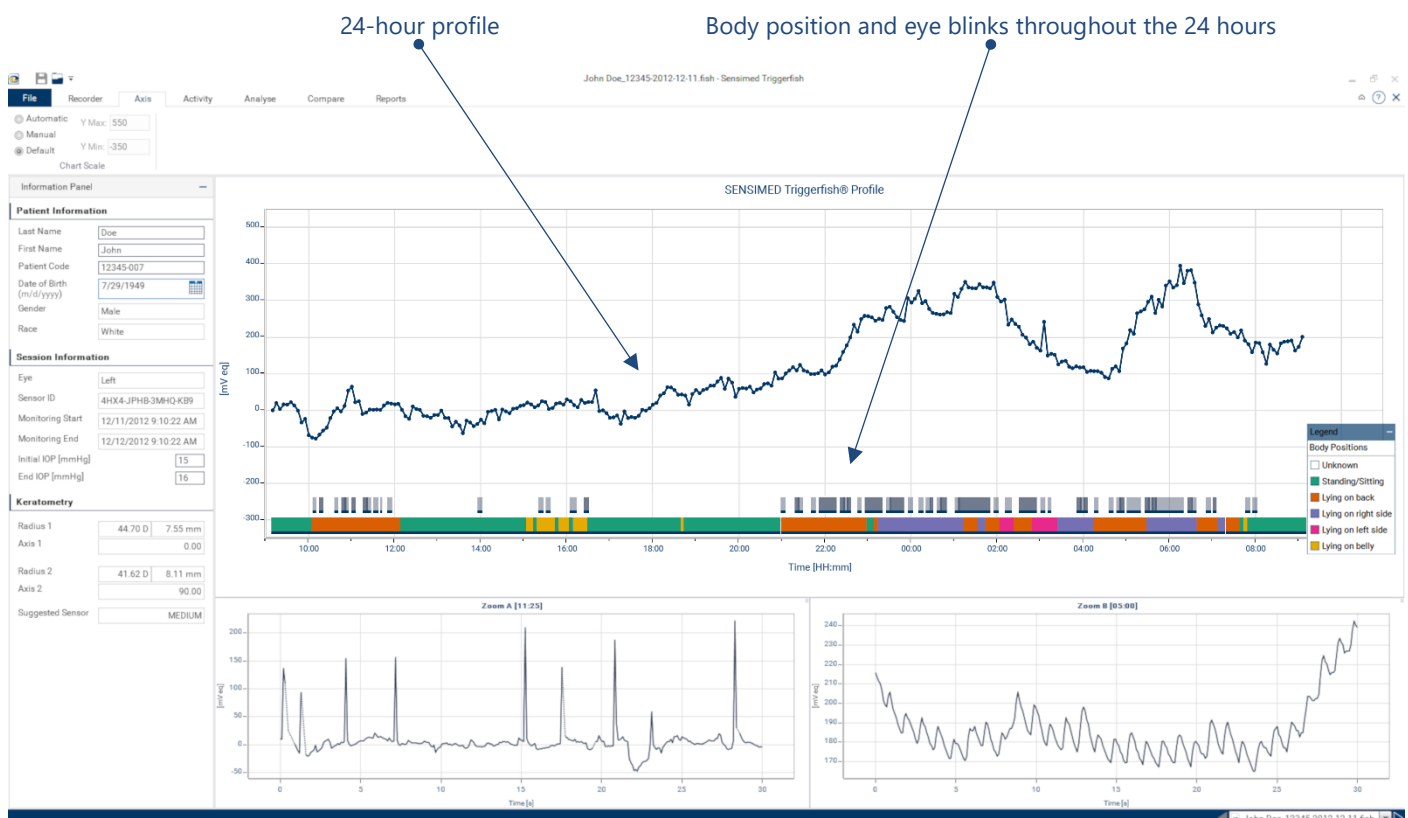
TF software contains an algorithm capable of identifying eye blinks over the 24-hour session, allowing for various analysis on the recorded patient profile, such as the blink rates which can be used to estimate the sleep period.¹⁰

TF is also equipped with 3-axis accelerometers included in the portable recorder, worn on the subject's chest, and in the data cable connector localized on the subject's temple. A specific body position is detected when the recorder or the data cable is within $\pm 40^\circ$ range around a defined orientation. Following body positions are detectable: upright (seated or standing), supine, prone, right lateral decubitus position and left lateral decubitus position. If no position can be determined, "Unknown" is assigned to the position.

TF is a **CE** marked product also approved by **FDA** (US) and **PMDA** (Japan).

SENSIMED Triggerfish® use

In clinical settings, a single monitoring session with TF provides individual continuous and qualitative information on the subject's circadian ocular dimensional profile related to IOP, with respect to the habitual body position. Indeed, in addition to identifying the time of the day or night when an IOP peak is expected and the potential duration of such a peak, TF is also able to indicate the changes in ocular dimensions in habitual body positions following daily activities, including sleep. Below is an example of the TF output.



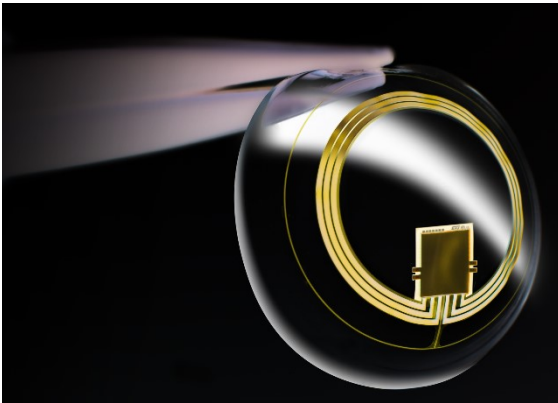
Conclusion

SENSIMED Triggerfish® is a non-implantable device capable of identifying the peak pattern related to IOP changes outside office hours, likely to influence the risk of disease onset and/or progression. The device may also help specifying the suspected contribution of recumbent posture in worsening of glaucomatous damages, especially during the nocturnal period.

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About Us



Sensimed SA, a Swiss company, has developed a unique technology platform on non-invasive soft contact lens-based solution. The first application, the SENSIMED Triggerfish®, provides an automated recording of continuous ocular dimensional change over 24 hours with the aim of revolutionizing glaucoma management enhancing personalization of patient care.

The SENSIMED Triggerfish® received the CE mark in 2010 and was approved by the U.S. Food and Drug Administration (FDA) in 2016. Since 2018 the device is registered in Japan at the Pharmaceuticals and Medical Devices Agency (PMDA).

Other non-invasive on-eye sensing applications are in development to provide clinically pertinent data with the same continuous monitoring approach. The Company is furthermore focused on expanding the knowledge of how this individual data can best be used in the clinical setting to deliver customized treatment. The data, analysed and modelled on an ongoing basis, is processed in an attempt to identify pathological patterns that can be used to differentiate indication, personalize treatment and assess efficacy of treatment.

The Company is directly positioned at the convergence between devices, treatment and information. Sensimed believes that with this global knowledge-based approach it will be possible to provide valuable insights that allow ophthalmologists to better understand and treat glaucoma.

Sensimed became a subsidiary of SEED Co., Ltd after the acquisition of a majority participation end of 2019.

SENSIMED 
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