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FOR IMMEDIATE RELEASE

Heidelberg Engineering and RetInSight to offer AI-based OCT fluid quantification solution

Heidelberg, Germany – Heidelberg Engineering GmbH and RetInSight GmbH intend to interface the RetInSight AI-based fluid monitor application with the Heidelberg Engineering product portfolio, using cloud exchange and application marketplace technologies. Both companies see great potential in the combination of RetInSight's AI expertise with Heidelberg Engineering's high-quality images and data management experience.

RetInSight utilizes a novel, proprietary algorithm, that supports the detection, localization and quantification of intra- and subretinal fluid in OCT images in an accurate and reliable manner[1]. The fluid monitor application aims to facilitate early diagnosis and therapeutic guidance in the most common diseases of the retina, i.e., neovascular age-related macular degeneration (AMD), diabetic macular edema (DME)[2,3] and retinal vein occlusion (RVO). In combination with the Heidelberg Eye Explorer HEYEX 2 technology, RetInSight fluid monitor application will offer an efficient clinical workflow.

"*This automated service provides precision and speed beyond human expert capacity. It will display intuitive results through a user-friendly RetInSight viewer or via an ePDF report within the HEYEX 2 platform",* said Dr. Amir Sadeghipour, Chief Technology Officer of RetInSight.

RetInSight's algorithm was designed under a quality management system according to ISO 13485:2016, and CE marking in conformance with the EU Medical Device Regulation is anticipated in June 2021. In the USA, regulatory submission is targeted for 2022.

The aim of the HEYEX 2 workflow interface with the cloud-based RetInSight service is to enable SPECTRALIS users to send OCT volume scans for analysis quickly and securely.

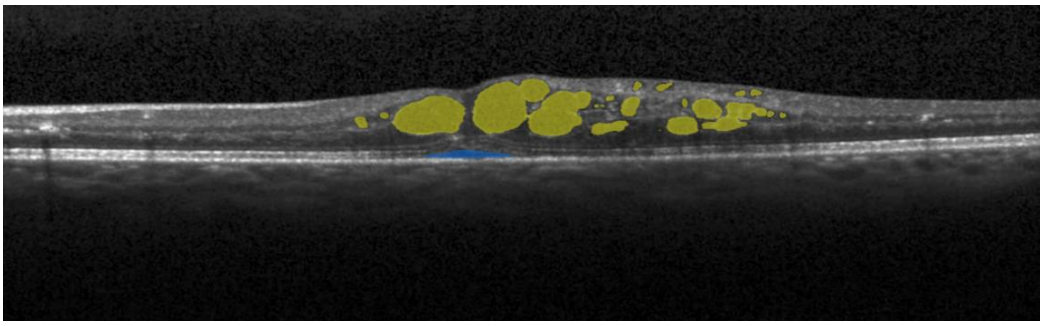
[1] Schmidt-Erfurth U, Sadeghipour A, Gerendas BS, Waldstein SM, Bogunović H. Artificial intelligence in retina [Prog Retin Eye Res. 2018; 67:1-29] https://www.sciencedirect.com/science/article/pii/S1350946218300119?via%3Dihub

[2] Michl M, Fabianska M, Seeböck P, et al. Automated quantification of macular fluid in retinal disease and their response to anti-VEGF therapy. Br. J Ophthalmology. October 2020: bjophthalmology-2020-317416

[3] Roberts PK, Vogel WD, Gerendas BS, et al. Quantification of Fluid Resolution and Visual Acuity Gain in Patients With Diabetic Macular Edema Using Deep Learning. JAMA Ophthalmol. 2020 Sep 1; 138(9): 945-953

Heidelberg Engineering also plans to provide a workflow solution for legacy HEYEX users, as well as for third party OCT devices.

"*The availability of the RetInSight application within the HEYEX 2 image management platform will lead to highly efficient disease management. Combining Heidelberg Engineering image quality with this novel AI-service will empower SPECTRALIS owners to improve patient care*", said Martin Schinkmann, Head of Product Management for HEYEX 2 and HEYEX PACS and Managing Director of MedicalCommunications, a Heidelberg Engineering company.



The RetInSight fluid monitor application identifies, localizes and classifies intraretinal (yellow) and subretinal (blue) fluid accurately on each single pixel of the 3-dimensional OCT retina scan. Based on this segmentation, the exact volume of each fluid type is calculated (in nanoliter).

About RetInSight GmbH:

RetInSight, the legal manufacturer of the fluid quantification application, was founded in 2020 as a spin-off of the department of ophthalmology at the Medical University of Vienna, Austria, and has a track record of eight years in high-level development of validated retinal biomarker algorithms by an interdisciplinary team of AI scientists and retina experts. RetInSight develops transformational AI solutions to improve patient outcomes, increase clinical efficiency and reduce healthcare costs in the management of retinal diseases. The company provides digital reading services on clinical data and retinal images to international pharma & biotech companies involved in drug development targeting eye diseases.

About Heidelberg Engineering GmbH:

Heidelberg Engineering continuously optimizes imaging and healthcare IT technologies to provide ophthalmic diagnostic solutions that empower clinicians to improve patient care. From its inception in 1990, the company has collaborated with scientists, clinicians and industry to develop innovative products that deliver clinically relevant benefits.

Uncompromising quality and education play a large part in fostering the diagnostic confidence that has become synonymous with the global brand. The company's substantial expertise in the development and implementation of intelligent image and data management solutions complements its distinguished history in the design, manufacture and distribution of ophthalmic diagnostic instruments.

Heidelberg Engineering's growing product portfolio combines these core technologies: confocal microscopy, scanning lasers and optics, optical coherence tomography (OCT), real-time image processing and analytics, multimodal image management solutions (PACS), electronic medical records (EMR) and large-scale data analysis.

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