REVENIO

U.S. FDA cleared the new iCare MAIA microperimeter

Revenio Group Corporation | Press Release | March 28, 2025 at 09:00:00 EET

Icare, a subsidiary of Revenio Group, has today announced that the U.S. Food and Drug Administration (FDA) has cleared the new iCare MAIA microperimeter. This clearance marks a significant milestone in our growth and innovation strategy, aimed at better meeting market diagnostic needs, particularly within the ophthalmic research segment focusing on geographic area therapies development.

The new iCare MAIA microperimeter is now available for sale in the United States, with deliveries starting in mid-April 2025.

The new iCare MAIA also has marketing authorization in other key countries such as Canada, the UK, and Australia. The new iCare MAIA will receive CE marking in the coming few weeks, allowing sales to commence within the European Union as well.

The new iCare MAIA has a renewed hardware platform with fully automated operations and a 15" multi-touch display making it easier than ever. The unparalleled structure-function correlation is now improved thanks to the introduction of the 60° field of view and the TrueColor confocal technology.

"iCare MAIA retains all the key elements that made it the gold standard in microperimetry technology. The introduction of the 60° TrueColor imaging capabilities brings the new iCare MAIA to the next level of structure-function correlation in microperimetry," said Daniele Mantovano, iCare's Business Line Director. "We strongly believe in microperimetry and its usefulness in the research ophthalmic segment, and we have been intensely working on this project since the discontinuation of the previous iCare MAIA model."

Clinical validation indicates full interchangeability with the previous MAIA generation with equivalent sensitivity results in mesopic testing.

iCare MAIA has a 15" multi-touch display and an intuitive User Interface allowing easy-to-follow operations. The new iCare MAIA can import data from the previous model and use it as a reference for follow-up examination, guaranteeing full continuity with clinical historical data.

For further information, please contact

Global Business Line Diagnostics Director Daniele Mantovano tel. +39 346 100 8040 daniele.mantovano@icare-world.com

REVENIO

Distribution

Main media www.reveniogroup.fi/en

Revenio Group in brief

Revenio is a global provider of comprehensive eye care diagnostic solutions. The group offers fast, user-friendly, and reliable tools for diagnosing glaucoma, diabetic retinopathy, and macular degeneration (AMD). Revenio's ophthalmic diagnostic solutions include intraocular pressure (IOP) measurement devices (tonometers), fundus imaging devices, and perimeters as well as software solutions under the iCare brand.

In 2024, the Group's net sales totaled EUR 103.5 million, with an operating profit of EUR 25.0 million. Revenio Group Corporation is listed on Nasdaq Helsinki with the trading code REG1V.

Attachments

U.S. FDA cleared the new iCare MAIA microperimeter