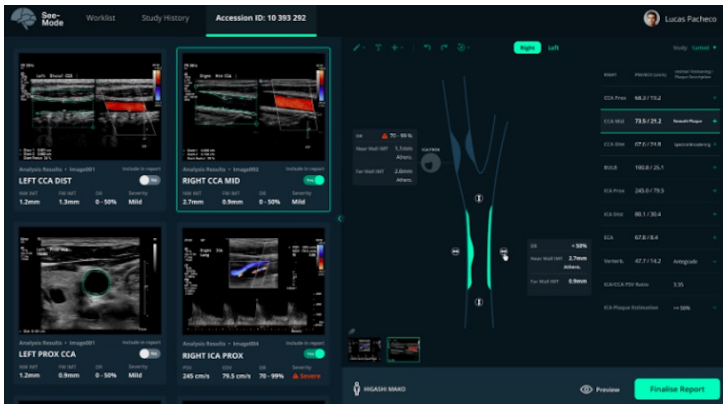# See-Mode Tech receives CE Mark, Australian approval for debut product

02 February 2021 | News

See-Mode's AVA received FDA 510(k) clearance in 2020, and was also approved by Singapore's Health Sciences Authority (HSA) as a Class B medical device in 2019

See-Mode Technologies, a MedTech start-up based in Singapore and Australia that seeks to empower clinicians to better predict stroke, announced that it has received two more regulatory approvals – the CE Mark and Therapeutic Goods Administration (TGA) approval for its debut product, the Augmented Vascular Analysis (AVA) software. AVA uses artificial intelligence (AI) to perform automated analysis and reporting of vascular ultrasound scans, enabling clinicians to interpret and report on these scans more efficiently and with higher quality.

See-Mode's AVA received FDA 510(k) clearance in 2020, and was also approved by Singapore's Health Sciences Authority (HSA) as a Class B medical device in 2019. With these four major regulatory approvals – all received within a span of three years from the inception of the company – See-Mode now has a firm foundation to rapidly scale its business across its core markets, namely Australia, Europe, the US and Singapore.

Through its use of deep learning, text recognition, and signal processing, AVA improves the speed and quality of the process significantly. With a single click and in less than a minute, AVA can analyse a full vascular ultrasound scan, minimising the need for manual drawings. This helps to augment the clinical workflow, resulting in greater overall productivity, accuracy, and improved patient outcome.

Dr Sadaf Monajemi, Co-Founder and Director, See-Mode Technologies said, "Achieving four regulatory approvals as a three-year-old start-up was no easy feat. This clearly demonstrates the scientific rigour with which we have built and validated our product and we are extremely thankful to have the support of our clinical partners. Having reached this significant milestone for See-Mode, we look forward to continuing our commercial growth trajectory in Europe and Australia."

See-Mode is continuously adding more image interpretation and reporting capabilities to AVA and expanding the product's capabilities to new clinical use cases. Continuing on its mission to assist doctors in predicting and preventing stroke, See-Mode is currently running clinical validation studies for its future algorithms on the detection of high risk plaques and high risk blood flow with partners across Singapore, Australia, Europe and the US.