

# ASX Release

## CONTINUOUS INNOVATION GENERATES ENHANCED ALGORITHM PERFORMANCE

**EMVision Medical Devices Limited (ASX:EMV)** ("EMVision" or the "Company") is pleased to provide a progress update on its continuous innovation efforts which have generated enhanced AI-powered 'ischemia or not' diagnostic performance.

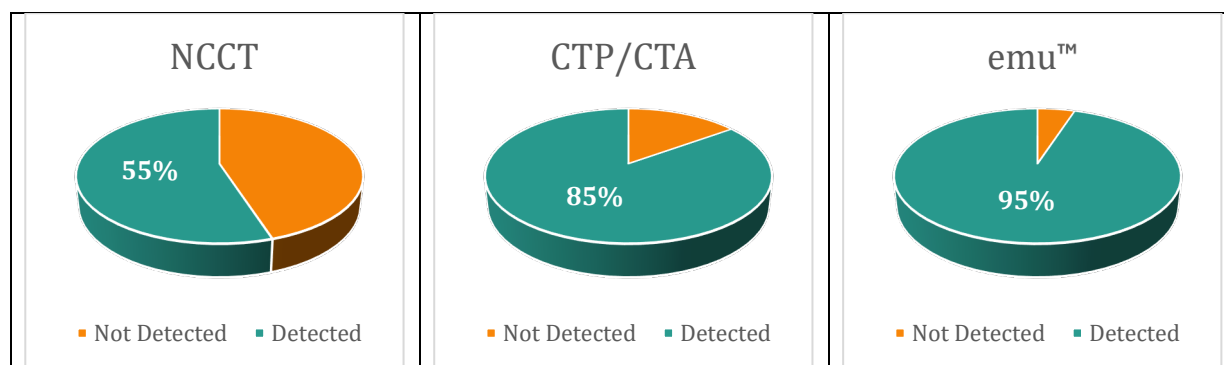
This updated data will be included in a presentation to be given at the 11th European Stroke Organisation Conference (ESOC 2025) in Helsinki, Finland, 21-23 May 2025.

As previously advised, the AI-based 'ischemia or not' diagnostic algorithm achieved a sensitivity of 85% and specificity of 78% in the 'EMView' pre-validation trial.<sup>1</sup> In this study conducted at Liverpool Hospital Sydney, The Royal Melbourne Hospital and Princess Alexandra Hospital in Brisbane, the AI-powered 'ischemia or not' diagnostic algorithm was trained on over 240 patient cases enrolled in the study and following that training the algorithm was applied to an unseen test dataset that was isolated and not used in training.

As part of continuous innovation efforts, the AI-powered 'ischemia or not' diagnostic algorithm has been re-trained, using cleaned training data and re-evaluated. In this dataset, the AI-powered 'ischemia or not' diagnostic algorithm performance has improved as follows:

	Ischemic	Not Ischemic	
<b>Total Test Cases</b>	<b>20</b>	<b>50</b>	Including 10 haemorrhages, 18 stroke mimics, 2 transient ischaemic attacks, 20 healthy cases
<b>Correctly Identified Cases</b>	<b>19</b>	<b>40</b>	
<b>Performance</b>	<b>95% Sensitivity</b>	<b>80% Specificity</b>	

In a limited sensitivity analysis of the 20 ischemic test cases, the emu™ RF-based model missed one case, whereas in first-line Non-Contrast Computed Tomography (NCCT) imaging, nine cases were not detected. Notably, three of the cases were also not identified on Computed Tomography Perfusion (CTP) / Computed Tomography Angiography (CTA) and were only confirmed on follow-up imaging (MRI DWI) after 48 hours.



<sup>1</sup> Refer to ASX Announcement "EMVision's Neurodiagnostic Algorithms Deliver Excellent Results" released on 12 November 2024.

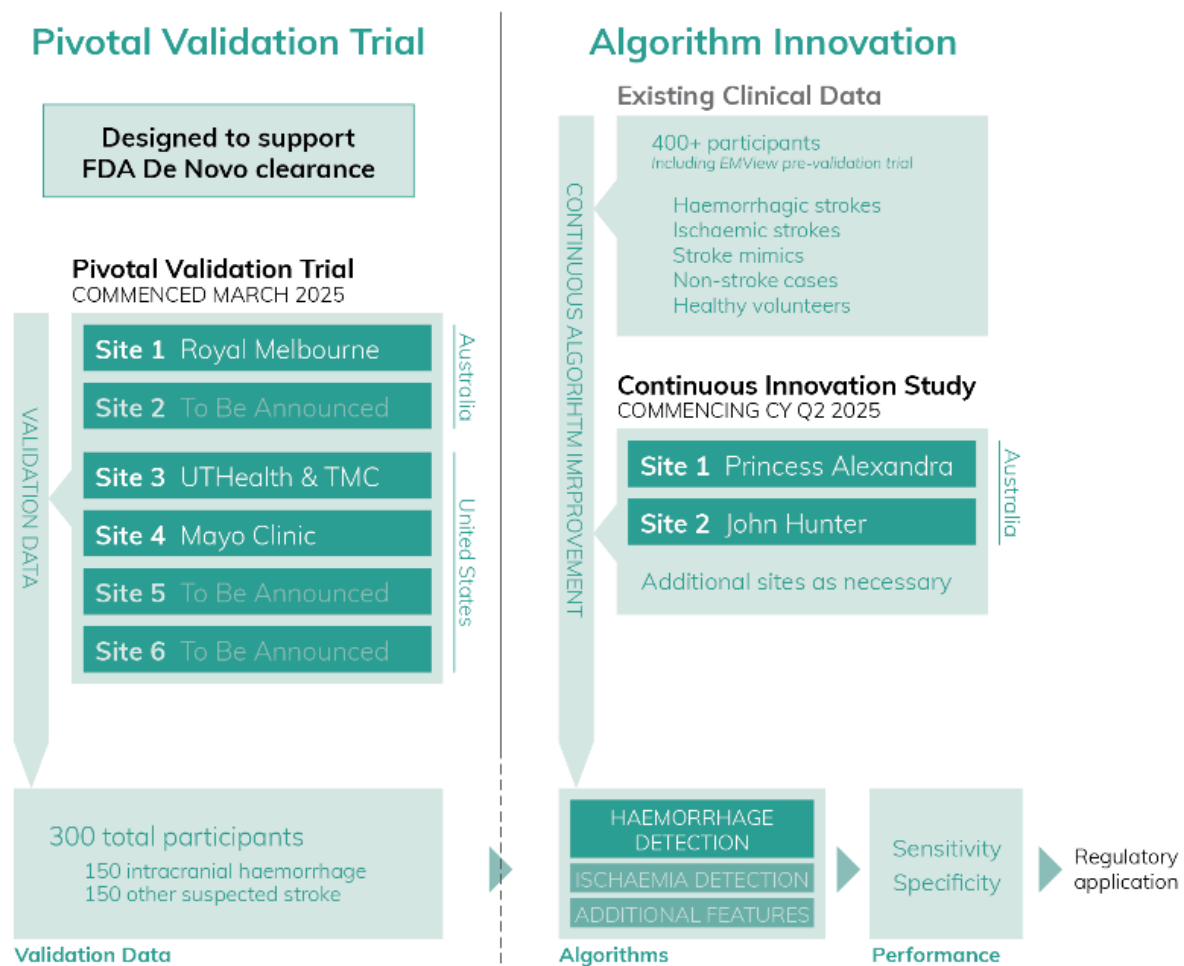
**Pie charts comparing ischemic stroke detection sensitivity in the test data across three modalities: NCCT (left), CTP/CTA (center), and the emu™ RF-based detection and classification model (right). The green region indicates detected cases, while the orange region indicates those not detected. Note - this comparison does not evaluate specificity.**

Whilst encouraging, due to the design of the study and limited sample size, the data does not yet allow statistically significant or generalisability conclusions to be drawn on the performance of the updated 'ischemia or not' AI-powered model. The recently commenced pivotal trial is designed to validate algorithm performance and support FDA De Novo clearance of the emu™ brain scanner device.

EMVision is implementing a cost-effective strategy for continued device innovation and enhancement during the Pivotal (Validation) trial via a parallel Continuous Innovation Study. Additional patients will be scanned at multiple sites in Australia outside of the Pivotal (Validation) trial, including the Princess Alexandra Hospital, Brisbane and John Hunter Hospital.

This study data will be used to progress the development of additional device features, scale the training library for EMVision's diagnostic AI algorithms, including ongoing 'ischemia or not' detection and classification development, and potentially extend indications by the enrolment of patients with traumatic brain injury. EMVision observed meaningful performance increases in the sensitivity/specificity of its diagnostic AI algorithms during the previous 'EMView' pre-validation study when additional training data was utilised. This study is separate to, and isolated from, the Pivotal (Validation) trial dataset.

## emu™ Point-of-Care Brain Scanner - Clinical Program Overview



Authorised for release by the Board of the Company.

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For further information, media or investor enquiries, please contact:

Andrew Keys  
Keys Thomas Associates  
+61 400 400 380  
andrew.keys@keysthomas.com

Sling & Stone  
Media and Communications  
emvision@slingstone.com  
02 8073 5390

Scott Kirkland  
CEO and Managing Director  
+61 2 8667 5337  
skirkland@emvision.com.au

## **About EMVision Medical Devices**

EMVision Medical Devices Limited (ASX:EMV) is an innovative Australian medical device company developing a novel approach to looking inside the human body. Our product pipeline includes portable, non-invasive, affordable and safe neurodiagnostic devices.

Our vision is to help transform and improve the timely diagnosis and treatment of stroke and other time sensitive medical emergencies, at the point-of-care.

EMVision has offices in Sydney and Brisbane [www.emvisionmedical.com](http://www.emvisionmedical.com)

## **Forward-looking Statements**

This release may contain certain forward-looking statements with respect to matters including but not limited to the financial condition, results of operations and business of EMVision and certain of the plans and objectives of EMVision with respect to these items. These forward-looking statements are not historical facts but rather are based on EMVision's current expectations, estimates and projections about the industry in which EMVision operates, and its beliefs and assumptions. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates", "guidance" and similar expressions are intended to identify forward looking statements and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the endeavour of building a business around such products and services. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and other factors, some of which are beyond the control of EMVision, are difficult to predict and could cause actual results to differ materially from those expressed or forecasted in the forward-looking statements. EMVision cautions shareholders and prospective shareholders not to place undue reliance on these forward-looking statements, which reflect the view of EMVision only as of the date of this release. The forward-looking statements made in this announcement relate only to events as of the date on which the statements are made. EMVision will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.

## **Inherent risks of Investment in Medical Device development Companies**

There are a number of inherent risks associated with the development of new medical device products to a marketable stage. The clinical trial process, which is often lengthy, is designed to assess the safety and efficacy of a device prior to commercialisation and there is no guarantee of achieving the outcomes necessary to generate a viable commercial product. Other risks include uncertainty of patent protection and proprietary rights, the obtaining of necessary regulatory authority approvals and the evolving competitive landscape. Companies such as EMVision are dependent on the success of their research and development projects, product development and on the ability to attract funding to support these activities. Investment in research and development and novel product development cannot be assessed on the same fundamentals as trading and manufacturing enterprises. Therefore investment in Companies specialising in such development must be regarded as speculative. EMVision recommends that professional investment advice be sought prior to such investments and cautions investors that the risks of an investment in an entity such as EMVision is not limited to the risks disclosed in this announcement.