

ASX Release

FIRST RESPONDER SCANNER IN SUCCESSFUL AEROMEDICAL TESTING

Key Highlights:

- **First Responder device in successful aeromedical retrieval environment testing.**
- **Ethics application under review, under which Royal Flying Doctor Service staff will enrol and scan patients in a usability and workflow implementation study in the coming weeks.**
- **Additional Mobile Stroke Unit (MSU) study ethics application also in progress.**
- **First Responder device aims to address significant unmet need in stroke and traumatic brain injury care by enabling earlier triage, transfer or treatment decisions at the point-of-care.**

EMVision Medical Devices Limited (ASX:EMV) (“EMVision” or the “Company”) is pleased to advise that its First Responder Proof-of-Concept (PoC) device has taken to the skies in aeromedical environment testing.

A series of volunteer scans with EMVision’s First Responder PoC device have been carried out in remote settings, in collaboration with the Royal Flying Doctor Service (RFDS) and the Australian Stroke Alliance. RFDS staff received preliminary training in the operation of the device and the scans were successfully completed under an existing ethics approval. Pleasingly, the First Responder device demonstrated an ability to withstand the physical stress, environmental conditions and operational constraints unique to aeromedical retrieval.



‘Scanner in the skies’
EMVision’s First Responder PoC device pictured with RFDS team member and volunteer.

The First Responder device represents an opportunity to fundamentally transform stroke and traumatic brain injury (TBI) outcomes for all patients, regardless of their location, by delivering sophisticated neurodiagnostic technology directly to the patient at their first interaction with the healthcare system. “Time is brain” in both stroke and TBI care, meaning the longer a stroke or bleeding goes untreated, the more brain cells die. Rapid triage, transfer and treatment decisions are critical to minimize brain damage, disability, and death.



First Responder PoC device pictured alongside carry case, accessories and consumables (L) and preliminary device training with South Australia Ambulance Service (SAAS) and RFDS personnel (R).

An ethics application has been submitted and is under review, under which RFDS staff will enrol and scan patients in a usability and workflow implementation study in the coming weeks (Clinical Investigation Summary outlined below). The study involves a collaboration of RFDS, SAAS's emergency retrieval service MedStar, South Australia Health's Rural Support Services, the Royal Adelaide Hospital and the Australian Stroke Alliance. The study will evaluate the device's usability, reliability, functionality, workflow metrics and other tests as necessary to meet user and international regulatory requirements. In parallel, product development activities are underway to transition from advanced prototype PoC devices to production equivalent commercial devices.

A further ethics application is in process to undertake EMVision First Responder scans during acute suspected stroke cases attended by the Melbourne Mobile Stroke Unit (MSU). This additional study provides a unique opportunity to collaborate with the only MSUs in Australia and one of a few MSUs globally who participate in clinical research. The study aims to evaluate the use of the EMVision First Responder PoC device during pre-hospital emergency response to acute suspected stroke patients, while gathering contemporaneous ground-truth MSU CT-scan data.

Zoe Schofield, National Stroke Project Manager for Aeromedical Retrieval, Royal Flying Doctor Service, commented "It's incredibly exciting to see this project come to life with the first successful test of the scanner's array in a remote setting, a major step toward bringing rapid stroke assessment to aeromedical retrieval and rural and remote communities."

Co-Chair of the Australian Stroke Alliance, neurologist Professor Geoffrey Donnan AO, commented "The Australian Stroke Alliance is pleased to see these trials of the First Responder after years of design and development of this world-first brain imaging device. Patients in rural and remote locations experience 17 per cent more strokes than urban dwellers and receive less specialist stroke care due to the challenges of transport and distances to be travelled. Urgent onsite brain imaging is a critical first step in the stroke treatment pathway. The RFDS and EMVision have an essential role to play as we prepare to take urgent stroke care to rural patients."

EMVision CEO, Scott Kirkland, commented "We are thrilled to have successfully taken the EMVision First Responder PoC device into the field for the first time. We are grateful for the support of our collaborators. These studies are a key step in the development program of the EMVision First Responder device and learnings generated will inform progress from the current advanced prototype to production equivalent commercial units. We are excited by the opportunity to have a substantial positive impact in the reduction of the global burden of stroke."

Authorised for release by the Board of the Company.

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Clinical Investigation Summary

Study Title	Usability and Workflow Implementation of the EMVision First Responder Brain Scanner in Aeromedical Retrievals.
Investigational Site	Royal Flying Doctor Service, Adelaide Base.
Design of the Clinical Investigation	Single-arm, non-randomised, workflow implementation of the EMVision First Responder device.
Objectives	To determine the workflow impacts and usability of in-field (i.e., not at a hospital) brain scan procedures conducted during aeromedical retrievals.
Endpoints	<ul style="list-style-type: none"> • Usability of the device as assessed by users • Workflow metrics • Safety
Inclusion Criteria	<ol style="list-style-type: none"> 1. Adults \geq 18 years of age 2. Patients receiving an aeromedical transport 3. Head size deemed suitable to fit the device 4. The use of the EMVision First Responder Brain Scanner will not delay the treatment of the patient
Exclusion Criteria	<ol style="list-style-type: none"> 1. Patients who cannot freely provide consent 2. Contraindicated to the EMVision First Responder scan 3. Patients suffering from or suspected of suffering from an acute head injury (e.g., concussion, scalp laceration, skull fracture)¹ 4. Patients suffering from or suspected of suffering from an acute neurological condition (e.g., stroke, seizure, migraine)¹ 5. Unable to lie still for the duration of the scan 6. Any other medical or logistical contraindication at the discretion of the aeromedical retrieval team or attending physician <p>¹Exclusion criteria 3 and 4 are due to potential for confusion of the patient resulting from a brain scan unrelated to their condition.</p>
Sample Size	The research team will actively recruit participants for a total period of 8 weeks. It is anticipated that during this time approximately 30 participants will be enrolled.
Duration of Clinical Investigation	The total study duration including site training, site activation, closure is anticipated to be \leq 6 months.

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

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.