

# **ASX** Release

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# ENCOURAGING HAEMORRHAGIC IMAGES WITH CLASSIFICATION CAPABILITIES

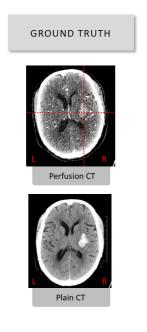
**EMVision Medical Devices Limited (ASX: EMV) ("EMVision" or the "Company"),** a medical device company focused on the development and commercialisation of portable medical imaging technology, is pleased to provide preliminary detection, localisation and classification images of haemorrhagic strokes (bleeds) from its clinical trial. Previously EMVision has shown preliminary detection and localisation images of ischaemic strokes (clots) as per EMVision's announcement on 21 April 2020.

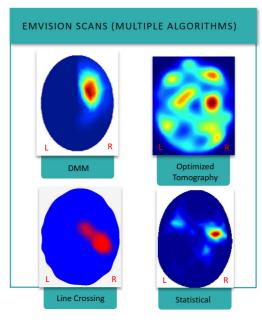
In this small patient cohort, whom have been selected on the basis of their haemorrhagic stroke type, a selection of EMVision's imaging algorithms were able to detect, localise and classify haemorrhagic stroke. The conductivity, permittivity and related electromagnetic values identified in these scans differed from those in previous ischaemic stroke patient datasets. These valuable datasets serve to demonstrate the potential of EMVision's techniques to not only detect and localise strokes, but importantly to classify them based on variances in conductivity, permittivity and related electromagnetic changes between blood, ischaemic tissue or oedema (swelling due to fluid accumulation). The images and classification chart are provided below.

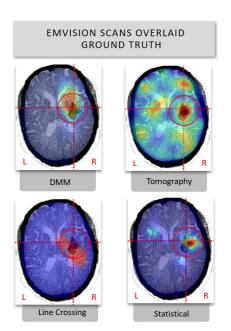
Neuro imaging plays an essential role in stroke treatment but today it is not accessible by the bedside or at the point of care (including pre-hospital). Neuro imaging helps differentiate the stroke type (ischaemic or haemorrhagic), irreversible damaged tissue from salvageable tissue, treatment planning including intravenous clot busting drugs (thrombolytics) and intraarterial thrombectomy (physical retrieval of clots) as well as post-treatment monitoring for complications and secondary haemorrhages (including ischaemic stroke that can transform into a bleed). Whilst haemorrhagic strokes represent only approximately 13% of all stroke cases, early exclusion is essential in providing proven time-sensitive thrombolytic therapy and ideally would be possible before arrival at hospital.

#### PATIENT X

Haemorrhagic Stroke (Right Side)

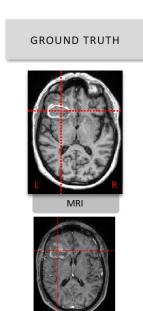


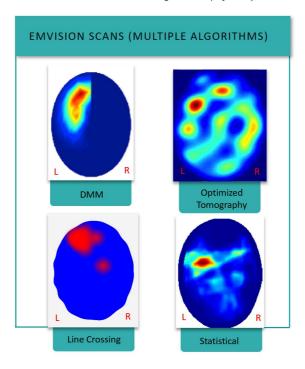


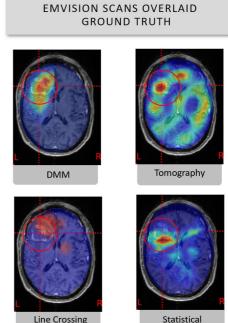


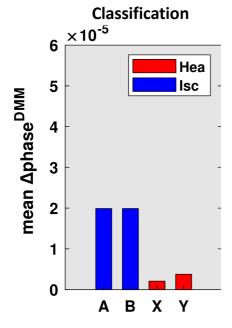
## **PATIENT Y**

Haemorrhagic Stroke (Left Side)









The above EMV images are obtained by inferring the electrical properties of tissues, on the basis of their complex and differing interactions with electromagnetic microwaves in the spectrum 0.5 – 2.4 GHz. Both patient cases are haemorrhagic. Other algorithms remain under development for this stroke type and will be refined as further data is collected and processed.

This classification method (left) is derived from one of EMVision's algorithms (Direct Mapping or DMM). The method uses certain properties of the electromagnetic signals (particularly the phase characteristics) after interaction with brain tissue to make the classification. Cases A+B (previously released ischaemic cases) and cases X+Y (haemorrhagic) show a clear difference using the phase information in the image. The tissue properties surrounding ischemia and haemorrhagic strokes are quite different and as such the signal is disrupted in different ways. A larger cohort of stroke patients, beyond this initial dataset, will be required to establish the statistical significance of this classification method.

EMVision clinical advisor and neurologist specialising in stroke, Prof Michael O'Sullivan commented "These are highly promising early examples. The need to exclude haemorrhage – generally not possible until arrival in hospital – delays the use of thrombolytic therapy, leading to greater damage from stroke as 'time is brain'. These cases suggest that there are differences in the properties of abnormal tissue, which could lead to a novel approach to differentiate between haemorrhage and ischaemia in the field and at the bedside."

EMVision Managing Director and CEO, Dr Ron Weinberger, commented "These preliminary images support the approach we are taking to deliver a unique bedside device for stroke monitoring, and in the future, prehospital, to assist clinicians with earlier interventions and treatment choices. We now have shown the ability

to identify both stroke types and importantly distinguish between them. These results are preliminary and subject to further testing but provide validation of the fundamental principles of the technology."

The primary endpoint of EMVision's pilot clinical trial, which commenced in late January 2020, is to generate a dataset of stroke patient scans which improves the understanding of stroke on electromagnetic scattering effects in the brain. The Company will use this data to refine and select the optimal imaging algorithms as well as generating early data on correlation with CT and/or MRI images. At this point in time, Cases A+B and X+Y are the only cases that have gone through the full end-to-end clinical review process. These cases have been prioritised for review to inform the technology's ability to detect and distinguish between different types of stroke.

The clinical trial will inform commercial product development as well as FDA regulatory strategy and pivotal trial design. The Clinical Trial summary is part of this ASX Announcement as Appendix A. EMVision anticipates completing its 30-patient enrolment target during CY Q3 2020. Shortly after enrolment is complete, all datasets will be processed and the final results of the clinical study, when completed, will undergo a detailed review by the Company's clinical advisors and be released via the ASX.

Authorised for release by the Board of the Company.

#### [ENDS]

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#### **About EMVision Medical Devices**

EMVision Medical Devices Limited is focused on the development and commercialisation of medical imaging technology. The Company is developing and seeking to commercialise a potentially cost effective, portable, medical imaging device using electromagnetic microwave imaging for diagnosis and monitoring of stroke and other medical applications. The technology is the result of over 10 years of development by researchers at the University of Queensland. The team of approximately 30 researchers is led by co-inventors Professor Amin Abbosh, who is considered a global leader in electromagnetic microwave imaging, along with Professor Stuart Crozier, who created technology central to most MRI machines manufactured since 1997. EMVision's CEO, Dr Ron Weinberger, is the Former Executive Director and CEO of Nanosonics' (ASX:NAN), a \$1.9 billion market cap healthcare company. Dr Weinberger has over 25-years' experience developing and commercialising medical devices. During his time at Nanosonics, Dr Weinberger codeveloped the company's platform technology and launched their breakthrough product 'Trophon' globally, which would go on to become the gold standard for infection prevention. Dr Weinberger was instrumental in transforming Nanosonics from a research and development company to one of Australia's leading medical device commercialisation success stories.

#### **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.

### Appendix A – Clinical Trial Summary

Study Title	Feasibility Study to Obtain Imaging Data from Participants with a Diagnosed Stroke to Refine the Algorithms for the EMVision Brain Scanner
Development Phase	Feasibility
Indication	Stroke
Study Device	EMVision Brain Scanner
Number of Participants	30
Number of Centres	1 in Australia
Site	Princess Alexandra Hospital, Brisbane
Study Duration	Approximately 6 months
Primary Objective (s)	To obtain a set of data from stroke participants to refine the algorithm of
	the software component of the EMVision brain scanner
Primary Endpoint	A dataset of stroke patient scans which improves the understanding of
	stroke on electromagnetic scattering effects in the brain.
Study Design	This study is a single-centre, two (2) groups, observational study of
	participants with a diagnosed stroke. Imaging data acquired would be used to
	refine the algorithm of the software component of the EMVision brain
	scanner. Up to twenty (20) participants will be enrolled in each group:
	haemorrhagic stroke (group A) and ischaemic stroke (group B) with up to 30
	patients. No intervention or modification to the usual hospital based treatment
	of stroke is proposed as part of this trial. An initial set of 3 patients will be
	used to define standard operating
	procedures around clinical scanning.
Inclusion Criteria	1. Adults >=18 years of age.
	2. Admitted to hospital with new neurological signs and confirmed
	diagnosis of stroke supported by conventional brain imaging.
	3. Ability to provide informed consent. Participants will provide
	written informed consent. Where this is not possible, surrogate consent will
	be obtained.
	4. Ability to adhere to study visit schedule and other protocol
	requirements.
	5. Confirmed diagnosis of stroke within 72h of admission.
Fredrice Oritoria	6. Head size deemed suitable for scanning with the EMVision brain scanner.
Exclusion Criteria	1. Experiences seizures from onset of stroke, or known history of seizure episodes.
	2. Has injury or known medical condition on the head that would not
	allow the placement of EMVision brain scanner.
	3. Is unable to lie still for the duration of the scan.
	4. Is not a suitable candidate according to the assessing investigator.
	5. Has any metal implants in the head or neck for example stents,
	aneurysm clips, surgical clips, pressure monitors and drains.
	6. Is known to be pregnant or lactating.
Study	Potential participants with a confirmed diagnosis of stroke would be
Procedure/Follow-up	reviewed to participate in the study. The participant would be assessed and, if
'	eligible, the participant or participant's legal representative would be
	approached for consent to participating in the study. After consent, the first
	scan using the EMVision brain scanner would be conducted and follow-up
	scans would be conducted as deemed appropriate by the investigator. Each
	scan will be repeated to obtain paired image acquisitions for comparison.
	Patients will be followed for up to 28 days
	following admission as inpatients, or until discharge (whichever is sooner).