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## ASX Release

# POSITIVE SAFETY OBSERVATIONS FROM HEALTHY HUMAN TRIALS FOR BRAIN SCANNER PROGRAM

### Highlights:

- *EMvision announces positive safety observations from healthy human trials*
- *Volunteers rated the test and overall fit and comfort of the headset positively*
- *Scanning lasted approximately 6 seconds and data acquisition occurred successfully within the first 3 seconds*
- *Absorption of energy in subjects was confirmed to be well below the accepted levels as identified by IEEE international standard*
- *No adverse events were reported*
- *Successful outcome of these trials is a key precursor to ongoing clinical development*

**EMvision Medical Devices Limited (ASX: EMV)** (“EMvision” or the “Company”), a medical device company focused on the development and commercialisation of medical imaging technology, today announces positive safety observations from healthy human trials conducted at the University of Queensland.

The purpose of these trials was to test a clinical prototype on healthy human volunteers to provide key learnings and the necessary safety and usability information. EMvision is confident that the information collected from the healthy human trials can be used towards obtaining ethics approval, which is required as a precursor to EMvision undertaking its planned clinical trial later in 2019.

This study was undertaken to ISO 14155 guidelines “Clinical investigation of medical devices for human subjects - good clinical practice”. Ten volunteers were investigated to assess initial safety and usability of the clinical prototype, including observing acceptable specific absorption rate (SAR) levels and the absence of adverse events. SAR is a measure of the rate of RF (radiofrequency) energy absorption by the body from the source being measured.

The calculated SAR values were significantly less than the Institute of Electrical and Electronics Engineers (IEEE)<sup>1</sup> defined exposure limit, indicating the safe use of the presented system. There was a possibility that an effect of the absorbed energy would be an increase in temperature of the tissue. To assess this potential effect, a thermal camera was used to capture the induced temperature on patients while illuminated by microwave signals. Several thermal images of patients were recorded at various stages, i.e., before, during and immediately after the experiment was underway.

Results of this sample of ten volunteers indicated that no warming of the tissue was observed, in fact a slight cooling effect was observed due to the coupling liquid within the headset. No adverse events were reported for any volunteer taking part in this study.

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<sup>1</sup> IEEE C95.1–2005 Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz

Usability of the device and the scanning procedure was measured using participant and operator questionnaires collecting observations using a well-established rating scale. The results indicated that participants provided a positive response, with no discomfort and minimal time spent in the device.

Configuration of the specific elements within the headset worked well together, including unique antennae materials and construction which allowed excellent signal penetration and rapid data acquisition. Valuable data was acquired to facilitate advancements in the imaging algorithms in the lead up to clinical trials.

EMvision CEO, Dr Ron Weinberger stated; “this study confirms our earlier predictions that the current device embodiment and technology are completely safe for the patient. Speed of scan time allows patients to be rapidly assessed and then moved to treatment, reducing patient risk and improving workflow. We have also acquired critical data that feeds into our development program and ethics approval in the build up to our clinical trials.”

## **[ENDS]**

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## **ABOUT EMVISION**

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 over 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.